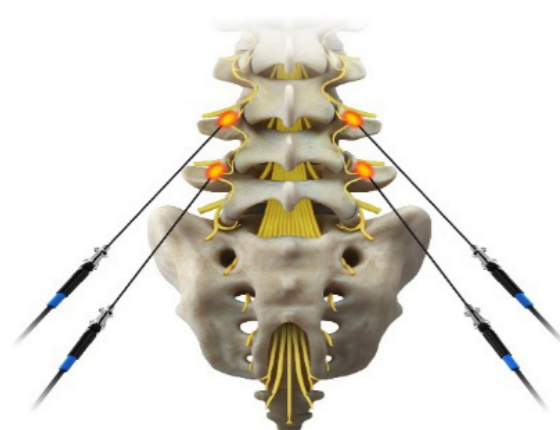




Radiofrequency Clinical Evidence

Compendium

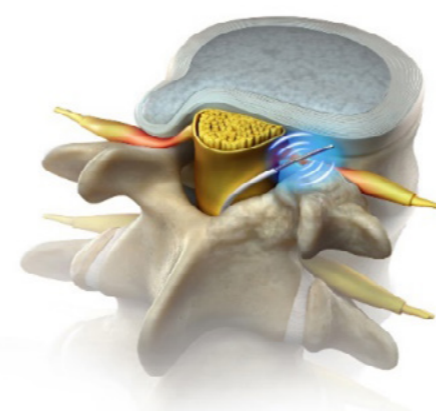
RADIOFREQUENCY TREATMENT IN INTERVENTIONAL PAIN MANAGEMENT: INDICATIONS



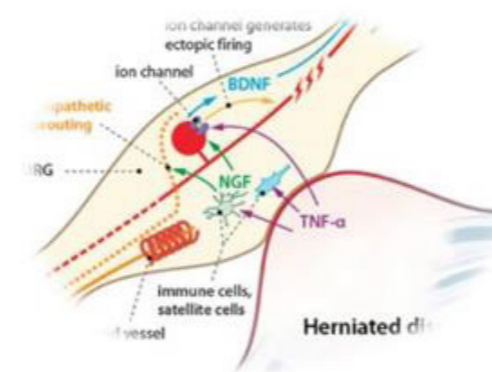
RF FOR LUMBAR PAIN



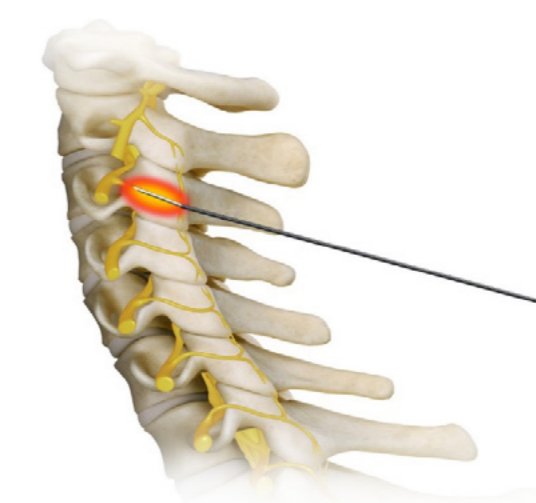
RF FOR SACROILIAC JOINT PAIN



PULSED RF FOR RADICULAR PAIN

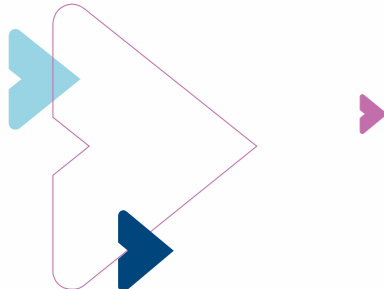


PULSED RF MECHANISM OF ACTION



RF FOR CERVICAL PAIN

REAL-WORLD & PROSPECTIVE RF STUDIES



REAL-WORLD & PROSPECTIVE RF STUDIES

RAPID: An International, Prospective, Multicenter Study of Radiofrequency Ablation Outcomes in Chronic Pain Patients

Joseph Atallah¹, Bradley Holt², Michael Denker³, Binit Shah⁴, David Provenzano⁵, Albert Singh⁶, Harsh Sachdeva⁷, Sherri Haas⁸, Mazaz Iqbal⁹, Rajat Sekher¹⁰, Yu Pei¹¹, Kristen Leichter¹², Mitch Patel¹³, Roshni Jain¹⁴

BACKGROUND
Various treatment approaches including medications, physical therapy, and surgery are typically utilized for chronic pain patients. Minimally-invasive interventional pain procedures, such as radiofrequency ablation (RFA), have steadily progressed to become a key segment of the therapeutic armamentarium now available to the chronic pain patient population.

RESULTS
The RAPID Study (NCT04749332) is a prospective, multicenter, international clinical study designed to collect outcomes of chronic pain patients treated with RFA. Here, we present preliminary results collected up to 3 months post-procedure.

CONCLUSIONS
Preliminary data from this prospective, multicenter, real-world outcomes radiofrequency ablation (RFA) study of 184 enrolled patients (178 subjects with RFA procedure completed) shows significant improvement in pain scores at 1- and 3-months post-procedure. High responder rates (>80% at 1 and 3 months post-procedure) and high patient satisfaction was reported at both 1- and 3-months post-procedure. 92% reported improvement (very much, much, or minimally improved) at 1-month (n = 24) and sustained up to 3 months post-procedure (100%, n = 20) as assessed by PGC.

INS 15th WORLD CONGRESS BARCELONA

Real-World Outcomes Using Pulsed or Thermal Radiofrequency Ablation for Treatment of Chronic Pain in Europe

Felice Occhigrossi¹, Georgios Kyriakopoulos², Fabrizio Cassini³, Lilly Chen⁴, Roshni Jain⁵

BACKGROUND
Treating general chronic intractable pain symptoms with a diverse set of strategies has been consistently shown to be successfully carried out using radiofrequency (RF). Conventional thermal RF (TRF) uses the application of heat (temperature) to thermocoagulate spinal nerve roots and ablate neural tissue. Alternatively, pulsed RF (PRF) is performed using short pulses typically 20ms every 0.5ms at much lower temperatures usually no higher than 42°C, thus avoiding destruction of neural tissue. Although these RF methods have specific advantages and disadvantages, they both offer similar distributions for consideration for the particular aspects of the chronic pain condition as well as the overall health and performance of each patient.

RESULTS
Of 137 patients who underwent RFA procedures for the treatment of their chronic pain, 44 received Pulsed RF (PRF) and 79 received Thermal RF (TRF).

CONCLUSIONS
Preliminary data from this ongoing, European, multicenter, observational case-series of 137 chronic pain patients (no new onset of pain at follow-up) who utilized radiofrequency (pulsed or thermal) is presented here. Study results demonstrate significant improvement in pain scores at post-procedure and at last follow-up (mean = 292 days). High responder rates (proportion of patients with >30% pain relief) was reported post-procedure and sustained up to last follow-up. Both TRF and PRF were observed to very similarly and effectively treat patients with chronic pain.

INS 15th WORLD CONGRESS BARCELONA

RAPID: An International, Prospective, Multicenter Study of Radiofrequency Ablation Outcomes in Chronic Pain Patients

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INS 15th WORLD CONGRESS BARCELONA

PROSPECTIVE RF OUTCOMES (ATALLAH, 2022 INS)

PULSED AND THERMAL RF OUTCOMES (OCCHIGROSSI, 2022 INS)

KNEE RF COHORT (ATALLAH, 2022 INS)





RAPID: An International, Prospective, Multicenter Study of Radiofrequency Ablation Outcomes in Chronic Pain Patients

Joseph Atallah¹, Bradley Holt², Michael Danko³, Binit Shah⁴, David Provenzano⁵, Albert Singh⁶, Harsh Sachdeva⁷, Sherri Haas⁸, Maaz Iqbal⁹, Rajat Sekhar¹⁰, Yu Pei¹¹, Kristen Lechleiter¹¹, Nilesh Patel¹¹, Roshini Jain¹¹

1. The Toledo Clinic, Toledo, OH USA 2. Tucson Orthopaedic Institute, Tucson, AZ USA 3. Premier Pain Treatment Institute, Loveland OH, USA 4. Carolinas Pain Center, Huntersville, NC USA 5. Pain Diagnostics and Interventional Care, Sewickley, PA USA 6. Quincy Medical Group, Quincy, IL USA 7. UC Health Pain Medicine, Cincinnati, OH USA 8. Twin Cities Pain Clinic & Surgery Center, Edina, MN USA 9. Elite Pain and Spine Institute, Mesa, AZ USA 10. St. Vincent's Medical Center, Bridgeport, CT USA 11. Boston Scientific Neuromodulation, Valencia, CA USA

Abstract #586



BACKGROUND

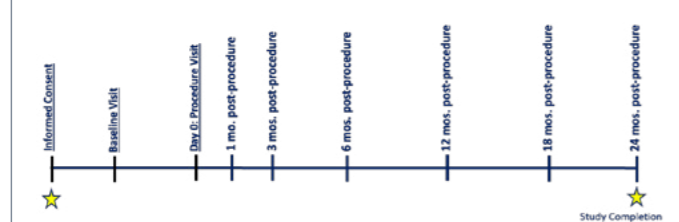
Various treatment approaches including medications, physical therapy, and surgery are typically utilized by chronic pain patients. Minimally-invasive interventional pain procedures, such as radiofrequency ablation (RFA), have steadily progressed to become a key segment of the therapeutic armamentarium now available to the chronic pain patient population.

The RAPID Study (NCT04673032) is a prospective, multicenter, international clinical study designed to collect outcomes of chronic pain patients treated with RFA. Here, we present preliminary results collected up to 3-months post-procedure.

METHODS

Study Design	Multicenter, Prospective, International Outcomes Study with consecutive enrollment
Study Device	Commercially-approved RFA Systems (Boston Scientific, USA)
Subjects	184 enrolled subjects at 10 sites; 178 subjects with RFA procedure completed
Study Eligibility Criteria	<p>Key Inclusion Criteria: Study candidate is scheduled to be treated with a commercially approved Boston Scientific RF system for pain per local Directions for Use (DFU)</p> <p>Key Exclusion Criteria: Meets any contraindications per locally applicable Directions for Use (DFU)</p>

STUDY SCHEMATIC



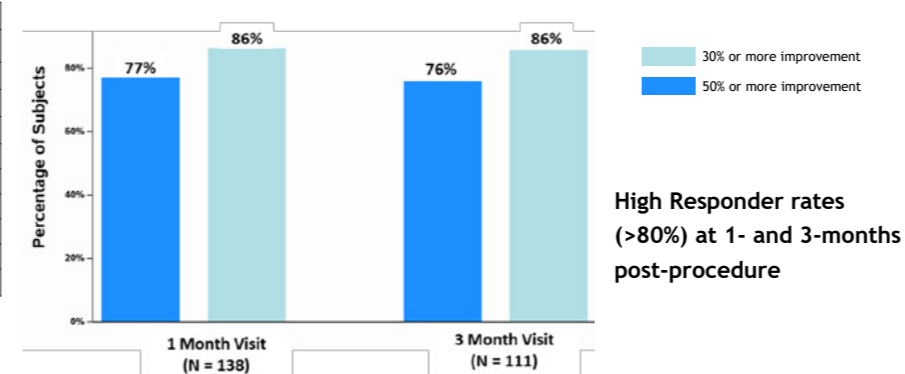
RESULTS

Baseline Characteristics (n = 184)

Gender - Females (%)	55.3% (n = 100/181)
Age (years) [Mean (SD)]	61.0 ± 12.6 years (n = 181)
Pain Duration (years) [Mean (SD)]	11.5 ± 11.2 years (n = 180)
Baseline Targeted Pain Score [Mean (SD)]	6.6 ± 1.7 (n = 159)
Number of Study RF Procedures [Mean (SD)]	1.6 ± 0.7 procedures (n = 179)
Regions treated with RF (with initial procedure completed)	Lumbar - 76.8% (n = 136/177)
	Cervical - 20.9% (n = 37/177)
	Sacroiliac - 18.6% (n = 33/177)
	Hip - 7.3% (n = 13/177)
Knee - 10.7% (n = 19/177)	
Follow-up Duration [Mean (SD)]	118.9 ± 98 days (n = 178)

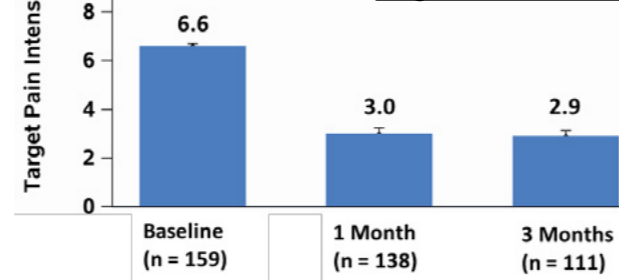
Targeted Pain is the area of pain intended to be treated with RF

Responder Rates (Targeted Pain) post-procedure



High Responder rates (>80%) at 1- and 3-months post-procedure

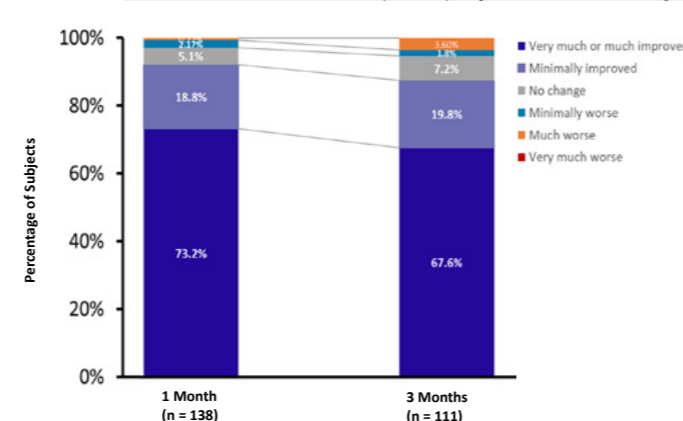
Targeted Pain Scores up to 3-months post-procedure



Significant improvement (p < 0.0001) in pain scores was noted post-procedure

- 3.5-point improvement (6.6 → 3.0) at 1-month
- 3.6-point improvement (6.6 → 2.9) at 3-months

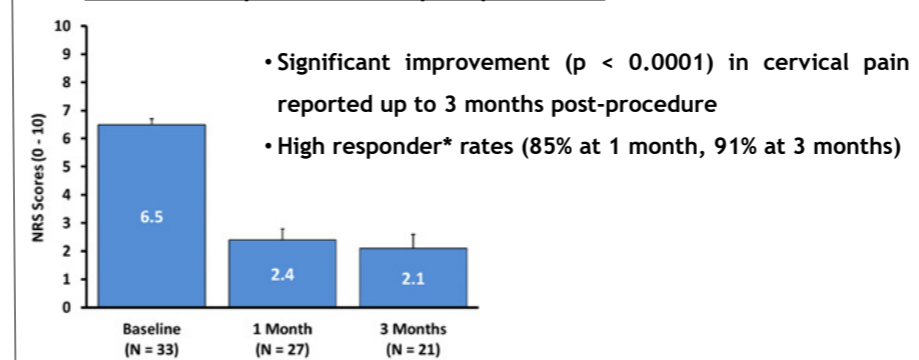
Patient Satisfaction (PGIC) up to 3-months post-procedure



92% reported improvement (very much, much, or minimally improved) at 1-month and sustained up to 3 months post-procedure (87%)

Cervical RFA Outcomes

Pain Scores up to 3-months post-procedure



- Significant improvement (p < 0.0001) in cervical pain reported up to 3 months post-procedure
- High responder* rates (85% at 1 month, 91% at 3 months)

92% reported improvement (very much, much, or minimally improved) at 1-month (n = 26) and sustained up to 3 months post-procedure (100%, n = 20) as assessed by PGIC.

*30% or more improvement

CONCLUSIONS

- Preliminary data from this prospective, multicenter, real-world outcomes radio-frequency ablation (RFA) study of 184 enrolled patients (178 subjects with RFA procedure complete) shows significant improvement in pain scores at 1- and 3-months post-procedure.
- High responder rates (>80%) and high patient satisfaction was reported at both 1- and 3-months post-procedure.
- 92% reported improvement (varying degrees) at 1-month post-procedure that was sustained up to 3 months (87%)
- Among patients receiving RFA for cervical zygapophyseal joints pain, significant improvement in pain (p < 0.0001) and satisfaction were noted up to 3 months post-procedure.

DISCLOSURES

This study is sponsored by Boston Scientific. Drs. Atallah, Shah, and Provenzano have consulting agreements with Boston Scientific. Yu Pei, Kristen Lechleiter and Roshini Jain are employees of Boston Scientific.



PROSPECTIVE RF OUTCOMES (ATALLAH, 2022 INS)



Real-World Outcomes Using Pulsed or Thermal Radiofrequency Ablation for Treatment of Chronic Pain in Europe

Felice Occhigrossi¹, Georgios Kyriakopoulos², Fabrizio Cassini³, Lilly Chen⁴, Roshini Jain⁴

1. San Giovanni-Addolorata Hospital, Rome, Italy 2. St. Marien-Hospital Hamm; Hamm, Germany 3. Presidio Ospedaliera Civile Santi Antonio e Biagio; Alessandria, Italy 4. Boston Scientific, Valencia, CA, USA

Abstract #593



BACKGROUND

Treating several chronic intractable pain syndromes with a diverse set of etiologies has been consistently shown to be successfully carried out using radiofrequency (RF). Conventional thermal RF (TRF) uses the application of heat (temperature) to thermo-coagulate spinal nerve roots and ablate neural tissue. Alternatively, pulsed RF (PRF) is performed using short pulses (typically 20-ms every 0.5 sec) at much lower temperatures usually no higher than 42°C, thus avoiding destruction of neural tissue. Although these RF methods have specific advantages and disadvantages, they both offer viable alternatives for consideration per the particular aspects of the chronic pain condition as well as the overall health and preference of each patient.¹

While RF is now a well-established therapeutic modality for chronic pain, periodic assessment of real-world patient data can contribute to the overall compendium of existing evidence as well as spur the initiation of new clinical studies. As such, in this report, we describe our assessment of outcomes from a European case-series of patients who underwent an RF procedure for the treatment of chronic pain.

METHODS

Study Design	Multi-center, Observational, Case-Series. Data collected by site personnel.
Study Device	Pulsed and/or Thermal RF Systems (Boston Scientific, USA)
Patients	n = 137
Key Inclusion	Chronic Pain Patients (with no new onset pain at follow up) who underwent either Pulsed or Thermal RF Ablation

RESULTS

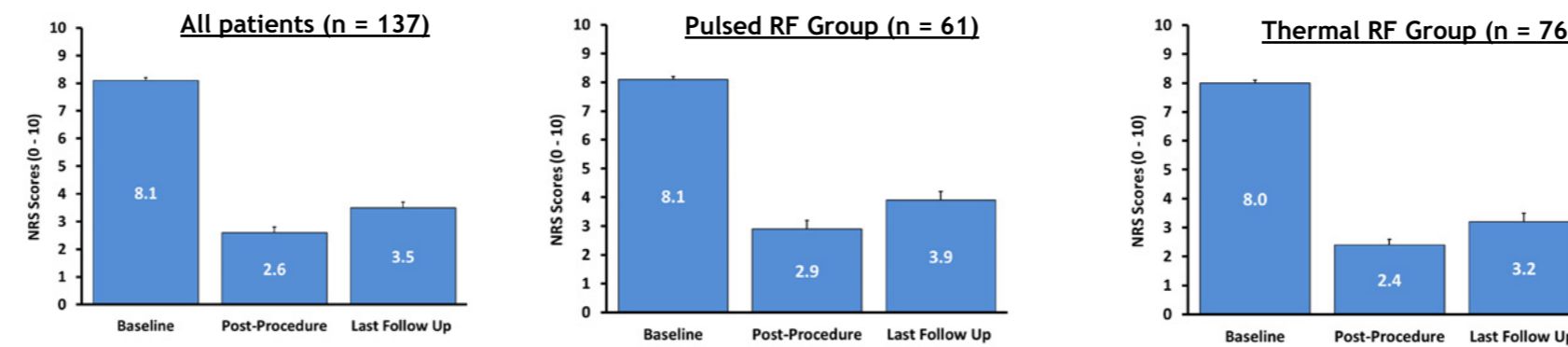
Baseline Characteristics (n = 137)

Gender - Females (%)	60.6% (n = 83/137)
Age [Mean (SD)]	67.4 (15.7) years, n = 128
Baseline NRS [Mean (SD)]	8.1 (1.1), n = 136
Follow-up Duration [Mean (SD)]	292.5 (285) days, n = 137

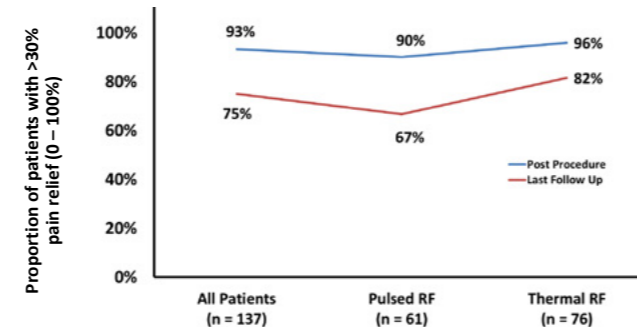
Pain Location (may have multiple locations)	Joints (20.4%)
	Back (73%)
	Hip (8.8%)

Of 137 patients who underwent RFA procedures for the treatment of their chronic pain
• 61 received Pulsed RF (PRF)
• 76 received Thermal RF (TRF)

Overall Pain Scores Post-Procedure and at Last Follow-Up



Responder Rate



High responder rate (proportion of patients with >30% pain relief) post-procedure and at last follow-up

Significant improvement (p < 0.0001) in pain scores was noted at post-procedure and last follow-up

- All patients: A 4.5-point improvement (8.1 → 3.5) at last follow-up (mean = 292.5 days)
- PRF Group: A 4.1-point improvement (8.1 → 3.9) at last follow-up (mean = 268.3 days)
- TRF Group: A 4.8-point improvement (8.0 → 3.2) at last follow-up (mean = 311.9 days)

CONCLUSIONS

- Preliminary data from this ongoing, European, multicenter, observational case-series of 137 chronic pain patients (no new onset of pain at follow up) who utilized radiofrequency (pulse or thermal) is presented here.
- Study results demonstrate significant improvement in pain scores at post-procedure and at last follow-up (mean = 292 days).
- High responder rates (proportion of patients with >30% pain relief) was reported post-procedure and sustained up to last follow-up.
- Both TRF and PRF were observed to very similarly and effectively treat patients with chronic pain.

REFERENCES

1. Ahadian FM. Pulsed radiofrequency neurotomy: advances in pain medicine. Curr Pain Headache Rep. 2004;8(1):34-40..

DISCLOSURES

Study is sponsored by Boston Scientific. Lilly Chen and Roshini Jain are employees of Boston Scientific.



INS 15TH WORLD CONGRESS
21 – 26 MAY 2022, BARCELONA, SPAIN

BARCELONA

PULSED AND THERMAL RF OUTCOMES (OCCHIGROSSI, 2022 INS)



RAPID: An International, Prospective, Multicenter Study of Radiofrequency Ablation Outcomes in Chronic Pain Patients

Joseph Atallah¹, Bradley Holt², Michael Danko³, Binit Shah⁴, David Provenzano⁵, Albert Singh⁶, Harsh Sachdeva⁷, Sherri Haas⁸, Maaz Iqbal⁹, Rajat Sekhar¹⁰, Yu Pei¹¹, Kristen Lechleiter¹¹, Nilesh Patel¹¹, Roshini Jain¹¹

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Abstract #586

BACKGROUND

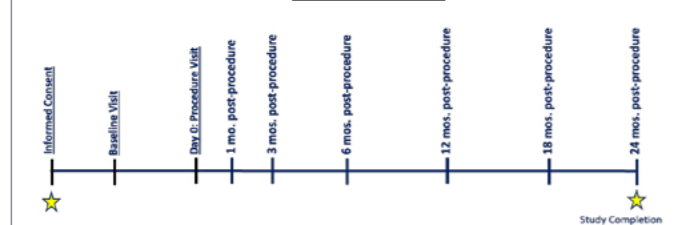
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The RAPID Study (NCT04673032) is a prospective, multicenter, international clinical study designed to collect outcomes of chronic pain patients treated with RFA. Here, we present preliminary results collected up to 3-months post-procedure.

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STUDY SCHEMATIC



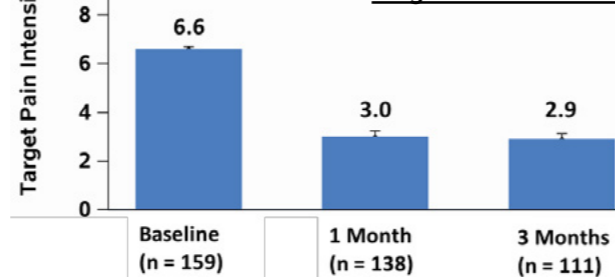
RESULTS

Baseline Characteristics (n = 184)

Gender - Females (%)	55.3% (n = 100/181)
Age (years) [Mean (SD)]	61.0 ± 12.6 years (n = 181)
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Baseline Targeted Pain Score [Mean (SD)]	6.6 ± 1.7 (n = 159)
Number of Study RF Procedures [Mean (SD)]	1.6 ± 0.7 procedures (n = 179)
Regions treated with RF (with initial procedure completed)	Lumbar - 76.8% (n = 136/177)
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	Sacroiliac - 18.6% (n = 33/177)
	Hip - 7.3% (n = 13/177)
Knee - 10.7% (n = 19/177)	
Follow-up Duration [Mean (SD)]	118.9 ± 98 days (n = 178)

Targeted Pain is the area of pain intended to be treated with RF

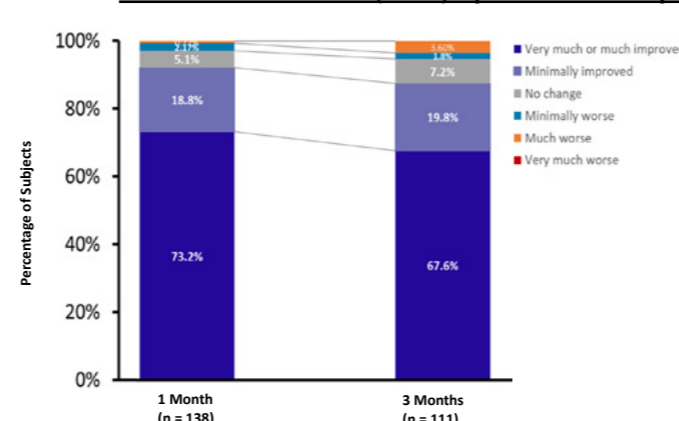
Targeted Pain Scores up to 3-months post-procedure



Significant improvement ($p < 0.0001$) in pain scores was noted post-procedure

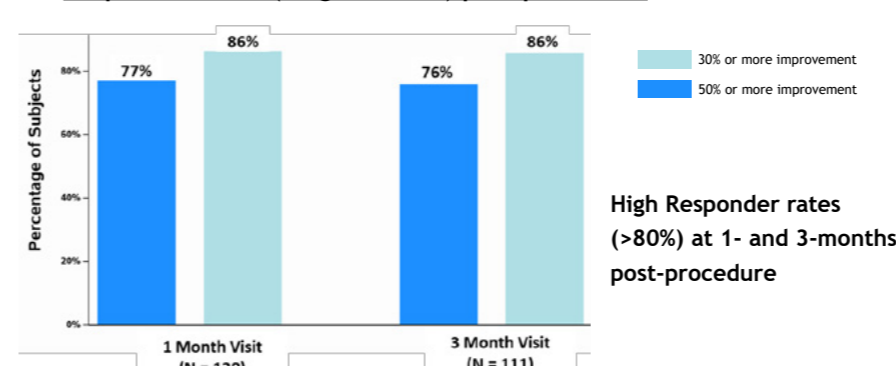
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Patient Satisfaction (PGIC) up to 3-months post-procedure



92% reported improvement (very much, much, or minimally improved) at 1-month and sustained up to 3 months post-procedure (87%)

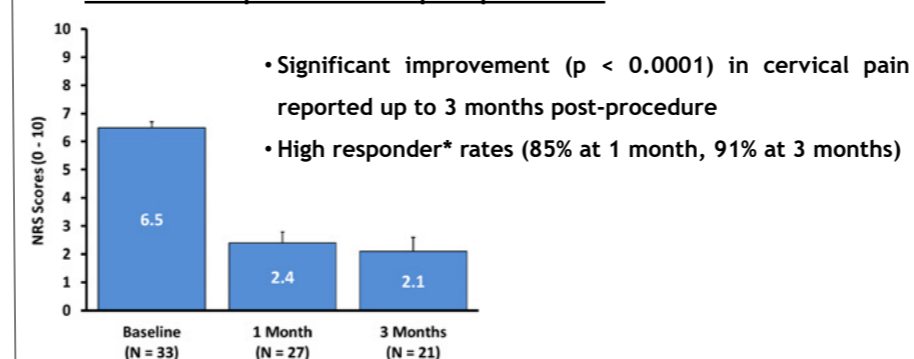
Responder Rates (Targeted Pain) post-procedure



High Responder rates (>80%) at 1- and 3-months post-procedure

Cervical RFA Outcomes

Pain Scores up to 3-months post-procedure



Significant improvement ($p < 0.0001$) in cervical pain reported up to 3 months post-procedure

- High responder* rates (85% at 1 month, 91% at 3 months)

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*30% or more improvement

CONCLUSIONS

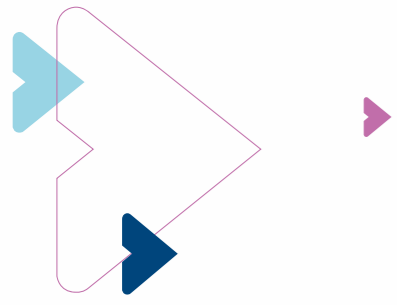
- Preliminary data from this prospective, multicenter, real-world outcomes radio-frequency ablation (RFA) study of 184 enrolled patients (178 subjects with RFA procedure complete) shows significant improvement in pain scores at 1- and 3-months post-procedure.
- High responder rates (>80%) and high patient satisfaction was reported at both 1- and 3-months post-procedure.
- 92% reported improvement (varying degrees) at 1-month post-procedure that was sustained up to 3 months (87%)
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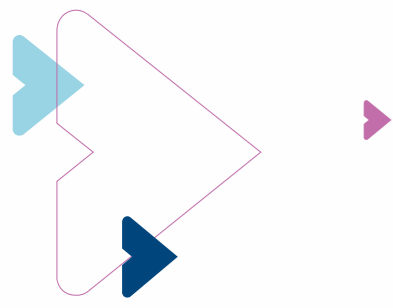


KNEE RF COHORT (ATALLAH, 2022 INS)



Radiofrequency ablation for Lumbar Pain





RF FOR
LUMBAR PAIN

RF FOR SACROILIAC
JOINT PAIN

PULSED RF FOR
RADICULAR PAIN

PULSED RF
MECHANISM OF ACTION

RF FOR
CERVICAL PAIN

Introduction > MacVicar et al., 2013 > Cosman et al., 2014 > Provenzano et al., 2018

Introduction

Low back pain (LBP) is one of the most common musculoskeletal complaints encountered in clinical practice. It is considered one of the leading causes of disability in the developed world and an unparalleled cost generator for society and, unquestionably, for healthcare providers¹.

Prevalence: Despite variable epidemiological evidence, some studies implicate **the lumbar facets as the primary pain generator in 10% to 15% of young adult patients with chronic LBP. In older populations, this prevalence increases to 40% to 45%**^{2,3}.

Treatment: The treatment for lumbosacral facet pain usually follows a multidisciplinary approach. Non-invasive procedures include management with pain medication and physiotherapy. More invasive options are lumbar facet blocks and steroid injections; that offer rather limited pain relief³. **Lumbosacral radiofrequency ablation (RFA) is a commonly used intervention that**

involves selective destruction of medial branch nerves by thermal lesioning to disrupt nociception from painful lumbar facet joints.

Effectiveness of RFA: Although the clinical efficacy of lumbar facet and SIJ RF denervation has been a matter of debate in recent years, (See publication: Interpreting the MINT RCT by Provenzano et al), there is a conclusive body of evidence that upholds the **safe utilization of the procedure in the clinical practice.**

Indeed, the **safety and quality-of-life improvements after lumbosacral RFA were established in two large retrospective real-world studies.** A first study, including almost **50K patients**, quantified the rates of recurring RFA procedures and opioid use after lumbosacral RFA, demonstrating that repeat RFA is performed in one-third of the patients over 3 years. Moreover, **RFA was associated with reduced opioid prescription rates**⁴.

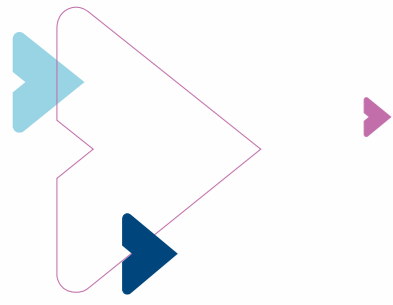
In complement, a second real-world study including **1661 patients** who underwent lumbosacral RFA (out of 4653 analyzed cases) showed not only a **marked reduction in healthcare services utilization after 12 months following RFA but also fewer physician visitations, with some patients eliminating opioid use**⁵. Additional supportive evidence can be found in the review study of Leggett L.E⁶, which includes the collective results of five independent clinical studies that show the efficacy of conventional RFA in reducing lumbar facet joint pain.

This cumulative evidence provides **real-world insight into the utilization of lumbosacral RFA as well as the effectiveness and safety of the procedure**, hence justifying the clinical use of this modality for the most ubiquitous pain condition: chronic low back pain.

References

1. Breivik H et al. Eur J Pain. 2006; 10(4):287-333.
2. Manchikanti L et al. World J Orthop. 2016; 18;7(5):315-37.
3. Perolat R et al. Insights Imaging. 2018; 9(5):773-789
4. Starr JB et al. Spine J. 2020; 20(3):344-351.
5. Loh E et al. Reg Anesth Pain Med. 2019; 44:398-405.
6. Leggett L.E. Pain Res Manag. 2014 Sep-Oct; 19(5): e146-e153.





RF FOR
LUMBAR PAIN

RF FOR SACROILIAC
JOINT PAIN

PULSED RF FOR
RADICULAR PAIN

PULSED RF
MECHANISM OF ACTION

RF FOR
CERVICAL PAIN

Introduction > **MacVicar et al., 2013** > Cosman et al., 2014 > Provenzano et al., 2018

Lumbar Medial Branch Radiofrequency Neurotomy in New Zealand

Study Goal

To determine the effectiveness of lumbar medial branch radiofrequency neurotomy (RFN) in conventional practice.

Methodology

RFN practitioners: Lumbar RFN was performed by two experienced practitioners (two independent practices) trained according to rigorous guidelines.

Patients: 106 patients were selected to receive RFN based on complete lumbar pain relief following diagnostic medial branch blocks.

- Patient's VAS and NRS pain scores, as well as daily living activities were recorded before treatment and during follow-up visits post-procedure. Data recording and analysis were performed in a double-blind setup.

- Complete pain relief, for at least 6 months, accompanied by complete restoration of daily living activities (including the return to work), and no need for any other health care intervention, was adopted as the cardinal criterion for a successful outcome.

RFN procedure: All procedures were carried out with 16-gauge (1.6 mm diameter) Cosman RRE electrodes.

- Either 10 cm or 15 cm electrodes were used, depending on the size of the patient. Electrodes with either 5 mm or 10 mm exposed tips were placed parallel to the medial branches, across the necks of the superior articular processes.
- RFN lesions were created to cover the likely location of the nerves.

Authors:

MacVicar J, Borowczyk J, MacVicar A, Loughnan B, and Bogduk N.

Study type:

Prospective, multicenter, real-world study

Publication:

Pain Medicine 2013; 12(5): 639-45
([Link to PubMed](#) 🔍)

Key Words:

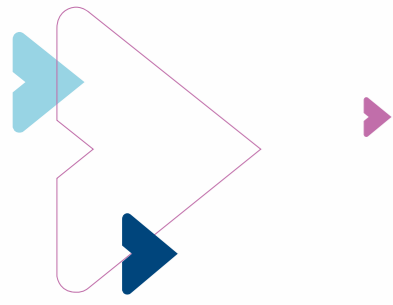
Chronic back pain – Lumbar Medial Branch – Thermal RF

Graphs created by Boston Scientific based on the published data

References

1. Breivik H et al. Eur J Pain. 2006; 10(4):287-333.
2. Manchikanti L et al. World J Orthop. 2016; 18;7(5):315-37.
3. Perolat R et al. Insights Imaging. 2018; 9(5):773-789
4. Starr JB et al. Spine J. 2020; 20(3):344-351.
5. Loh E et al. Reg Anesth Pain Med. 2019; 44:398-405.
6. Leggett L.E. Pain Res Manag. 2014 Sep-Oct; 19(5): e146-e153.





RF FOR LUMBAR PAIN

RF FOR SACROILIAC JOINT PAIN

PULSED RF FOR RADICULAR PAIN

PULSED RF MECHANISM OF ACTION

RF FOR CERVICAL PAIN

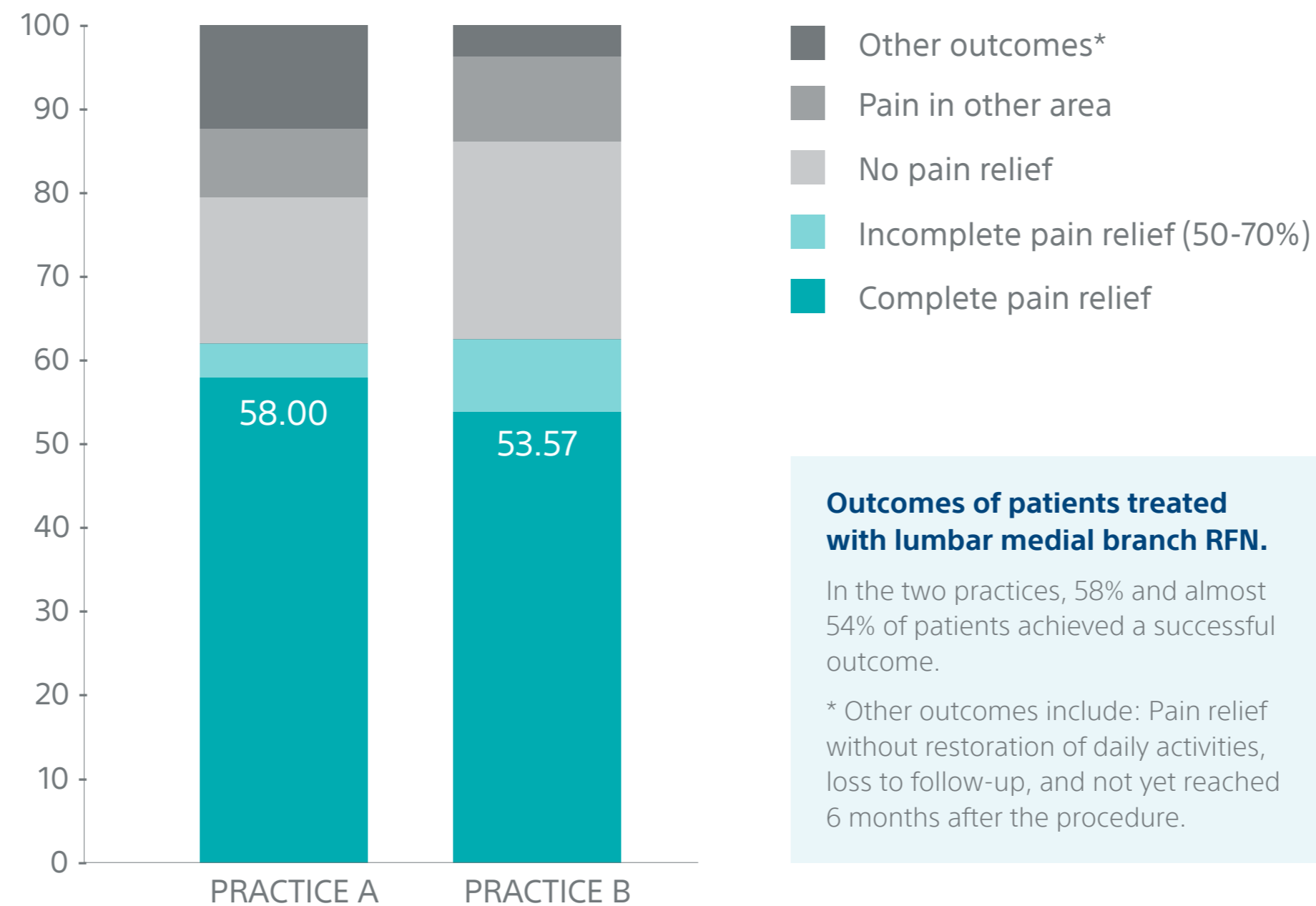
Introduction > **MacVicar et al., 2013** > Cosman et al., 2014 > Provenzano et al., 2018

Lumbar Medial Branch Radiofrequency Neurotomy in New Zealand

Results

- In the two practices, 58% (Practice A) and 53% (Practice B) of patients achieved a successful outcome, with complete pain relief and restoration of daily activities.
- In both practices, pain relief lasted 15 months, from the first RFN procedure.
- Allowing for repeat treatment, patients had sustained pain relief for a median duration of 13 months, with 70% of the patients still reporting relief at follow-up.

CLINICAL OUTCOMES LUMBAR RF (% PATIENTS)



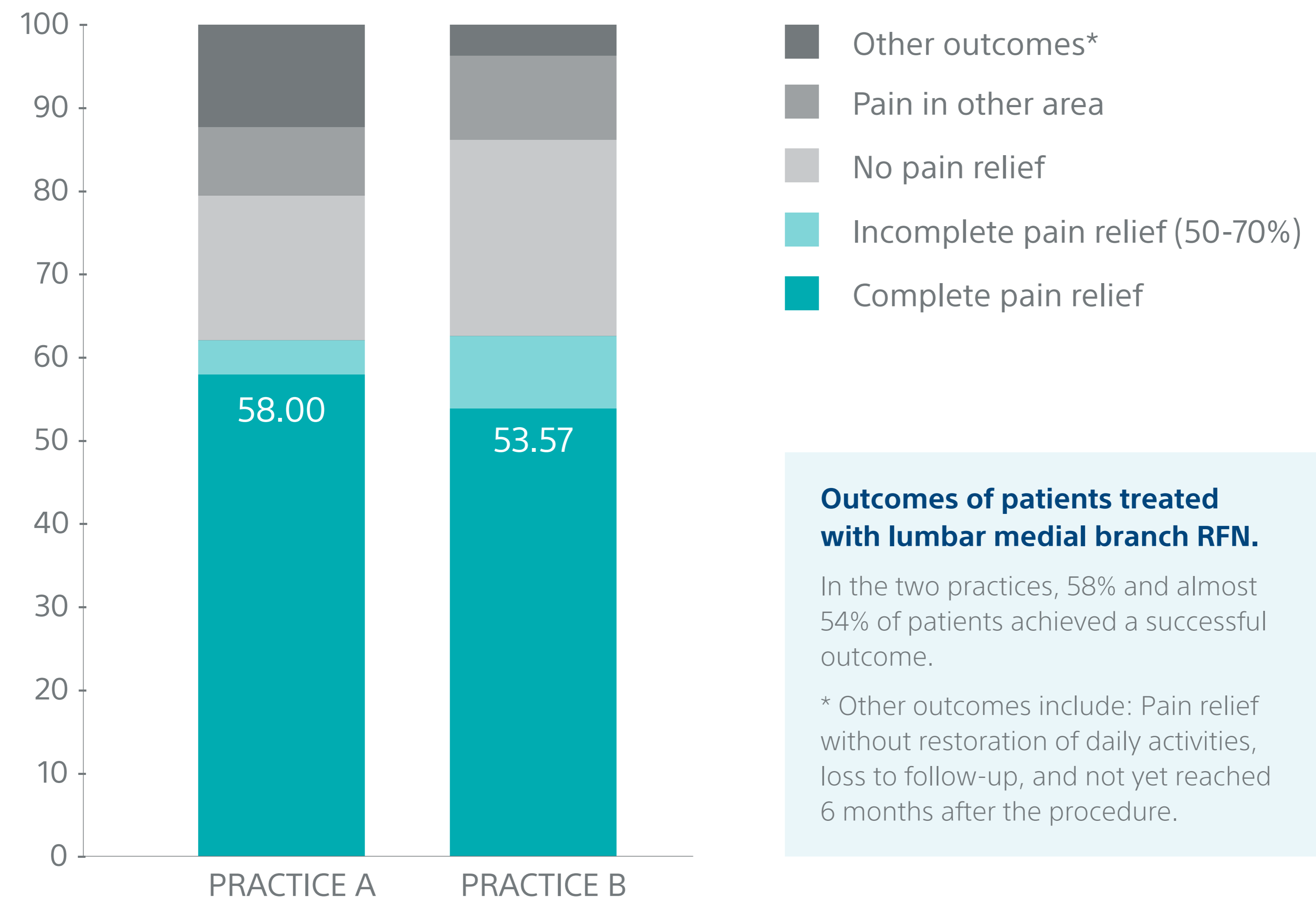
Author's conclusions

- Lumbar RFN can be very effective when performed in a rigorous manner in appropriately selected patients.
- Chronic back pain, mediated by the lumbar medial branches, can be stopped and patients fully restored to normal living, if treated with RFN.





CLINICAL OUTCOMES LUMBAR RF (% PATIENTS)

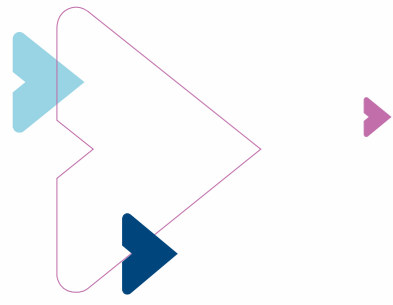


Outcomes of patients treated with lumbar medial branch RFN.

In the two practices, 58% and almost 54% of patients achieved a successful outcome.

* Other outcomes include: Pain relief without restoration of daily activities, loss to follow-up, and not yet reached 6 months after the procedure.





RF FOR LUMBAR PAIN

RF FOR SACROILIAC JOINT PAIN

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PULSED RF MECHANISM OF ACTION

RF FOR CERVICAL PAIN

Introduction > MacVicar et al., 2013 > **Cosman et al., 2014** > Provenzano et al., 2018

Factors That Affect Radiofrequency Heat Lesion Size

Study Goal

- To compare RF heat lesion size across a broad range of active tip diameters, active tip lengths, set temperatures, set times, and modalities available for interventional pain management.
- To evaluate typical cannula and generator configurations, configurations that maximize lesion size, the RRE "Ray" electrode, cooled RF, and bipolar RF under controlled conditions.

Methodology

Monopolar RF lesions were generated in bovine liver, using sharp cannulae with varying tip diameters (22-, 23-, 20-, 16-, and, 18-Gauge), tip lengths (5, 6, 10 and, 15 mm), set temperatures (60°, 70°, 80° and, 90°C) and set times (1, 1.5, 2, 3, 5, and, 10 minutes). For lesion size comparison, the following cannulas were used:

TYPE OF RF LESION	COSMAN CANNULA USED
Monopolar and parallel-tip bipolar	Standard, sharp, bevel-tipped RF cannulae, and Nitinol TC electrodes
Monopolar	Trocar-tipped "Ray" electrode
Monopolar Cooled-RF*	18-ga/4 mm tip internally cooled electrode*



RF Cannulae.

From top to bottom: 1. Curved, sharp, bevel-tip; 2. Straight, sharp, bevel-tip with stylet; 3. RF thermocouple electrode (TE) with nitinol shaft; 4. RF-TE within cannula's inner lumen; 5. Trocar-tip "Ray" RRE electrode.


Authors:

Cosman E. Jr, Dolensky JR, and Hoffman RA.

Study type:

Feasibility – Prospective, single center

Publication:

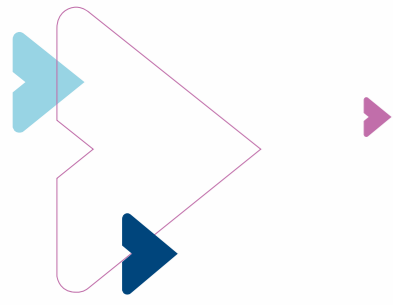
Pain Medicine 2014; 15(12): 2020-36 (Link to PubMed )

Key Words:

Sacroiliac Joint - Bipolar RF vs Cooled RF - Lesion Geometry

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RF FOR
LUMBAR PAIN

RF FOR SACROILIAC
JOINT PAIN

PULSED RF FOR
RADICULAR PAIN

PULSED RF
MECHANISM OF ACTION

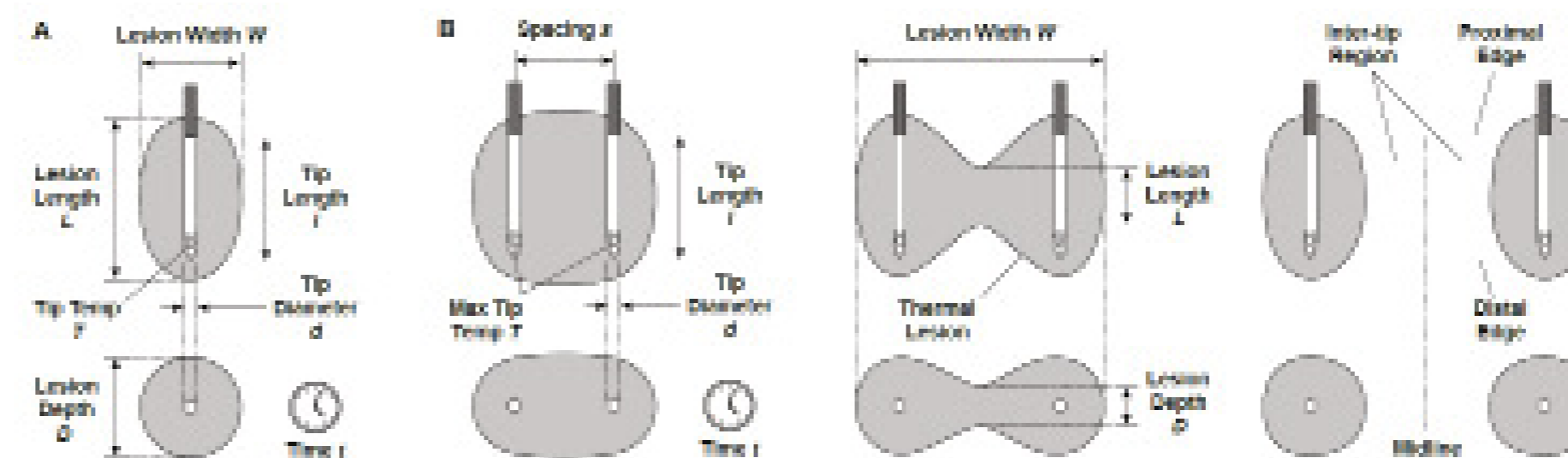
RF FOR
CERVICAL PAIN

Introduction > MacVicar et al., 2013 > **Cosman et al., 2014** > Provenzano et al., 2018

Factors That Affect Radiofrequency Heat Lesion Size

Results

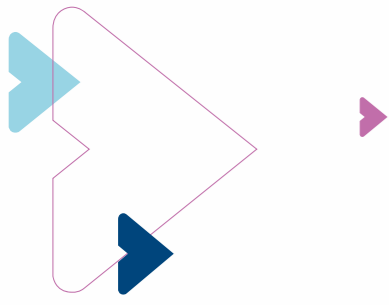
- All the factors (cannula diameters, active tip lengths, set temperatures, and set times) analyzed in the study, were found to significantly affect RF heat lesion size.
- Increasing temperature and/or time enables a thinner cannula to generate lesion dimensions similar to those produced by a thicker cannula at lower temperatures or shorter times.
- With proper selection of generator settings; monopolar RF using a standard 18-gauge or 16-gauge cannulae produces heat lesions similar to those generated by cooled RF for the treatment of SIJ pain
- Bipolar RF between parallel cannulae produces a rounded brick-shaped lesion of comparable shape to three sequential monopolar lesions generated using the same cannulae and generator settings.



RF heat lesion size and influencing factors.

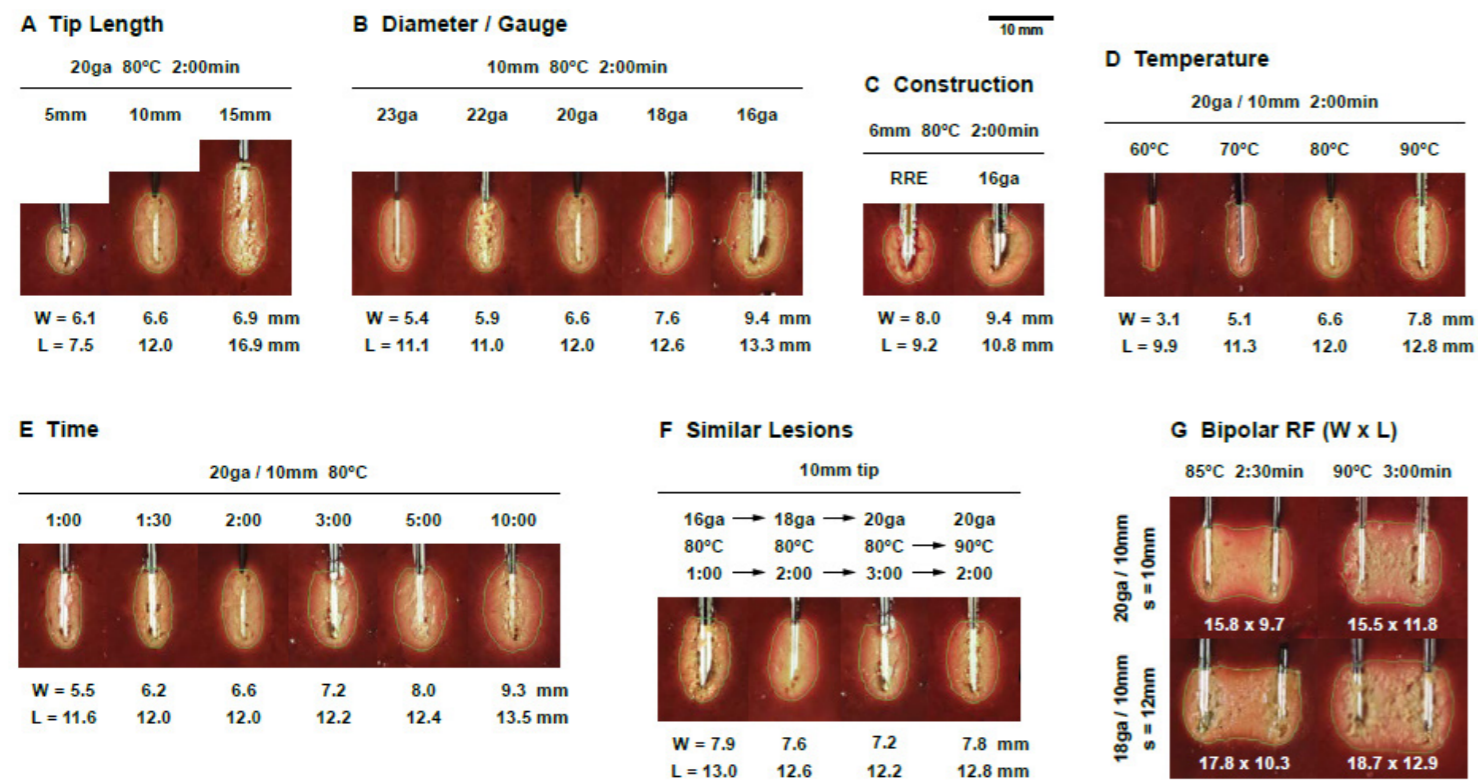
A. Monopolar lesions are egg-shaped. W and D are similar, due to the active tip's predominant radial symmetry. Lesion size depends on d , l , T , t . B. Bipolar lesions are influenced by s . The electric field and current density are more intense between closer tips. As s increases, the lesion expands in W and narrows in both L and D at the midline. For nearby parallel tips, bipolar lesions have a rounded brick shape. At large distances, bipolar lesions have a monopolar shape. Length L , Lesion Width W , depth D , tip diameter/gauge d , tip length l , tip temperature T , lesion time t



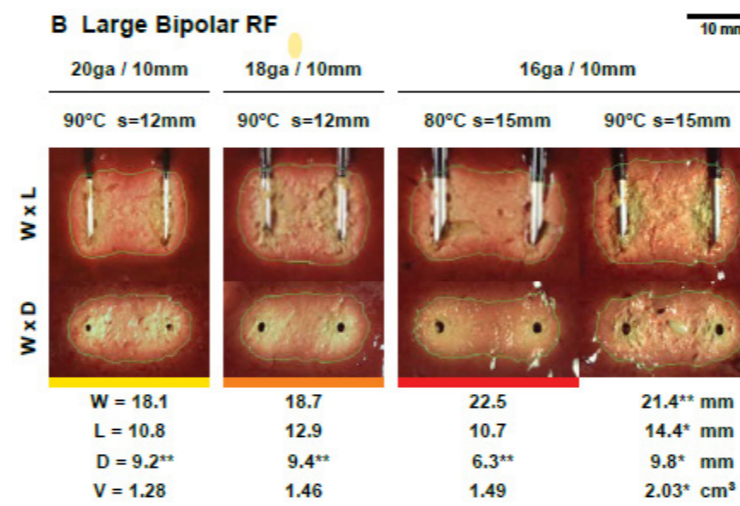
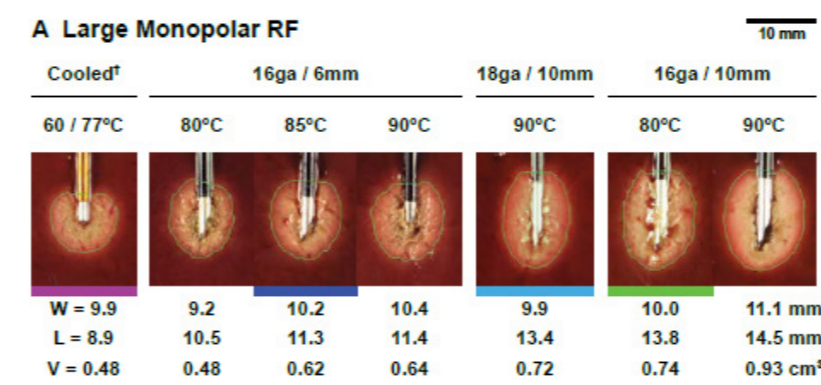


Introduction > MacVicar et al., 2013 > **Cosman et al., 2014** > Provenzano et al., 2018

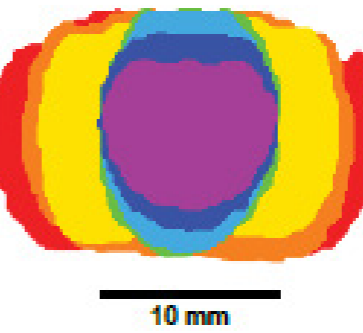
Factors That Affect Radiofrequency Heat Lesion Size



Average size of RF lesions for tested conditions. A. Cannula tip length; B. Cannula diameter/gauge; C. Tip size effect; D. Comparison with RRE electrode (Trocar-tip "Ray"); E. Temperature; E. Time; F. Higher temperature and/or longer lesion size compensate for smaller cannula diameter, and G. Bipolar RF lesion size depends on tip spacing (s), tip length, diameter, temperature and time.



Average size of large RF lesions – Monopolar vs Bipolar RF. A. Monopolar heat lesions, including cooled RF. B. Bipolar lesions. C. Bipolar lesions compared to monopolar lesions at the minimal temperature achieving 10mm average width.



Author's conclusions

Tip gauge, tip length, temperature, and time substantially affect RF lesion size.





TYPE OF RF LESION	COSMAN CANNULA USED
Monopolar and parallel-tip bipolar	Standard, sharp, bevel-tipped RF cannulae, and Nitinol TC electrodes
Monopolar	Trocar-tipped "Ray" electrode
Monopolar Cooled-RF*	18-ga/4 mm tip internally cooled electrode*



RF Cannulae.

From top to bottom: 1. Curved, sharp, bevel-tip; 2. Straight, sharp, bevel-tip with stylet; 3. RF thermocouple electrode (TE) with nitinol shaft; 4. RF-TE within cannula's inner lumen; 5. Trocar-tip "Ray" RRE electrode.

Authors:
Cosman E. Jr, Dolensky JR, and Hoffman RA

Study type:
Feasibility – Prospective, single center

Publication:
Pain Medicine 2014; 15(12): 2020-36
([Link to PubMed](#))

Key Words:
Sacroiliac Joint - Bipolar RF vs Cooled RF - Lesion Geometry

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Factors That Affect

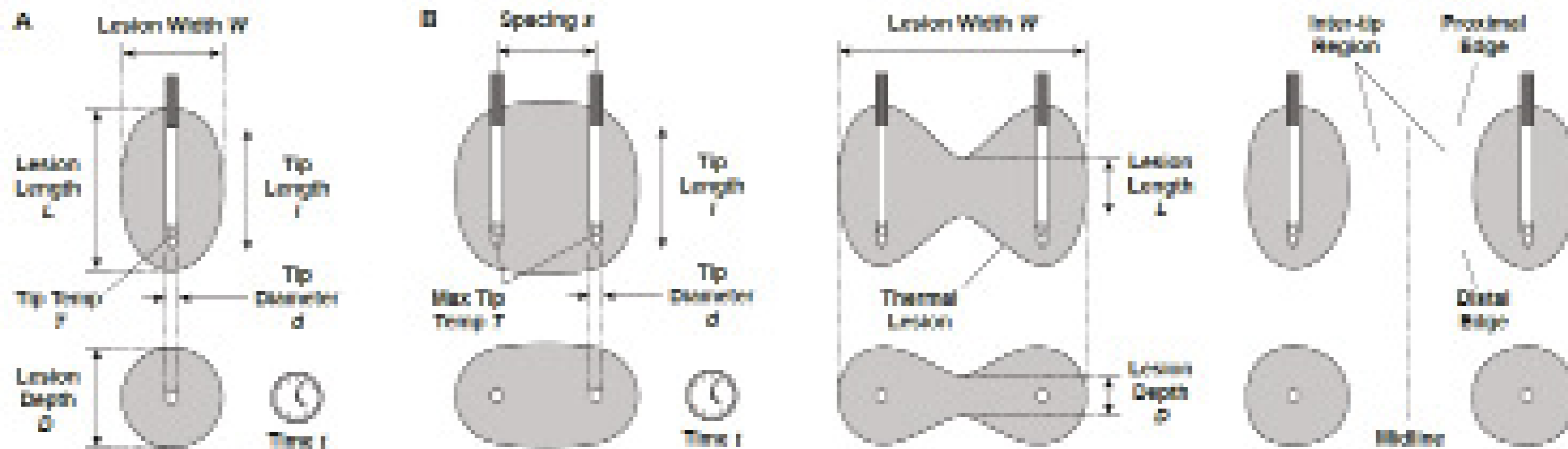
Study Goal

- To compare RF heat lesion size across a range of active tip diameters, active temperatures, set times, and modalities for interventional pain management.
- To evaluate typical cannula and geometry configurations, configurations that vary in size, the RRE "Ray" electrode, cooled RF, and internal cooling under controlled conditions.

Methodology

Monopolar RF lesions were generated using sharp cannulae with varying tip diameters (20-, 16-, and, 18-Gauge), tip lengths (1, 1.5, 2, 3, 5, and, 10 minutes). For lesion creation, the following cannulas were used:





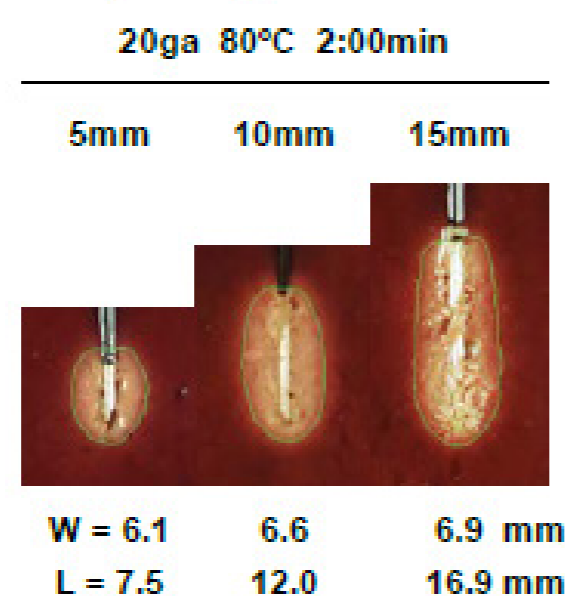
RF heat lesion size and influencing factors.

A. Monopolar lesions are egg-shaped. W and D are similar, due to the active tip's predominant radial symmetry. Lesion size depends on d , l , T , t . B. Bipolar lesions are influenced by s . The electric field and current density are more intense between closer tips. As s increases, the lesion expands in W and narrows in both L and D at the midline. For nearby parallel tips, bipolar lesions have a rounded brick shape. At large distances, bipolar lesions have a monopolar shape. Length L , Lesion Width W , depth D , tip diameter/gauge d , tip length l , tip temperature T , lesion time t

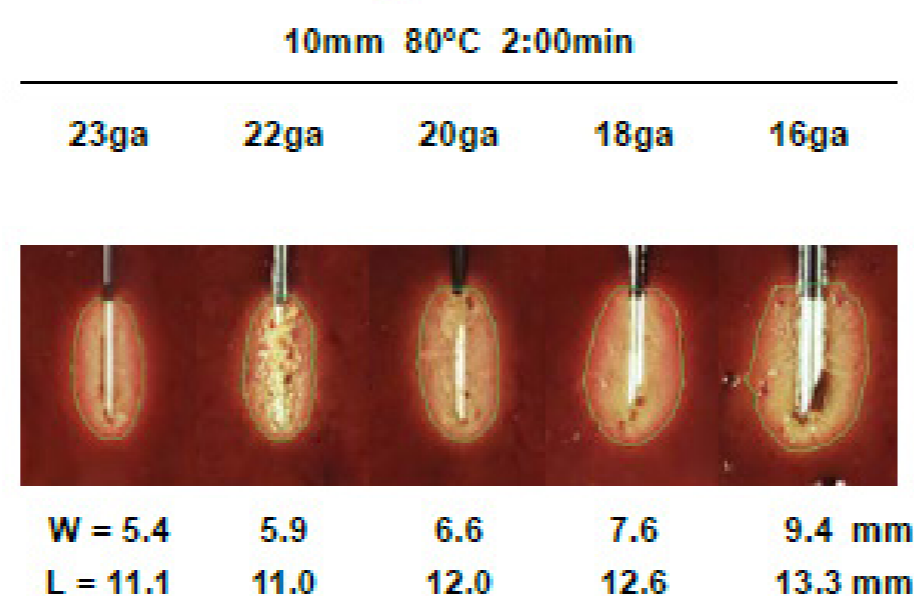




A Tip Length

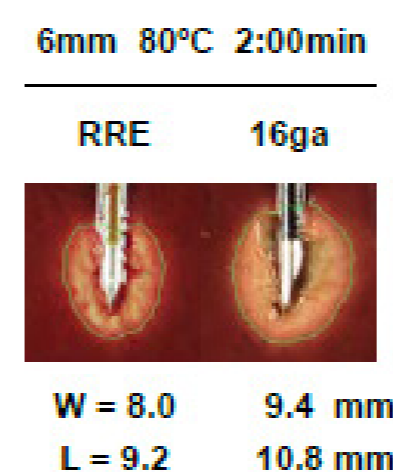


B Diameter / Gauge

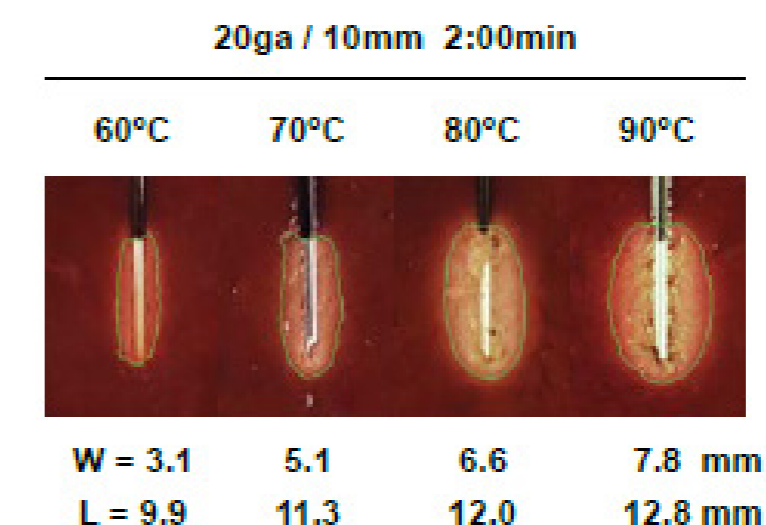


10 mm

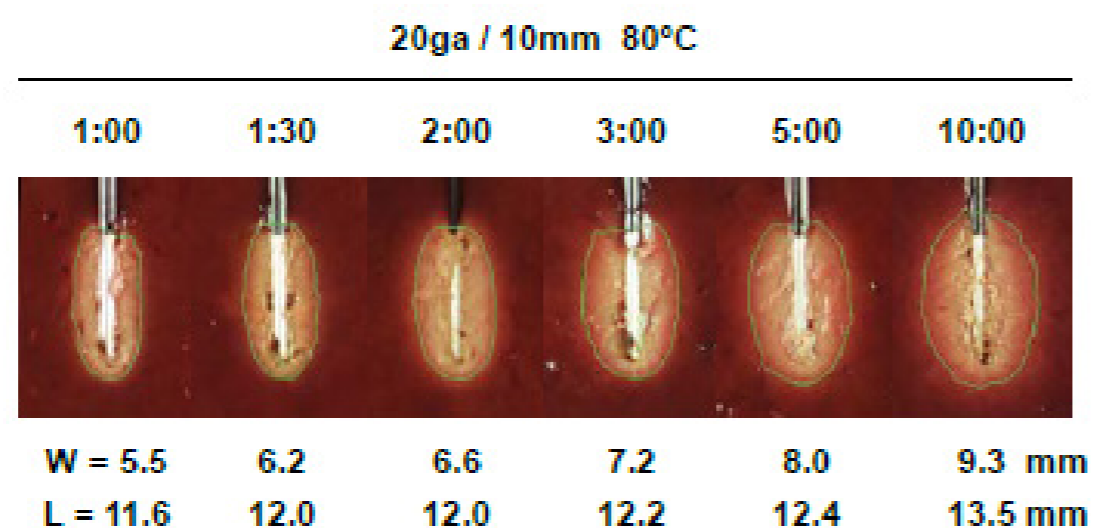
C Construction



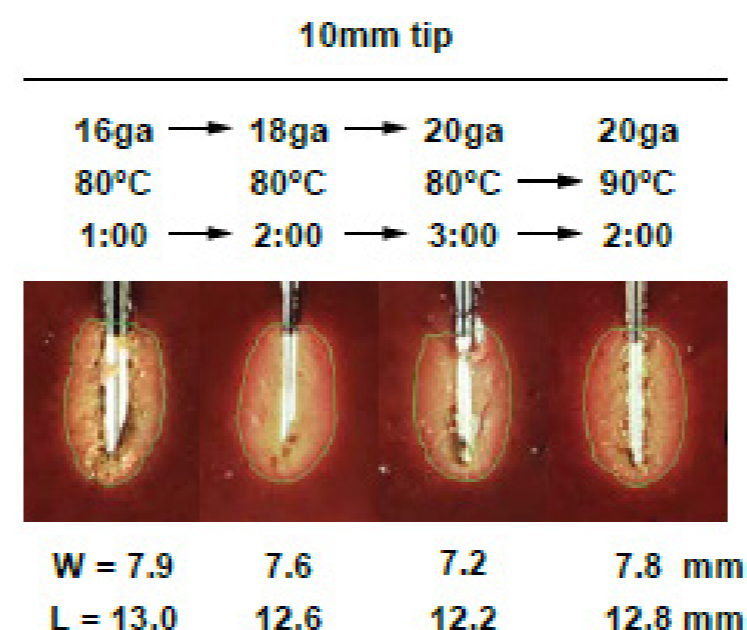
D Temperature



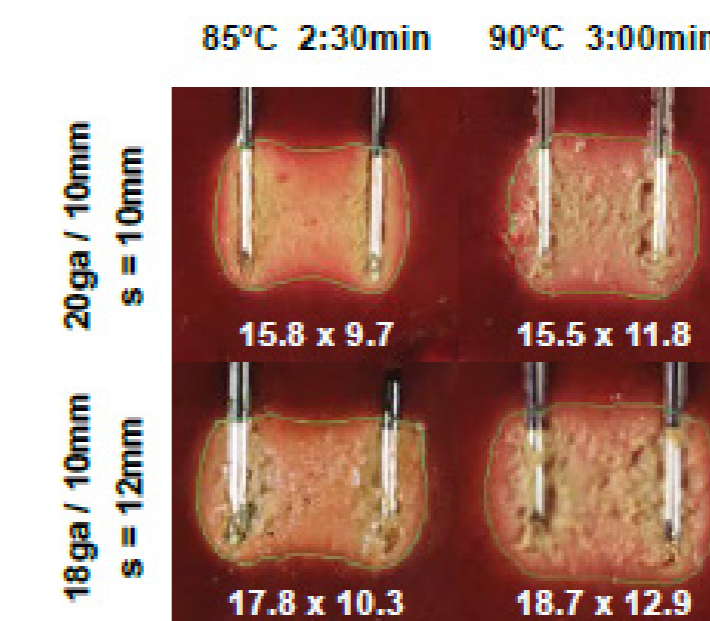
E Time



F Similar Lesions



G Bipolar RF (W x L)

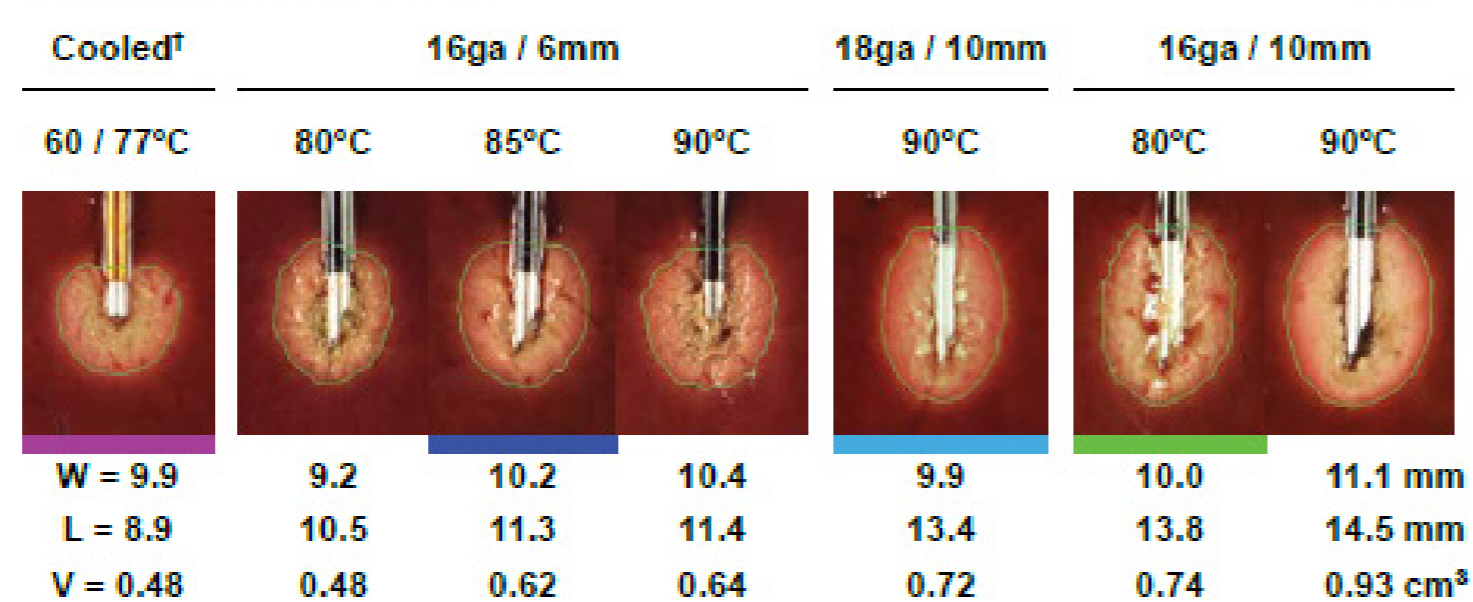


Average size of RF lesions for tested conditions. **A.** Cannula tip length; **B.** Cannula diameter/gauge; **C.** Tip size effect; **D.** Comparison with RRE electrode (Trocar-tip “Ray”); **E.** Temperature; **E.** Time; **F.** Higher temperature and/or longer lesion size compensate for smaller cannula diameter, and **G.** Bipolar RF lesion size depends on tip spacing (s), tip length, diameter, temperature and time.

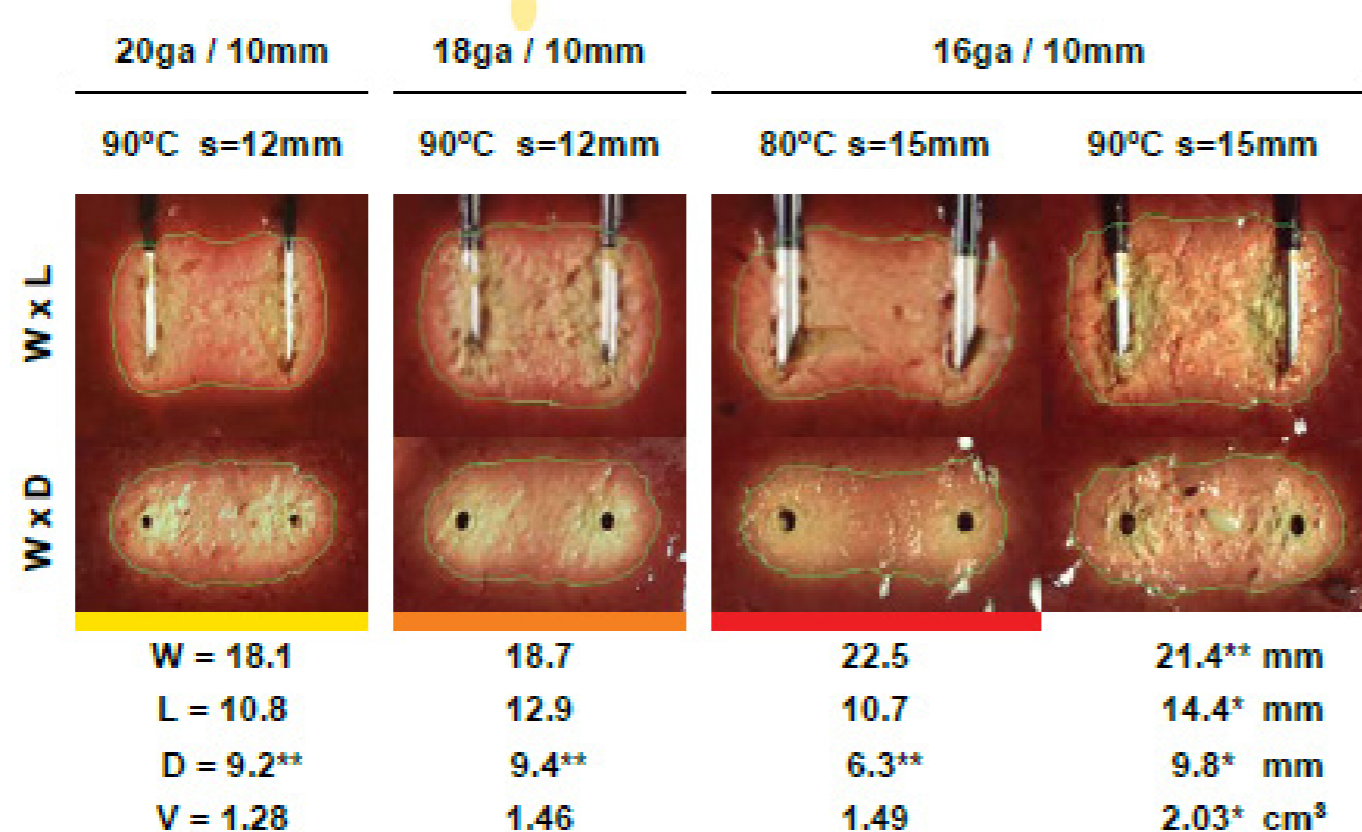




A Large Monopolar RF

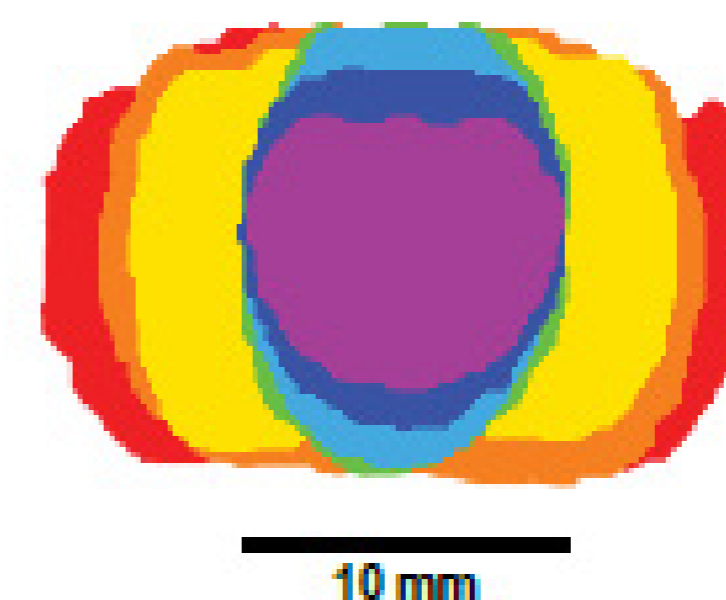


B Large Bipolar RF



C Monopolar vs. Bipolar RF

- Bipolar 16ga/10mm 80°C
- Bipolar 18ga/10mm 90°C
- Bipolar 20ga/10mm 90°C
- Monopolar 16ga/10mm 80°C
- Monopolar 18ga/10mm 90°C
- Monopolar 16ga/6mm 85°C
- Cooled 18ga/4mm 60/77°C†

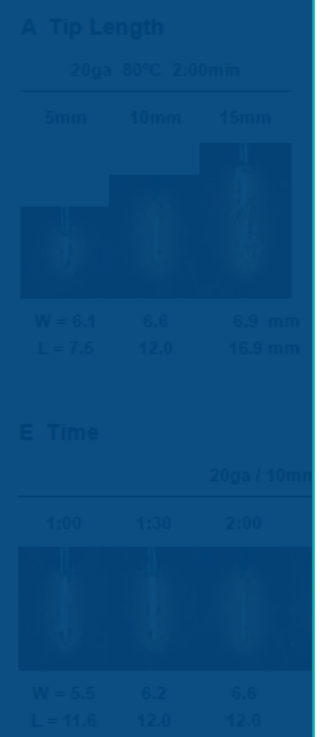


Average size of large RF lesions – Monopolar vs Bipolar RF. A. Monopolar heat lesions, including cooled RF. B. Bipolar lesions. C. Bipolar lesions compared to monopolar lesions at the minimal temperature achieving 10mm average width.

RF F
LUMBA

Introduction >

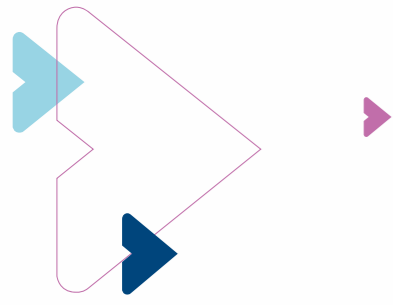
Factors T



Average size of RF lesion
gauge, C. Tip size vs
Time, F. Higher temp
and G. Bipolar RF lesion

RF's
usions
tip length
RF and time
RF lesion





RF FOR
LUMBAR PAIN

RF FOR SACROILIAC
JOINT PAIN

PULSED RF FOR
RADICULAR PAIN

PULSED RF
MECHANISM OF ACTION

RF FOR
CERVICAL PAIN

Introduction > MacVicar et al., 2013 > Cosman et al., 2014 > **Provenzano et al., 2018**

Interpreting the MINT Randomized Trials Evaluating Radiofrequency Ablation for Lumbar Facet and Sacroiliac Joint Pain

Background

In July 2017, Juch* and collaborators published the results of three randomized clinical trials (RCTs) evaluating the effect of radiofrequency denervation on pain intensity among patients with chronic low back pain.

These RCTs were the base of the MINT study (Minimal Interventional Treatment), published in the Journal of the American Medical Association (*Juch, JNS, et al. JAMA. 2017;318:68–81).

The study was funded by the Netherlands Organization for Health Research and Development, the Dutch Society of Anesthesiology, and the Dutch Health Insurance Companies.

MINT study claims

The MINT study raised important questions regarding the efficacy of RFA, as it concluded the following:

- RFA combined with a standardized exercise program results in no clinically meaningful

improvement in chronic low-back pain; compared with the standardized exercise program alone.

- The use of RFA in the treatment of low back pain cannot be supported and should be reserved for research purposes.
- Radiofrequency denervation is no longer being reimbursed in the Netherlands. Exercise and physiotherapy are reimbursed only for a limited number of sessions; for those who can afford private health insurance.


Authors:

Provenzano D,
Buvanendran A, de León
O, Narouze S, and Cohen S.

Study type:

Critical opinion – response
to a publication

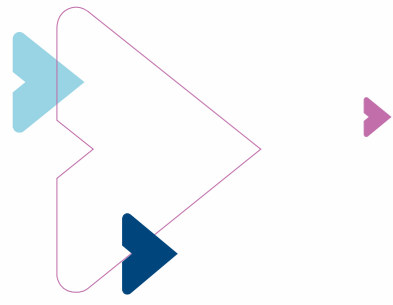
Publication:

Reg. Anesth.
Pain Med 2018; 43(1)
([Link to PubMed](#) )

Key Words:

*Chronic low back pain -
Thermal RF - Procedure
validation*





RF FOR
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RF FOR
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Introduction > MacVicar et al., 2013 > Cosman et al., 2014 > **Provenzano et al., 2018**

Interpreting the MINT Randomized Trials Evaluating Radiofrequency Ablation for Lumbar Facet and Sacroiliac Joint Pain

Response to the MINT study – Provenzano et al.

Six months after the publication of the MINT study, a response to the claims thereof came from Provenzano and collaborators.

The authors conclude that the MINT RCT was significantly flawed in three major areas:

- Study design and data interpretation: The MINT analyses were not blinded. Moreover, statistical analyses applied were not valid, as they failed to adjust to multiple group averages.
- Patient selection: The authors of the MINT study did not use controlled diagnostic facet blocks, which is a critical step in selecting patients that could benefit from RFA.
- RFA procedure technical aspect: the anatomical approach for cannula insertion as well as the lesion time were not appropriate and might have influenced the outcomes of the study.

Conclusions

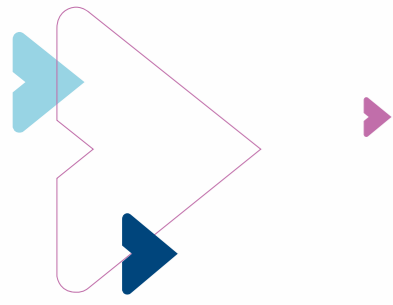
Provenzano and collaborators conclude that the MINT study is flawed and inconclusive. Moreover, it obstructs the management of patients with chronic low back pain, originating from the facet and sacroiliac joints, from receiving properly performed RFA.





Radiofrequency ablation for Sacroiliac Joint Pain





RF FOR
LUMBAR PAIN

RF FOR SACROILIAC
JOINT PAIN

PULSED RF FOR
RADICULAR PAIN

PULSED RF
MECHANISM OF ACTION

RF FOR
CERVICAL PAIN

Introduction > Cheng et al., 2016 > Cosman and Gonzalez, 2011

Introduction

The sacroiliac joint (SIJ) syndrome is defined as a mechanical pain originated in the SIJ, generally localized in the gluteal region. Nevertheless, referred SIJ pain might be also perceived in the lower lumbar region, groin, upper lumbar region, and rarely, in the abdomen. Consequently, SIJ pain can be difficult to distinguish from other forms of low back pain¹.

Prevalence: Depending on the diagnostic criteria employed (SIJ provocation maneuvers, intra-articular block test, or medical imaging), the reported prevalence of SIJ pain varies between 16% and 30%; among patients with chronic low back pain complaints. Risk factors for SIJ pain include leg-length discrepancy, abnormal gait pattern, and trauma; among others¹.

Treatment: Conventionally, the SIJ syndrome has been managed with intra- and extra-articular steroid injections that offer rather mild and limited pain management. Thermal Radiofrequency Ablation (RFA) is an accepted, effective, and long-lasting alternative for the treatment of SIJ pain that relies on RF-generated thermal energy (80-90°C) to coagulate the sensory nerve fibers of the SIJ, thereby interrupting nociceptive neurotransmission¹.

Effectiveness of RFA: Clinical evidence corroborating the effectiveness of thermal RFA for the management of SIJ pain has been consolidated in two meta-analyses and two recent literature review studies¹⁻⁴ that encompass not only the main clinical findings reported in more than 10 publications (including various observational,

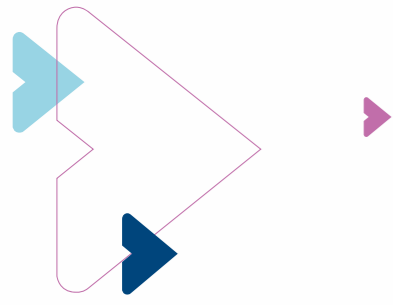
retrospective and randomized clinical studies) but also the outcomes of more than 300 patients. These studies indicate that patients treated with RF for SIJ pain achieve significant pain relief (more than 50%) for at least 6 months, compared with other conservative nonsurgical treatments. Moreover, this cumulative evidence also points toward a significant improvement in functional outcomes; i.e., disability and quality of life improvement scores¹⁻³

The palisade RFA procedure using the Palisade™ block (Cosman) is included as a standardized approach for the denervation of the SIJ in the interventional pain guidebook for the FIPP exam (World Institute of Pain's (WIP) -Fellow of Interventional Pain (FIPP) examination)⁵.

References

1. Vanelderen P et al. Pain Pract. 2010; 10:470-8.
2. Aydin SM et al. PM&R. 2010; 2:842-851.
3. Chen CH et al. Medicine. 2019; 98:26 (e16230).
4. Yang A et al. PM&R. 2019; 11 Suppl 1:S105-S113.
5. de Andres Ares J. 2020; In book: Stogicza A.R., et al. Interventional Pain. Springer. 195-201.





RF FOR
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RF FOR SACROILIAC
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RADICULAR PAIN

PULSED RF
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CERVICAL PAIN

Introduction > **Cheng et al., 2016** > Cosman and Gonzalez, 2011

A New Radiofrequency Ablation Procedure to Treat Sacroiliac Joint Pain

Study Goal

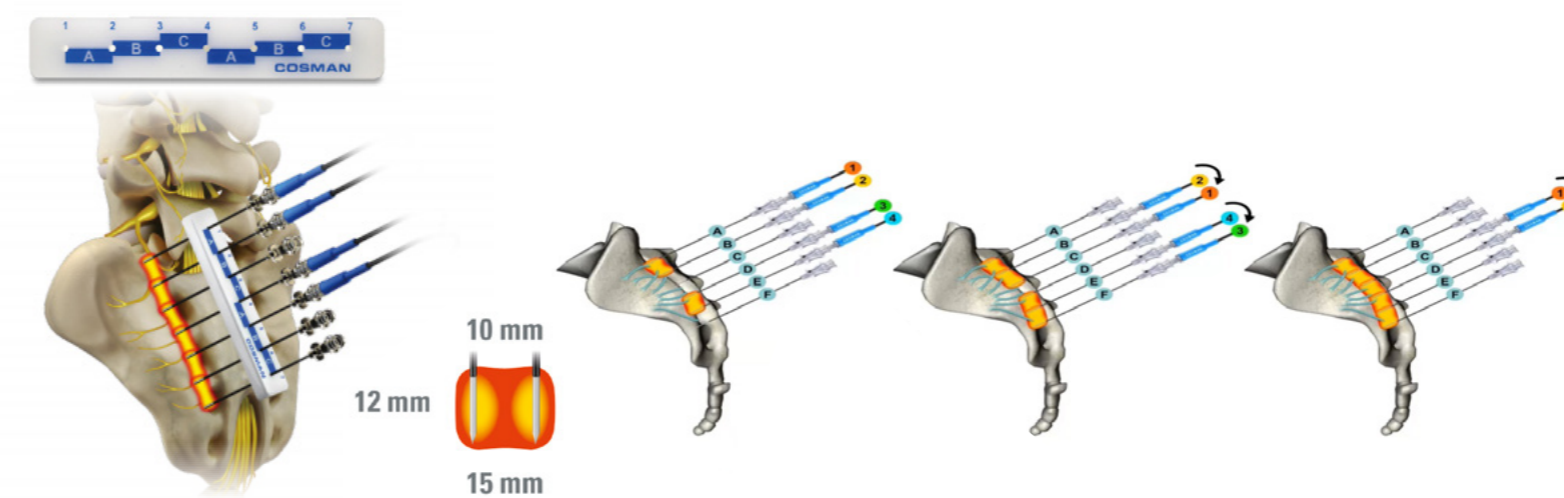
In this study, the authors developed a novel bipolar radiofrequency (bRFA) ablation technique to relieve pain secondary to SIJ disorders. This study also compared the effectiveness of bRFA ablation with cooled RF (cRFA).

Strategy

- Devise a guide-block device that facilitates accurate placement of multiple electrodes to simultaneously ablate the L5 dorsal ramus and lateral branches of the S1, S2, and S3 dorsal rami.
- Use of bipolar RF ablation to create a strip-like lesion covering from the lateral border of the base of the sacral superior articular process (L5-S1 facet joint) to the lateral border of the S3 sacral foramen.

Methodology

- Apply this novel technique in N=31 patients and compare the procedural and clinical outcomes with a group of N=62 patients who were treated with cRFA.
- Study outcomes included: Pain relief at one-year follow-up, operating time, and radiation exposure and dose.



The SIJ area is a difficult area to treat, due to size, accessibility, and varying patients' anatomy. The disposable Palisade™ guide-block simplifies the placement and alignment of cannulas, to create larger lesions and/or two bipolar lesions at once.


Authors:

Cheng J, Chin S.L,
Zimmerman N,
Dalton J.E, La Salle G,
Rosenquist R.W

Study type:

Methodology
development.
Prospective non-
randomized trial.

Publication:

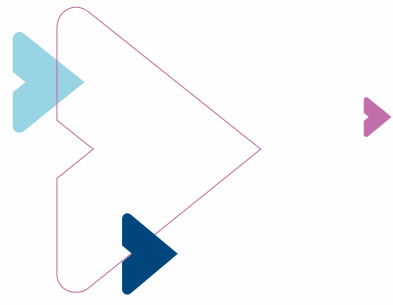
Pain Physician 2016;
19:603-615
(Link to PubMed )

Key Words:

Chronic Low back pain
– Sacroiliac Joint –
bipolar RF vs cooled RF -
Palisade™

Graphs created by Boston Scientific
based on the published data.





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RF FOR SACROILIAC JOINT PAIN

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RF FOR CERVICAL PAIN

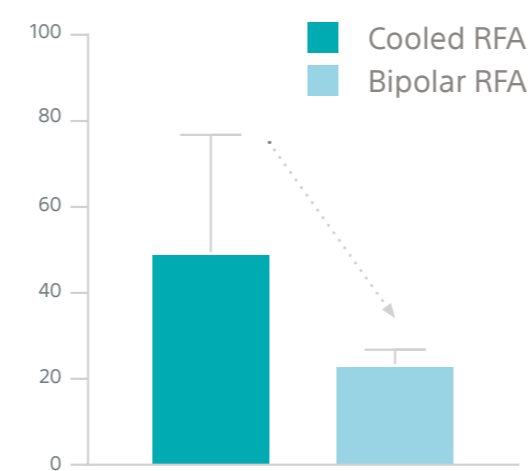
Introduction > **Cheng et al., 2016** > Cosman and Gonzalez, 2011

A New Radiofrequency Ablation Procedure to Treat Sacroiliac Joint Pain

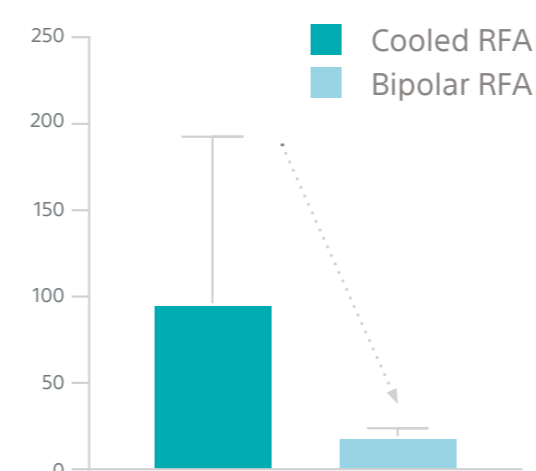
Results

- bRFA, aided by the new guide-block device (Palisade™), provided satisfactory pain relief ($p < 0,001$, 1, 3, 6, and 12 months), and demonstrated to be clinically and statistically superior to cRFA.
- Operating time and X-ray exposure were reduced by >50% and >80%, respectively. Procedural costs were reduced by > \$1,000 per case.

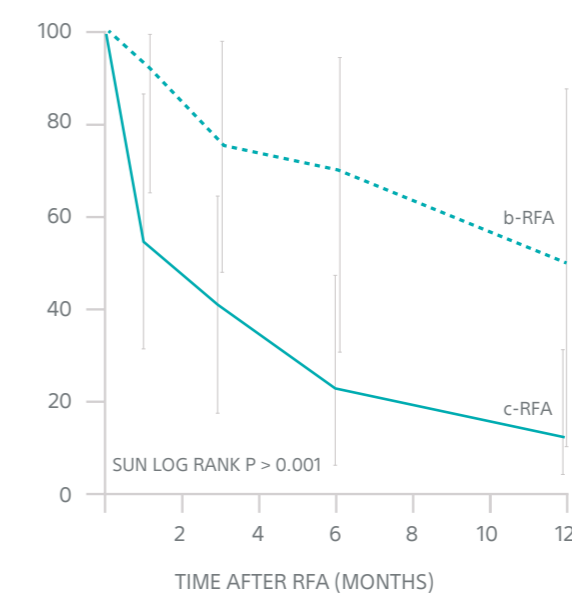
OPERATING TIME (MINUTES)



X-RAY EXPOSURE TIME (SEC)



PERCENT WITH >50% PAIN RELIEF

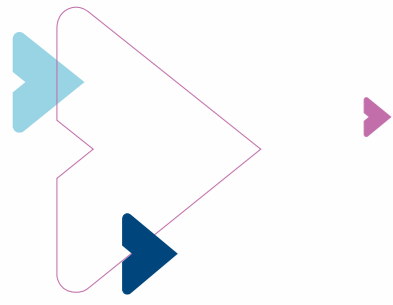


Operating time. (bRFA: 23.5 ± 3.27 vs cRFA: 49.5 ± 27.25). **X-ray exposure time.** (bRFA: 19.1 ± 4.7 vs cRFA: 96.3 ± 96.2). Wide standard deviation (cRFA) reflects procedure difficulties and operators' experience. bRFA patients experienced a longer duration of >50% pain relief

Author's conclusion

This new method of RF ablation is safe, efficacious, and cost-effective.





RF FOR LUMBAR PAIN	RF FOR SACROILIAC JOINT PAIN	PULSED RF FOR RADICULAR PAIN	PULSED RF MECHANISM OF ACTION	RF FOR CERVICAL PAIN
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Introduction > Cheng et al., 2016 > **Cosman and Gonzalez, 2011**

Bipolar Radiofrequency Lesion Geometry: Implications for Palisade™ Treatment of Sacroiliac Joint Pain

Study Goal

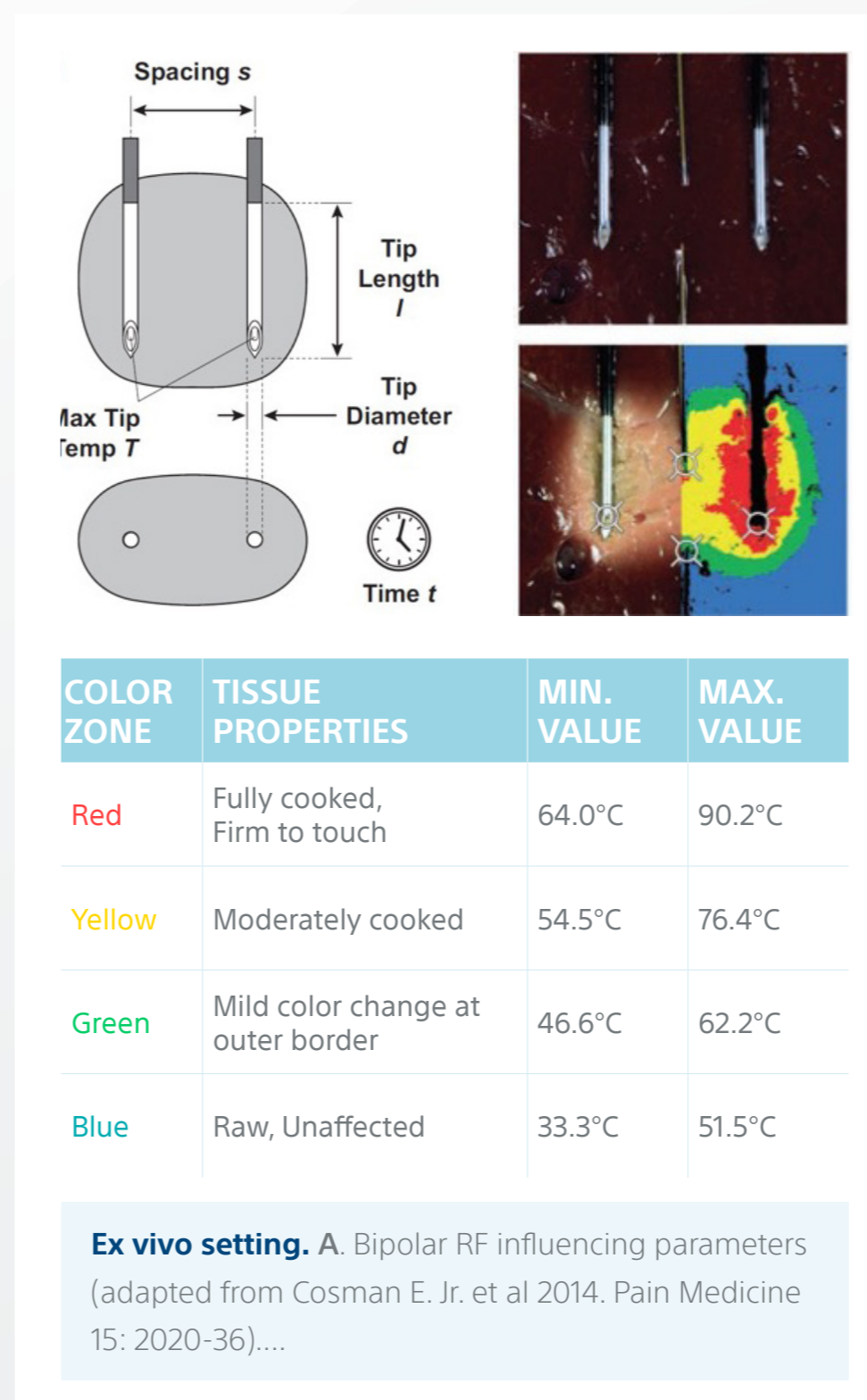
To optimize the use of bipolar radiofrequency (RF) for lesioning the dorsal Sacroiliac Joint (SIJ) innervation to improve treatment and clinical outcomes in back pain management.

Strategy

The effect of different RF parameters on RF lesion geometry was tested by temperature mapping, both ex vivo and in vivo. These observations were translated into a new straightforward method for lesioning the dorsal SIJ innervation, to create a more continuous lesion zone than other RF methods.

Methodology

Ex vivo setup: Bipolar RF lesions were generated in bovine liver varying several configuration parameters: electrode inter-tip spacing (s), cannulae diameter (d), tips length (l), tip temperature (T), and lesion time (t). Photographic temperature mapping was used to facilitate the interpretation of post-lesions images. Quantification of RGB pixel values correlate with temperature measurements (e.g., yellow color for a “cooked” zone indicates temperatures greater than 50°C).



Authors:
Cosman E. Jr. and Gonzalez C.

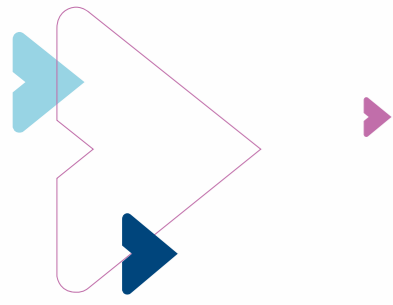
Study type:
Experimental validation. Ex vivo and In vivo data collection

Publication:
Pain Practice 2011; 11(1):3-22
([Link to PubMed](#))

Key Words:
Chronic Back Pain – Sacroiliac Joint – Bipolar RF – Lesion Geometry

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RF FOR LUMBAR PAIN

RF FOR SACROILIAC JOINT PAIN

PULSED RF FOR RADICULAR PAIN

PULSED RF MECHANISM OF ACTION

RF FOR CERVICAL PAIN

Introduction > Cheng et al., 2016 > **Cosman and Gonzalez, 2011**

Bipolar Radiofrequency Lesion Geometry: Implications for Palisade™ Treatment of Sacroiliac Joint Pain

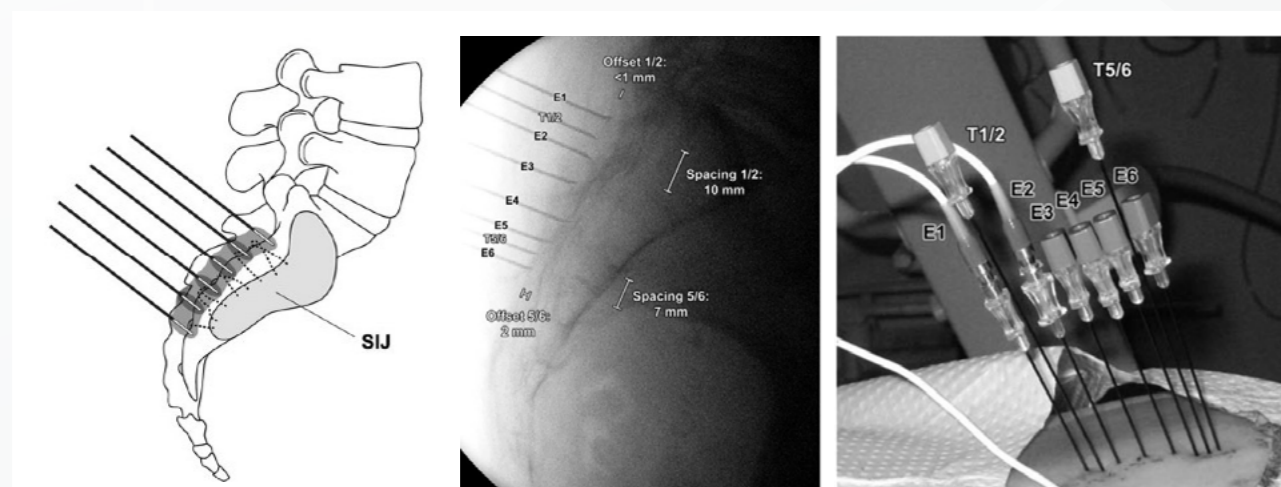
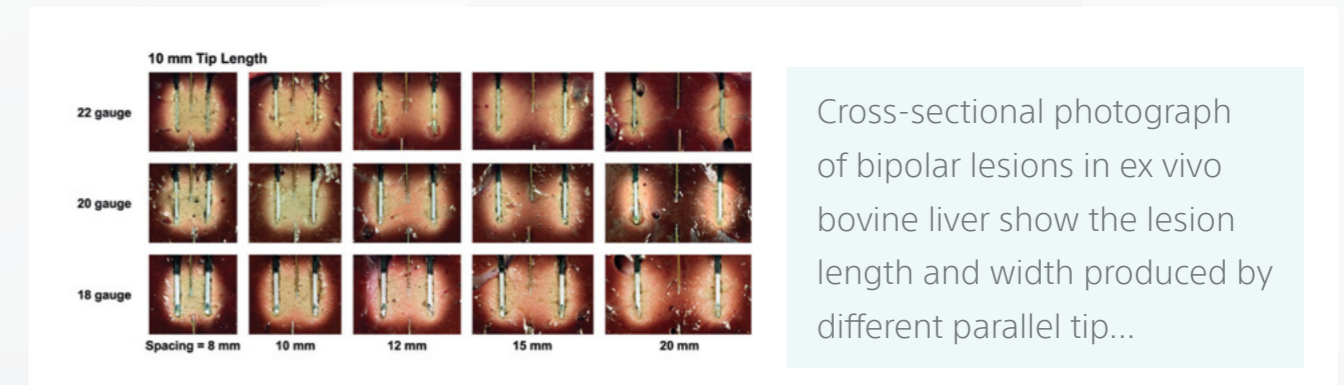
In vivo setup: Palisade treatment to ablate dorso-sacral innervations of the SIJ was performed in 8 patients who presented with unilateral SIJ pain.

Remote temperature probes, placed at the sacral surface between two lesion cannulae, were used to confirmed sustained neurolytic temperatures.

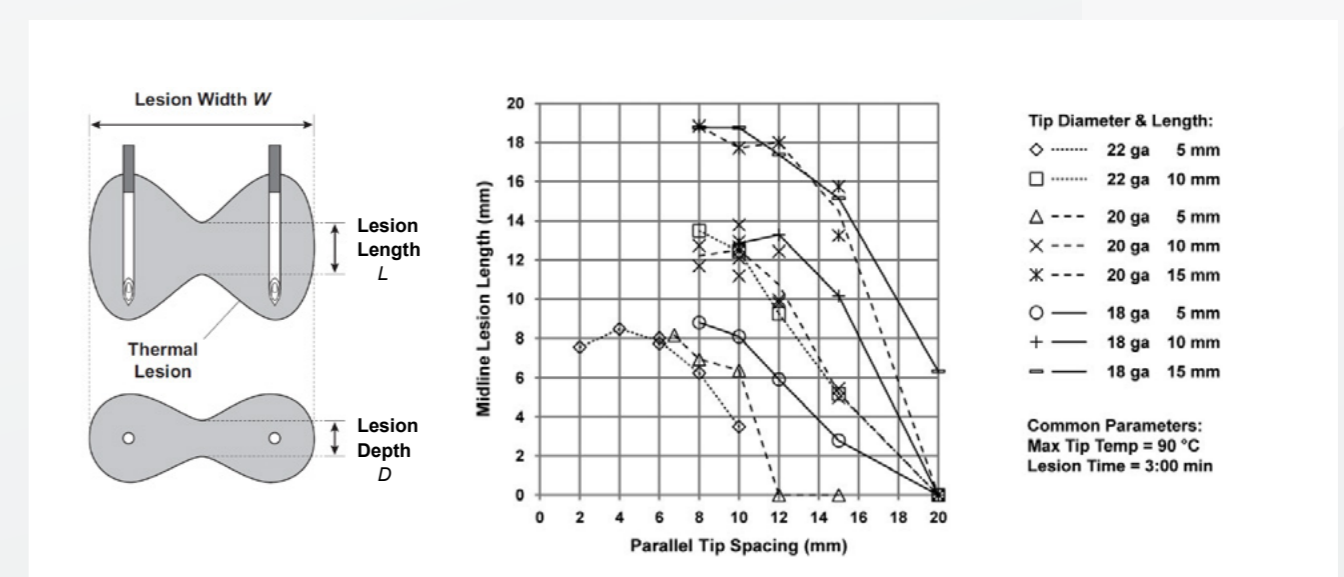
Results

Ex vivo setup

- Animal tissue experiments demonstrated that heating (lesioning) between bipolar tips is enhanced as tip diameter, tip length, tip temperature, and/or lesion time are increased.
- Lesion geometry is insensitive to variations in inter-tip angles and offsets.
- Both ex vivo and in vivo data indicate that a parallel spacing of 10 mm is a conservative choice for generating a rounded rectangular bipolar lesion (using 10mm or 15mm tip lengths, 18- or 20-gauge cannulae, and 90°C set temperature, within a 3-minute lesion time).

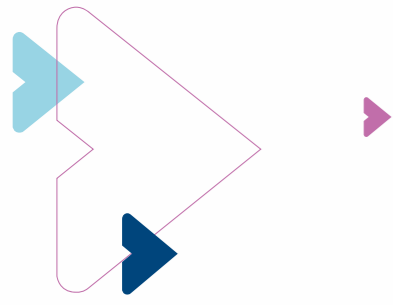


In vivo setting. A. Palisade treatment of SIJ pain. A row of six RF cannulae (20-gauge diameter, 10mm tip length, 10mm inter-spacing) were inserted to target the dorsal sacral surface between S1-S3 dorsal foramina and....



Measurements of midline lesion length (L) in ex vivo bovine liver produced by variable tip parallel spacings, diameters, and lengths (90°C tip temperature and 3-minute lesion time). Midline lesion length increases with higher cannulae diameter and tip length





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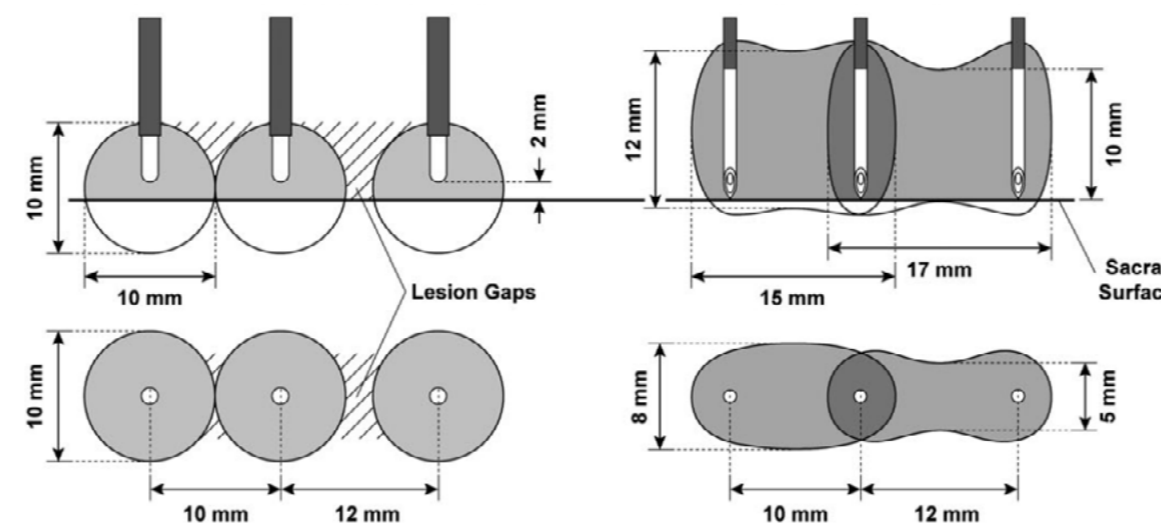
RF FOR
CERVICAL PAIN

Introduction > Cheng et al., 2016 > **Cosman and Gonzalez, 2011**

Bipolar Radiofrequency Lesion Geometry: Implications for Palisade™ Treatment of Sacroiliac Joint Pain

In vivo setup

- Clinical outcomes of the palisade denervation of the SIJ were positive, although assessed over a short follow-up time.
- Bipolar RF lesions can be as large as those achieved with cooled RF
- Temperature control is better achieved with bipolar RF compared to cooled RF, as it can be directly measured in a known position, within the electrode tip(s) or inter-tip(s) region(s). In cooled RF, the maximum tissue temperature is reached at a variable distance from the electrode tip.



In cooled RF, an increase in tip-to-tip distance can give rise to gaps between adjacent lesions in the sacral surface, whereas individual bipolar lesions can be larger than cooled RF lesions

Bipolar palisade RF produces lesions of consistent height, width, and depth, with no gaps.

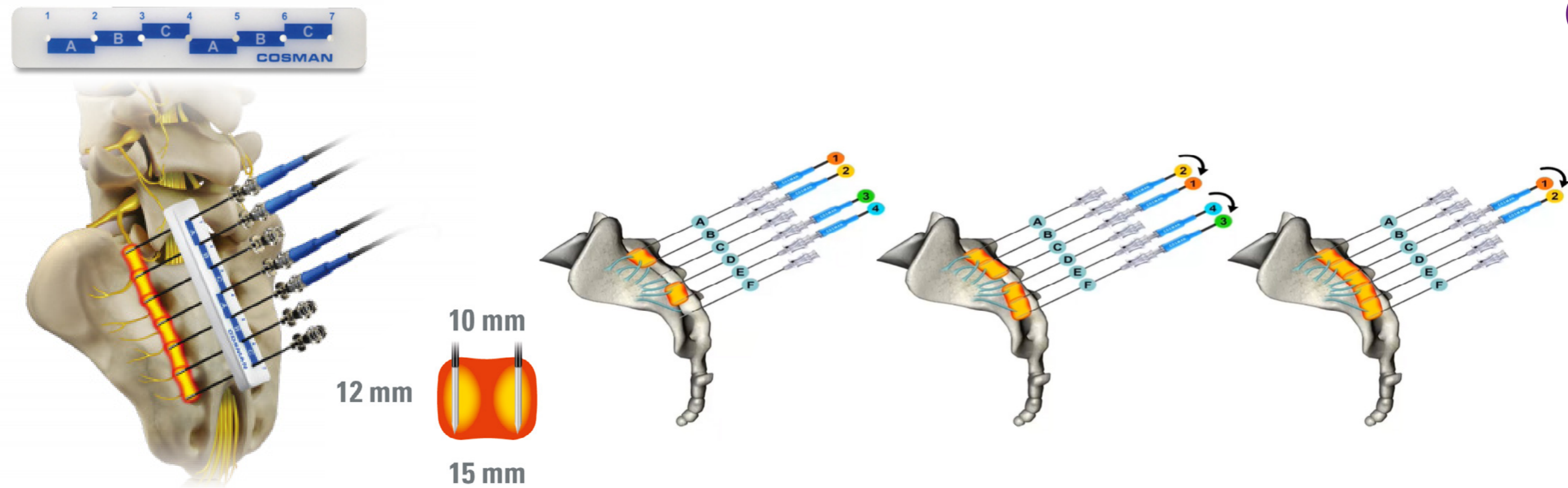
Figure adapted from Cosman E. Jr. et al 2014. Pain Medicine 15: 2020-36.

Author's conclusion

- The new bipolar palisade (a defensive fence) creates a continuous lesion area that covers the multiple sacral lateral branch nerves innervating the SIJ.
- The size and shape of palisade bipolar RF lesions might be advantageous for pain management cases where larger lesions or lesions side-by-side (without gaps) are desired.



RF FOR SACROILIAC JOINT PAIN



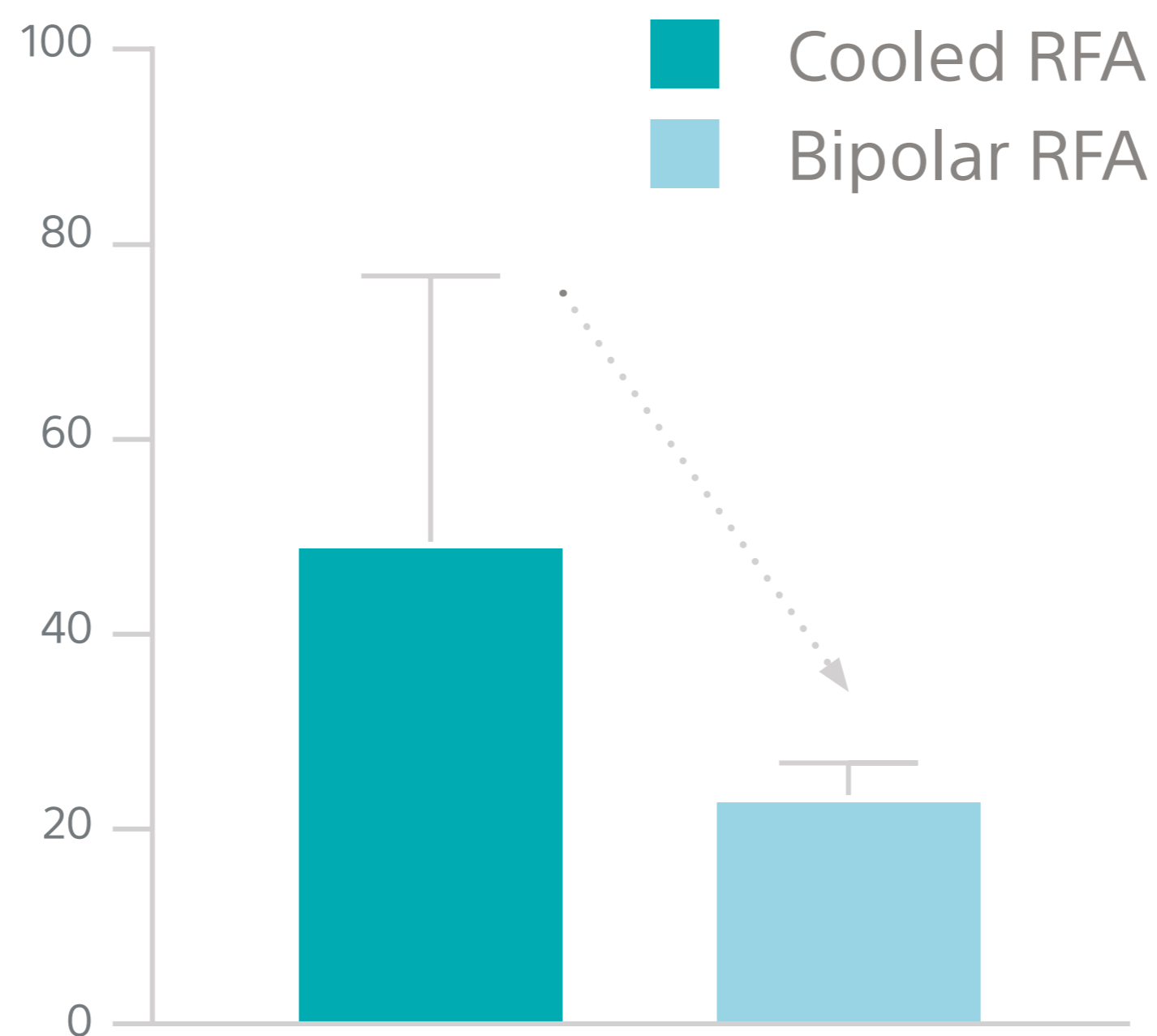
The SIJ area is a difficult area to treat, due to size, accessibility, and varying patients' anatomy. The disposable Palisade™ guide-block simplifies the placement and alignment of cannulas, to create larger lesions and/or two bipolar lesions at once.

disposable Palisade™ guide-block simplifies the placement and alignment of cannulas, to create larger lesions and/or two bipolar lesions at once.

Graphs created by Boston Scientific based on the published data.



OPERATING TIME (MINUTES)



Operating time.

(bRFA: 23.5 ± 3.27 vs cRFA: 49.5 ± 27.25).

X-ray exposure time.

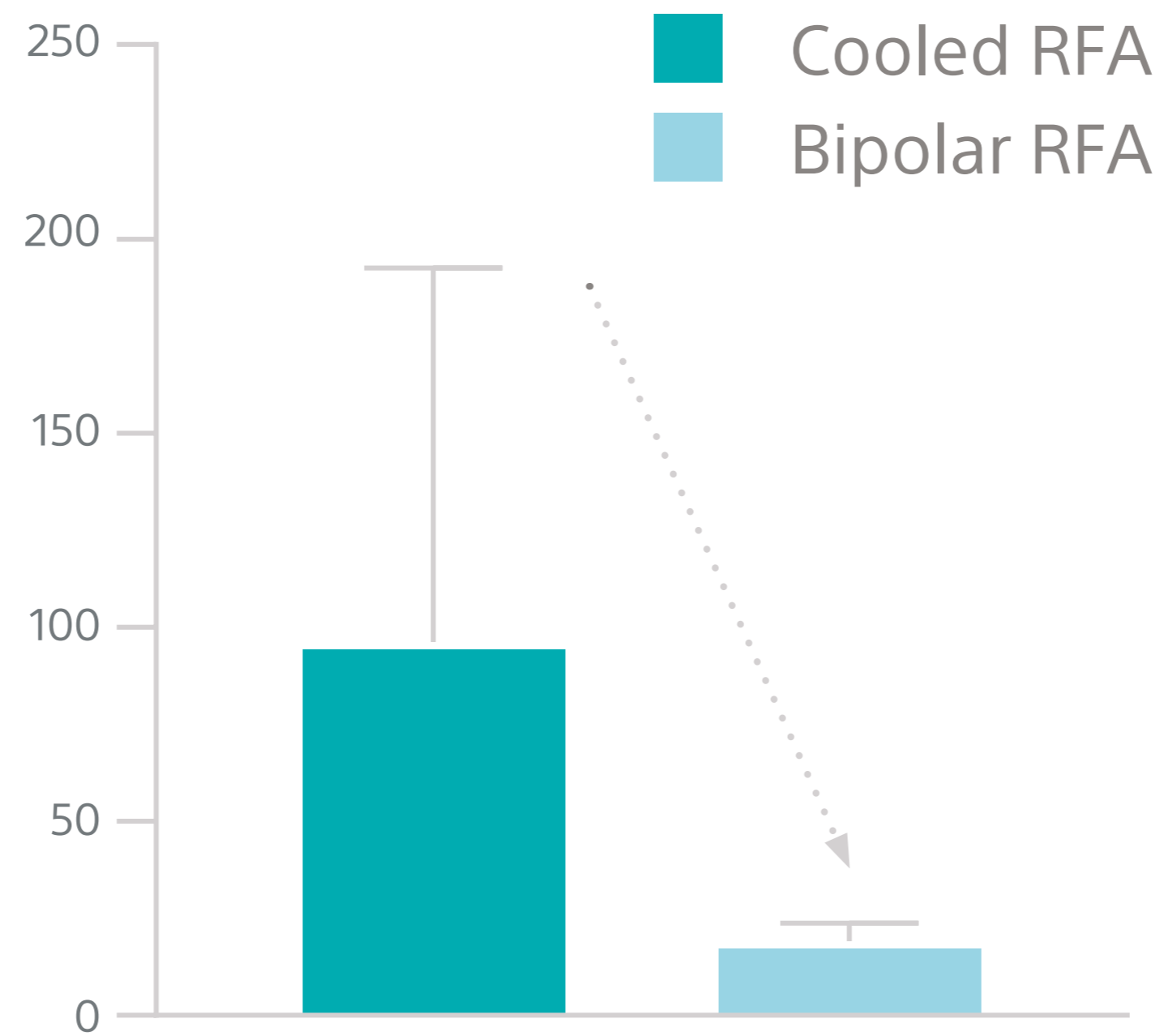
(bRFA: 19.1 ± 4.7 vs cRFA: 96.3 ± 96.2). Wide standard deviation (cRFA) reflects procedure difficulties and operators' experience. bRFA patients experienced a longer duration of >50% pain relief

Author's conclusion

This new method of RF ablation is safe, efficacious, and cost-effective.



X-RAY EXPOSURE TIME (SEC)



Operating time.

(bRFA: 23.5 ± 3.27 vs cRFA: 49.5 ± 27.25).

X-ray exposure time.

(bRFA: 19.1 ± 4.7 vs cRFA: 96.3 ± 96.2). Wide standard deviation (cRFA) reflects procedure difficulties and operators' experience. bRFA patients experienced a longer duration of >50% pain relief

Abstract
Introduction

Introduction > Cheng et al.

A New Radiofrequency

Results

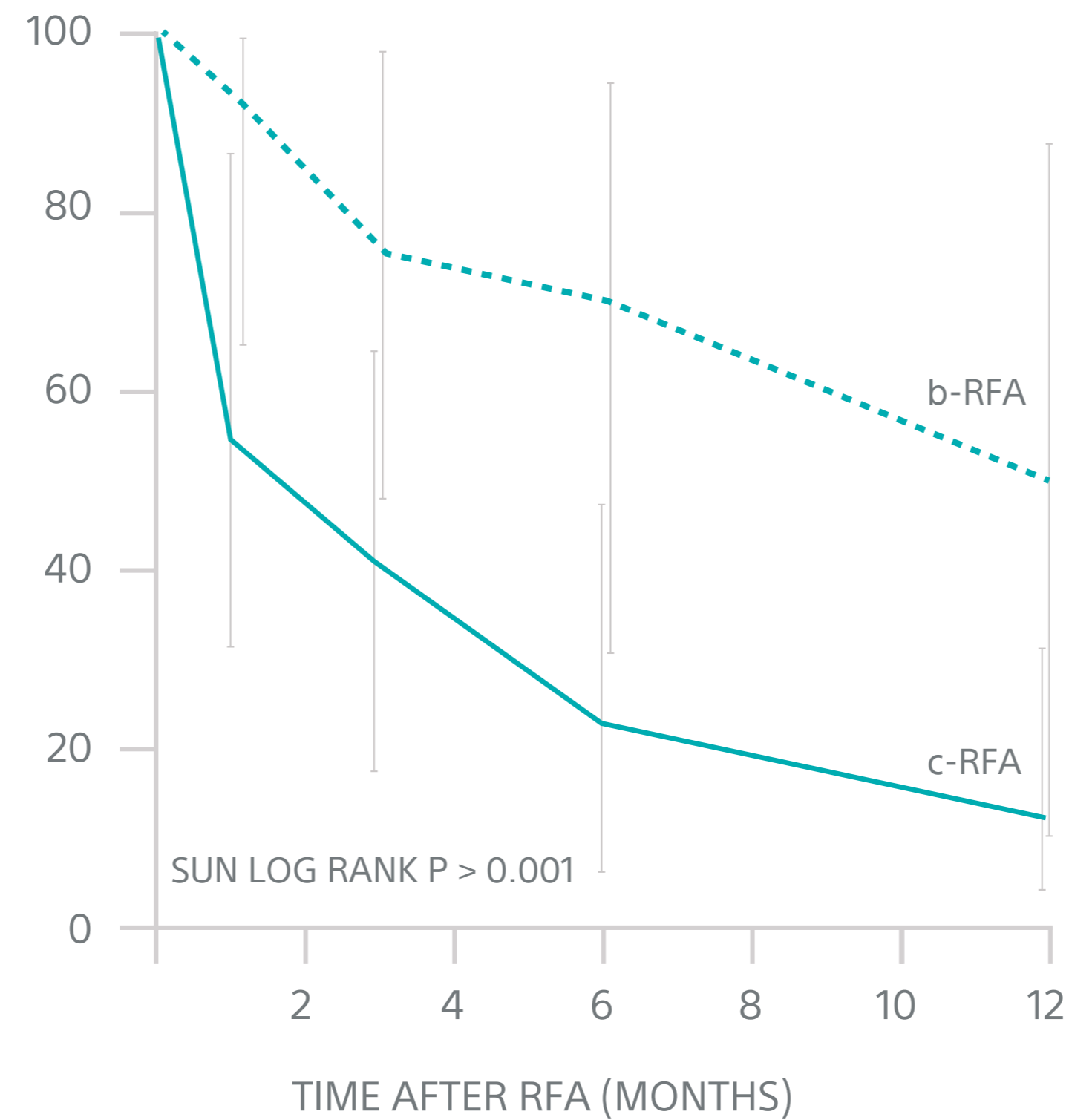
- bRFA, aided by the new g... provided satisfactory pain relief (12 months), and demonstrated statistically superior to cRFA
- Operating time and X-ray exposure time were reduced by >50% and >80%, respectively, and cost was reduced by > \$1,000 per case

Author's conclusion

This new method of RF ablation is safe, efficacious, and cost-effective.



PERCENT WITH >50% PAIN RELIEF



Operating time.

(bRFA: 23.5 ± 3.27 vs cRFA: 49.5 ± 27.25).

X-ray exposure time.

(bRFA: 19.1 ± 4.7 vs cRFA: 96.3 ± 96.2). Wide standard deviation (cRFA) reflects procedure difficulties and operators' experience. bRFA patients experienced a longer duration of >50% pain relief

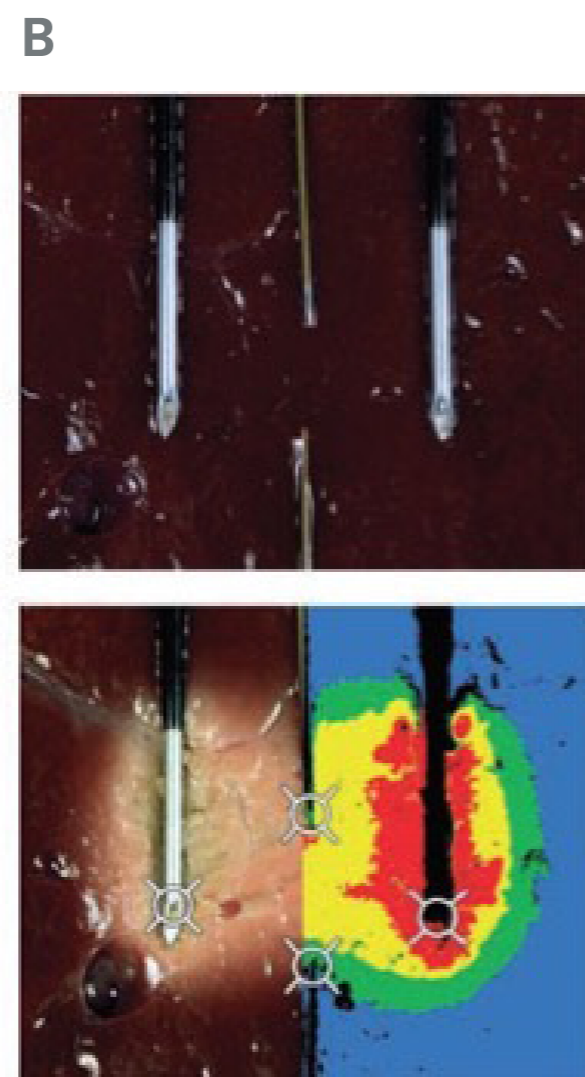
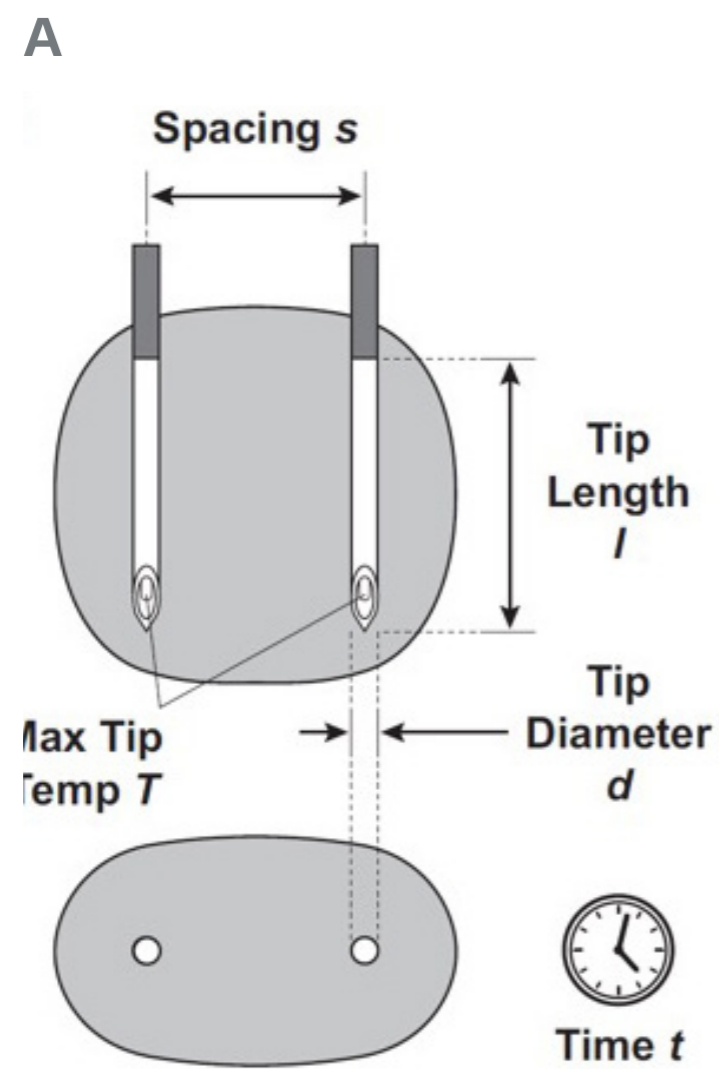
Abstract
Clinical trial

Author's conclusion

This new method of RF ablation is safe, efficacious, and cost-effective.



RF FOR SACROILIAC



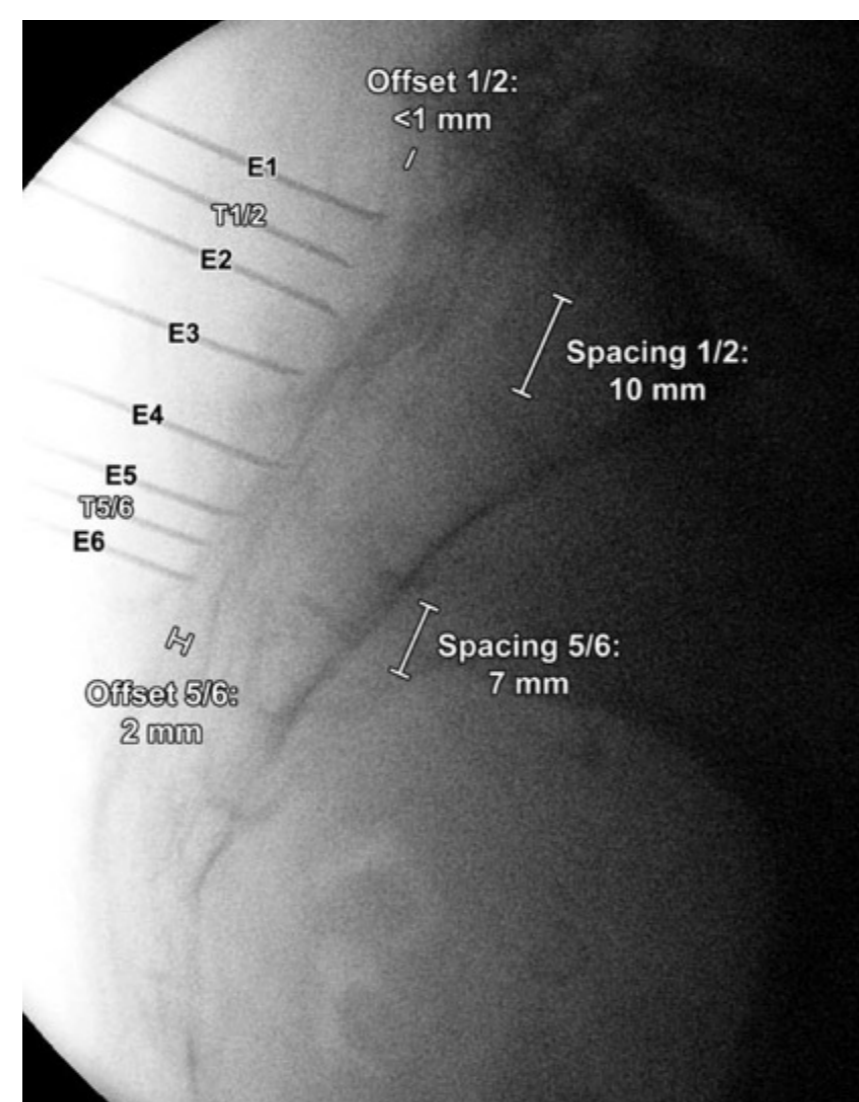
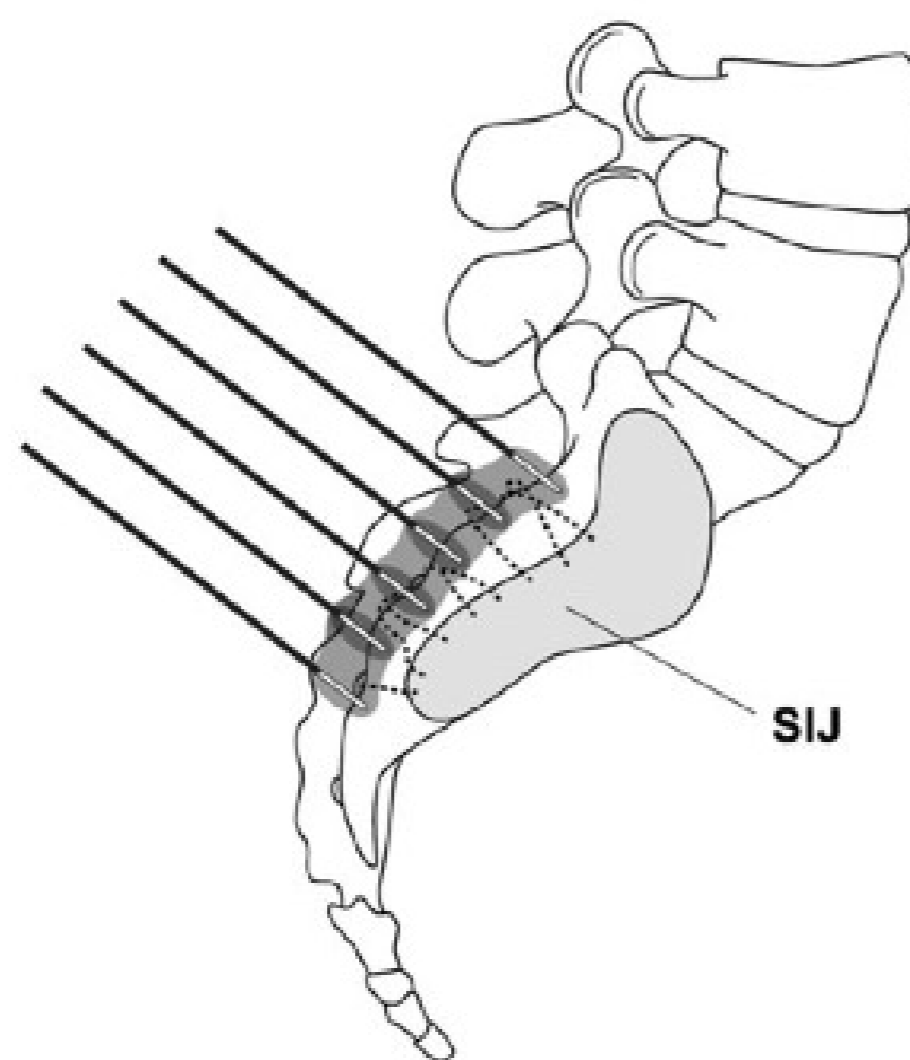
COLOR ZONE	TISSUE PROPERTIES	MIN. VALUE	MAX. VALUE
Red	Fully cooked, Firm to touch	64.0°C	90.2°C
Yellow	Moderately cooked	54.5°C	76.4°C
Green	Mild color change at outer border	46.6°C	62.2°C
Blue	Raw, Unaffected	33.3°C	51.5°C

Ex vivo setting. **A.** Bipolar RF influencing parameters (adapted from Cosman E. Jr. et al 2014. Pain Medicine 15: 2020-36), **B.** Pre- and post-lesion photographs of a bipolar RF configuration ex vivo. Crosshairs depict the position of the electrode's thermocouple wires. RGB pixel values are distributed into 4 color zones. **C.** Temperatures measured at each color zone at the end of a 3-minute lesion (based on 154 thermocouple measures).

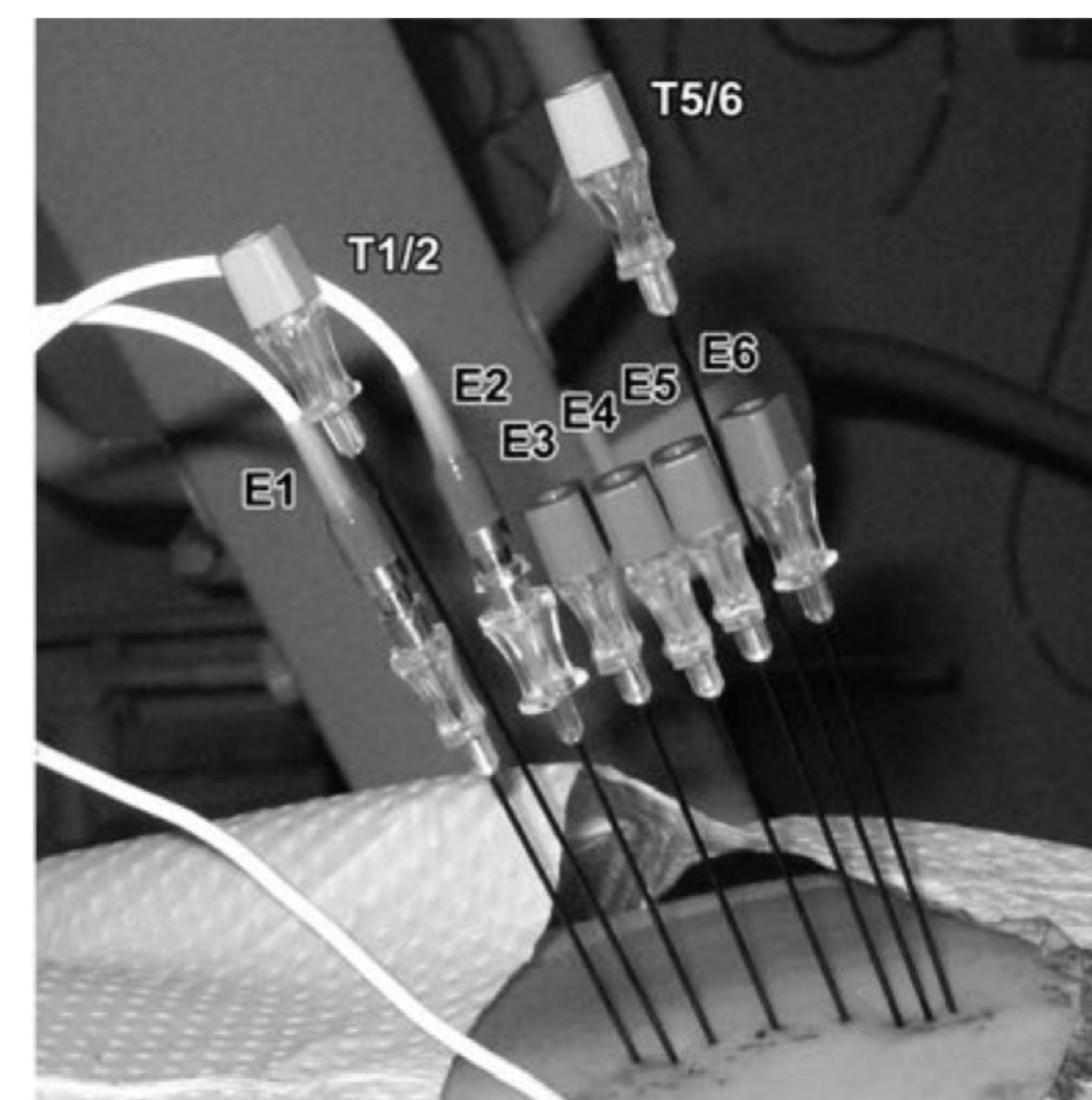
Ex vivo setting. A. Bipolar RF influencing parameters (adapted from Cosman E. Jr. et al 2014. Pain Medicine 15: 2020-36).



A



B



In vivo setting. **A.** Palisade™ treatment of SIJ pain. A row of six RF cannulae (20-gauge diameter, 10mm tip length, 10mm inter-spacing) were inserted to target the dorsal sacral surface between S1-S3 dorsal foramina and the SIJ line (90°C, 3- minutes lesion time). A continuous lesion is generated between adjacent cannula. **B.** Probes T1/2 and T5/6 include a thermocouple sensor to measure sustained neurolytic temperatures.

Tip Diameter & Length:
 20 ga - 5mm
 20 ga - 10mm
 20 ga - 8mm
 20 ga - 10mm
 20 ga - 15mm
 19 ga - 8mm
 18 ga - 10mm
 18 ga - 15mm

Common Parameters:
 Max Tip Temp = 90 °C
 Lesion Time = 3-5 min

Power produced by
 the temperature
 with higher

Introduction

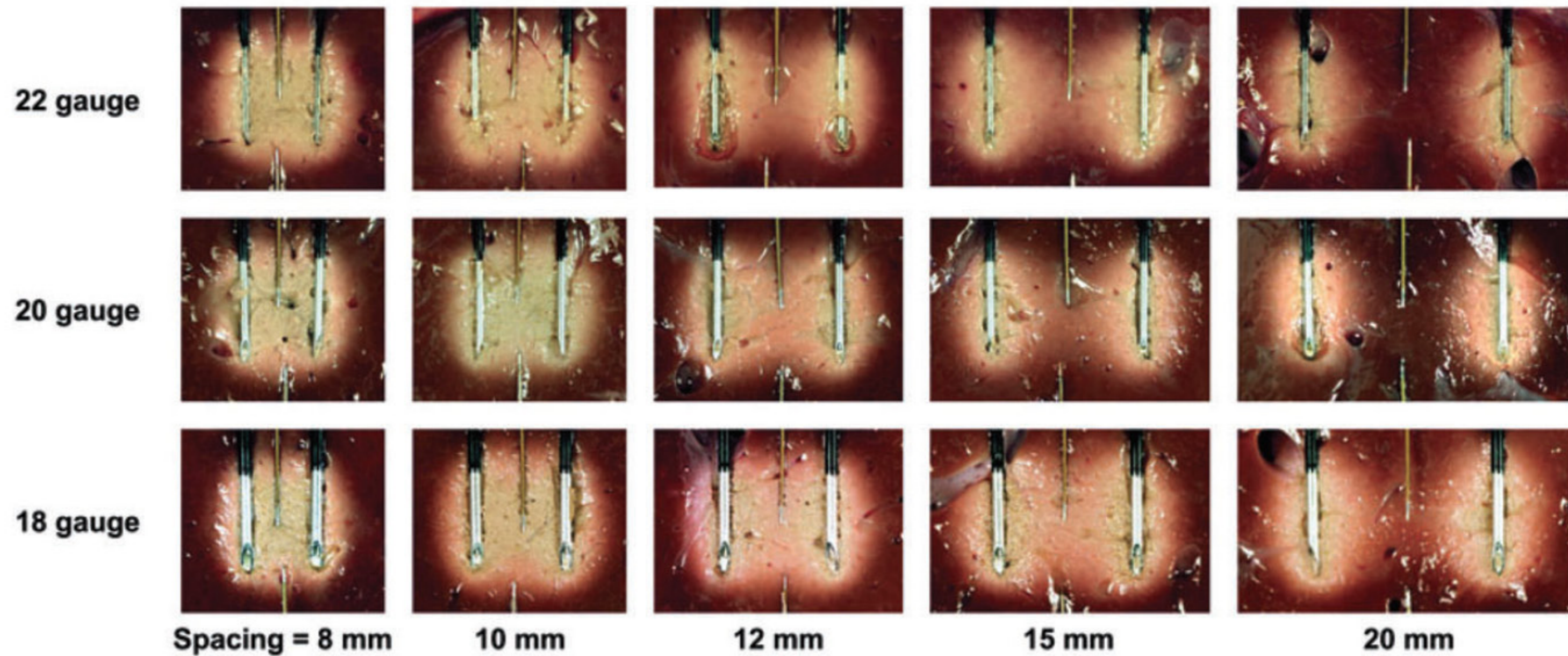
Bipolar
Implica

In vivo setup:
innervations of
presented with
Remote temper
between two le
sustained neu

In vivo setting. A
20-gauge diamet
target the dorsa



10 mm Tip Length



Cross-sectional photograph of bipolar lesions in ex vivo bovine liver show the lesion length and width produced by different parallel tip spacings and tip diameters (90°C tip temperature and 3-minute lesion time)

Tip Diameter & Length:
 22 ga - 5 mm
 20 ga - 10 mm
 18 ga - 8 mm
 16 ga - 10 mm
 14 ga - 15 mm
 Common Parameters:
 Max Tip Temp = 90 °C
 Lesion Time = 3:00 min

Introduction

Bipolar Implica

In vivo setup: innervations of presented with

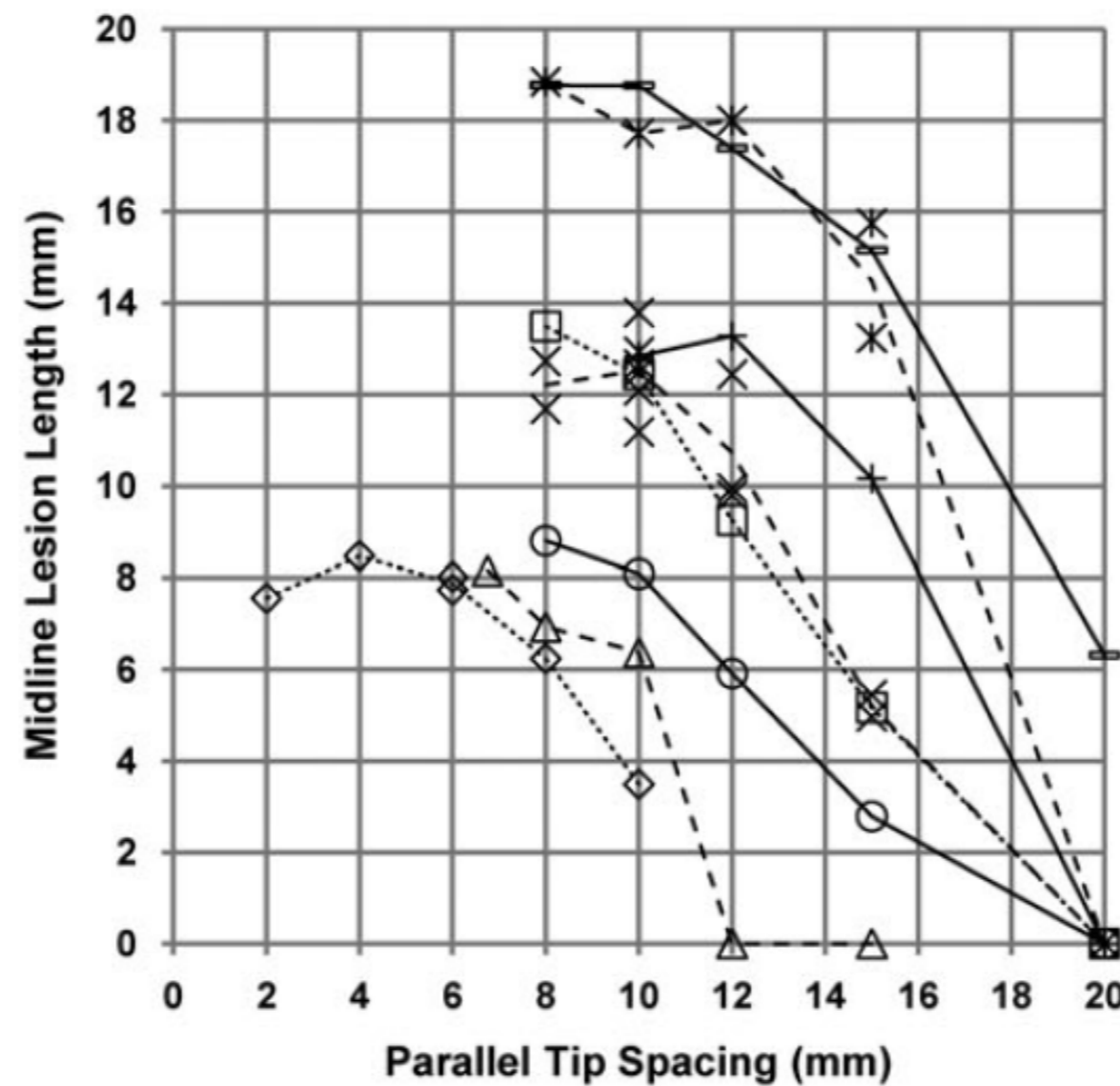
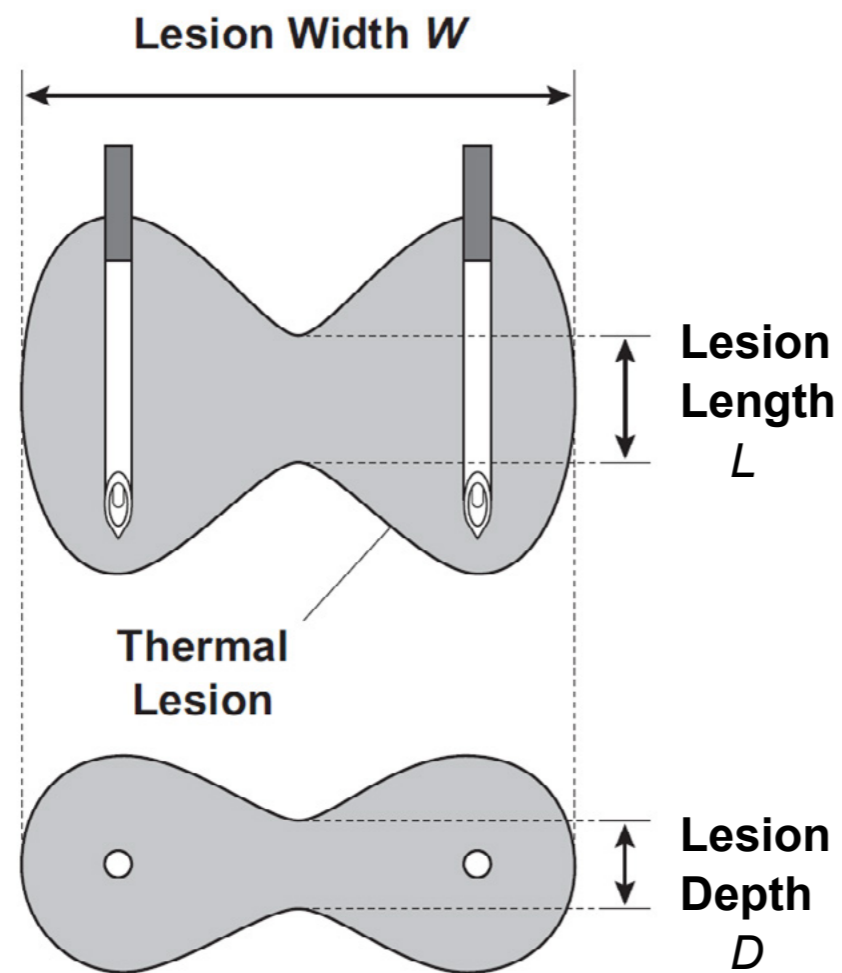
Remote temper between two sustained neur

In vivo setting. A 20-gauge diameter target the dorsal

Photograph shows in ex vivo show the lesion width produced by parallel tip.

Lesion produced by tip temperature with higher





Tip Diameter & Length:

- ◇ 22 ga 5 mm
- 22 ga 10 mm
- △ --- 20 ga 5 mm
- × --- 20 ga 10 mm
- ✱ --- 20 ga 15 mm
- — 18 ga 5 mm
- + — 18 ga 10 mm
- = — 18 ga 15 mm

Common Parameters:
 Max Tip Temp = 90 °C
 Lesion Time = 3:00 min

Measurements of midline lesion length (L) in ex vivo bovine liver produced by variable tip parallel spacings, diameters, and lengths (90°C tip temperature and 3-minute lesion time). Midline lesion length increases with higher cannulae diameter and tip length

Tip Diameter & Length:
 ◇ 22 ga 5 mm
 □ 22 ga 10 mm
 △ --- 20 ga 5 mm
 × --- 20 ga 10 mm
 ✱ --- 20 ga 15 mm
 ○ — 18 ga 5 mm
 + — 18 ga 10 mm
 = — 18 ga 15 mm

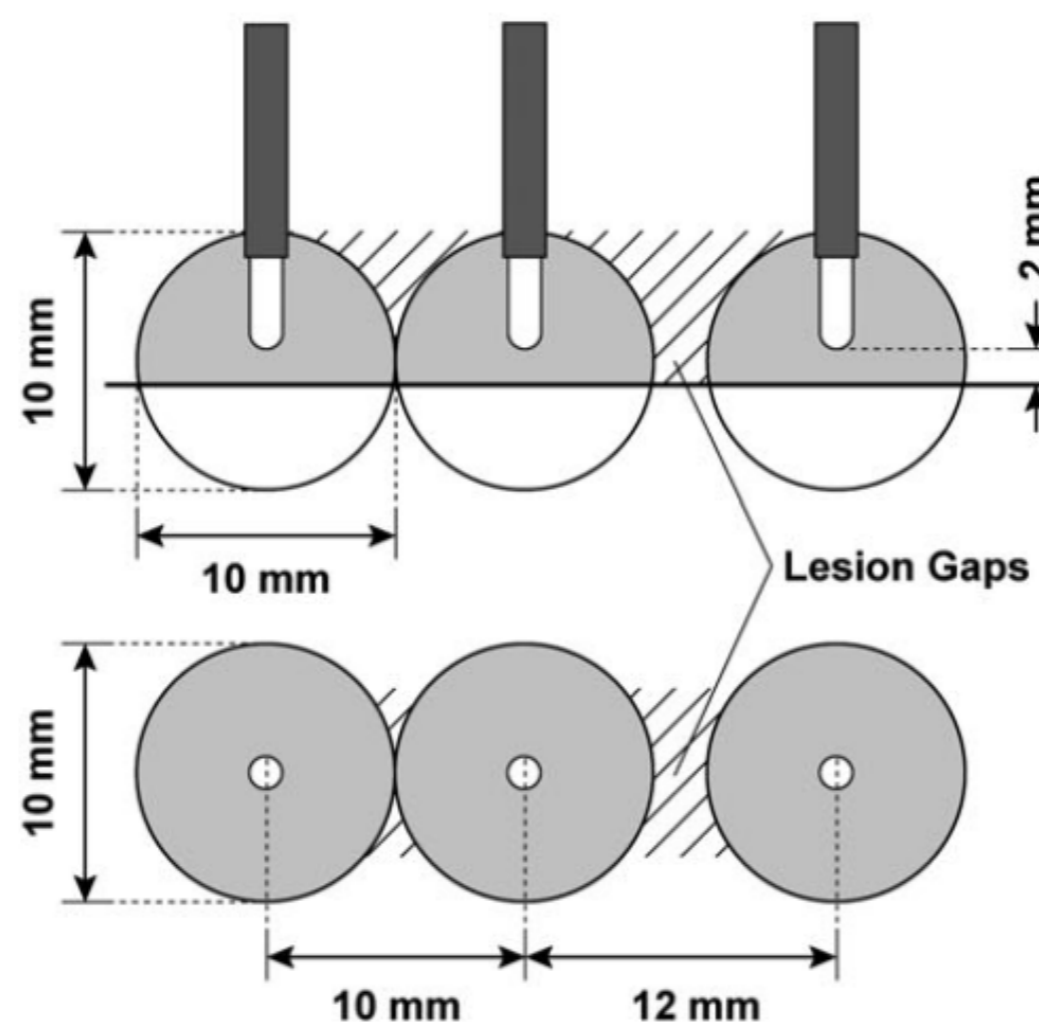
Common Parameters:
 Max Tip Temp = 90 °C
 Lesion Time = 3:00 min

liver produced by
 tip temperature
 with higher



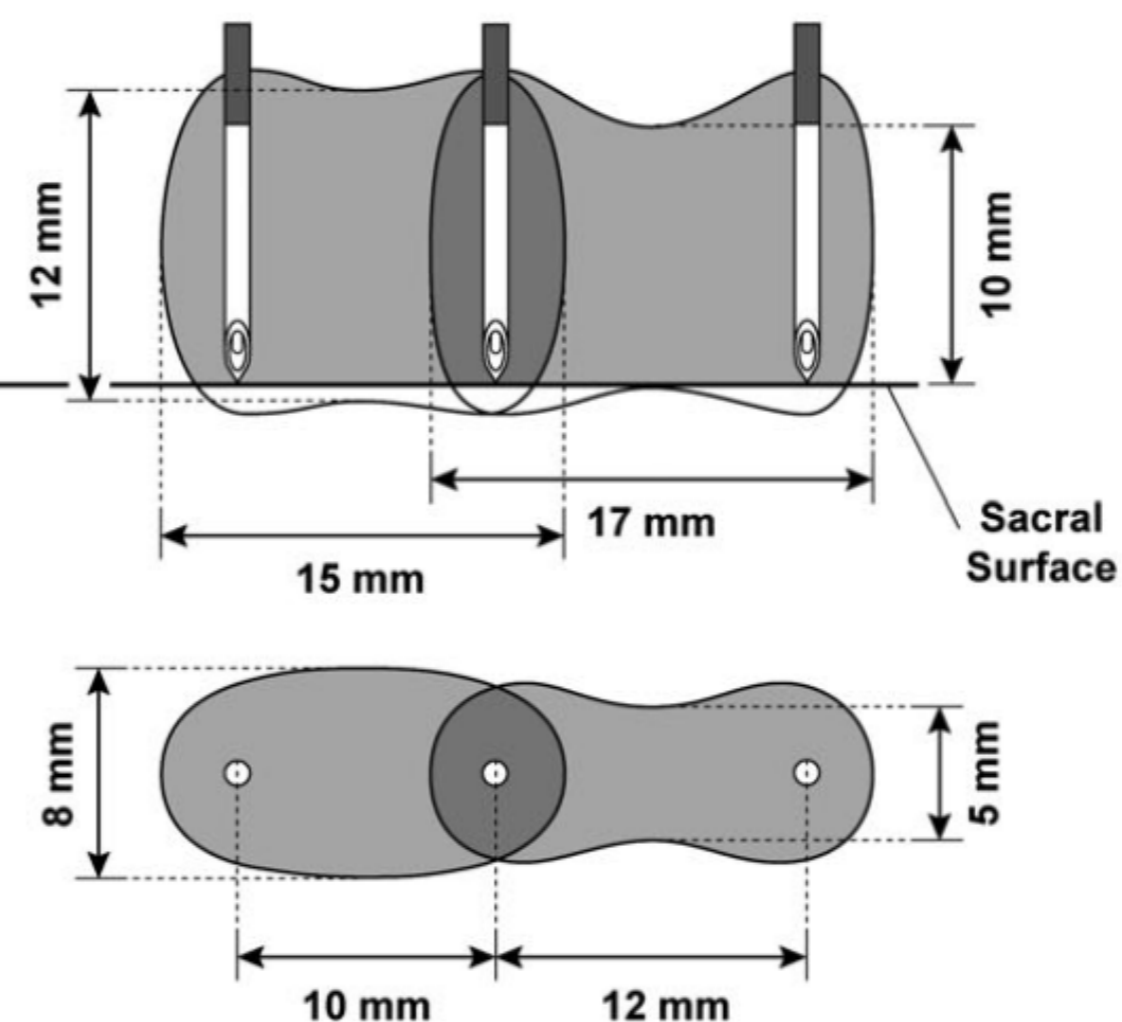


COOLED MONOPOLAR RF



18-gauge, 4mm tip, 60°C,
and 3-minute lesion time

BIPOLAR RF



20-gauge, 10mm tip, 90°C,
and 3-minute lesion time

In cooled RF, an increase in tip-to-tip distance can give rise to gaps between adjacent lesions in the sacral surface, whereas individual bipolar lesions can be larger than cooled RF lesions.

Bipolar palisade RF produces lesions of consistent height, width, and depth, with no gaps.

Figure adapted from Cosman E. Jr. et al 2014. Pain Medicine 15: 2020-36.

Author's conclusion

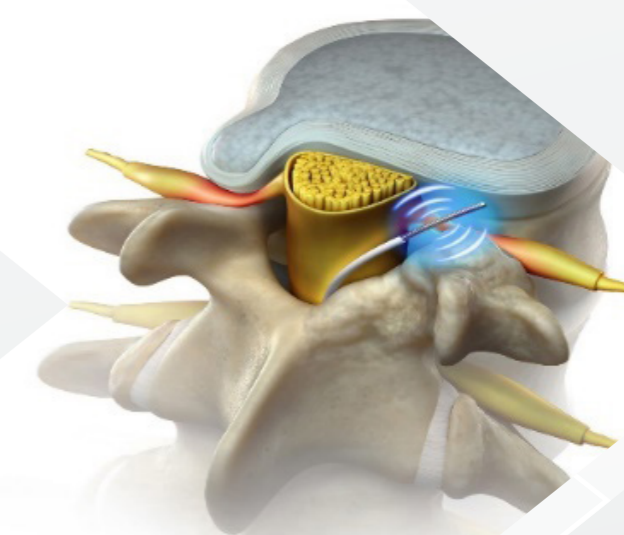
- The new bipolar palisade (a defensive fence) creates a continuous lesion area that covers the multiple sacral lateral branch nerves innervating the SIJ.
- The size and shape of palisade bipolar RF lesions might be advantageous for pain management cases where large lesions or lesions side-by-side (without gaps) are needed.

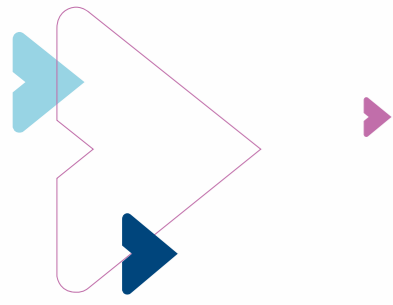
- Clinical outcomes of the palisade SIJ were positive, although follow-up time

- Bipolar RF lesions can be a with cooled RF

- Temperature control is better compared to cooled RF, as in a known position, within inter-tip(s) region(s). In cooled temperature is reached at electrode tip.

Pulsed Radiofrequency for radicular pain





RF FOR
LUMBAR PAIN

RF FOR SACROILIAC
JOINT PAIN

PULSED RF FOR
RADICULAR PAIN

PULSED RF
MECHANISM OF ACTION

RF FOR
CERVICAL PAIN

Introduction > Lee et al., 2020 > Liu et al., 2020 > Yang and Chang, 2020 > Chang and Ahn, 2017

Introduction

Radicular pain arises by the ectopic activation of nociceptive afferent fibers in a spinal nerve or its root; the dorsal root ganglion (DRG). This activation is perceived as pain that travels or “radiates” from one site to another, following the course (dermatome) of the compromised spinal nerve root.

The underlying cause of radicular pain are lesions that either directly compromises the DRG (mechanical compression) or indirectly compromise the spinal nerve and/or its roots by causing ischemia or inflammation of the neuronal tracts (injury). Thereby, the most common causes of radiculopathy are disc herniation in the lumbar spine, failed back surgery syndrome (FBSS), and disc herniation and spondylosis in the cervical spine¹.

Prevalence: Lumbosacral radicular pain, is probably **the most commonly occurring form of neuropathic pain; with an annual prevalence of 9.9 to 25%** (10-25 of 1000 adults). **Cervical radicular pain affects approximately 1 of 1000 adults** (0.1% prevalence). The health burden for patients with painful radiculopathy can be higher than the estimated for other major diseases including diabetes, heart failure and, cancer².

Treatment: The conservative treatment of radicular pain combines oral pharmacological management and physiotherapy. Interventional pain management is the alternative of choice for patients whose pain is refractory to conservative methods. Epidural corticosteroid injections can provide pain relief; however, the long-term

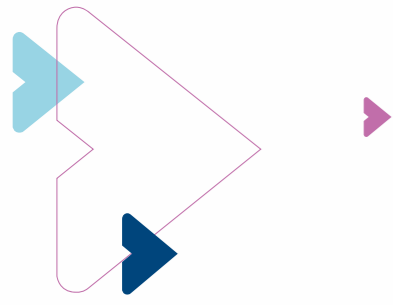
efficacy of this approach is debated, due to procedural complications³.

Effectiveness of RFA: Compelling clinical evidence demonstrating the clinical utility, long-term effectiveness and, safety of PRF stimulation in the management of radicular pain stems from a recent systematic review by Yang et al⁴; that thoroughly analyzed the **PRF therapeutic outcomes reported in almost 40 publications -including 10 RCTs. This study concludes that PRF stimulation is effective for the treatment of cervical, lumbosacral and thoracic radicular disorders. Most importantly, none of the reviewed publications reported any serious complications associated with PRF treatment.**

References

1. Manchikanti L et al. Review of Neurotherapeutics, 2015; 15:6, 681-693.
2. Van Boxtel K et al. Reg Anesth Pain Med, 2014; 39(2):149-59.
3. Galan-Martin MA et al. J Clin Med 2020; 9:E1201.
4. Yang S et al. Ann Palliat Med. 2020; 9(5):3528-3536.





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Introduction > **Lee et al., 2020** > Liu et al., 2020 > Yang and Chang, 2020 > Chang and Ahn, 2017

Effectiveness of Ultrasound-Guided Pulsed Radiofrequency Treatment in Patients with Refractory Chronic Cervical Radicular Pain

Study Goal

To evaluate the effectiveness of PRF with ultrasound (US) guidance in patients with chronic cervical radicular pain unresponsive to repeated transforaminal epidural steroid injections (TFESIs)

Methodology

Patients: The study included 49 consecutive patients diagnosed with cervical radicular pain with, at least, 6 months history of segmental pain radiating to the arm. Patients were refractory to repeated TFESIs. 19 patients had HCD (herniated cervical disc) and 30 had CFS (cervical foraminal stenosis) induced by facet joint hypertrophy.

NRS-11 (Numeric Rating Scale) pain scores and Neck Disability Index (NDI) were evaluated at pretreatment and up to 6 months posttreatment. Successful pain relief was defined as $\geq 50\%$ reduction in NRS-11 score vs pretreatment score.

PRF procedure: Target nerve identification and PRF catheter insertion (between the C7 spinal nerve and C7 posterior tubercle) were performed under US guidance. Sensory stimulation was performed with an RF generator (Cosman-G4) until pain was reported (<0.3 V). PRF was administered at 5 Hz, 5ms PW, and 45 V for 360 seconds, at a maximum 42°C.


Authors:

Lee S.H, Choi H.H, Roh E.Y and Chang M.C

Study type:

Prospective, single center

Publication:

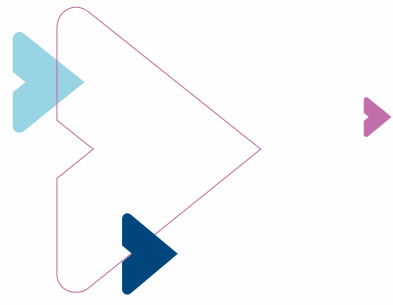
Pain Physician 2020; 23(3):E265-E272.
([Link to PubMed](#) )

Key Words:

Chronic Cervical Radicular Pain – Cervical Facet Joint – Pulsed RF

Graphs created by Boston Scientific based on the published data.





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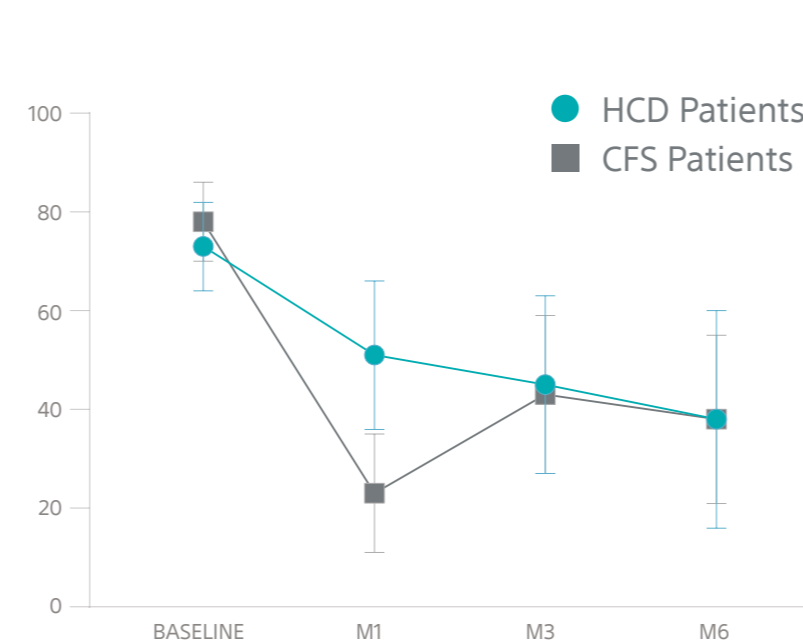
Introduction > **Lee et al., 2020** > Liu et al., 2020 > Yang and Chang, 2020 > Chang and Ahn, 2017

Effectiveness of Ultrasound-Guided Pulsed Radiofrequency Treatment in Patients with Refractory Chronic Cervical Radicular Pain

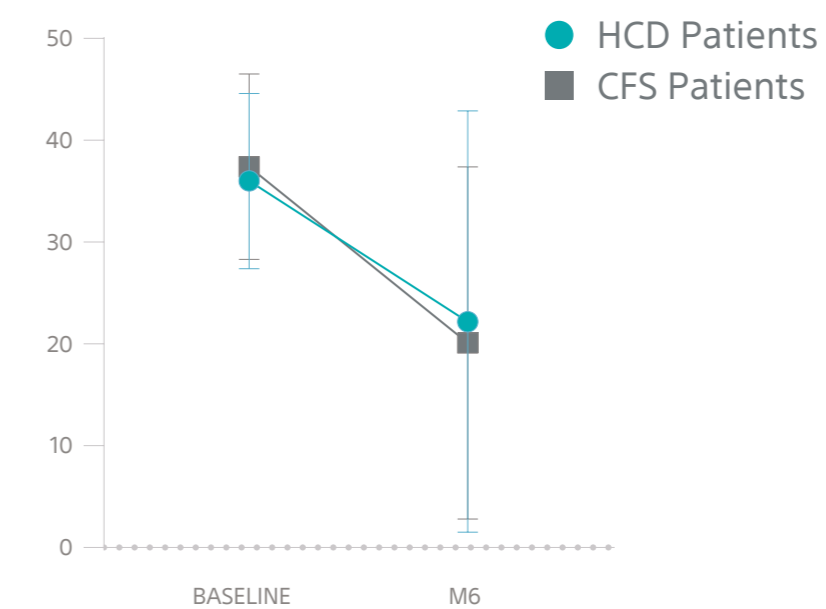
Results

- NRS-11 scores were significantly reduced ($p < 0.05$) at 1, 3 and 6 months following PRF treatment, for both HCD and CFS. Patients' functional disability also decreased significantly at 6 months
- 63.3% of the patients showed successful pain relief ($\geq 50\%$ pain reduction of initial pain) with US-guided PRF treatment.
- Overall, this study showed positive therapeutic outcomes regardless of pain etiology (HCD or CFS).

NUMERICAL RATING SCALE (NRS)



NECK DISABILITY INDEX (NDI)



Author's conclusion

PRF stimulation under the guidance of US is a potentially effective treatment method for managing refractory chronic cervical radicular pain.





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Introduction > Lee et al., 2020 > **Liu et al., 2020** > Yang and Chang, 2020 > Chang and Ahn, 2017

Clinical Study of Spinal Cord Stimulation and Pulsed Radiofrequency for Management of Herpes Zoster-Related Pain Persisting Beyond Acute Phase in Elderly Patients

Study Goal

To assess the efficacy of Spinal Cord Stimulation (SCS) and Pulsed Radiofrequency (PRF) in the treatment of herpes zoster-related pain persisting beyond the acute phase (i.e., post-herpetic neuralgia) in elderly patients.

Methodology

Patients: 63 patients aged over 50 years with herpes zoster (HZ) pain persisting for 20 to 180 days were selected and randomized to receive either SCS (N=31) or PRF (N=32).

The following outcomes were measured: Numeric Rating Scale (NRS-11) score, response rate (pain relief $\geq 50\%$), complete remission rate (pain score ≤ 3), and analgesics intake reduction.

SCS procedure: SCS electrodes were placed in the affected spinal ganglion under fluoroscopy-guidance. Patients received SCS for two weeks (electrodes were removed after treatment)


SCS parameters: Voltage 1-3 V; 1 Pulse width (PW) 20-210 ms; Frequency 30-60 Hz.

PRF procedure: The affected DRG was punctured with the RF needle under fluoroscopy guidance. A sensory test (50Hz and 0.3-06 V) was performed to confirm needle position and pain coverage. PRF treatment was performed with a Cosman G4 instrument.

PRF parameters: 40-60V; 20ms PW; 2Hz for 360 seconds. Electrode tip: 42°C.

Authors:
Liu B, Yang Y, Zhang Z,
Wang H, Fan B and Sima L.

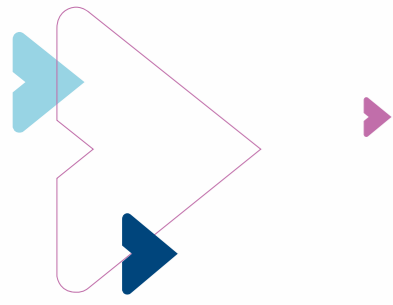
Study type:
Prospective, randomized-
controlled clinical trial

Publication:
Pain Physician 2020;
23(3):263-270
([Link to PubMed](#) )

Key Words:
*Post Herpetic Neuralgia
– Dorsal Root Ganglion
– Pulsed RF vs Spinal Cord
Stimulation*

Graph created by Boston Scientific
based on the published data





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PULSED RF
MECHANISM OF ACTION

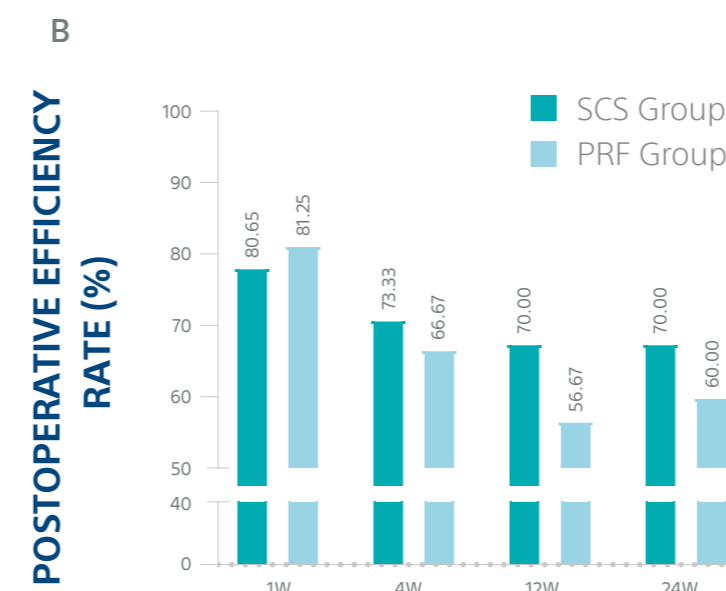
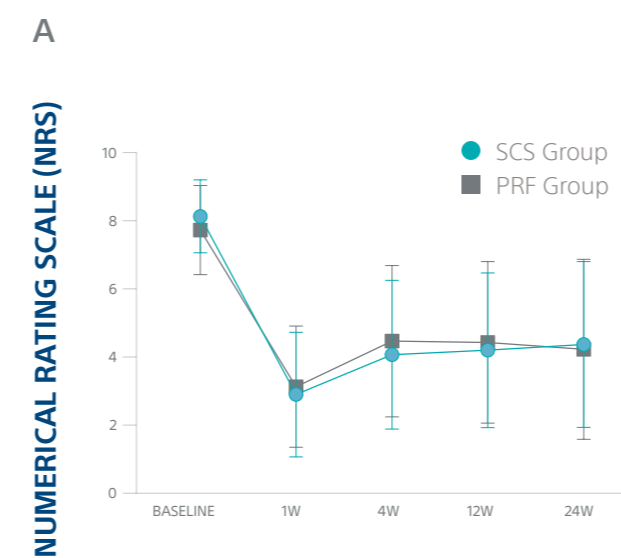
RF FOR
CERVICAL PAIN

Introduction > Lee et al., 2020 > **Liu et al., 2020** > Yang and Chang, 2020 > Chang and Ahn, 2017

Clinical Study of Spinal Cord Stimulation and Pulsed Radiofrequency for Management of Herpes Zoster-Related Pain Persisting Beyond Acute Phase in Elderly Patients

Results

- Pain scores in both SCS and PRF groups decreased significantly after surgery and at 1,4,12 and 24 weeks follow-up, compared to baseline score ($p < 0.001$).
- No significant difference was found between the SCS and PRF groups
- The effective rate of pain treatment, for both groups, was in the range of 57% to 81%, and the complete pain relief rate ranged from 37% to 71%.
- The number of patients who used analgesics and calcium channel antagonists decreased dramatically for both treatment groups ($p < .001$)

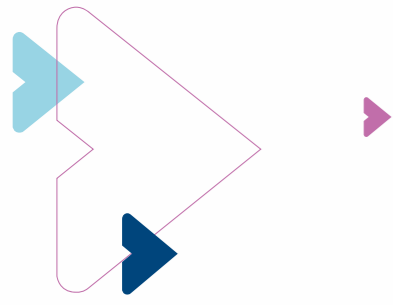


A. NRS-11 scores pre- and 1, 4, 12, and 24 weeks post-operation. The NRS-11 score in the SCS group decreased to 2.90 ± 1.83 (1W) and 4.37 ± 2.43 (24W), while that in the PRF group decreased to 3.13 ± 1.78 and 4.23 ± 2.64 , respectively (compared with baseline). **B.** Postoperative efficiency rates (pain relief $\geq 50\%$). **C.** Complete remission rates (pain score ≤ 3).

Author's conclusion

To a similar extent, SCS and PRF treatments can effectively improve post-herpetic neuralgia in elderly patients.





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Introduction > Lee et al., 2020 > Liu et al., 2020 > **Yang and Chang, 2020** > Chang and Ahn, 2017

Effect of bipolar pulsed radiofrequency on chronic cervical radicular pain refractory to monopolar pulsed radiofrequency

Study Goal

To evaluate the effect of bipolar pulsed radiofrequency (PRF) in patients with chronic cervical radicular pain who were refractory to monopolar PRF and transforaminal epidural steroid injection (TFESI)

Methodology

Patients: This study recruited 20 patients with chronic cervical radicular pain who were unresponsive to monopolar PRF and TFESI. Patients underwent bipolar PRF of their cervical dorsal root ganglion (DRG).

- Treatment outcomes were evaluated using the Numeric Rating Scale (NRS) for cervical radicular pain before treatment and 1-, 2-, and 3-months post-treatment.
- Successful pain relief was defined as $\geq 50\%$ reduction in baseline NRS score at 3 months.


- Patient global perceived effect (GPE) was assessed at 3-months post-treatment using a 7-point Likert scale. Patients that reported very good (score 7) or good results (score 6) were considered to be satisfied with the PRF procedure.

Bipolar PRF procedure: PRF stimulation of the cervical DRG was performed under fluoroscopy guidance as follows:

- Insertion of two catheter needles (22-gauge active curved-tip)
- Sensory stimulation with a PRF generator (Cosman G4 Medical™) until the patient reported a tingling sensation and/or dysesthesia at $< 0.3V$.
- PRF treatment: 5Hz and 5-millisecond pulsed width for 360 seconds at 45V
- Electrode tip temperature was maintained at or below 42°C.

Authors:
Yang, S and Chang M.C

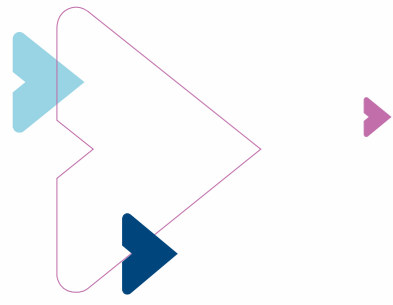
Study type:
Prospective, single center

Publication:
Ann. Palliat. Med. 2020;
9(2):169-174 (Link to
PubMed )

Key Words:
*Chronic Cervical Radicular
Pain – Cervical Dorsal Root
Ganglion –
Bipolar Pulsed RF*

Graph created by Boston Scientific
based on the published data





RF FOR
LUMBAR PAIN

RF FOR SACROILIAC
JOINT PAIN

PULSED RF FOR
RADICULAR PAIN

PULSED RF
MECHANISM OF ACTION

RF FOR
CERVICAL PAIN

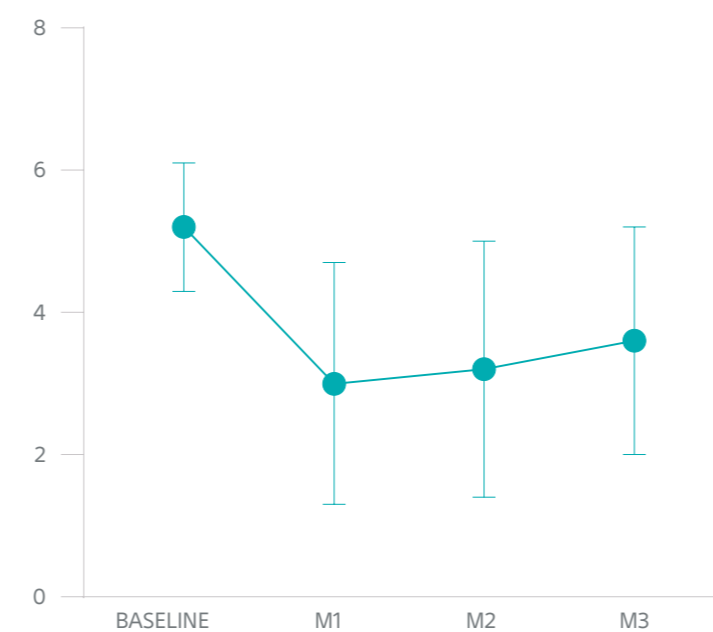
Introduction > Lee et al., 2020 > Liu et al., 2020 > **Yang and Chang, 2020** > Chang and Ahn, 2017

Effect of bipolar pulsed radiofrequency on chronic cervical radicular pain refractory to monopolar pulsed radiofrequency

Results

- Cervical radicular pain (NRS scores) was significantly reduced at 1, 2, and 3 months post-PRF ($P < 0.001$).
- 50% of the patients (10/20) reported successful pain relief ($\geq 50\%$ pain reduction of initial pain) at 3 months post-bipolar PRF of cervical DRG.
- All patients completed the study protocol and did not present with any adverse effect.

NUMERICAL RATING SCALE (NRS)



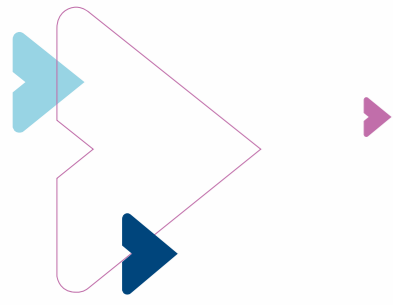
SCORE	% OF CHANGE	DESCRIPTION	PATIENTS (N)
7	≥ 75 improvement	Very good	1
6	50-74 improvement	Good	9
5	25-49 improvement	Fairly good	2
4	0-24 no change	Same as before	8
3	25-49 worse	Fairly bad	0
2	50-74 worse	Bad	0
1	≥ 75 worse	Very bad	0

Changes in NRS scores for cervical radicular pain. A. Average NRS scores declined from 5.2 at baseline to 3.0 at 1 month, 3.2 at 2 months, and 3.6 at 3 months after bipolar PRF treatment. B. Global perceived effect according to a Likert scale to assess patient's satisfaction with treatment.

Author's conclusion

Bipolar PRF of the cervical DRG could be considered a safe and effective modality for alleviating refractory chronic cervical radicular pain, especially when TFESI or monopolar PRF fail to achieve a therapeutic benefit.





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Introduction > Lee et al., 2020 > Liu et al., 2020 > Yang and Chang, 2020 > **Chang and Ahn, 2017**

Comparison between bipolar pulsed radiofrequency and monopolar pulsed radiofrequency in chronic lumbosacral radicular pain

Study Goal

To investigate the effect of bipolar Pulsed Radio Frequency (bPRF) stimulation of the DRG in patients with chronic lumbosacral radicular pain who were unresponsive to transforaminal epidural steroid injection (TFESI). The authors also compared the effect of bPRF to that of monopolar PRF (mPRF).

Methodology

Patients: 50 patients with chronic lumbosacral radicular pain, refractory to TFESI, were recruited and randomly assigned to one of two groups; the bPRF (N=25) or mPRF (N=25).

- All patients had a longer than 6-months history of lumbar or sacral segmental pain radiating from the back toward the leg.
- Imaging findings confirmed either herniated lumbar disc or lumbosacral stenosis in the patients.

- Pain intensity was assessed by a blinded investigator using a numeric rating scale (NRS) at pre-treatment, and 1, 2, and 3 months after treatment. Successful treatment was defined as more than 50% reduction in NRS scores at 3 months follow-up.

PRF procedure: The affected DRG was punctured with one (mPRF) or two (bPRF) catheter needles (active tip electrodes) under fluoroscopy guidance. A sensory test was performed using an RF Generator (Cosman G4) until the patients reported a tingling sensation or dysesthesia, at less than 0.3V.

The PRF treatment was administered at 45V; 5ms PW; 5Hz for 360 seconds. The electrode tip did not exceed 42°C.


Authors:

Chang MC, Cho YW,
and Ahn SH

Study type:

Prospective, Randomized
controlled trial

Publication:

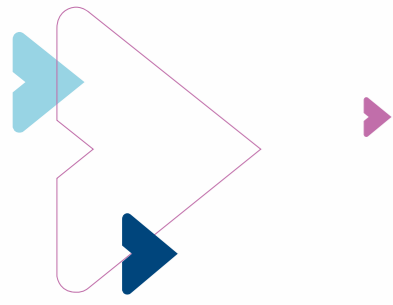
Medicine (Baltimore) 2017;
96(9):e6236
([Link to PubMed](#) )

Key Words:

*Lumbosacral Radicular
Pain – Dorsal Root
Ganglion – bipolar PRF vs
monopolar PRF*

Graph created by Boston Scientific
based on the published data





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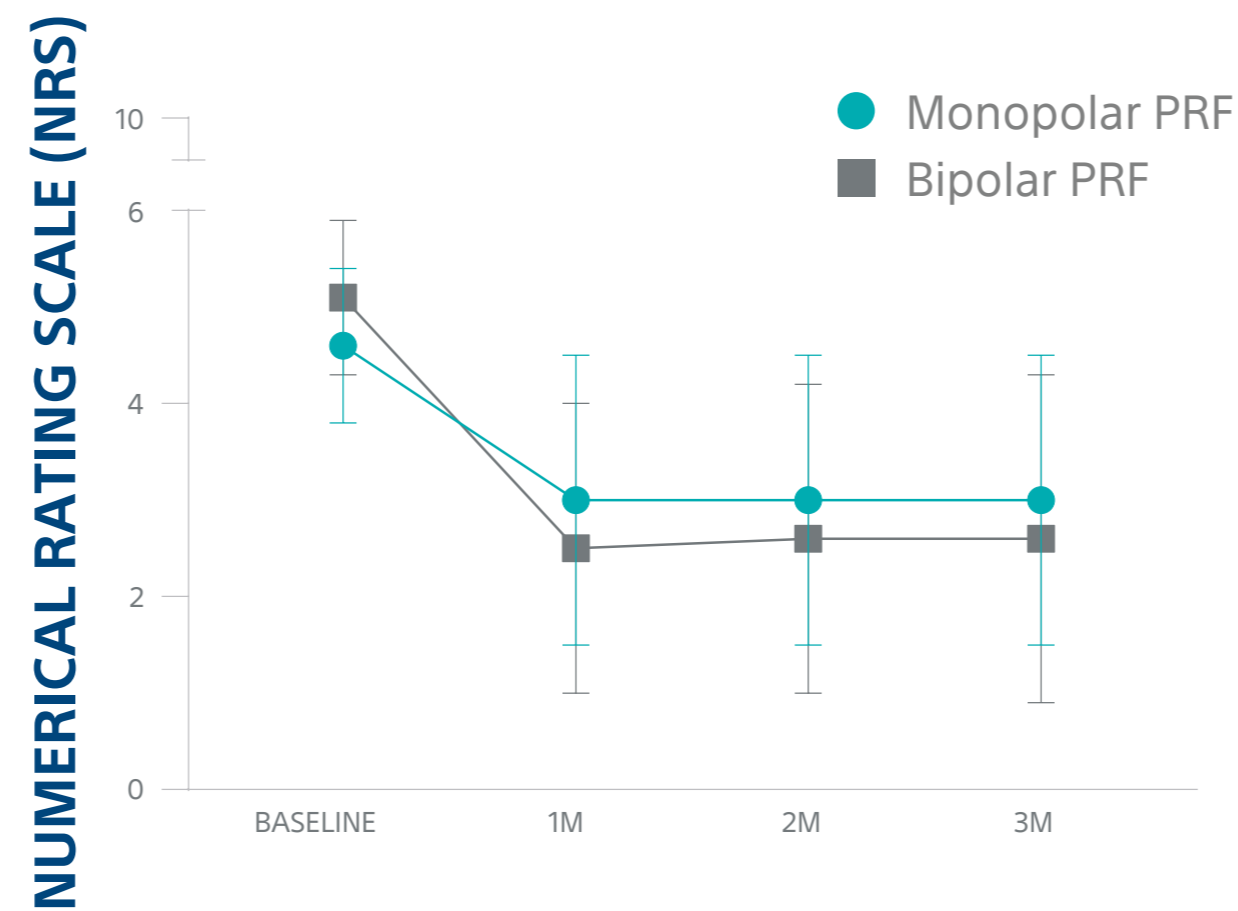
RF FOR
CERVICAL PAIN

Introduction > Lee et al., 2020 > Liu et al., 2020 > Yang and Chang, 2020 > **Chang and Ahn, 2017**

Comparison between bipolar pulsed radiofrequency and monopolar pulsed radiofrequency in chronic lumbosacral radicular pain

Results

- NRS scores in both bPRF and mPRF groups showed a significant reduction at 1, 2, and 3 months after treatment, compared to baseline scores.
- NRS scores decline over time was significantly larger in the bPRF group, compared to mPRF group, at all follow-up time points.
- The rate of successful pain relief at 3-months posttreatment was significantly better for the bRFA group (76%) than for the mRFA (48%).
- The number of patients who used analgesics and calcium channel antagonists decreased dramatically for both treatment groups.

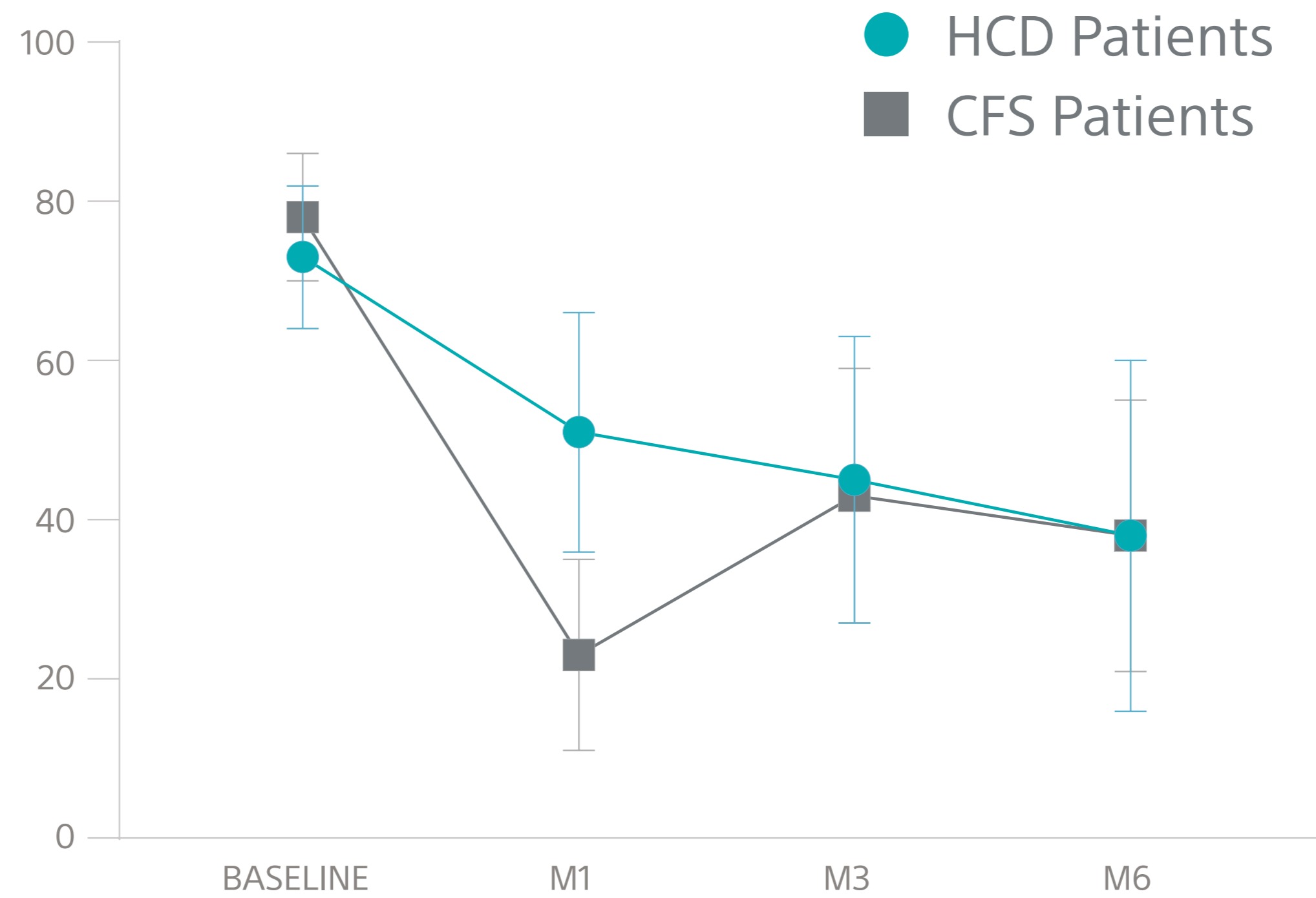


Author's conclusion

- The use of bPRF on the DRG can be an effective and safe interventional technique for chronic refractory lumbosacral radiculopathy.
- Bipolar PRF is a more effective method for managing chronic lumbosacral radicular pain compared to monopolar PRF.



NUMERICAL RATING SCALE (NRS)



Changes in NRS-11 scores for cervical radicular pain.

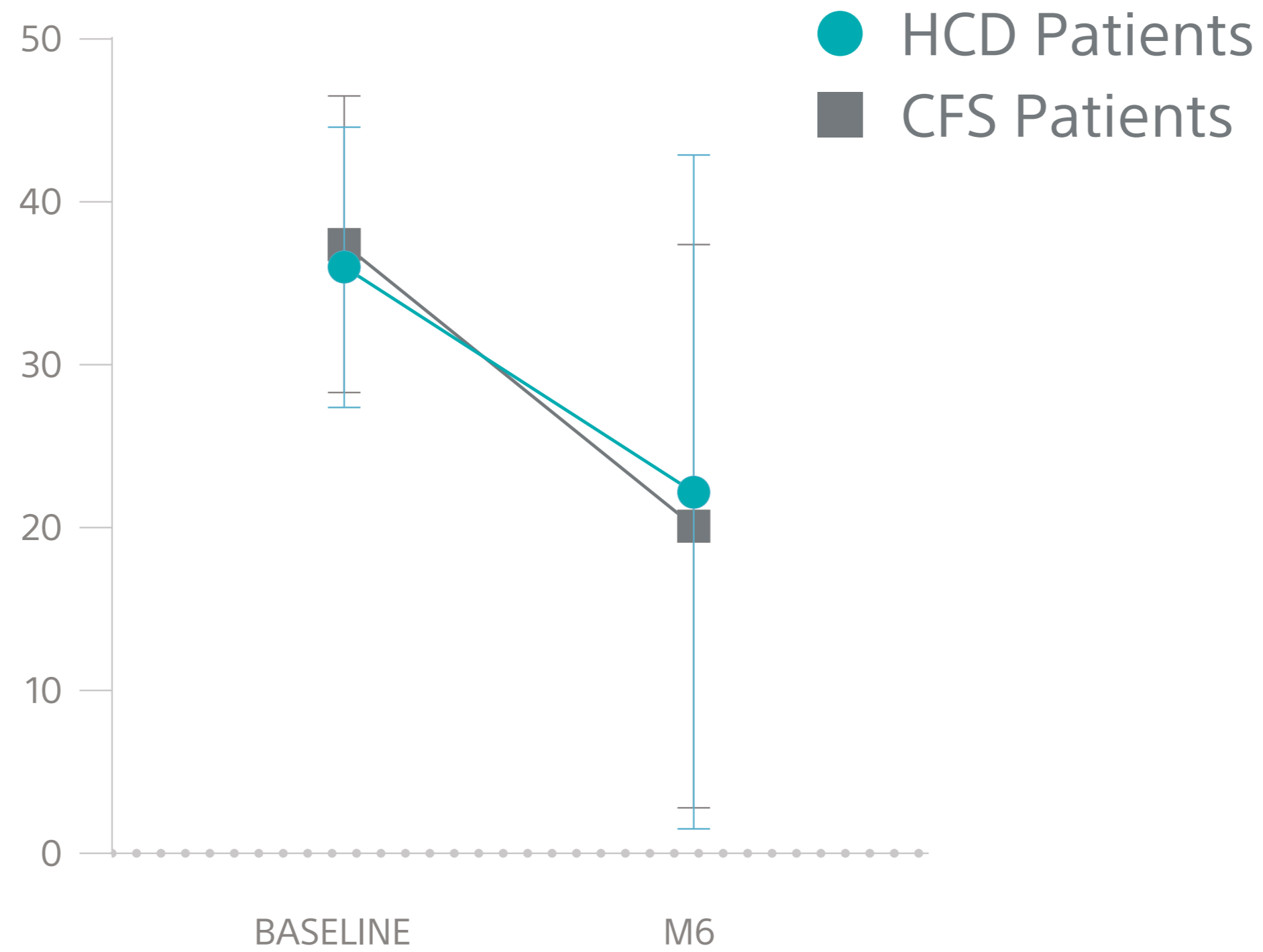
For the HCD group, NRS scores decreased from 7.3 before treatment to 3.8 at 6 months (6M) after PRF treatment. Similar results were found for CFS patients (7.8 before treatment to 3.8 at 6M).

Author's conclusion

PRF stimulation under the guidance of US is a potentially effective treatment method for managing refractory chronic cervical radicular pain.



NECK DISABILITY INDEX (NDI)



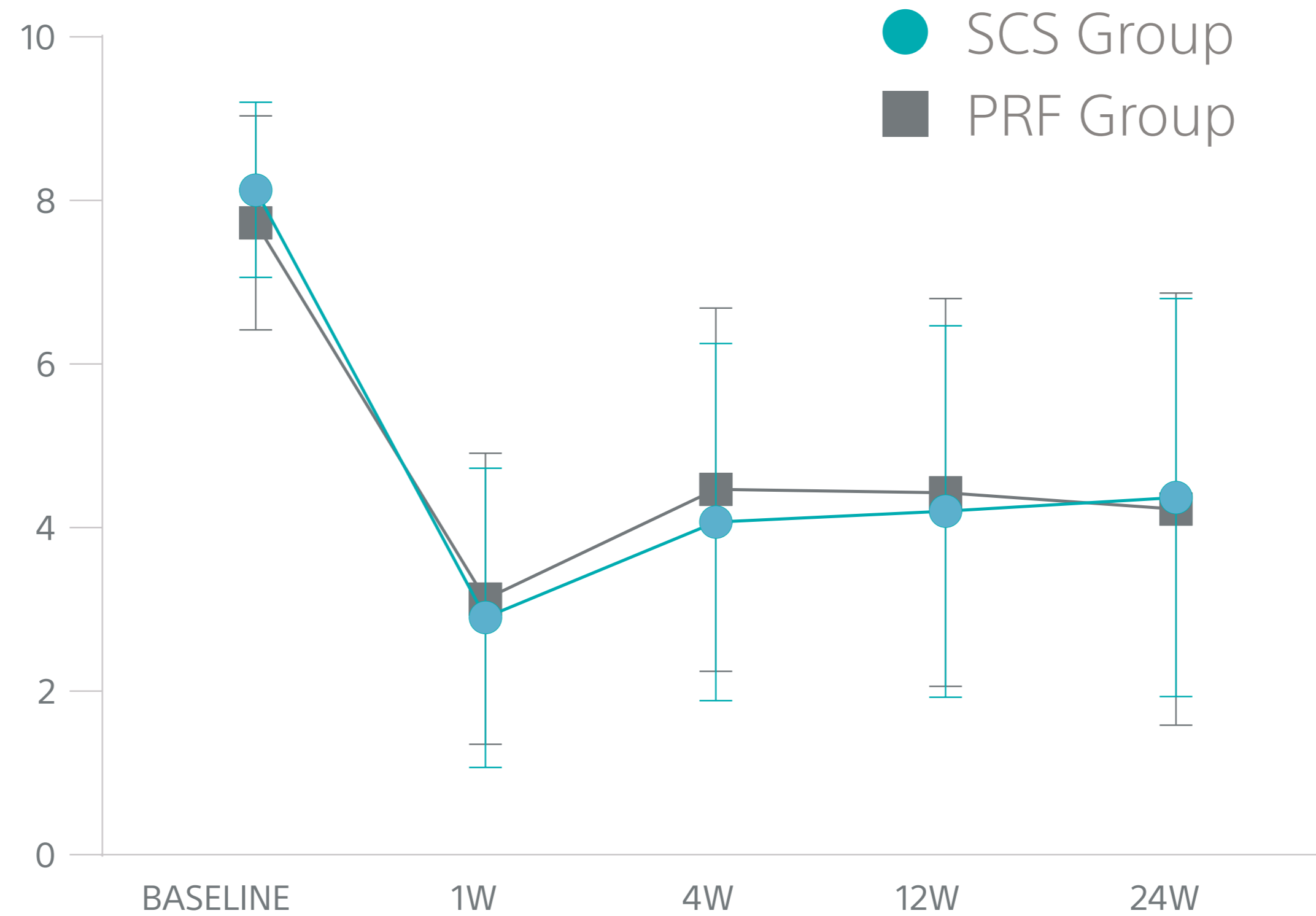
Changes in NRS-11 scores for cervical radicular pain.

NDI scores decreased from 36 and 37.4 to 20.7 and 20.1 at 6 months after treatment for HCD and CFS, respectively.

Author's conclusion

PRF stimulation under the guidance of US is a potentially effective treatment method for managing refractory chronic cervical radicular pain.

NUMERICAL RATING SCALE (NRS)



NRS-11 scores pre- and 1, 4, 12, and 24 weeks post-operation.

The NRS-11 score in the SCS group decreased to 2.90 ± 1.83 (1W) and 4.37 ± 2.43 (24W), while that in the PRF group decreased to 3.13 ± 1.78 and 4.23 ± 2.64 , respectively (compared with baseline)

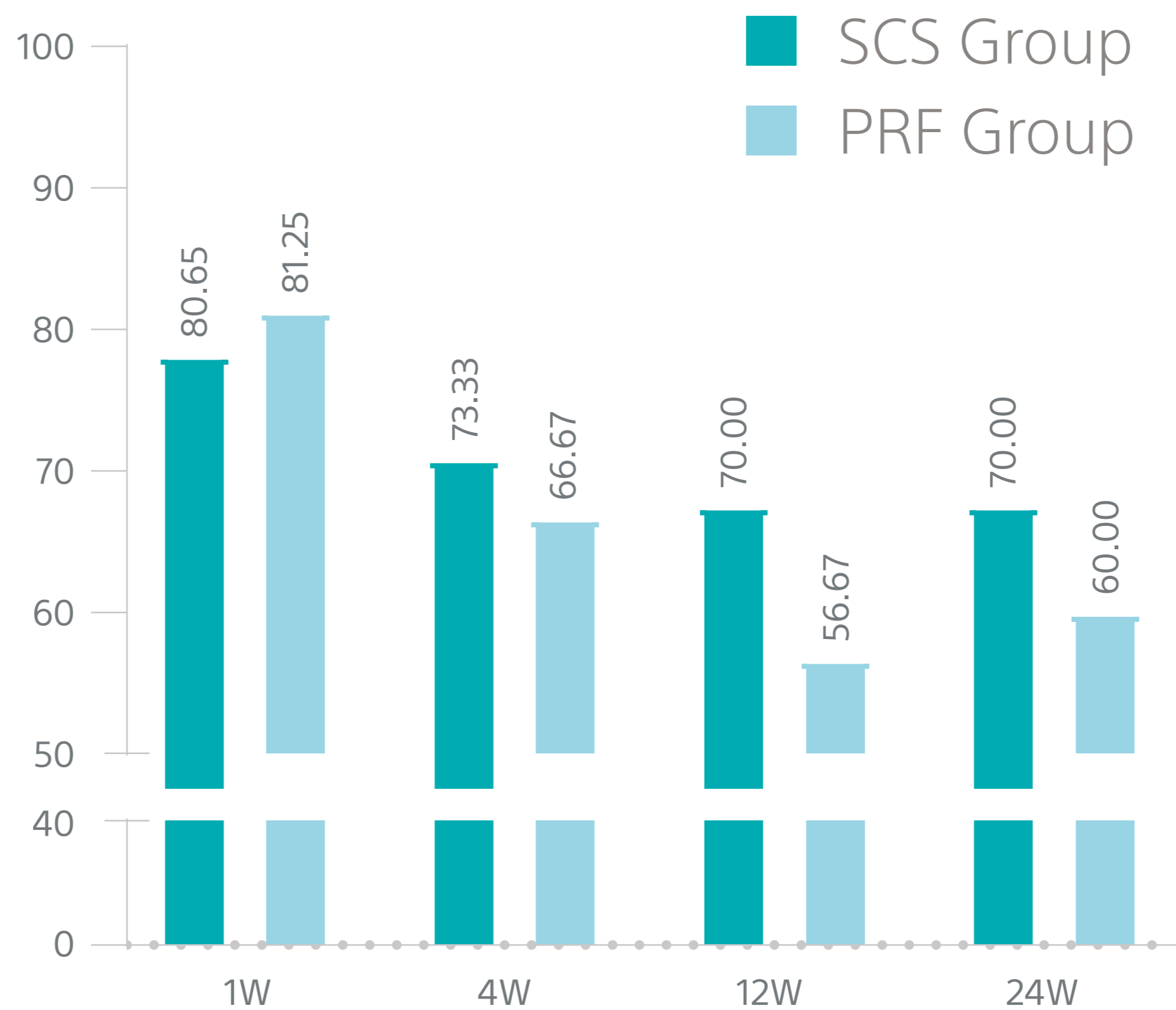
Management of patients

Author's conclusion

In a similar extent, SCS and PRF treatments can effectively improve post-herpetic neuralgia in elderly patients.



POSTOPERATIVE EFFICIENCY RATE (%)



Postoperative efficiency rates (pain relief $\geq 50\%$).

Introduction > Lee et al.

Clinical Study of Herpes Zoster

Results

- Pain scores in both SCS and PRF groups were significantly lower at 1, 4, 12, and 24 weeks post-surgery compared to baseline.
- No significant difference was observed between SCS and PRF groups.
- The effective rate of pain relief was in the range of 57% to 81% in the SCS group, and the relief rate ranged from 37% to 67% in the PRF group.
- The number of patients who required calcium channel antagonists was significantly lower in both treatment groups (p < 0.05).

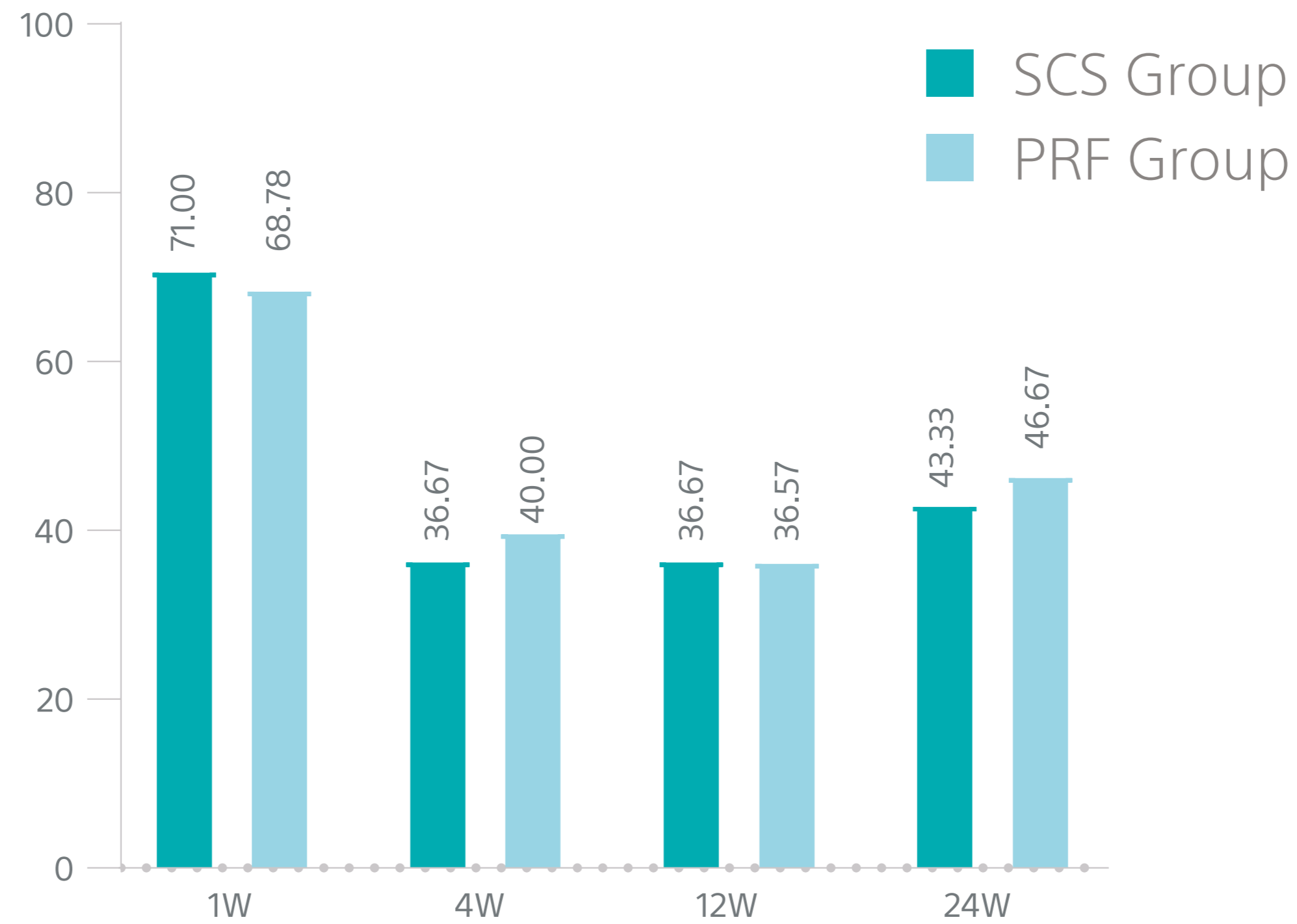
Pain Management in Herpes Zoster Patients

Author's conclusion

In a similar extent, SCS and PRF treatments can effectively improve post-herpetic neuralgia in elderly patients.



COMPLETE REMISSION RATE (%)



Complete remission rates (pain score ≤ 3)

Introduction > Lee et al.

Clinical Study of Herpes Zoster

Results

- Pain scores in both SCS and PRF groups significantly after surgery at 1W, 4W, 12W, and 24W follow-up, compared to baseline.
- No significant difference was observed between SCS and PRF groups.
- The effective rate of pain relief was in the range of 57% to 71% at 1W, and the relief rate ranged from 37% to 46% at 4W, 12W, and 24W.
- The number of patients who achieved complete remission (pain score ≤ 3) was similar in both treatment groups (p > 0.05).

Abstract
Clinical Study

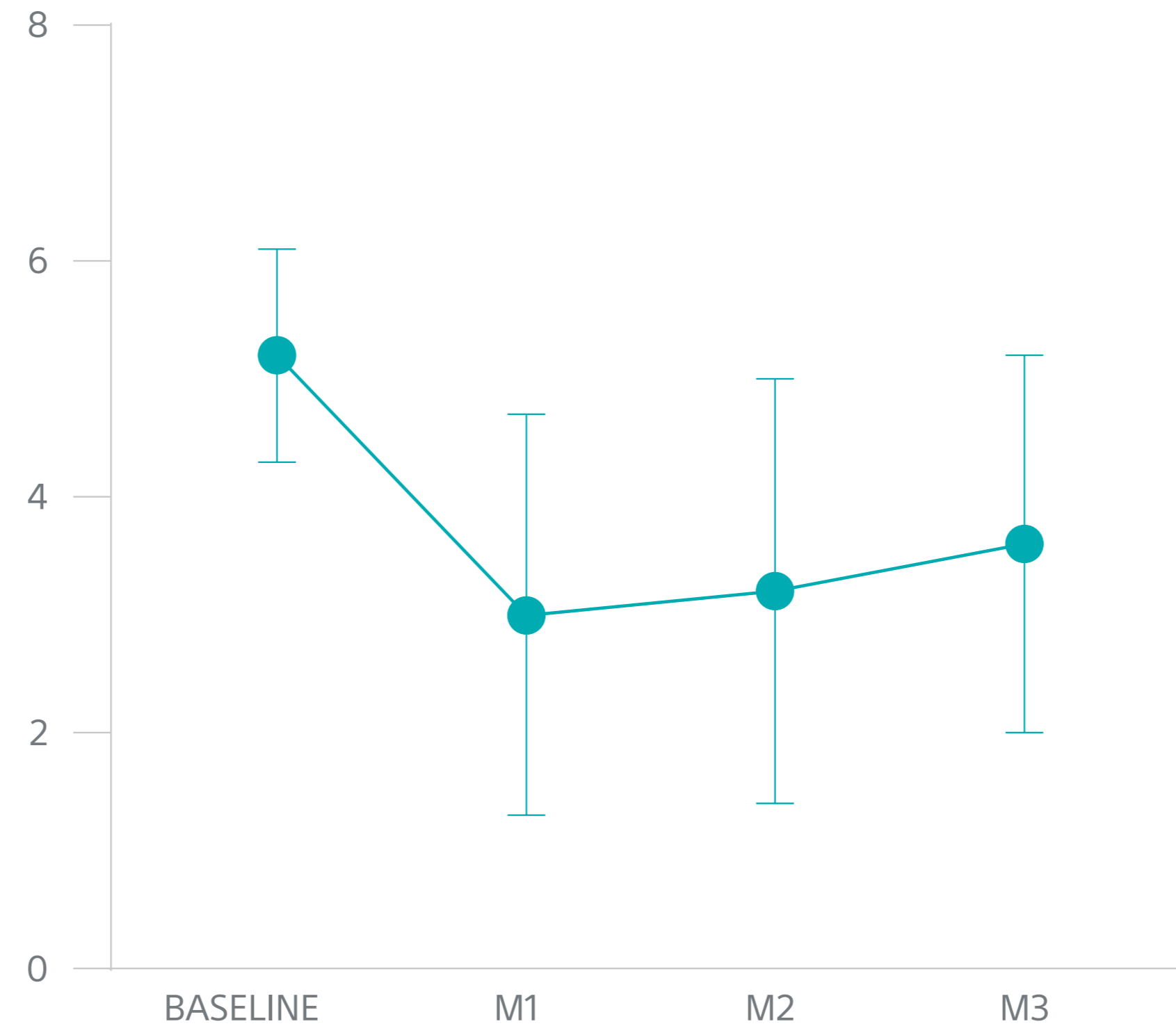
Management of Herpes Zoster in Elderly Patients

Author's conclusion

In a similar extent, SCS and PRF treatments can effectively improve post-herpetic neuralgia in elderly patients.



NUMERICAL RATING SCALE (NRS)



Changes in NRS scores for cervical radicular pain. Average NRS scores declined from 5.2 at baseline to 3.0 at 1 month, 3.2 at 2 months, and 3.6 at 3 months after bipolar PRF treatment

Author's conclusion

Bipolar PRF of the cervical DRG could be considered a safe and effective modality for alleviating refractory chronic cervical radicular pain, especially when TESI or monopolar PRF fail to achieve a therapeutic benefit.





SCORE	% OF CHANGE	DESCRIPTION	PATIENTS (N)
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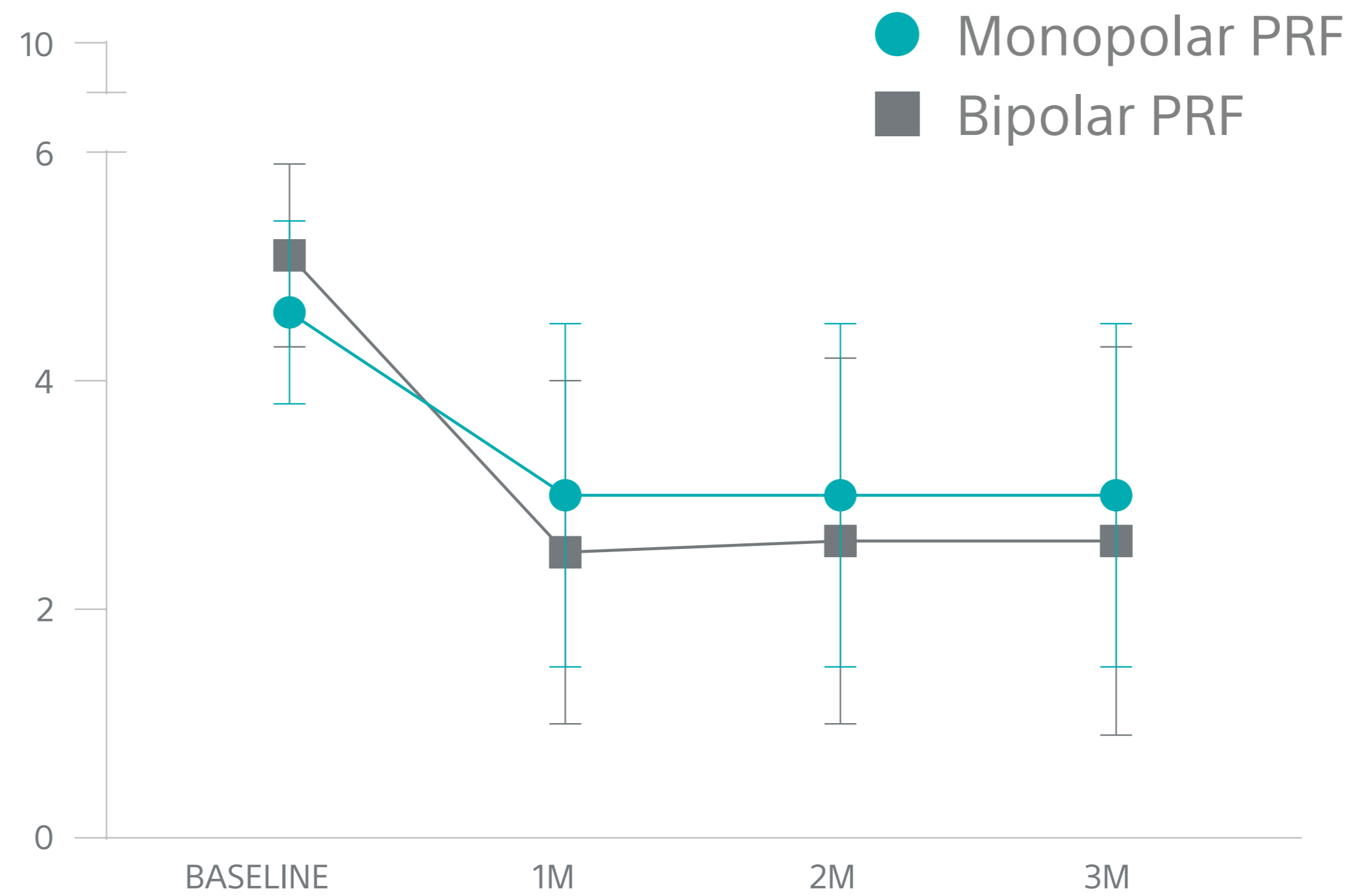
Changes in NRS scores for cervical radicular pain. Global perceived effect according to a Likert scale to assess patient' satisfaction with treatment.

Author's conclusion

Bipolar PRF of the cervical DRG could be considered a safe and effective modality for alleviating refractory chronic cervical radicular pain, especially when TENS or monopolar PRF fail to achieve a therapeutic benefit.



NUMERICAL RATING SCALE (NRS)

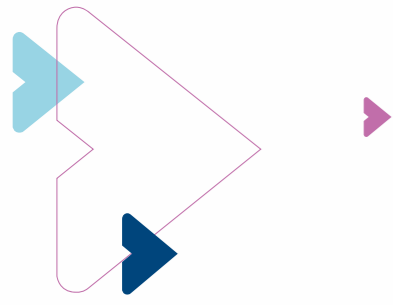


Changes in pain score. The NRS-10 score in the bPRF group decreased from 5.1±0.8 (baseline) to 2.6±1.7 (3M), whereas in the mPRF group decreased from 4.6±0.8 (baseline) to 3.0±1.5 (3M). NRS score was significantly lower in the bPRF group than in the mPRF group.

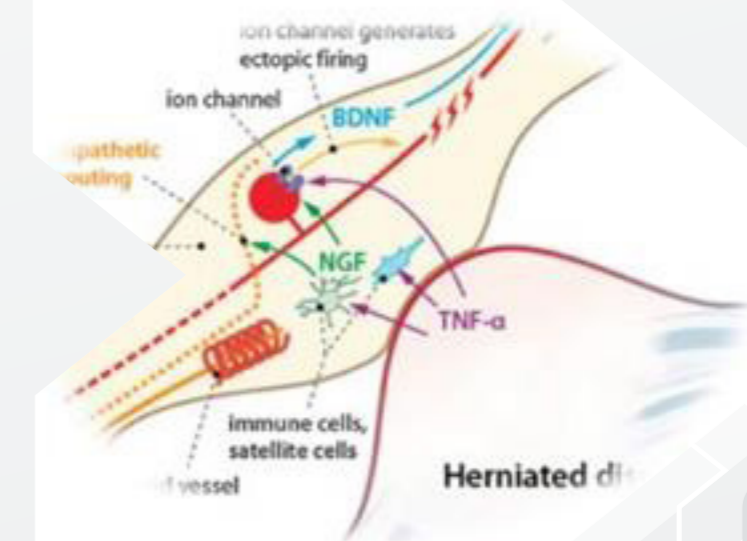
Author's conclusion

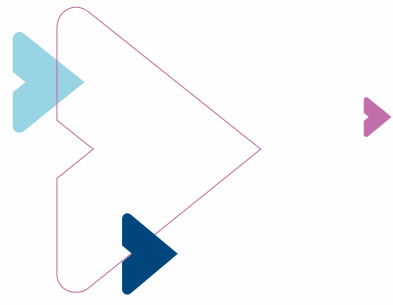
- The use of bPRF on the DRG can be an effective and safe interventional technique for chronic refractory lumbar spinal radiculopathy.
- Bipolar PRF is a more effective method for managing chronic lumbar spinal radicular pain compared to monopolar PRF.





Pulsed Radiofrequency Mechanism of Action





RF FOR
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JOINT PAIN

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Pathophysiology of Radicular Pain: Introduction > The Radicular Pain Cascade > When and Where PRF could modulate Radicular Pain

Introduction

Pulsed radiofrequency (PRF) is a relatively new procedure that relies on the intermittent administration of high-frequency current, which allows heat to disperse to the surrounding tissue but avoids the neuronal damage derived from surpassing temperatures beyond the critical level of 42°C (threshold of nerve damage). Thus, PRF is based on a different mechanism of action from conventional continuous radiofrequency (RFA), where temperature rises above this critical value, inducing tissue heating and thermal nerve coagulation. PRF therapeutic value relies on both reversible effect of thermal damage as well as on minimal cellular changes in the targeted Dorsal Root Ganglion (DRG); as corroborated by ultrastructure microscopic analyses¹⁻².

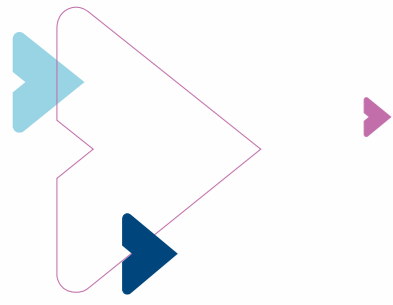
Although the mechanism of action of PRF is not fully understood, it has been postulated that the electric field generated by PRF could exert a neuromodulatory effect i.e. alteration of nerve activity at the targeted DRG. Indeed, preclinical studies in rats have shown that PRF on the DRG induces the expression of c-Fos, an indirect marker of neuronal activity, in the dorsal horn³. The effect of PRF on neurotransmission appears to act selectively on small-diameter axons (C and A δ pain fibers); hence explaining the analgesic effect of PRF, without interfering with sensory input².



References

1. Tun K et al. Surg Neurol. 2009;72(5):496–500.
2. Van Boxem K et al. Regional Anesthesia and Pain Medicine.2014;39:149–159.
3. Erdine S et al. Pain Pract. 2009;9:407–417.

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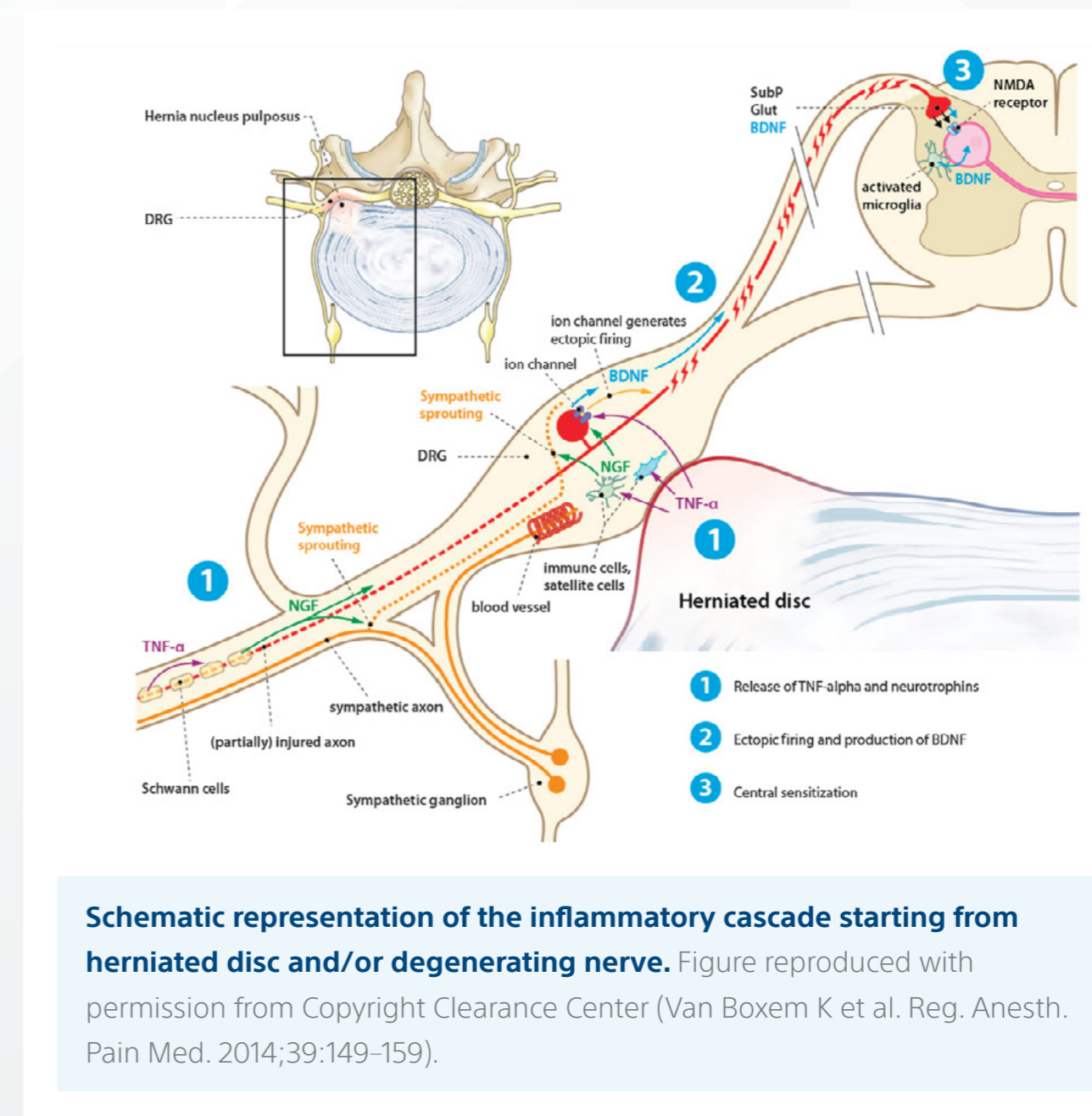
Pathophysiology of Radicular Pain: Introduction > **The Radicular Pain Cascade** > When and Where PRF could modulate Radicular Pain

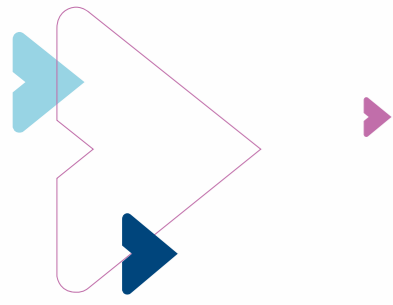
Pathophysiology of radicular pain: the radicular pain cascade

Radicular pain is characterized by the spreading of the nociceptive input in combination with complex cellular and molecular processes (at the axon and the DRG) that initiate and maintain the increased nociceptive signal input.

In the event of a disc degenerating nerve, the following cascade of events occur:

- 1. Pro-inflammatory cytokines are released at the site of lesion:** An inflammatory cascade is initiated by the release of inflammatory mediators or Cytokines, such as TNF- α (Tumor Necrosis Factor-alpha)
- 2. Ectopic or abnormal neuronal firing at the DRG driven by neurotrophins.** Once TNF- α reaches the DRG, the production of the neurotrophic factor NGF (nerve growth factor) in the surrounding inflamed tissue is stimulated. NGF triggers the production of another neurotrophic factor: BDNF (brain-derived neurotrophic factor)
- 3. Ectopic firing at the Dorsal Horn and central pain sensitization** Both NGF and BDNF are also important factors in the development of central sensitization. In other words, they interfere with neuronal excitability and transmission in the dorsal horn; maintaining abnormal pain signaling. Ectopic firing also induces microglia activation





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Pathophysiology of Radicular Pain: Introduction > The Radicular Pain Cascade > **When and Where PRF could modulate Radicular Pain**

Pathophysiology of Radicular Pain: When and Where PRF could modulate radicular pain

Various experimental neuropathic pain models have shown the pain-relieving effect of PRF on mechanical hypersensitivity and thermal allodynia. This effect has been linked to the following events:

1. PRF elicited response at the dorsal horn:

PRF elicits a glial response at the dorsal horn, by reducing several microglial markers OX-42*, BDNF*, PI3K* and, p-ERK*.

These markers are signaling molecules secreted by activated microglia cells that not only drive aberrant pain processing and inflammation in the spinal cord but also underlie peripheral and central pain sensitization¹⁻².

2. PRF stimulation modulates calcium levels:

PRF electric fields promote Calcium uptake in cultured cells, thus potentially influencing calcium-dependent

processes, such as synaptic communication, receptor activity, and calcium-dependent signaling pathways.

Reinforcing the latter, it has been shown that PRF may modulate the expression of the calcium-dependent peptide CGRP (Calcitonin gene-related peptide), which is a crucial player in the pain transduction pathway^{1,3}

3. PRF suppresses pro-inflammatory EEs release:

EEAs or Excitatory Amino Acids play a pivotal role in the development of the peripheral thermal and tactile hypersensitivity that drives the allodynic pain condition^{3,4}

4. PRF triggers endogenous opioid analgesia:

The level of Met-Enkephalin, an endogenous opioid molecule, was found to be significantly increased in the dorsal horn in the first 24 hours after PRF applications¹.

5. PRF modulates inhibitory descending pathways

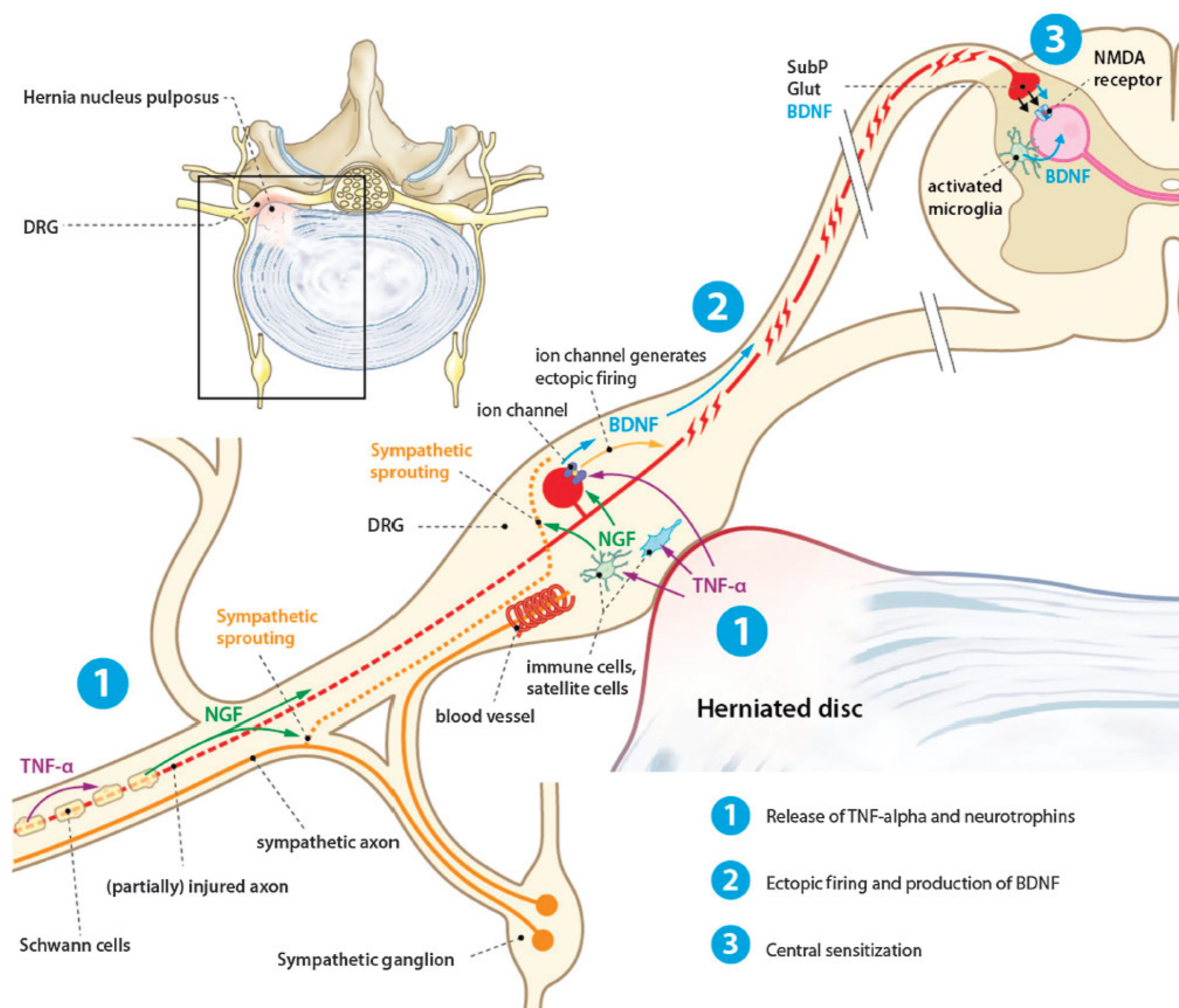
Given that PRF analgesic effect on thermal allodynia is attenuated by the administration of noradrenaline and serotonin receptors antagonists; it is hypothesized that the pain relief associated with PRF may also involve the descending noradrenergic and serotonergic inhibitory pathways; which are involved in the modulation of neuropathic pain¹.

* Brain-derived neurotrophic factor (BDNF), phosphatidylinositol 3-kinase (PI3K), and phosphorylated extracellular signal-regulated kinase (p-ERK)

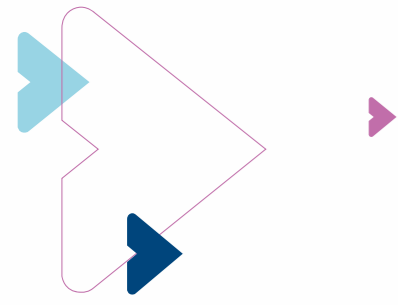
References

1. Van Boxtel K et al. Regional Anesthesia and Pain Medicine. 2014; 39:149-159.
2. Xu X et al. Pain Res Manag. 2019; Apr 28: 5948686.
3. Napoli A et al. Expert Review of Medical Devices. 2020; 17:2, 83-86.
4. Yang CH et al. Neuroreport. 2013; 24(8):431-436.



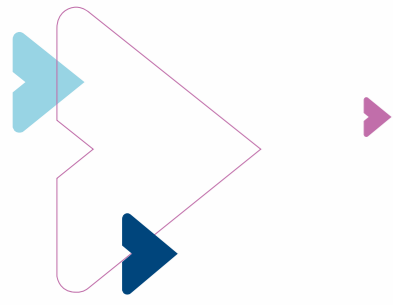


Changes in pain score. The NRS-10 score in the bPRF group decreased from 5.1 ± 0.8 (baseline) to 2.6 ± 1.7 (3M), whereas in the mPRF group decreased from 4.6 ± 0.8 (baseline) to 3.0 ± 1.5 (3M). NRS score was significantly lower in the bPRF group than in the mPRF group.



Radiofrequency ablation for Cervical Pain





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RF FOR
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Introduction > MacVicar et al., 2012 > Shin et al., 2019 > Kwak and Chang, 2018 > Trigeminal RF - Introduction > Huang et al., 2019 > Tsai et al., 2019

Introduction

Syndromic cervical facet pain is defined by a combination of symptoms including: axial neck pain that can radiate or not past the shoulders (radicular) or the head (cervicogenic), pain with pressure on the dorsal spinal column at the level of the cervical facet joints, limitation of neck extension and rotation, and absence of neurological symptoms¹.

Prevalence: Neck pain is the third most reported cause of musculoskeletal complaint in the general population, with a yearly prevalence ranging between 30% to 50%¹. Amongst this large group of individuals who would eventually develop a chronic neck pain condition, more than 50% thereof will suffer from facet- or zygapophyseal joint-related pain^{1,2}.

Treatment: Minimally invasive treatments for the treatment of chronic cervical pain include microvascular decompression, medial branch blocks, and intraarticular

steroid injections^{1,2}. These approaches, although effective in some cases, have limited long-term efficacy.

Whenever there is a clear indication that the pain has its origin in the cervical facet joints, radiofrequency ablation (RFA) is a good treatment option for the management of several types of refractory cervical pain. RFA utilizes thermal energy to coagulate the sensory nerves, thus interrupting the nociceptive input arising from the cervical facet joint(s).

Effectiveness of RFA: The **clinical utility and long-term effectiveness of therapeutic RFA for the management of cervical facetogenic** pain were thoroughly assessed in a systematic review by Manchikanti et al³. This study capitalized on the best evidence synthesis derived from one high-quality randomized clinical trial and several observational studies; thereby reporting the cumulative RFA outcomes of more than 300 treated patients. Beyond

sustained and significant pain relief -achieved in more than 70% of the patients-, this study also linked cervical RF procedures with a **functional status improvement and a reduced need for further medical procedures.**

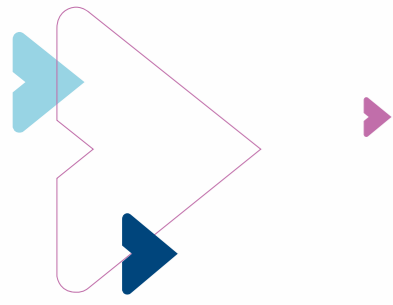
Complementary, two additional meta-analyses have corroborated the effectiveness and safety of pulsed RF (PRF) for the management of neuropathic cervical pain conditions, such as **trigeminal neuralgia and cervical radiculopathy**^{4,5}. Both studies provided high-quality and conclusive evidence that justify the therapeutic use of PRF for the management of these chronic refractory conditions.

References

1. van Eerd M et al. Pain Pract. 2010; 10(2):113-23.
2. Cohen SP et al. Reg. Anesth. Pain. Med. 2007; 32(6):495-503.
3. Manchikanti L et al. Pain Physician. 2015; 18(4):E535-82.
4. Wu H et al. J. Pain. Res. 2019; 12:423-441.
5. Kwak SG et al. Medicine (Baltimore). 2018; 97(31):e11761.

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Introduction > **MacVicar et al., 2012** > Shin et al., 2019 > Kwak and Chang, 2018 > Trigeminal RF - Introduction > Huang et al., 2019 > Tsai et al., 2019

Cervical Medial Branch Radiofrequency Neurotomy in New Zealand

Study Goal

To determine the effectiveness of cervical medial branch radiofrequency neurotomy (RFN) in conventional practice.

Methodology

RFN practitioners: Cervical RFN was performed by two experienced practitioners (two independent practices) trained according to rigorous guidelines.

Patients: 104 patients were selected to receive RFN based on complete cervical pain relief following diagnostic medial branch blocks. Patients presented with neck pain of potential cervical zygapophysial joint origin.

- Patient's VAS and NRS pain scores, as well as daily living activities were recorded before treatment and during follow-up visits post-procedure.
- Data recording and analysis were performed in a double-blind setup.
- Complete pain relief, for at least 6 months, accompanied by complete restoration of daily living activities and no need for any other health care intervention, was adopted as the cardinal criterion for a successful outcome.
- The electrodes were placed parallel to the medial branches, and sufficiently large lesions were created in both the sagittal and oblique planes (30° to sagittal), to cover the likely location of the nerves (C5). On average, two lesions in each plane were created.
- The temperatures used were 80° (sagittal) and 85° (oblique) and maintained for 90 seconds for each lesion.

RFN procedure: All procedures were carried out with 10 cm - 16-gauge (1.6 mm diameter) Cosman™ RRE electrodes with 5 mm exposed tips.


Authors:

MacVicar J, Borowczyk J, MacVicar A, Loughnan B, and Bogduk N.

Study type:

Prospective, multicenter, real-world study

Publication:

Pain Medicine 2012;
13(5): 647-54
(Link to PubMed )

Key Words:

Neck pain – cervical
medial branch -
zygapophysial joint –
Thermal RF

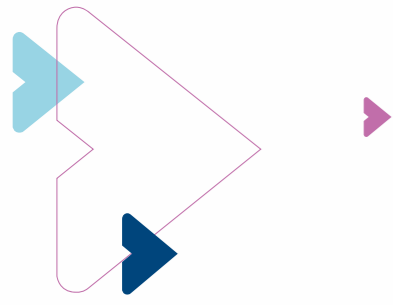
Graphs created by Boston Scientific
based on the published data



References

1. Tun K et al. Surg Neurol. 2009;72(5):496–500.
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PULSED RF MECHANISM OF ACTION

RF FOR CERVICAL PAIN

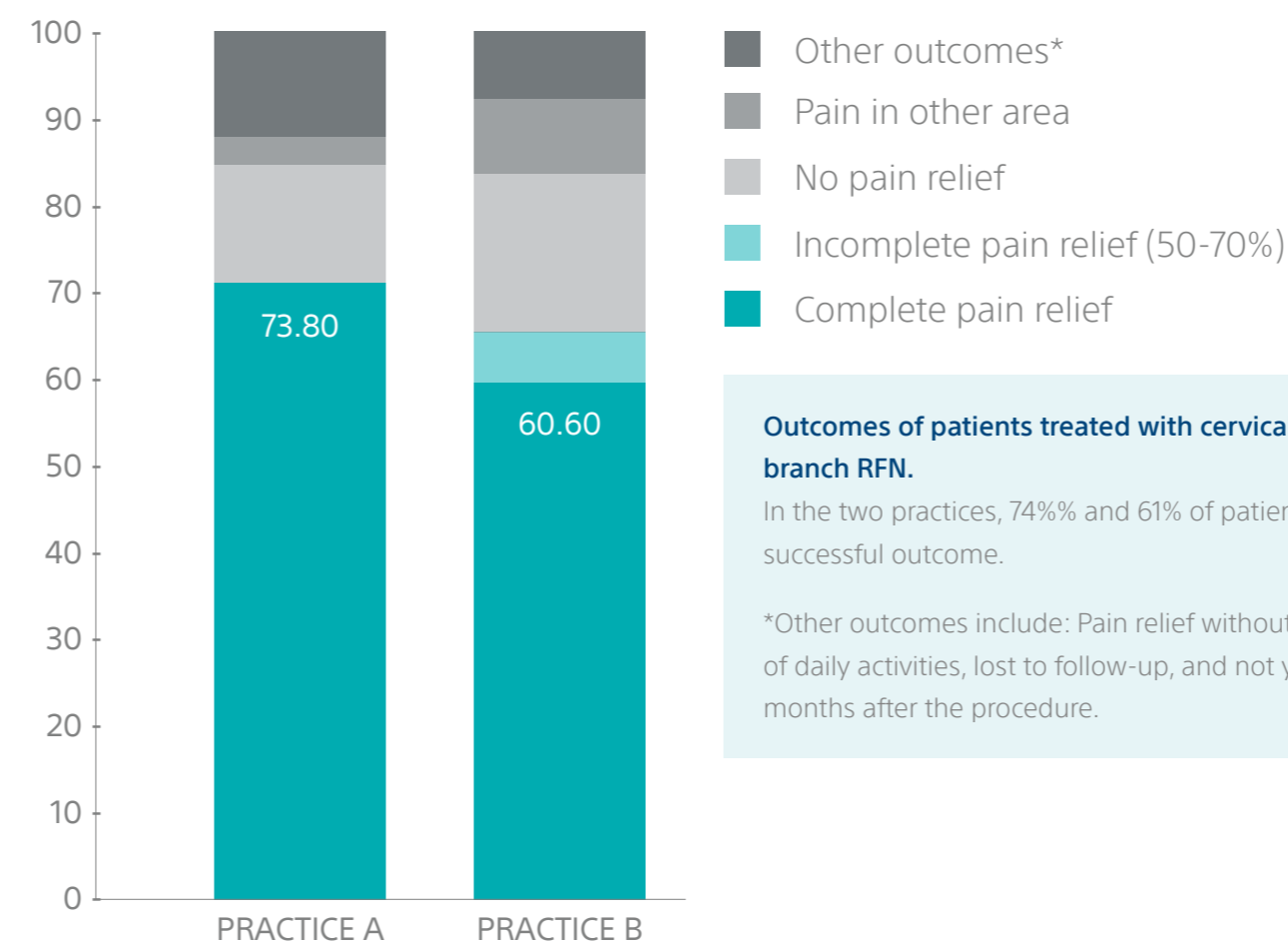
Introduction > **MacVicar et al., 2012** > Shin et al., 2019 > Kwak and Chang, 2018 > Trigeminal RF - Introduction > Huang et al., 2019 > Tsai et al., 2019

Cervical Medial Branch Radiofrequency Neurotomy in New Zealand

Results

- In the two practices, 74% (Practice A) and 61% (Practice B) of patients achieved a successful outcome, with complete pain relief and restoration of daily activities.
- In both practices, pain relief lasted 17-20 months from the first RFN procedure.
- Allowing for repeat treatment, patients had sustained pain relief for a median duration of 20-26 months, with 60% of the patients still having relief at follow-up.

CLINICAL OUTCOMES CERVICAL RF (% PATIENTS)



Outcomes of patients treated with cervical medial branch RFN.
 In the two practices, 74% and 61% of patients achieved a successful outcome.

*Other outcomes include: Pain relief without restoration of daily activities, lost to follow-up, and not yet reached 6 months after the procedure.

Author's conclusion

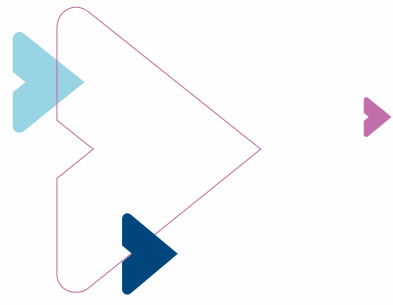
- Cervical RFN can be very effective when performed in a rigorous manner in appropriately selected patients.
- Chronic neck pain, mediated by the cervical medial branches, can be temporarily, but completely, relieved and patients fully restored to normal activities of daily living, if treated with RFN.



References

1. Tun K et al. Surg Neurol. 2009;72(5):496-500.
2. Van Boxem K et al. Regional Anesthesia and Pain Medicine.2014;39:149-159.
3. Erdine S et al. Pain Pract. 2009;9:407-417.

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RF FOR
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RF FOR SACROILIAC
JOINT PAIN

PULSED RF FOR
RADICULAR PAIN

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Clinical Effectiveness of Intra-articular Pulsed Radiofrequency Compared to Intra-articular Corticosteroid Injection for Management of Atlanto-occipital Joint Pain

Study Goal

To assess the effectiveness of pulsed radiofrequency (PRF) stimulation on the atlanto-occipital (AO) joint in patients with chronic joint pain. The authors also compared the effect of AO intra-articular (IA) PRF and AO-IA corticosteroid injection (ICI)

Methodology

Patients: 23 patients with spontaneous onset chronic upper cervical pain (suboccipital neck area) were prospectively recruited.

- All patients failed to respond to conservative treatments (physical therapy and medication).

- Patients presented with a limited range of lateral flexion upon rotation of the AO joint and sustained pain for at least 6 months.

Study groups: Patients were randomized to receive either PRF (N=12) or ICI (N=11). Treatment was carried out by one experienced clinician.

- A Numeric Rating Scale (NRS) score was used to evaluate pain severity before treatment and 1, 3, and 6 months after the procedure. Successful pain relief was defined as $\geq 50\%$ reduction in baseline NRS score at 6 months.

AO-PRF procedure: A 22-gauge, 10-cm cannula with a 10-mm active tip (Cosman™

RF-CC10522) was inserted in the uppermost portion of the AO joint. PRF was performed with a Cosman™-G4 RF generator at 5Hz and 5ms pulse width for 360s at 55 V. Electrode tip temperature was maintained at or below 42°C.

AO-ICI procedure: A 25-gauge spinal needle was inserted into the AO joint. A mixture of anesthetic and corticosteroid was slowly injected.


Authors:

Shin S.M, Kwak S.G, Lee D.G and Chang M.C

Study type:

Prospective, randomized, controlled, pilot study

Publication:

Acta Neurochirurgica 2019; 161(7):1427-34 (Link to PubMed )

Key Words:

Chronic Neck - Upper Cervical Pain - Atlanto-occipital joint - Pulsed RF

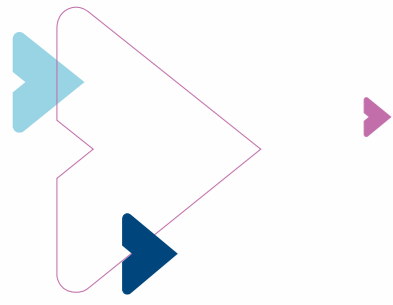
Graphs created by Boston Scientific based on the published data



References

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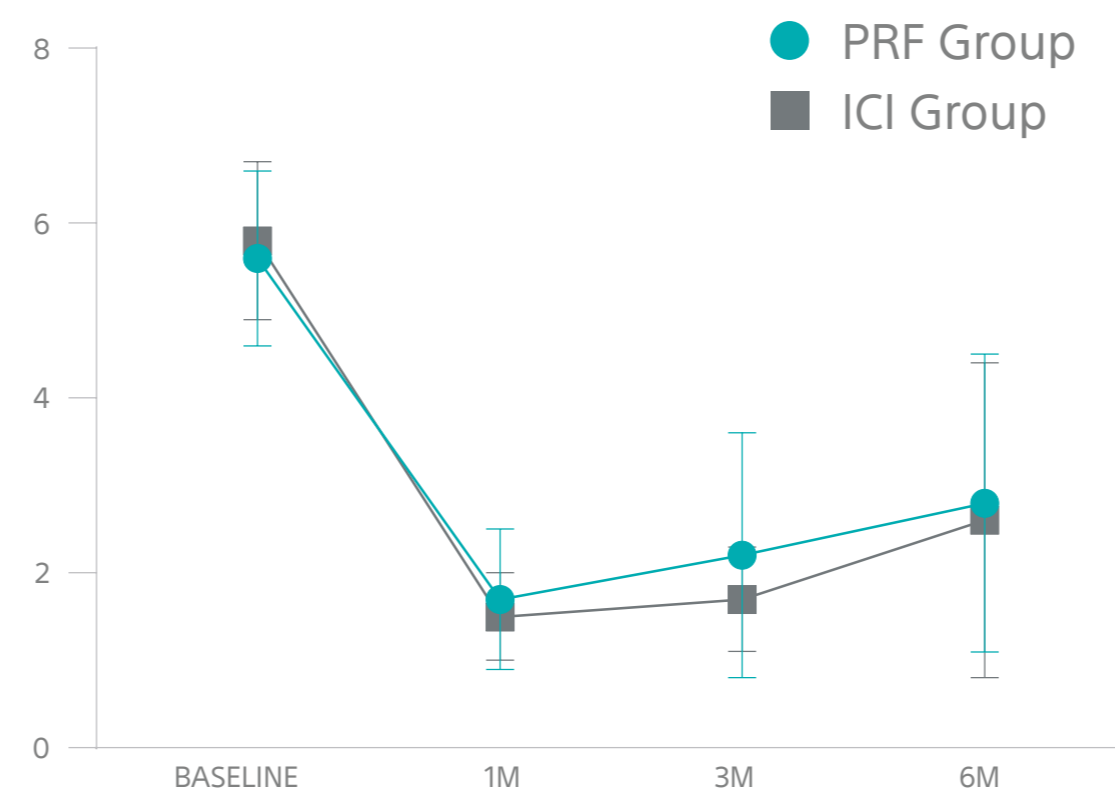
Introduction > MacVicar et al., 2012 > **Shin et al., 2019** > Kwak and Chang, 2018 > Trigeminal RF - Introduction > Huang et al., 2019 > Tsai et al., 2019

Clinical Effectiveness of Intra-articular Pulsed Radiofrequency Compared to Intra-articular Corticosteroid Injection for Management of Atlanto-occipital Joint Pain

Results

- Chronic joint pain severity (mean NRS scores) was significantly reduced at 1, 3, and 6 months after each procedure ($P < 0.001$).
- Successful pain relief was achieved in 66.7% (8/12) of patients in the PRF group and 63.6% (7/11) of the patients in the ICI group.
- The extent of pain reduction between the two procedures was not significantly different at 6 months post-treatment ($P = 0.879$).

NUMERICAL RATING SCALE (NRS)



Changes in NRS scores for chronic cervical joint pain. In the PRF group, mean NRS scores decreased from 5.6 at pre-treatment to 1.7, 2.2, and 2.8, respectively at 1-, 3-, and 6-months post-treatment. In the ICI group, mean NRS values decreased from 5.8 at pre-treatment to 1.5, 1.7, and 2.6, respectively at 1-, 3-, and 6-months post-treatment.

Author's conclusion

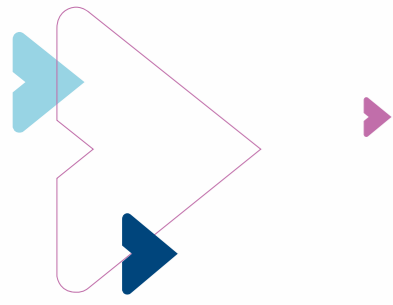
Intra-AO joint PRF stimulation could be a useful clinical treatment for patients with AO joint pain; especially for those prone to adverse effects derived from the use of corticosteroids.



References

1. Tun K et al. Surg Neurol. 2009;72(5):496-500.
2. Van Boxtel K et al. Regional Anesthesia and Pain Medicine. 2014;39:149-159.
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RF FOR LUMBAR PAIN	RF FOR SACROILIAC JOINT PAIN	PULSED RF FOR RADICULAR PAIN	PULSED RF MECHANISM OF ACTION	RF FOR CERVICAL PAIN
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Introduction > MacVicar et al., 2012 > Shin et al., 2019 > **Kwak and Chang, 2018** > Trigeminal RF - Introduction > Huang et al., 2019 > Tsai et al., 2019

Management of refractory chronic migraine using ultrasound-guided pulsed radiofrequency of greater occipital nerve

Study Goal

To report the response to pulsed radiofrequency (PRF) stimulation of the greater occipital nerve (GON) in two patients with refractory migraine.

Methodology

Patients: Two patients diagnosed with chronic migraine were recruited for the study. Oral medications, GON block with bupivacaine and dexamethasone, and botulinum toxin injections failed to alleviate the patient's migraine.

	PATIENT 1	PATIENT 2
Age and Sex	33 y/o - Men	34 y/o - Woman
Year of migraine onset	15 years	14 years
Frequency of headaches	Daily	Daily
Duration of headache attacks	12 to 48 hours	12 to 48 hours

PRF procedure: PRF stimulation of the GON was performed under the guidance of ultrasound as follows:

- Insertion of the catheter needle (22-gauge active curved-tip).
- Sensory stimulation with a PRF generator – RFG4, Cosman Medical™.

- PRF treatment: 5Hz and 5-millisecond pulsed width for 360 seconds at 45V.
- Electrode tip temperature was maintained at or below 42°C.

Authors:
Kwak S and Chang M.C

Study type:
Case report

Publication:
Case reports, Medicine
2018; 97(45):e13127
(Link to PubMed 🌐)

Key Words:
*Chronic Migraine –
Greater Occipital Nerve –
Pulsed RF*

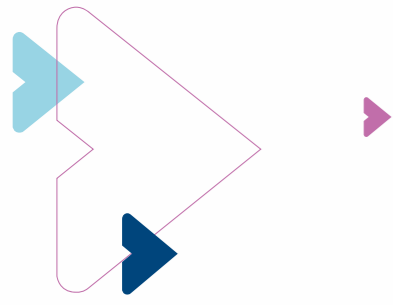
Graphs created by Boston Scientific based on the published data



References

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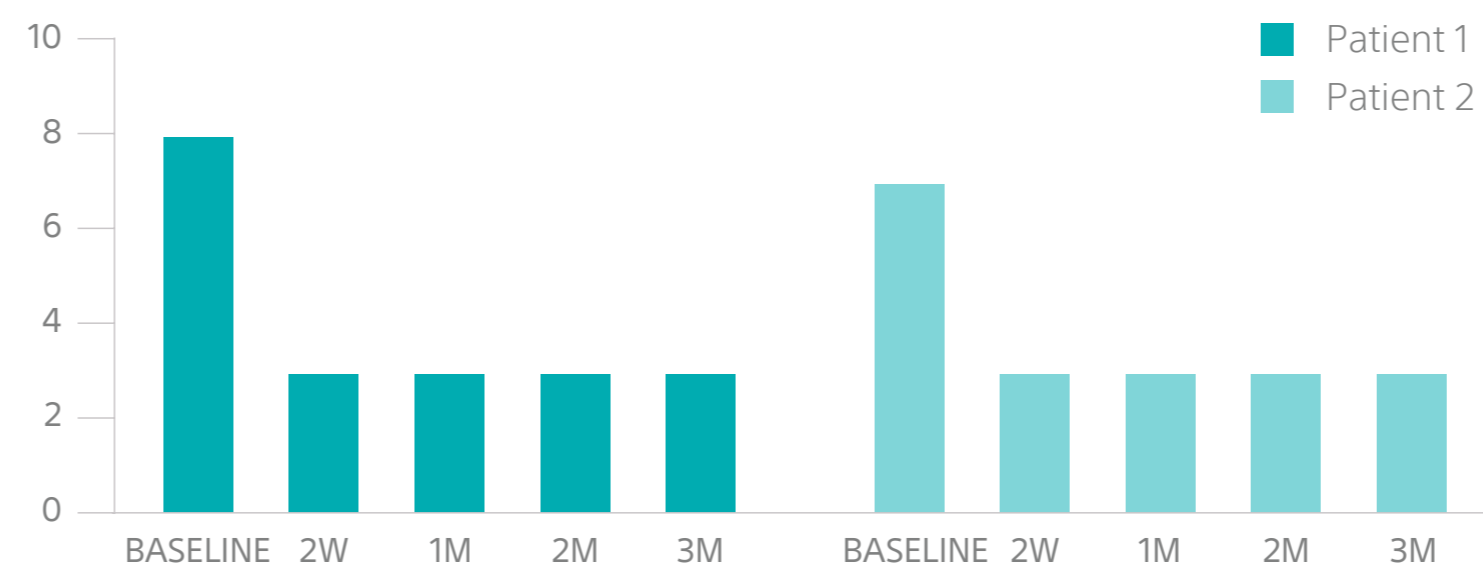
Introduction > MacVicar et al., 2012 > Shin et al., 2019 > **Kwak and Chang, 2018** > Trigeminal RF - Introduction > Huang et al., 2019 > Tsai et al., 2019

Management of refractory chronic migraine using ultrasound-guided pulsed radiofrequency of greater occipital nerve

Results

- Two weeks after applying PRF, the pain was reduced to NRS 3 in both patients, who also reported that the headaches became bearable after PRF.
- The effectiveness of PRF of the GON was sustained for at least 3 months in both patients.
- The number of migraine attacks per month and the duration of the attacks were not significantly changed.
- No adverse effects of the procedure were reported.

NUMERICAL RATING SCALE (NRS)



Author's conclusion

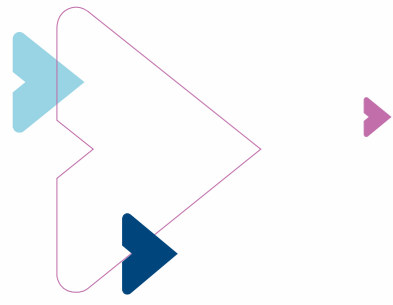
- PRF of the GON could be an effective treatment option for the therapeutic management of refractory migraine.
- Further studies involving more patients are still needed to confirm a positive therapeutic response to ultrasound-guided PRF of the GON.



References

1. Tun K et al. Surg Neurol. 2009;72(5):496-500.
2. Van Boxtel K et al. Regional Anesthesia and Pain Medicine. 2014;39:149-159.
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Improving safety and efficacy of radiofrequency trigeminal rhizotomy of the foramen ovale: Procedural techniques to optimize target localization and cannulation

Trigeminal neuralgia (TN): TN is a common neuropathic pain disorder with symptoms of transient pain affecting one or more branches of the trigeminal nerve. Talking, eating, brushing teeth, and slight touching can induce severe and brief pain.

Treatment with RF: Many invasive treatments are currently available for TN patients who respond poorly to oral medication. **Among them, radiofrequency trigeminal rhizotomy (RF-TR) treatment is a viable option with reliable initial and long-term clinical efficacy¹⁻²**

Nonetheless, patients undergoing RF-TR may develop several complications, such as facial or forehead numbness and eyelash or corneal hypoesthesia. These

complications have been associated with neuronal injury, produced by surgical puncture during the thermocoagulation procedure²

Procedure and limitations: The common procedural approach to treat TN is the percutaneous trans-foramen ovale (FO) RF ablation of the Gasserian Ganglion (GG) under fluoroscopic guidance. This approach, although effective, has been associated with treatment failure, recurrent pain, and a higher risk of neurological complications.

Novel RF techniques aiming to optimize anatomical localization of the lesion target (FO) are essential to improve clinical outcomes and patient safety³

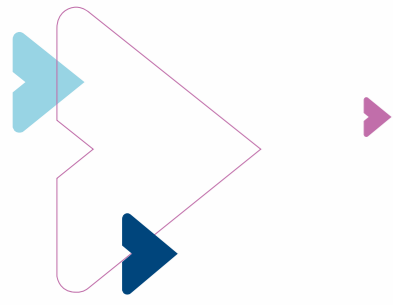
Here, **we summarize two important studies that assess the efficacy of novel RF-TN approaches.** These studies not only highlight the relevance of accurate imaging guidance and bipolar RF size lesion for TN treatment but also showcase the versatility of Boston Scientific technologies for these complex rhizotomy procedures.



References

1. Hong T et al. Biochem Res Int. 2020; 4: 3854284.
2. Wu H et al. J Pain Res. 2019; 18;12: 423-441.
3. Huang B et al. J Pain Res. 2019; 9 (12): 1465-1474.

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Improving safety and efficacy of Radiofrequency Trigeminal Rhizotomy of the Foramen Ovale: Procedural Techniques To Optimize Target Localization And Cannulation

Study Goal

In this study, the authors report the outcomes of a novel FO-RFA of the V3 mandibular nerve under CT-guidance using both mRFA and bRFA.

Methodology

Clinical outcomes and complications of mRFA and bRFA under CT-guidance were evaluated in 26 patients with isolated V3-TN. Patients were followed-up for up to 27 months.

Primary outcome: Complete sensory block of the V3. Secondary outcomes: Presence of residual pain, recurrent pain, and adverse clinical effects.

Guidance: The FO was identified on axial CT images. Needle trajectory was simulated on CT-software to allow a safe path without bony impediments.

RF procedure: Both sensory and motor tests were performed at the distribution of V3. BSC cannulas (20-gauge, 5mm bevel-tip) were used to access the FO. RF was conducted at 90°C for 90 seconds.


Authors:

Huang B, Xie K, Chen Y, Wu J, and Yao M.

Study type:

Feasibility – Prospective, single center

Publication:

Journal of Pain Research 2019; 12 1465-74
([Link to PubMed](#) )

Key Words:

Mandibular TN – Foramen Ovale – monopolar (m) RFA – bipolar (b) RFA – CT images

Study results and conclusions:

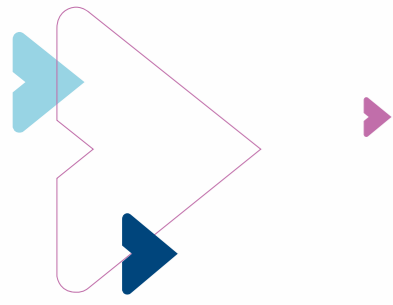
- Both extracranial monopolar and bipolar RF techniques, under CT guidance, led to complete and persistent V3 analgesia with a comparable minor risk of post-procedural facial hematoma.
- In the bipolar RF group, complete pain relief persisted in all patients (14/14) at 15 months follow-up. In the monopolar group, only one case (1/12) of recurrent pain was found at a 14 months follow-up.
- Authors report a 100% success rate of optimal needle placement and thus superiority to the standard approach.



References

1. Tun K et al. Surg Neurol. 2009;72(5):496–500.
2. Van Boxem K et al. Regional Anesthesia and Pain Medicine.2014;39:149–159.
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Introduction > MacVicar et al., 2012 > Shin et al., 2019 > Kwak and Chang, 2018 > Trigeminal RF - Introduction > Huang et al., 2019 > **Tsai et al., 2019**

Improving safety and efficacy of Radiofrequency Trigeminal Rhizotomy of the Foramen Ovale: Procedural techniques to optimize target localization and cannulation

Study Goal

To improve radiofrequency trigeminal rhizotomy (RF-TR) safety and precision by optimizing the visualization of the Trigeminal Cistern and Ganglion and by facilitating the localization of the RF lesion target (Foramen Ovale)

Methodology

This study enrolled 252 consecutive patients diagnosed with refractory TN. These patients underwent a total of 340 RF-TN procedures.

Guidance: The target structure (FO) was visualized either on intraoperative Computed Tomography (iCT) or magnetic

resonance images (MRI) and iCT fused images (Brainlab AG).

Clinical outcomes: Pain severity pre- and post-treatment and the occurrence of postoperative complications. Patients were followed up for 2-8 years via outpatient visits or phone interviews.

RF procedure: RF-TN was performed with a Tew electrode kit and a Radionics RTG-3CF generator. A sensory test was performed (50Hz; 1ms PW; 0-1V) before performing two consecutive RF lesions at 60-95°C for 100 seconds.

Authors:

Tsai P-J, Lee M-H, Chen K-T, Huang W-C, Yang J-T and Lin M. H-C

Study type:

Retrospective, single center

Publication:

Acta Neurochirurgica 2019; 161(7):1427-34
([Link to PubMed](#))

Key Words:

Refractory TN – Foramen Ovale – Thermal RF and Image iCT-MRI fusion

Study results and conclusions:

- iCT with MRI fusion was significantly associated with a greater degree of immediate pain relief, and a higher likelihood of a sustained response lasting over two years ($p < 0.01$).
- iCT with MRI fusion was also linked to a higher occurrence of CSF outflow; which is associated with better heat transfer and less tissue charring.
- Accurate anatomical localization of the FO using iCT-MRI image fusion could avoid puncture-related complications and provide sustained pain relief.



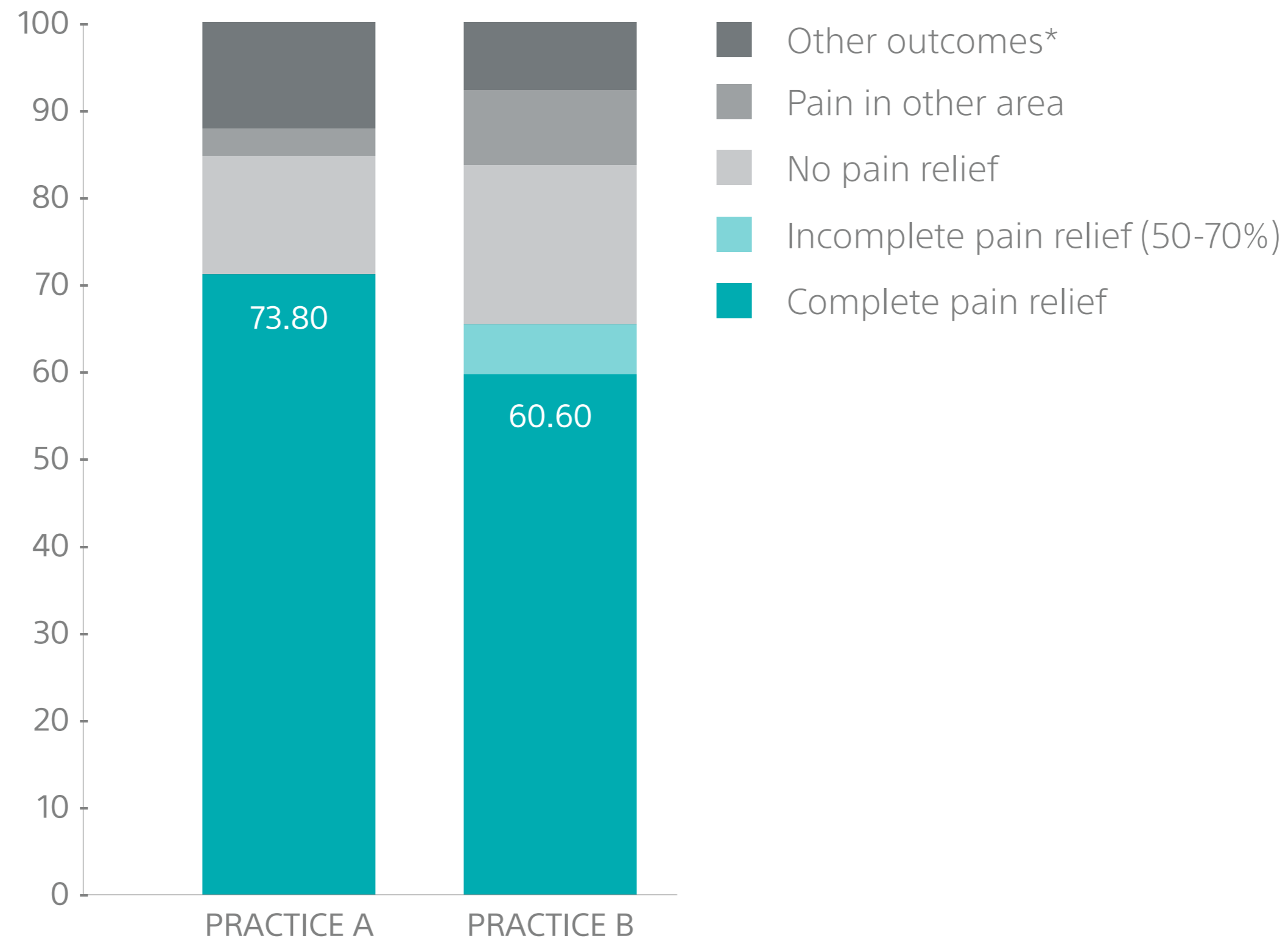
References

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CLINICAL OUTCOMES CERVICAL RFN (% PATIENTS)



Outcomes of patients treated with cervical medial branch RFN. In the two practices, 74%% and 61% of patients achieved a successful outcome.

*Other outcomes include: Pain relief without restoration of daily activities, lost to follow-up, and not yet reached 6 months after the procedure.

RF FOR CERVICAL PAIN

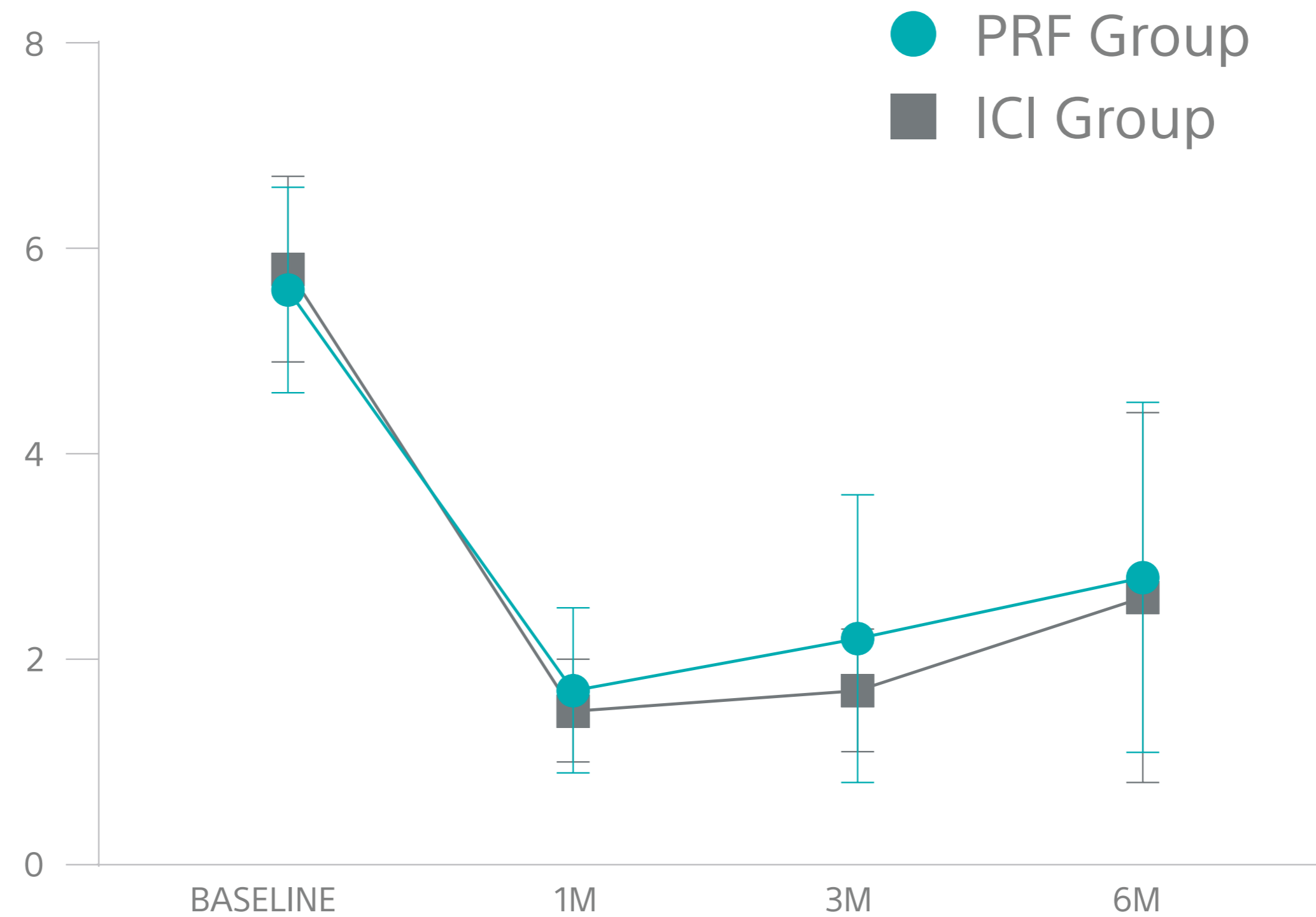
9 > Tsai et al., 2019

Author's conclusion

Cervical RFN can be an effective when performed in a rigorous manner in appropriately selected patients. Chronic neck pain mediated by the cervical medial branches can be temporarily but completely relieved and patients fully restored to normal activities of daily living if treated with RFN.



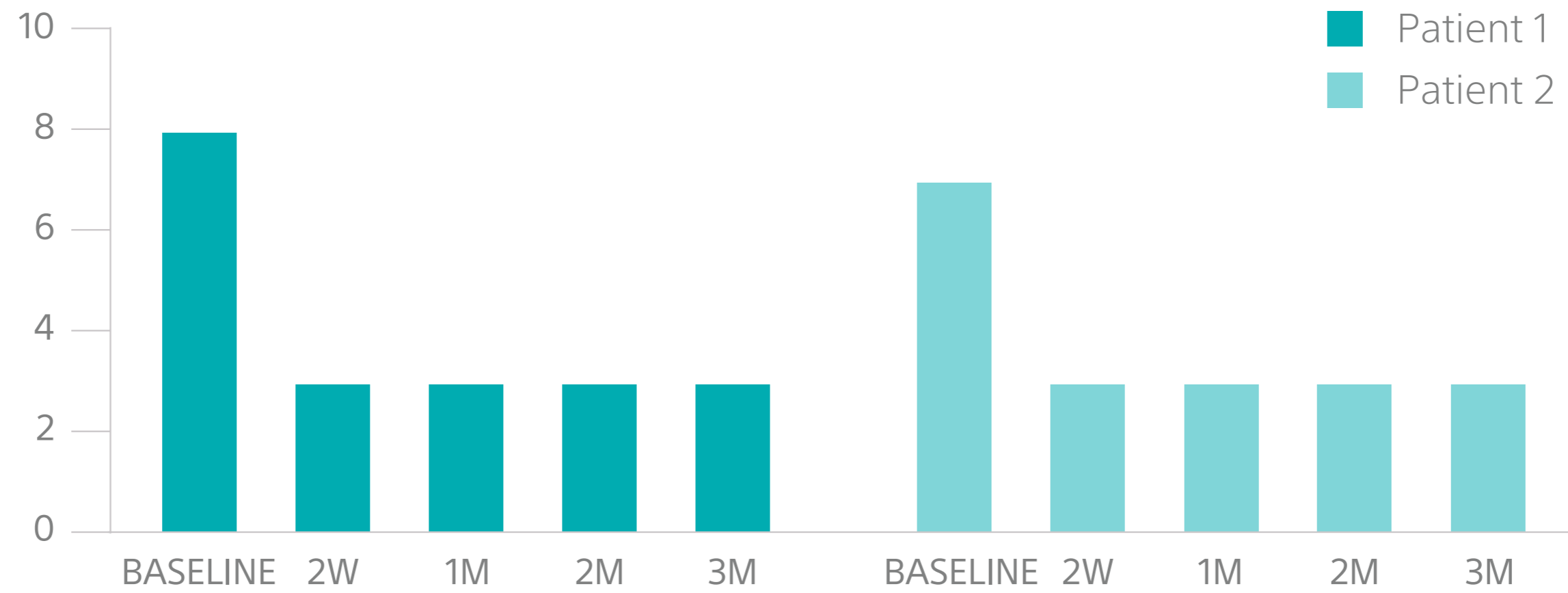
NUMERICAL RATING SCALE (NRS)



Changes in NRS scores for chronic cervical joint pain. In the PRF group, mean NRS scores decreased from 5.6 at pre-treatment to 1.7, 2.2, and 2.8, respectively at 1-, 3-, and 6-months post-treatment. In the ICI group, mean NRS values decreased from 5.8 at pre-treatment to 1.5, 1.7, and 2.6, respectively at 1-, 3-, and 6-months post-treatment.



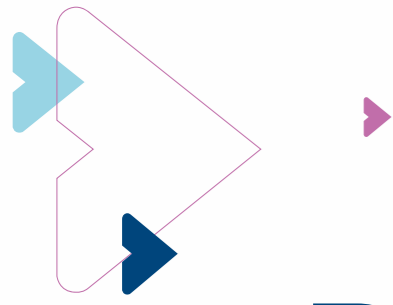
NUMERICAL RATING SCALE (NRS)



Author's conclusion

- PRF of the GON could be an effective treatment option for the therapeutic management of refractory migraine.
- Further studies involving more patients are still needed to confirm a positive therapeutic response to ultrasound-guided PRF of the GON.

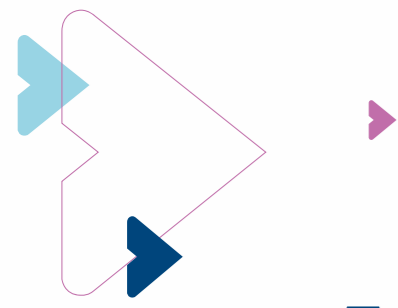




REFERENCES

- Chang MC, Cho YW, Ahn SH. Comparison between bipolar pulsed radiofrequency and monopolar pulsed radiofrequency in chronic lumbosacral radicular pain: A randomized controlled trial. *Medicine (Baltimore)*. 2017 Mar;96(9):e6236.
- Cheng J, Chen SL, Zimmerman N, Dalton JE, LaSalle G, Rosenquist R. A New Radiofrequency Ablation Procedure to Treat Sacroiliac Joint Pain. *Pain Physician*. 2016 Nov-Dec;19(8):603-615.
- Cosman ER Jr, Gonzalez CD. Bipolar radiofrequency lesion geometry: implications for palisade treatment of sacroiliac joint pain. *Pain Pract*. 2011 Jan-Feb;11(1):3-22
- Cosman ER Jr, Dolensky JR, Hoffman RA. Factors that affect radiofrequency heat lesion size. *Pain Med*. 2014 Dec;15(12):2020-36. doi: 10.1111/pme.12566. Epub 2014 Oct 14.
- Huang B, Xie K, Chen Y, Wu J, Yao M. Bipolar radiofrequency ablation of mandibular branch for refractory V3 trigeminal neuralgia. *J Pain Res*. 2019 May 9;12:1465-1474.
- Juch JNS, Maas ET, Ostelo RWJG, Groeneweg JG, Kallewaard JW, Koes BW, Verhagen AP, van Dongen JM, Huygen FJPM, van Tulder MW. Effect of Radiofrequency Denervation on Pain Intensity Among Patients With Chronic Low Back Pain: The Mint Randomized Clinical Trials. *JAMA*. 2017 Jul 4;318(1):68-81.
- Kwak S, Chang MC. Management of refractory chronic migraine using ultrasound-guided pulsed radiofrequency of greater occipital nerve: Two case reports. *Medicine (Baltimore)*. 2018 Nov;97(45):e13127.
- Lee SH, Choi HH, Roh EY, Chang MC. Effectiveness of Ultrasound-Guided Pulsed Radiofrequency Treatment in Patients with Refractory Chronic Cervical Radicular Pain. *Pain Physician*. 2020 Jun;23(3):E265-E272.
- Liu B, Yang Y, Zhang Z, Wang H, Fan B, Sima L. Clinical Study of Spinal Cord Stimulation and Pulsed Radiofrequency for Management of Herpes Zoster-Related Pain Persisting Beyond Acute Phase in Elderly Patients. *Pain Physician*. 2020 Jun;23(3):263-270.
- MacVicar J, Borowczyk JM, MacVicar AM, Loughnan BM, Bogduk N. Cervical medial branch radiofrequency neurotomy in New Zealand. *Pain Med*. 2012 May;13(5):647-54.
- MacVicar J, Borowczyk JM, MacVicar AM, Loughnan BM, Bogduk N. Lumbar medial branch radiofrequency neurotomy in New Zealand. *Pain Med*. 2013 May;14(5):639-45
- Provenzano DA, Buvanendran A, de León-Casasola OA, Narouze S, Cohen SP. Interpreting the MINT Randomized Trials Evaluating Radiofrequency Ablation for Lumbar Facet and Sacroiliac Joint Pain: A Call From ASRA for Better Education, Study Design, and Performance. *Reg Anesth Pain Med*. 2018 Jan;43(1):68-71
- Tsai PJ, Lee MH, Chen KT, Huang WC, Yang JT, Lin MH. Foramen ovale cannulation guided by intraoperative computed tomography with magnetic resonance image fusion plays a role in improving the long-term outcome of percutaneous radiofrequency trigeminal rhizotomy. *Acta Neurochir (Wien)*. 2019 Jul;161(7):1427-1434.
- Tsai PJ, Lee MH, Chen KT, Huang WC, Yang JT, Lin MH. Foramen ovale cannulation guided by intraoperative computed tomography with magnetic resonance image fusion plays a role in improving the long-term outcome of percutaneous radiofrequency trigeminal rhizotomy. *Acta Neurochir (Wien)*. 2019 Jul;161(7):1427-1434.
- Yang S, Chang MC. Effect of bipolar pulsed radiofrequency on chronic cervical radicular pain refractory to monopolar pulsed radiofrequency. *Ann Palliat Med*. 2020 Mar;9(2):169-174



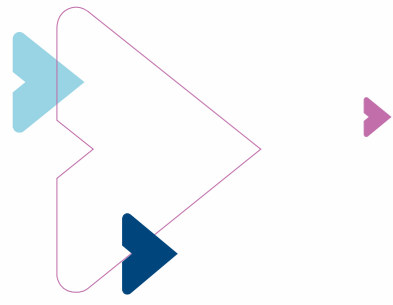


ACRONYMS

AO	Atlanto-Occipital
brFA	Bipolar Radiofrequency
bPRF	bipolar Pulsed Radio Frequency
CFS	Cervical Foraminal Stenosis
cRFA	Cooled Radiofrequency
CSF	Cerebro Spinal Fluid
CT	Computed Tomography
DRG	Dorsal Root Ganglion
FO	Foramen Ovale
GG	Gasserian Ganglion
GPE	Global Perceived Effect
GON	Greater Occipital Nerve
HCD	Herniated Cervical Disc
IA	Intra-Articular
ICI	Corticosteroid Injection

LBP	Low back pain
mRFA	monopolar Radiofrequency
mPRF	monopolar Pulsed Radio Frequency
MRI	Magnetic Resonance Imaging
NRS	Numeric Rating Scale
PRF	Pulsed Radiofrequency
RCT	Randomized Clinical Trial
RFN	Radiofrequency Neurotomy
RF-TR	Radiofrequency Trigeminal Rhizotomy
SIJ	Sacroiliac Joint
SCS	Spinal Cord Stimulation
TFESI	Transforaminal Epidural Steroid Injections
TN	Trigeminal Neuralgia
US	Ultrasound
VAS	Visual Analog Scale





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