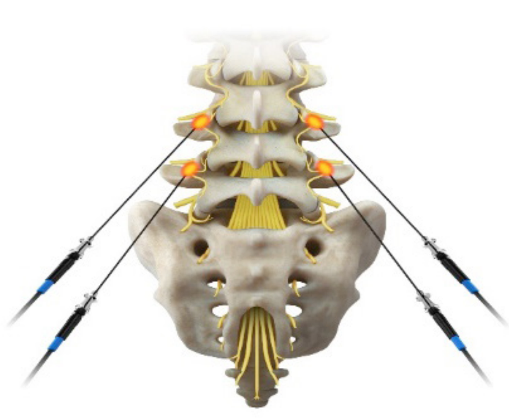
RADIOFREQUENCY CLINICAL EVIDENCE

Compendium

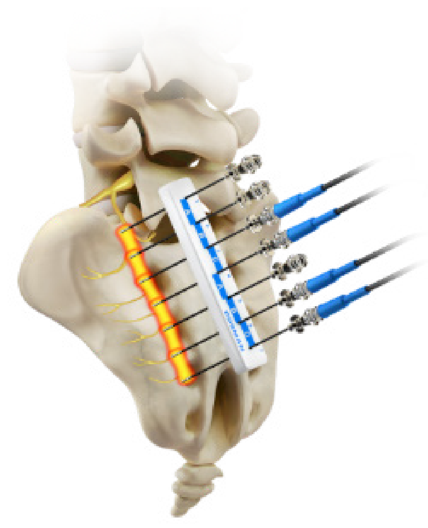
Radiofrequency Clinical Compendium – Supporting publications.
This summary is created by Boston Scientific and is intended to consolidate the paper for educational use only.

RADIOFREQUENCY TREATMENT IN INTERVENTIONAL PAIN MANAGEMENT: INDICATIONS

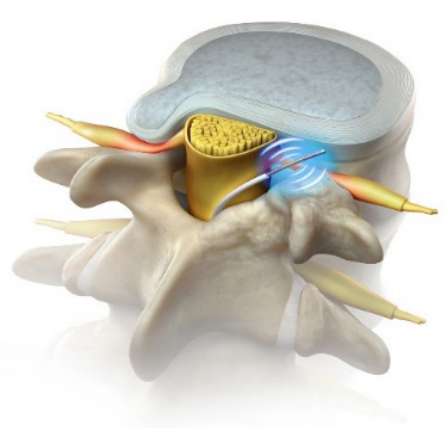
RF FOR LUMBAR PAIN



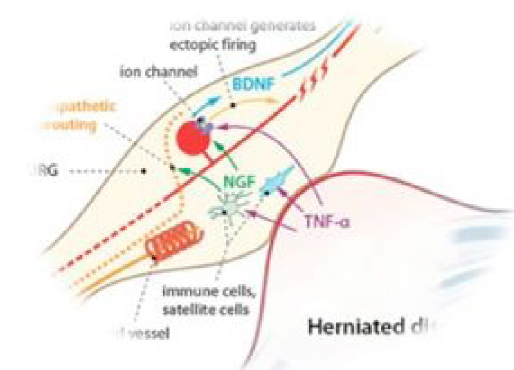
RF FOR SACROILIAC JOINT PAIN



PULSED RF FOR RADICULAR PAIN

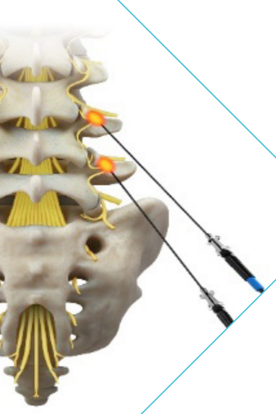


PULSED RF MECHANISM OF ACTION



RF FOR CERVICAL PAIN

RADIOFREQUENCY ABLATION FOR LUMBAR PAIN



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 providers[1].

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 relief[3]. **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.E[6], 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
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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.

LUMBAR MEDIAL BRANCH RADIOFREQUENCY NEUROTOMY IN NEW ZEALAND

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

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.

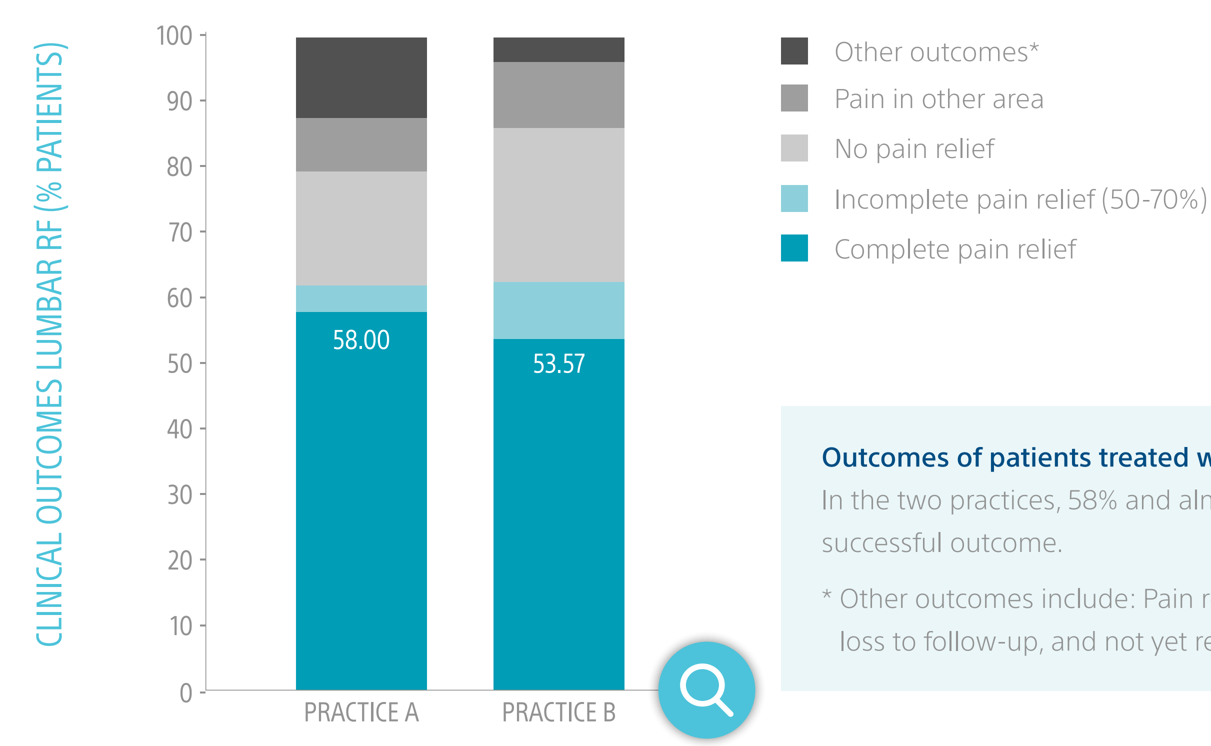
- Patient's VAS and NRS pain scores, as well as daily living activities were recorded before treatment and during follow-up visits post-procedure. Data recording and analysis were performed in a double-blind setup.
- Complete pain relief, for at least 6 months, accompanied by complete restoration of 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.

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.

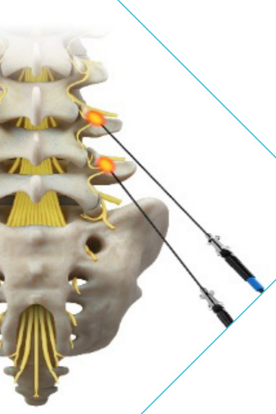


Outcomes of patients treated with lumbar medial branch RFN.
In the two practices, 58% and almost 54% of patients achieved a successful outcome.

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

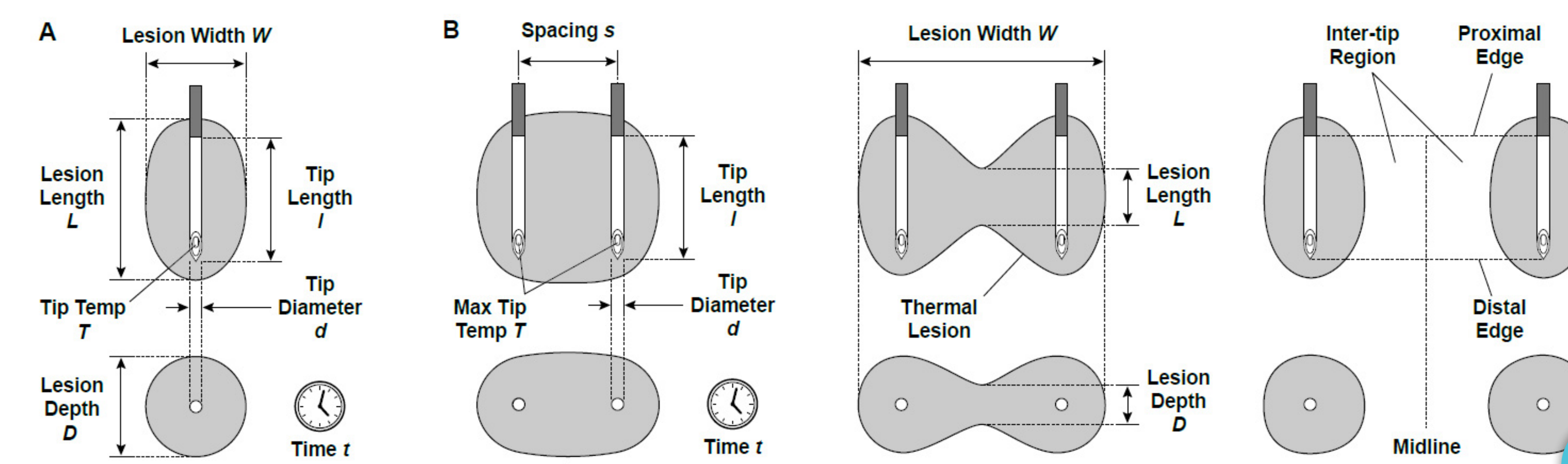
AUTHOR'S CONCLUSIONS

- 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.



FACTORS THAT AFFECT RADIOFREQUENCY HEAT LESION SIZE

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**



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

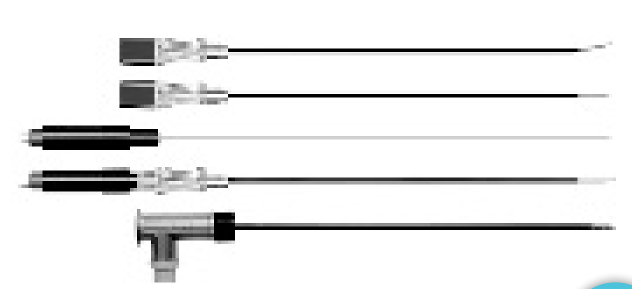
STUDY GOAL

- 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:

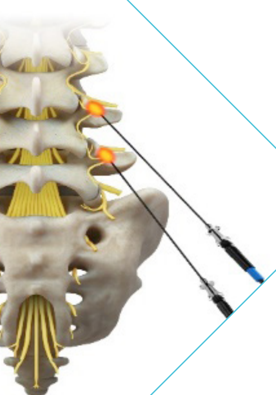
TYPE OF RF LESION	COSMAN CANNULA USED
Monopolar and parallel-tip bipolar	Standard, sharp, bevel-tipped RF cannulae, and Nitinol TC electrodes
Monopolar	Trocar-tipped "Ray" electrode
Monopolar Cooled-RF*	18-ga/4 mm tip internally cooled electrode*



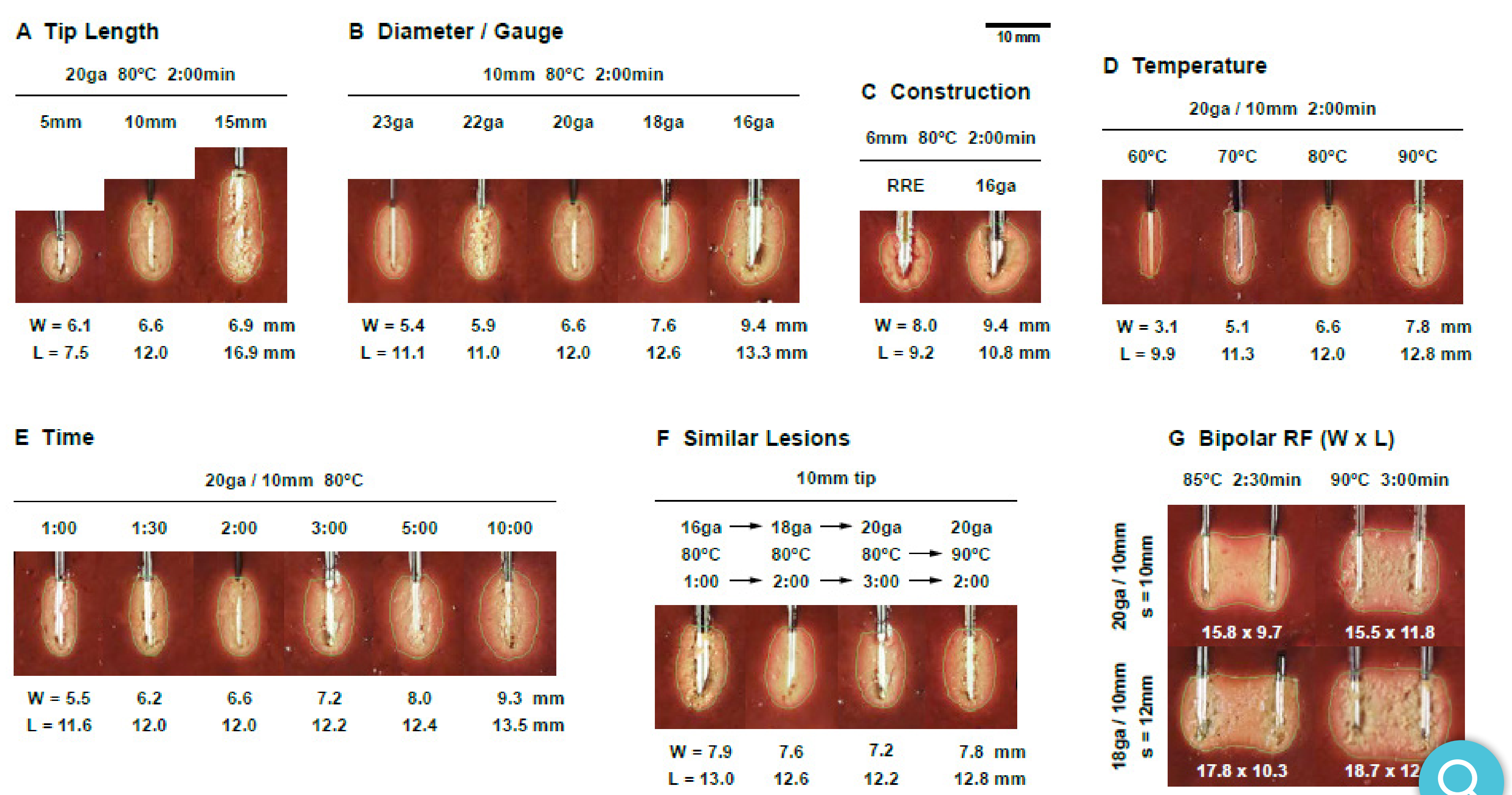
RF Cannulae. From top to bottom: **1.** Curved, sharp, bevel-tip; **2.** Straight, sharp, bevel-tip with stylet; **3.** RF thermocouple electrode (TE) with nitinol shaft; **4.** RF-TE within cannula's inner lumen; **5.** Trocar-tip "Ray" RRE electrode.

RESULTS

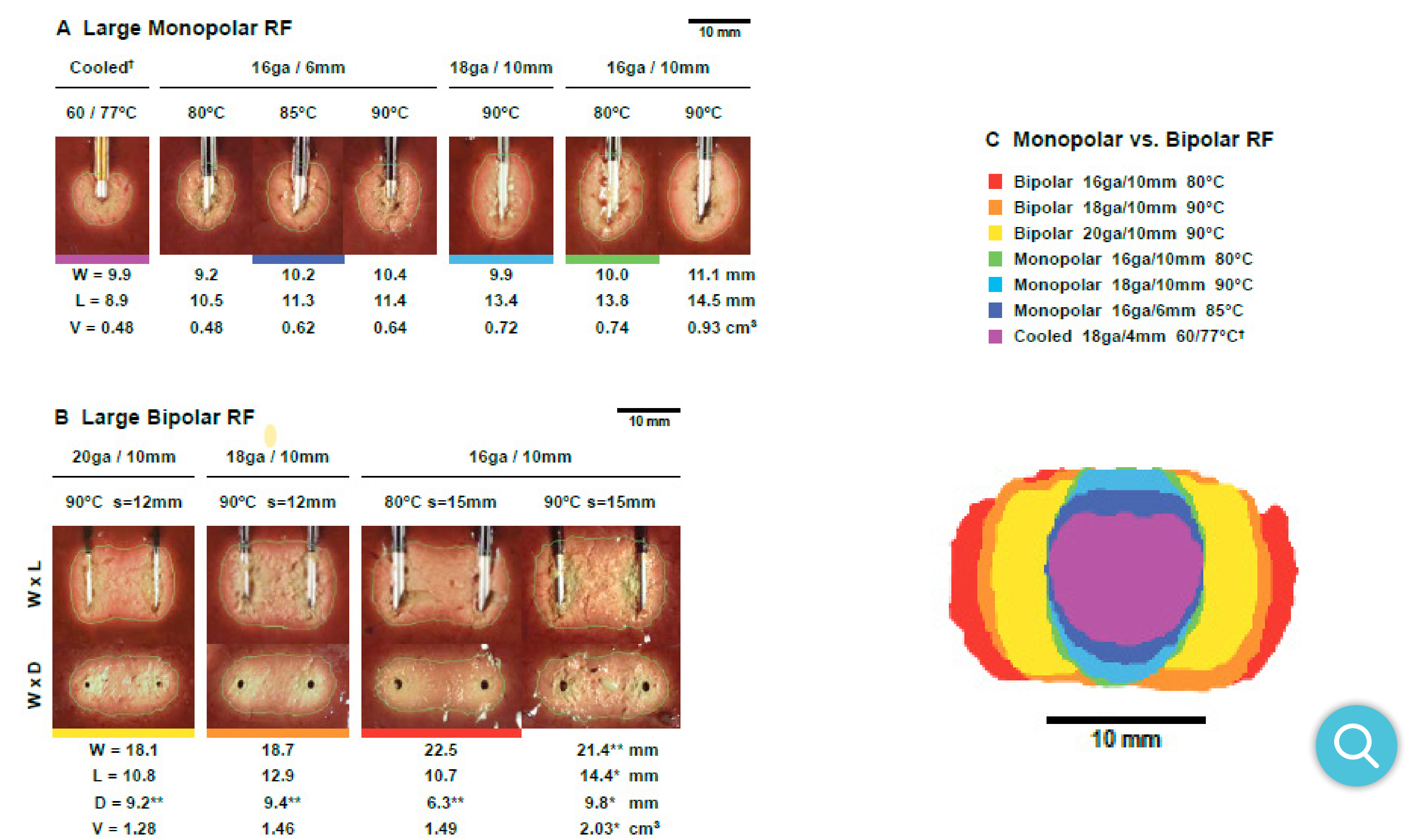
- All the factors (cannula diameters, active tip lengths, set temperatures, and set times) analyzed in the study, were found to significantly affect RF heat lesion size.
- Increasing temperature and/or time enables a thinner cannula to generate lesion dimensions similar to those produced by a thicker 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.



FACTORS THAT AFFECT RADIOFREQUENCY HEAT LESION SIZE



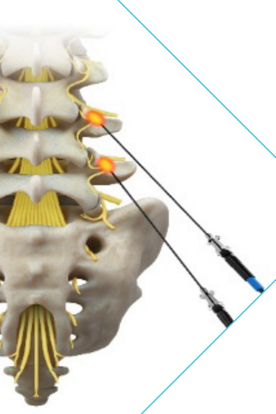
Average size of RF lesions for tested conditions. **A.** Cannula tip length; **B.** Cannula diameter/gauge; **C.** Tip size effect; **D.** Comparison with RRE electrode (Trocar-tip "Ray"); **E.** Temperature; **E.** Time; **F.** Higher temperature and/or longer lesion size compensate for smaller cannula 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 10 mm average width.

AUTHOR'S CONCLUSIONS

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



INTERPRETING THE MINT RANDOMIZED TRIALS EVALUATING RADIOFREQUENCY ABLATION FOR LUMBAR FACET AND SACROILIAC JOINT PAIN

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**

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.

RESPONSE TO THE MINT STUDY – PROVENZANO ET AT

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

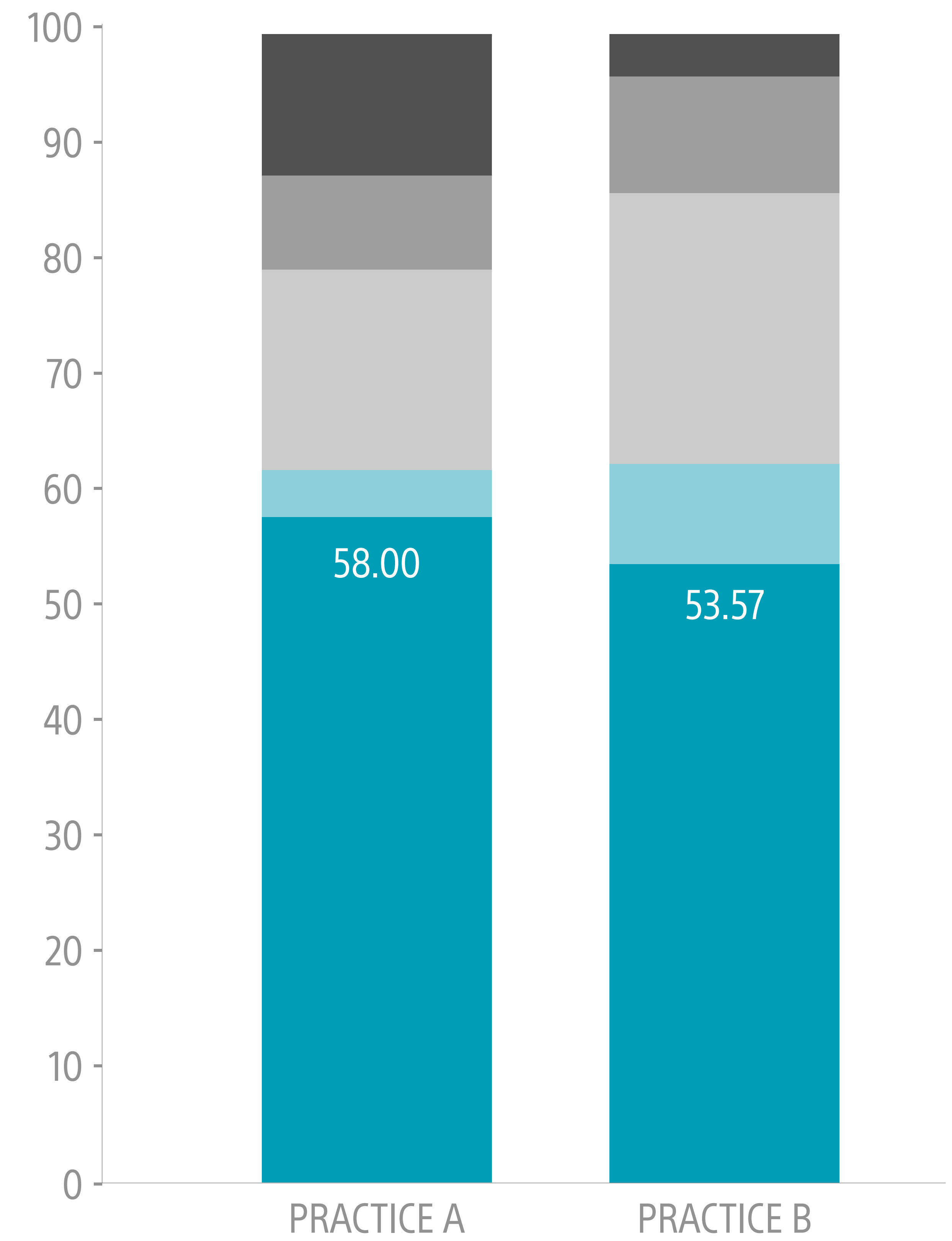
The authors conclude that the MINT RCT was significantly flawed in three major areas:

- 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.

CONCLUSION

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.

CLINICAL OUTCOMES LUMBAR RF (% PATIENTS)



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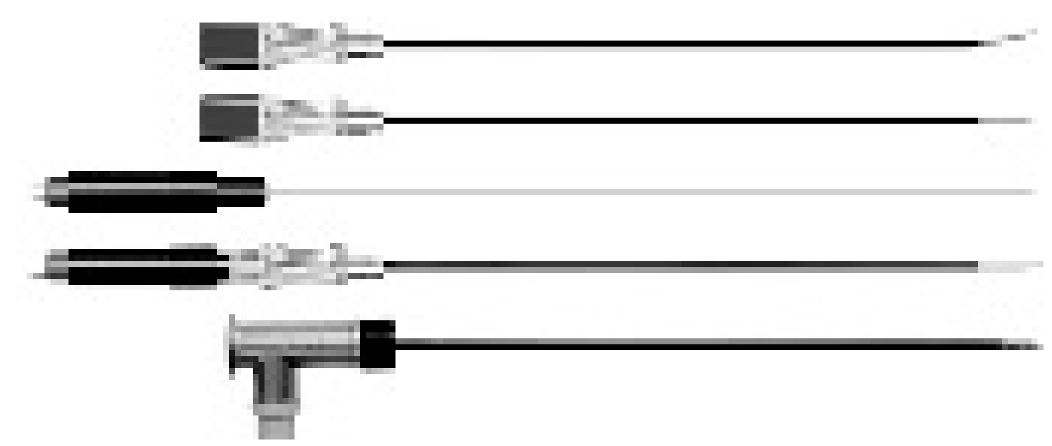

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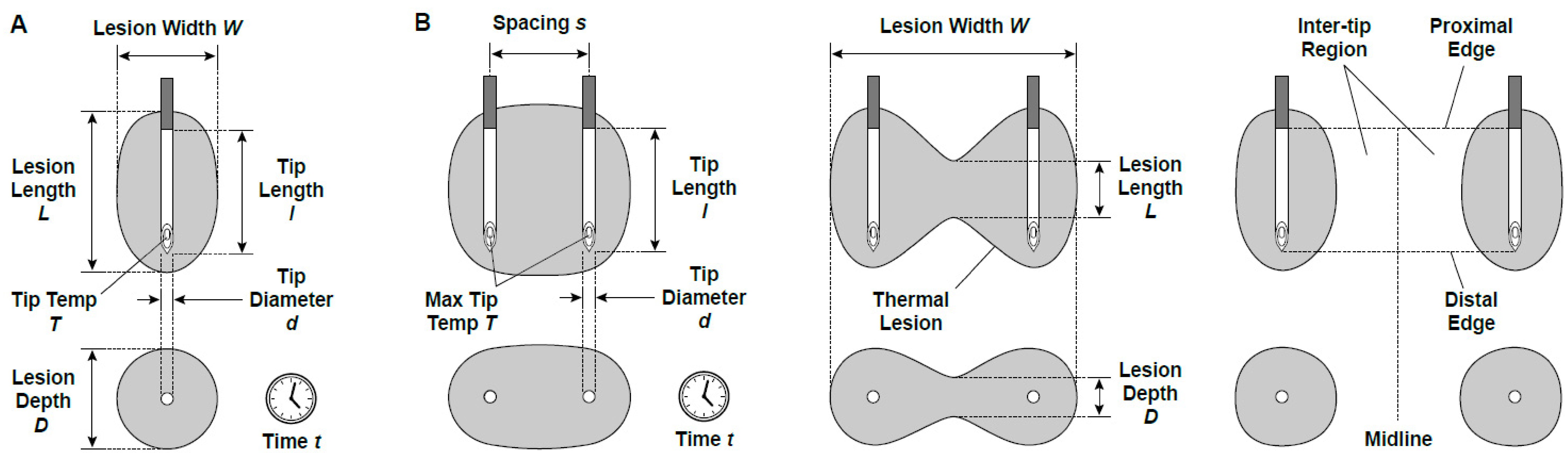

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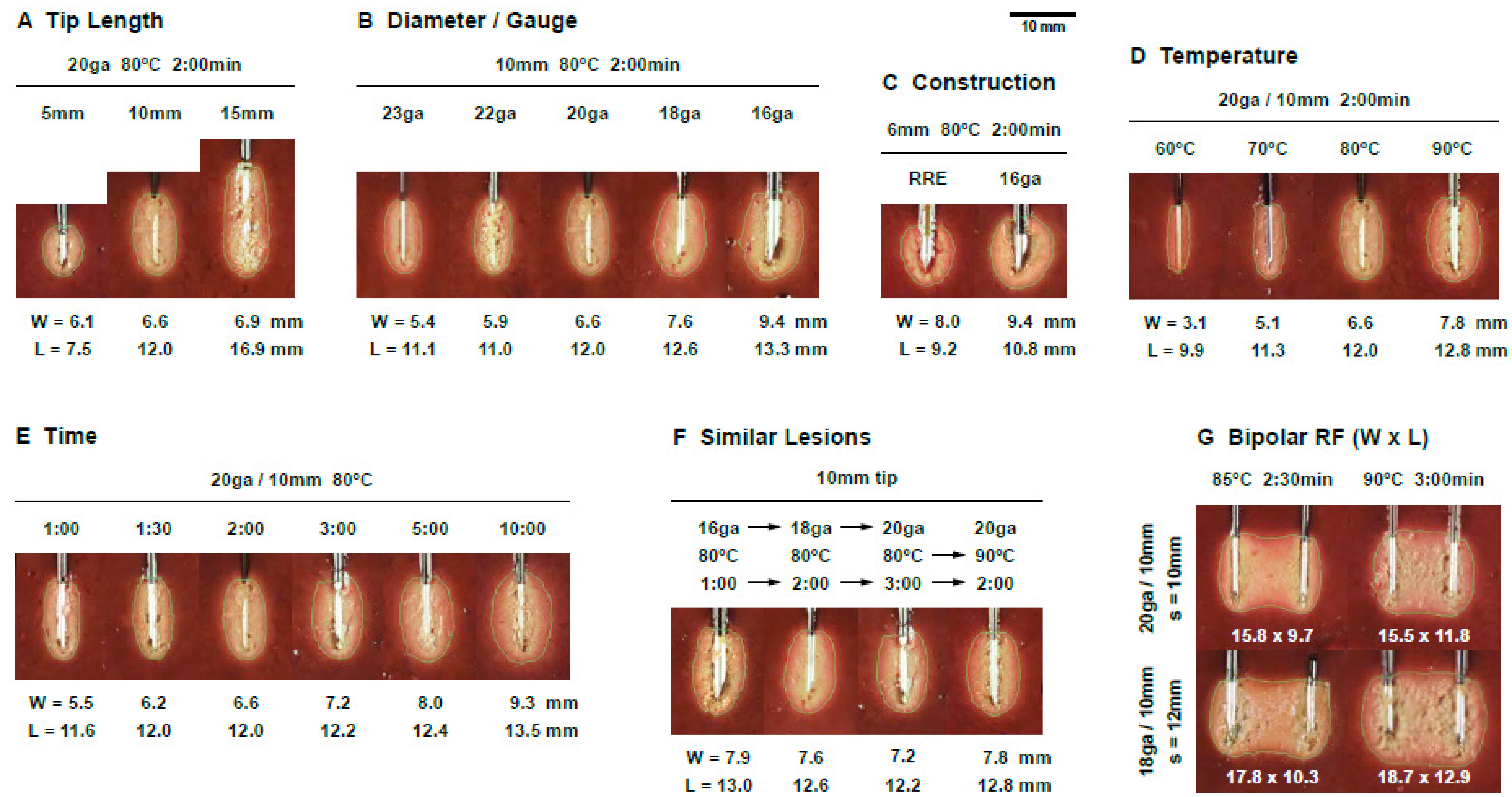

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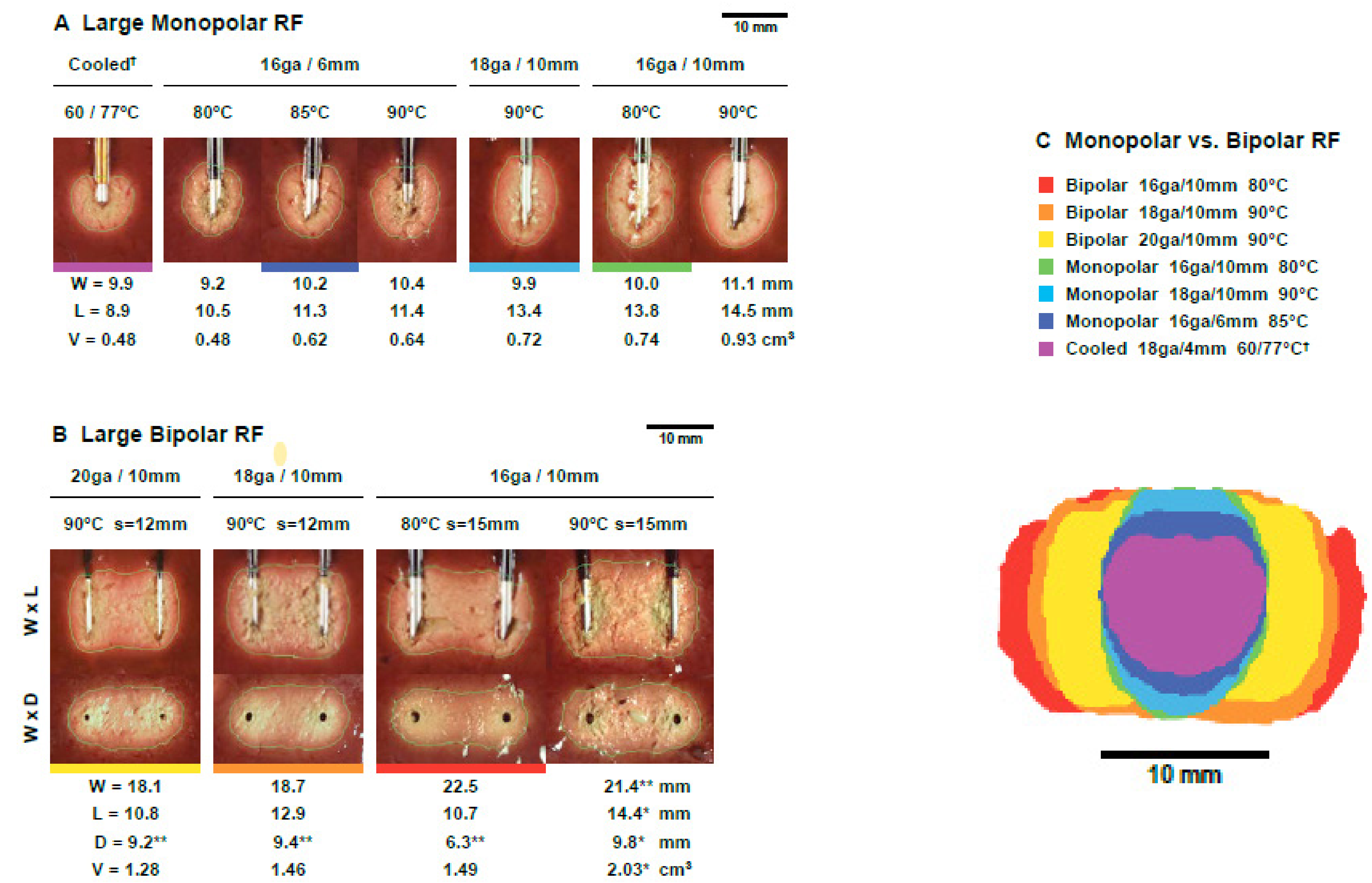

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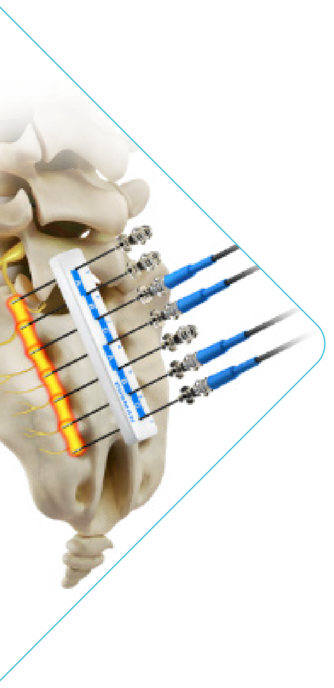
RADIOFREQUENCY ABLATION FOR SACROILIAC JOINT PAIN



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 pain[1].

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 others[1].

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 neurotransmission[1].

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 studies[1-4] 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 scores**[1-3]

The palisade **RFA procedure using the PalisadeTM 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
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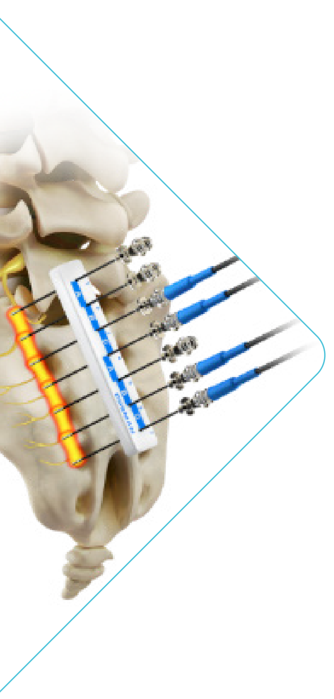
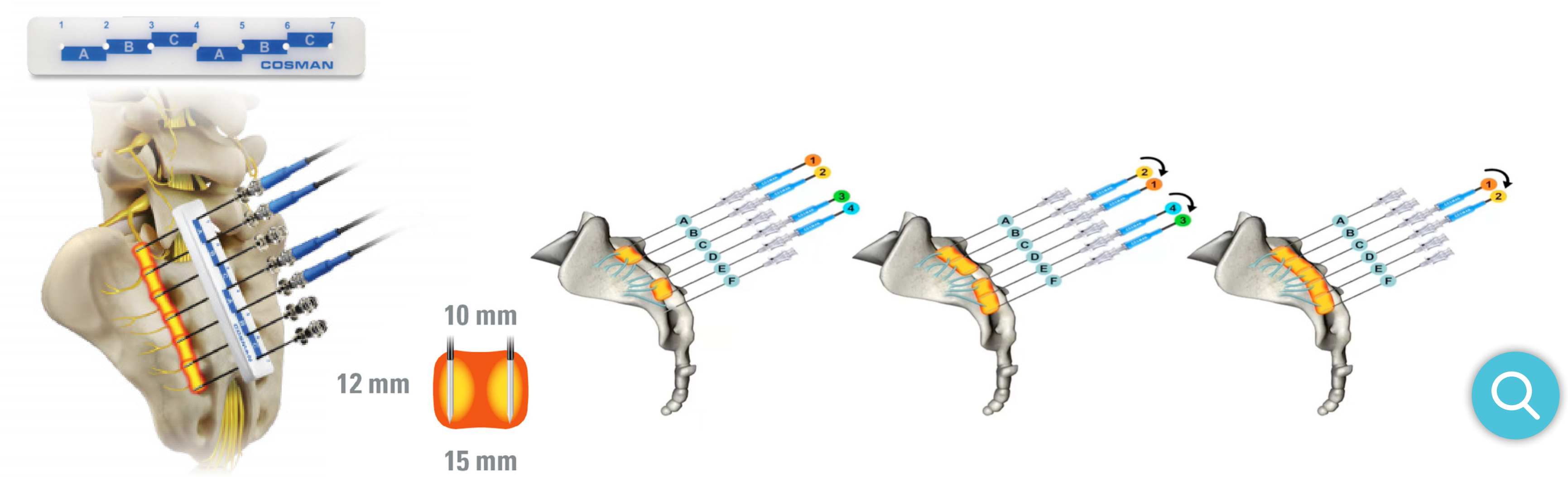


A NEW RADIOFREQUENCY ABLATION PROCEDURE TO TREAT SACROILIAC JOINT PAIN

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.



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.

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

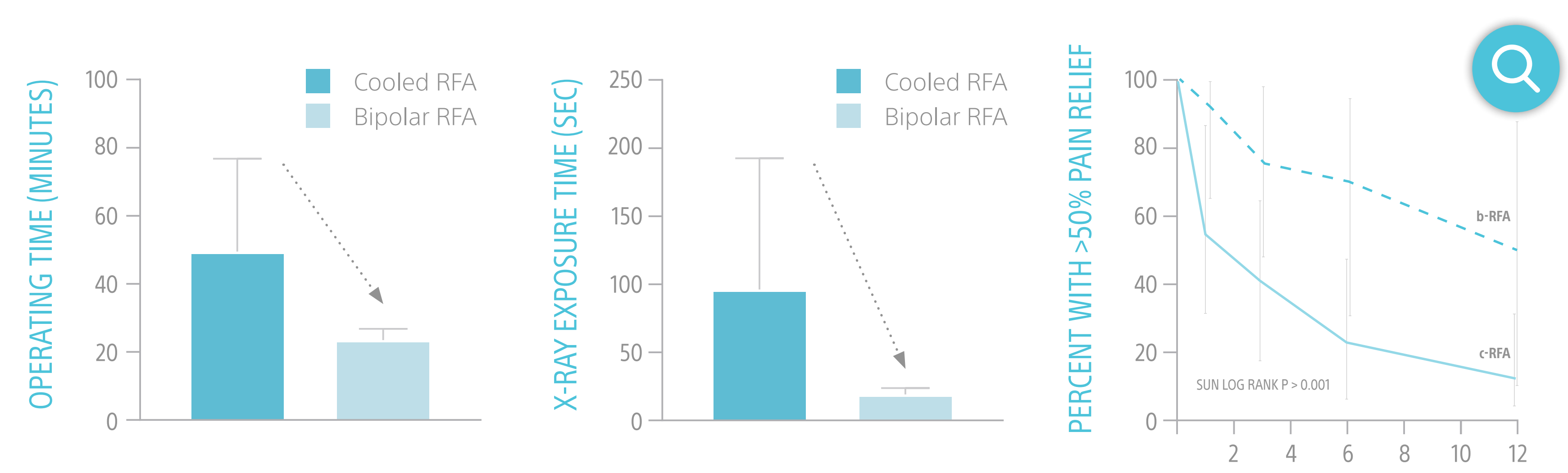
- Devise a guide-block device that facilitates accurate placement of multiple electrodes to simultaneously ablate the L5 dorsal ramus and lateral branches of the S1, S2, and S3 dorsal rami.
- Use of bipolar RF ablation to create a strip-like lesion covering from the lateral border of the base of the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

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.

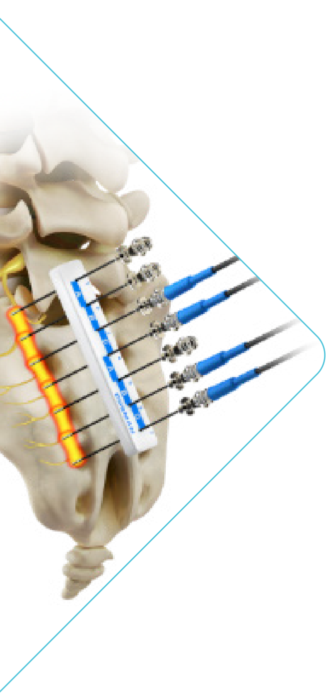


Operating time. (bRFA: 23.5 ± 3.27 vs cRFA: 49.5 ± 27.25). **X-ray exposure time.** (bRFA: 19.1 ± 4.7 vs cRFA: 96.3 ± 96.2).
Wide standard deviation (cRFA) reflects procedure difficulties and operators' experience. bRFA patients experienced a longer duration of >50% pain relief

AUTHOR'S CONCLUSION

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

Boston Scientific



BIPOLAR RADIOFREQUENCY LESION GEOMETRY: IMPLICATIONS FOR PALISADE TREATMENT OF SACROILIAC JOINT PAIN

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**

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).

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.

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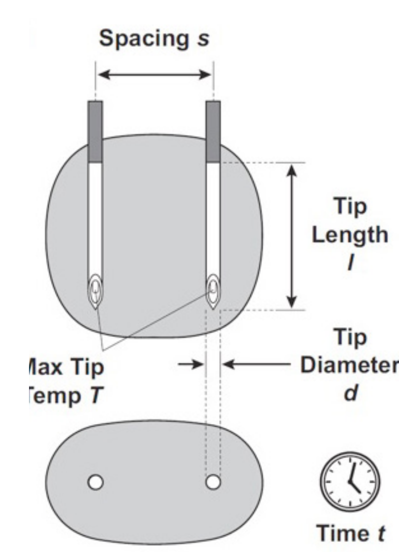

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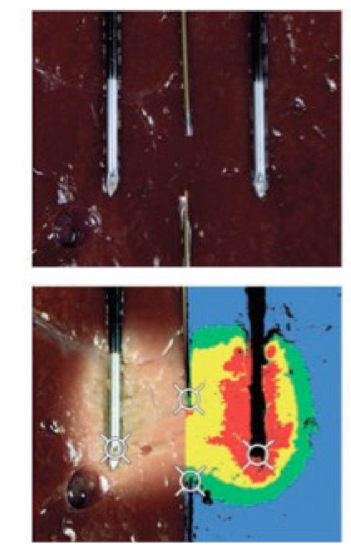
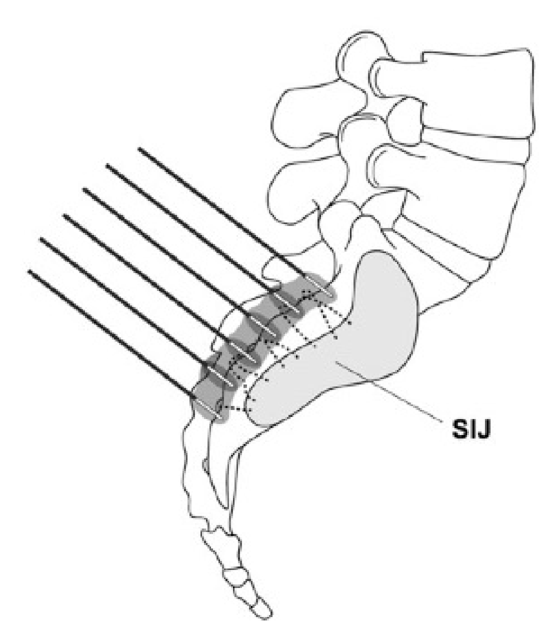


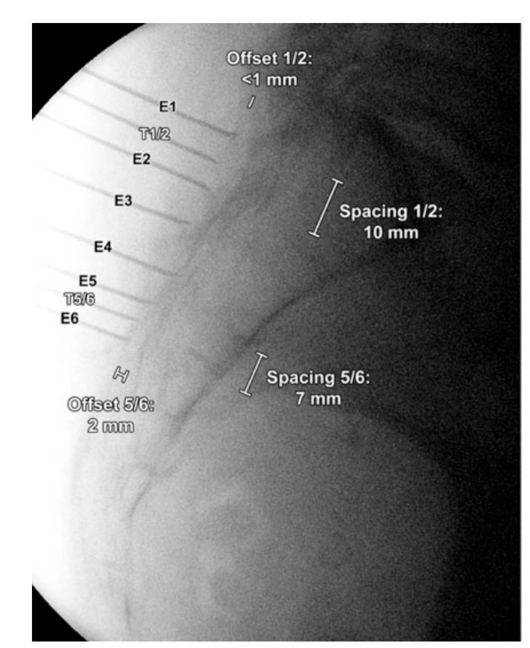
C

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).

A





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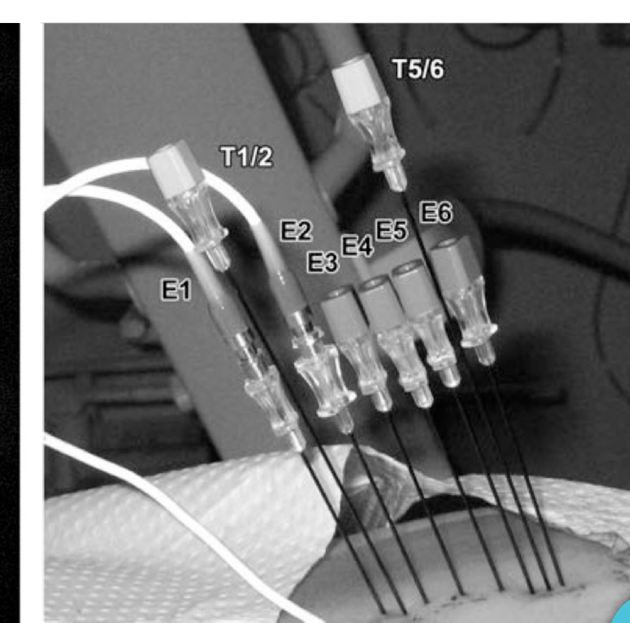
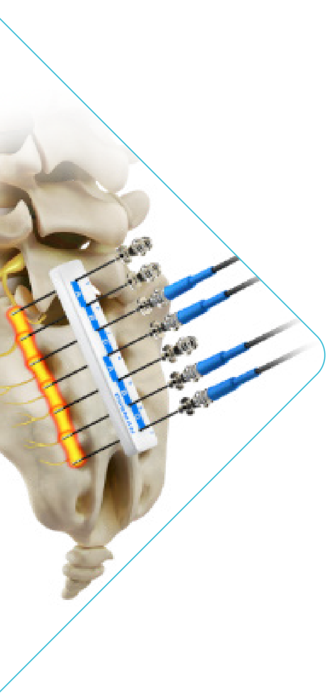


In vivo setting. A. Palisade treatment of SIJ pain. A row of six RF cannulae (20-gauge diameter, 10 mm tip length, 10 mm inter-spacing) were inserted to target the dorsal sacral surface between S1-S3 dorsal foramina and the SIJ line (90°C, 3- minutes lesion time). A continuous lesion is generated between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

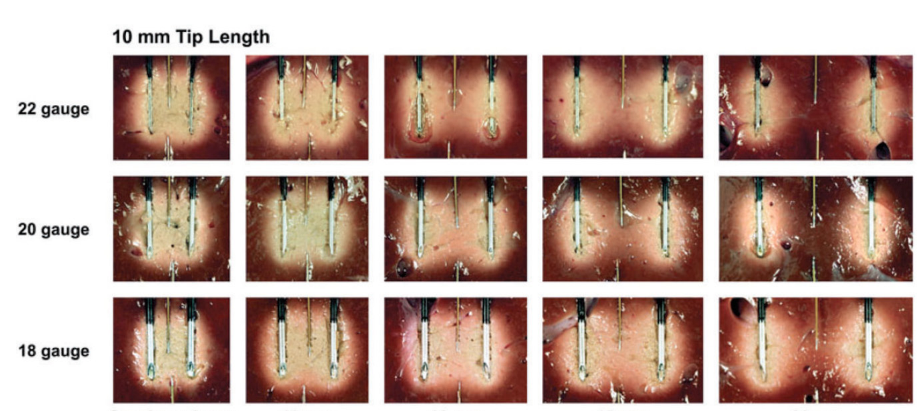


BIPOLAR RADIOFREQUENCY LESION GEOMETRY: IMPLICATIONS FOR PALISADE TREATMENT OF SACROILIAC JOINT PAIN

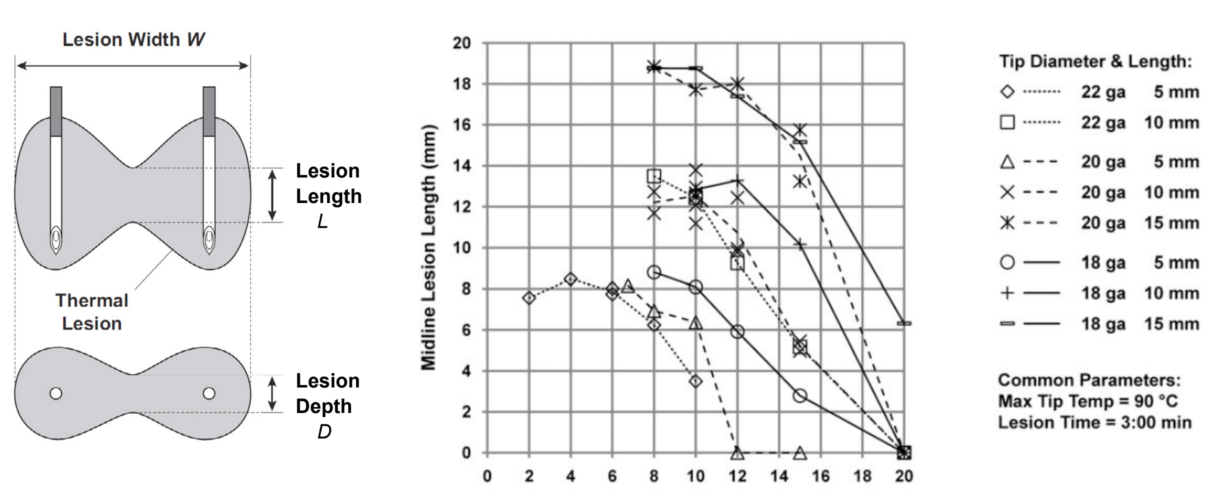
RESULTS

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.



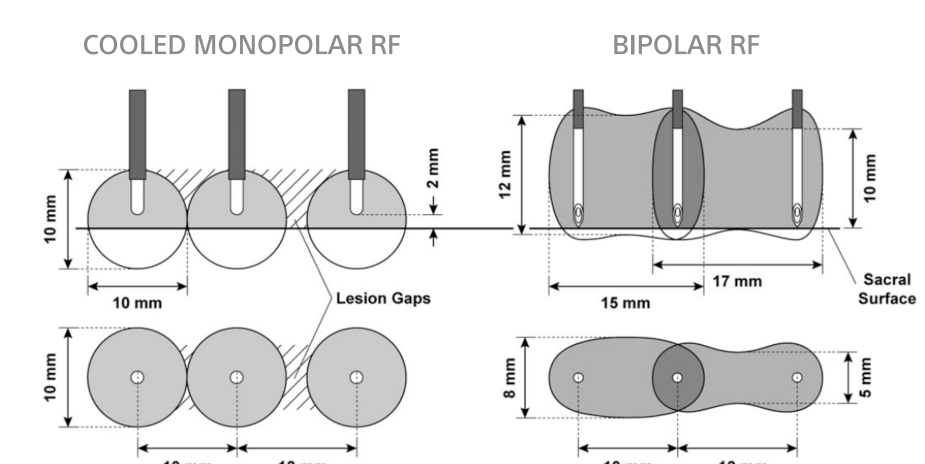
Cross-sectional photograph of bipolar lesions in ex vivo bovine liver show the lesion length and width produced by different parallel tip spacings and tip diameters (90°C tip temperature and 3-minute lesion time)



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

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.



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

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

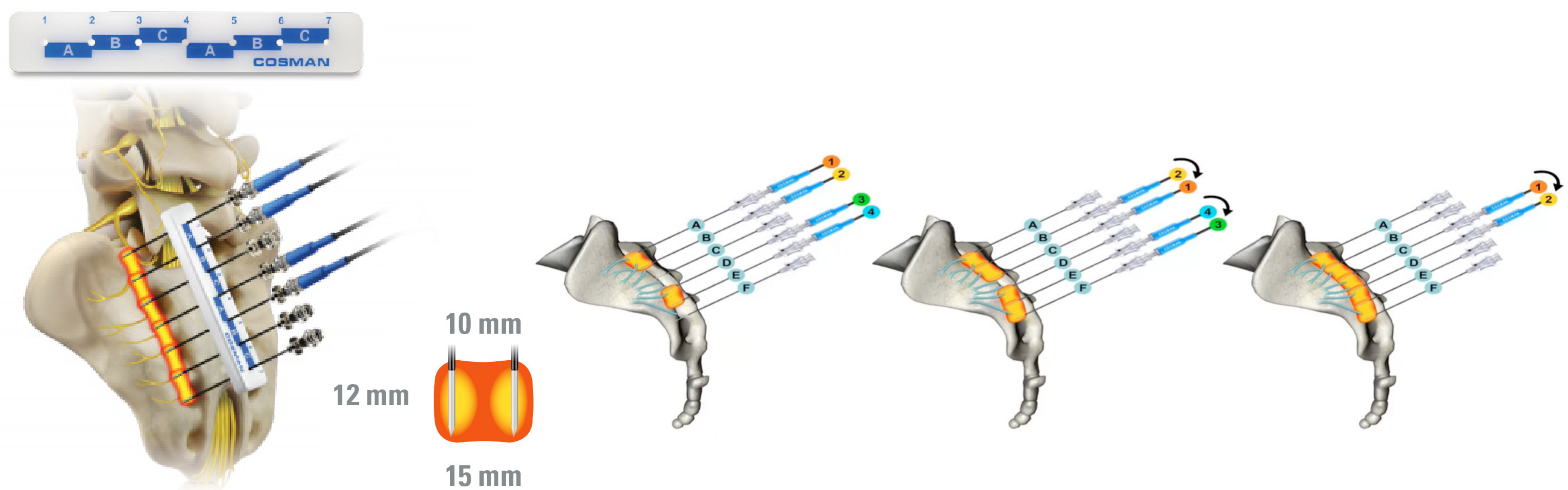
In cooled RF, an increase in tip-to-tip distance can give rise to gaps between adjacent lesions in the sacral surface, whereas individual bipolar lesions can be larger than cooled RF lesions

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 larger lesions or lesions side-by-side (without gaps) are desired.



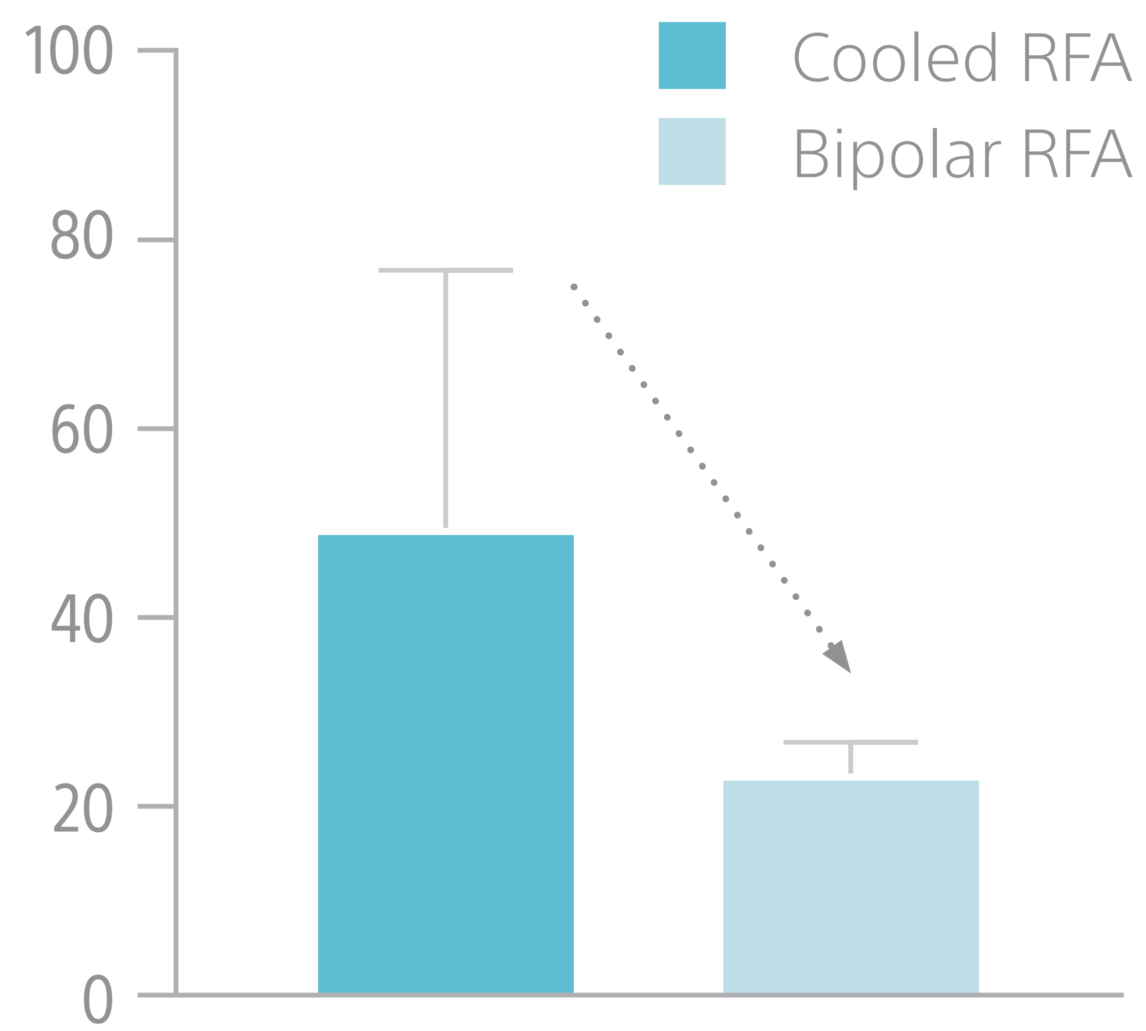
The SIJ area is a difficult area to treat, due to size, accessibility, and varying patients' anatomy. The disposable Palisade™ guide-block simplifies the placement and alignment of cannulas, to create larger lesions and/or two bipolar lesions at once.

Wide standard deviation (CRFA) reflects procedure difficulties and operator 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.

OPERATING TIME (MINUTES)

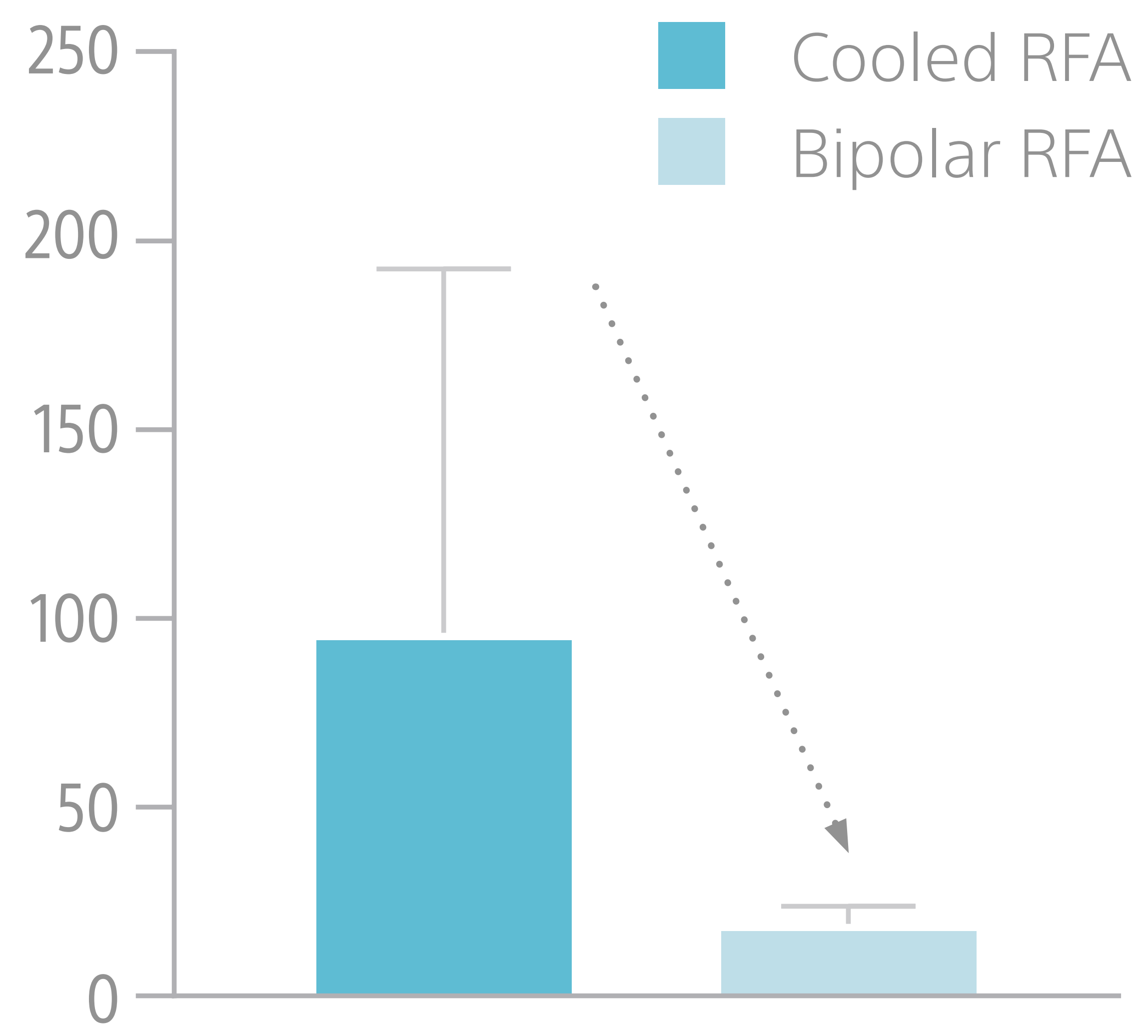


Operating time.
(bRFA: 23.5 ± 3.27 vs cRFA: 49.5 ± 27.25).
X-ray exposure time.
(bRFA: 19.1 ± 4.7 vs cRFA: 96.3 ± 96.2).
Wide standard deviation (cRFA) reflects procedure difficulties and operators' experience. bRFA patients experienced a longer duration of >50% pain relief

A B C

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).
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A B C

AUTHOR’S CONCLUSION

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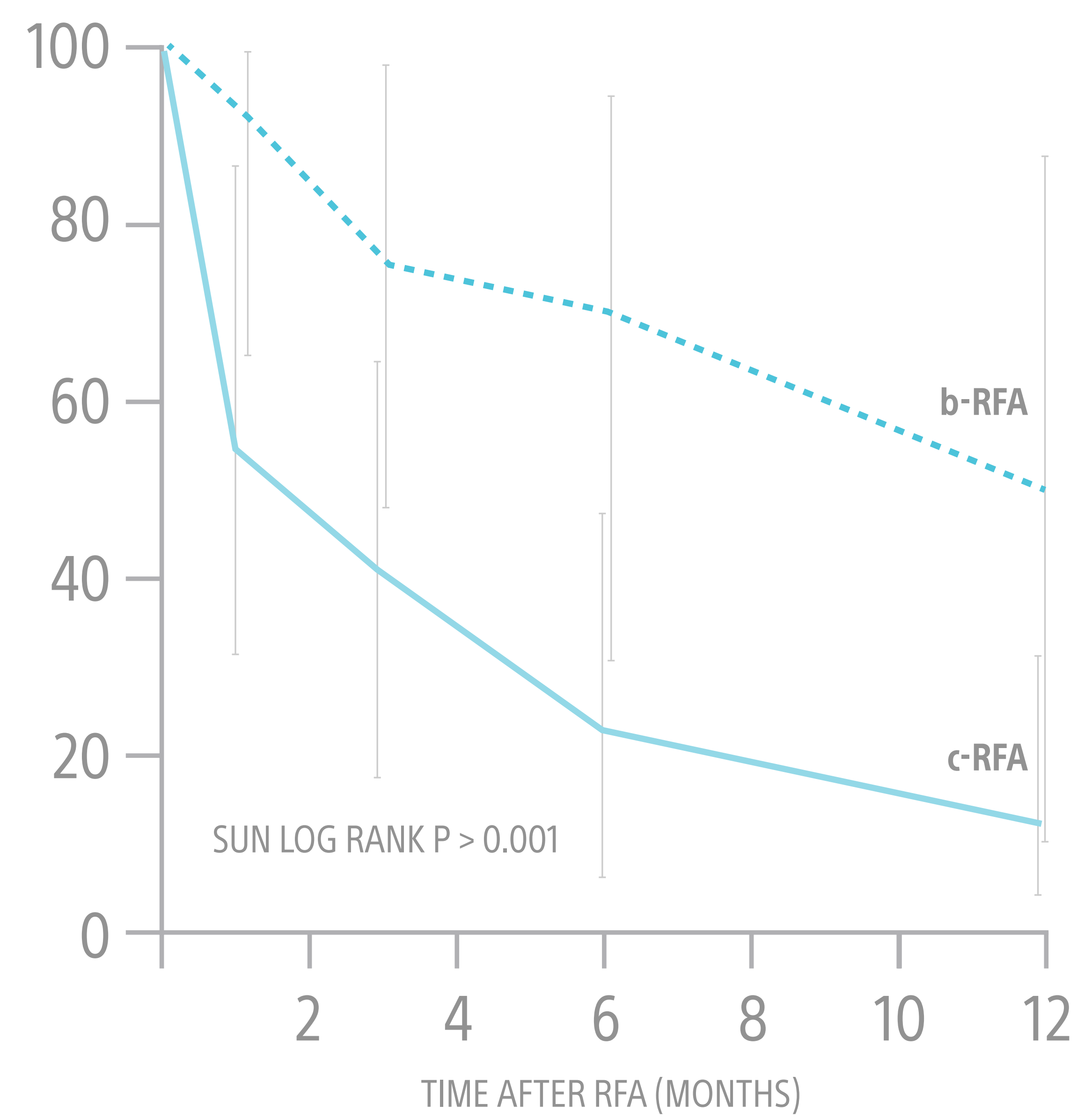
PERCENT WITH >50% PAIN RELIEF



Operating time.
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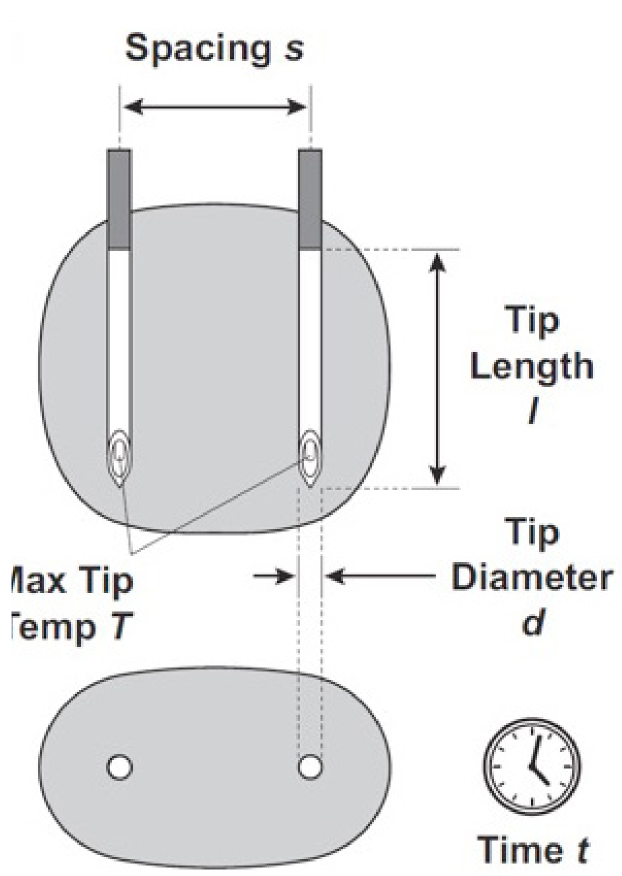
A



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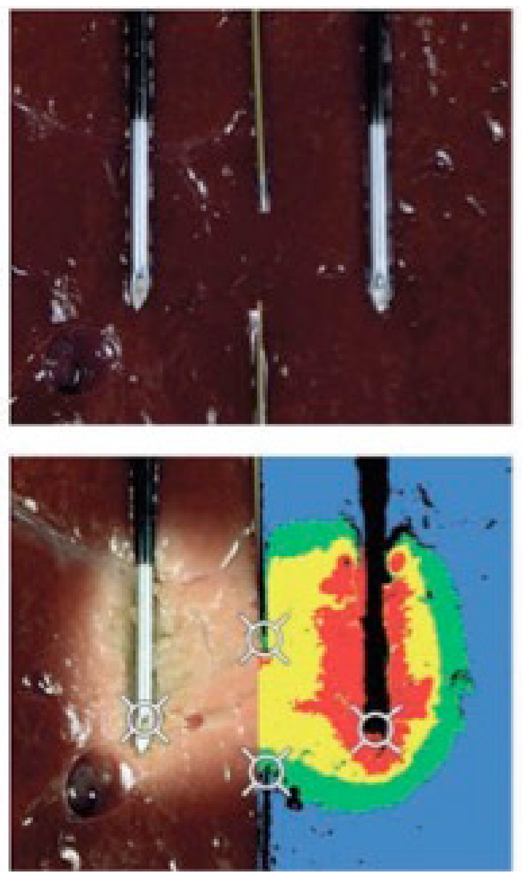


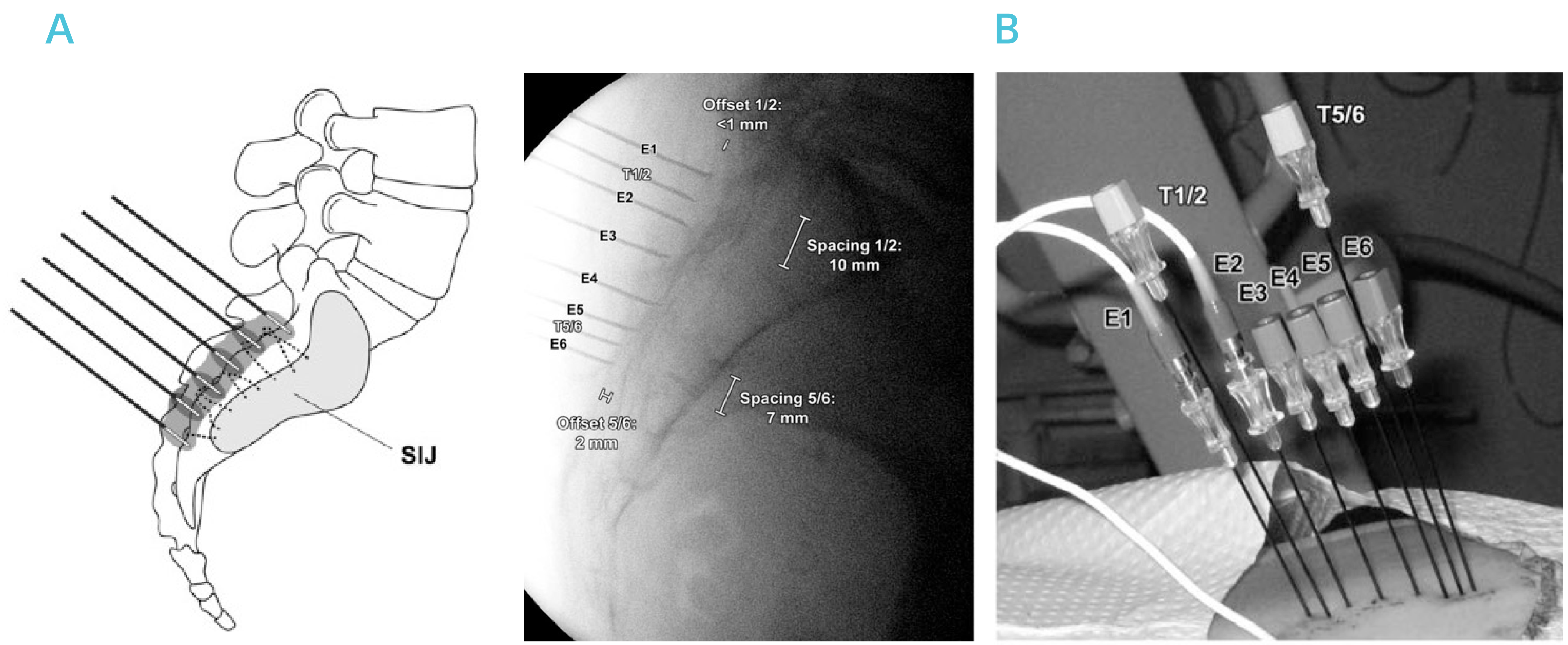
C

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).

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

In vivo setting. A. Palisade treatment of SIJ pain. A row of six RF cannulae (20-gauge diameter, 10 mm tip length, 10 mm 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.



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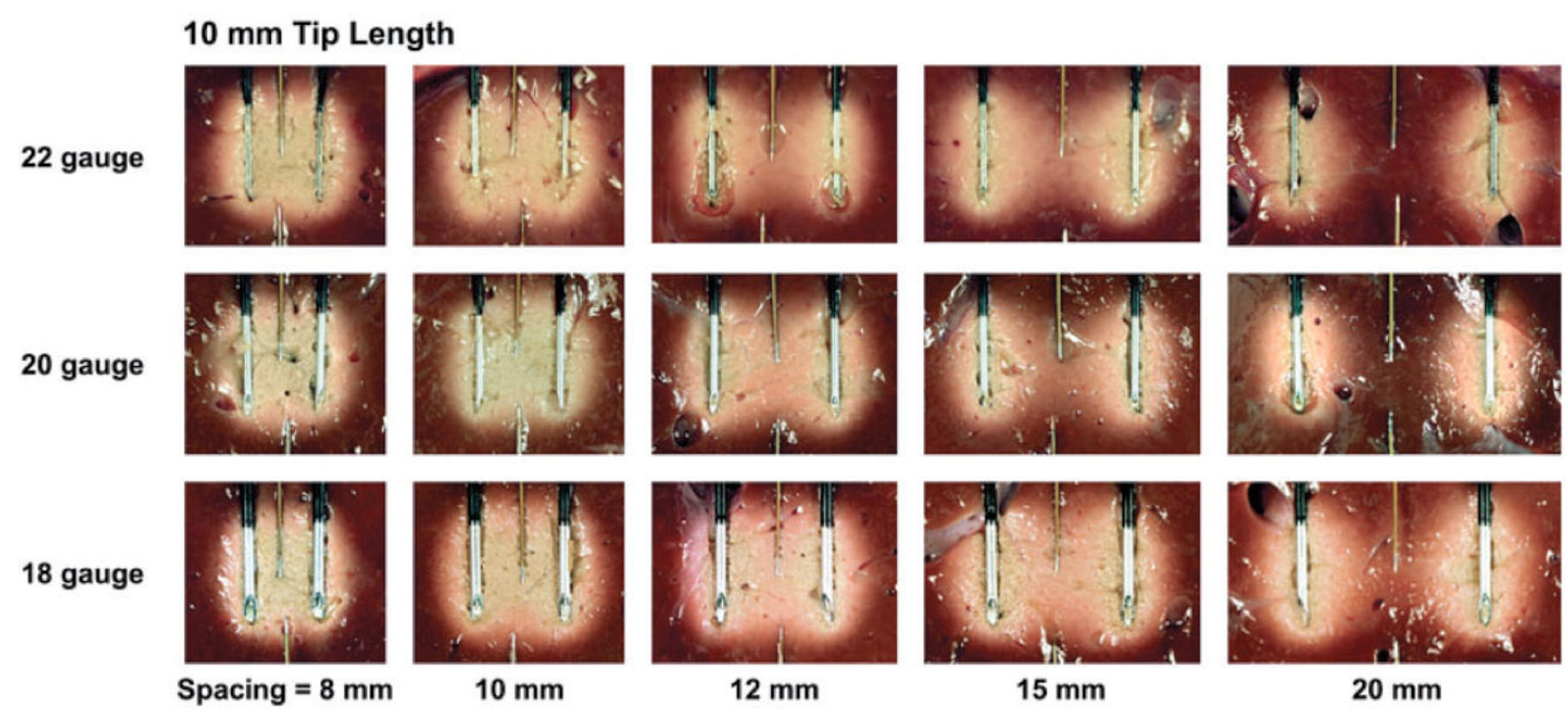
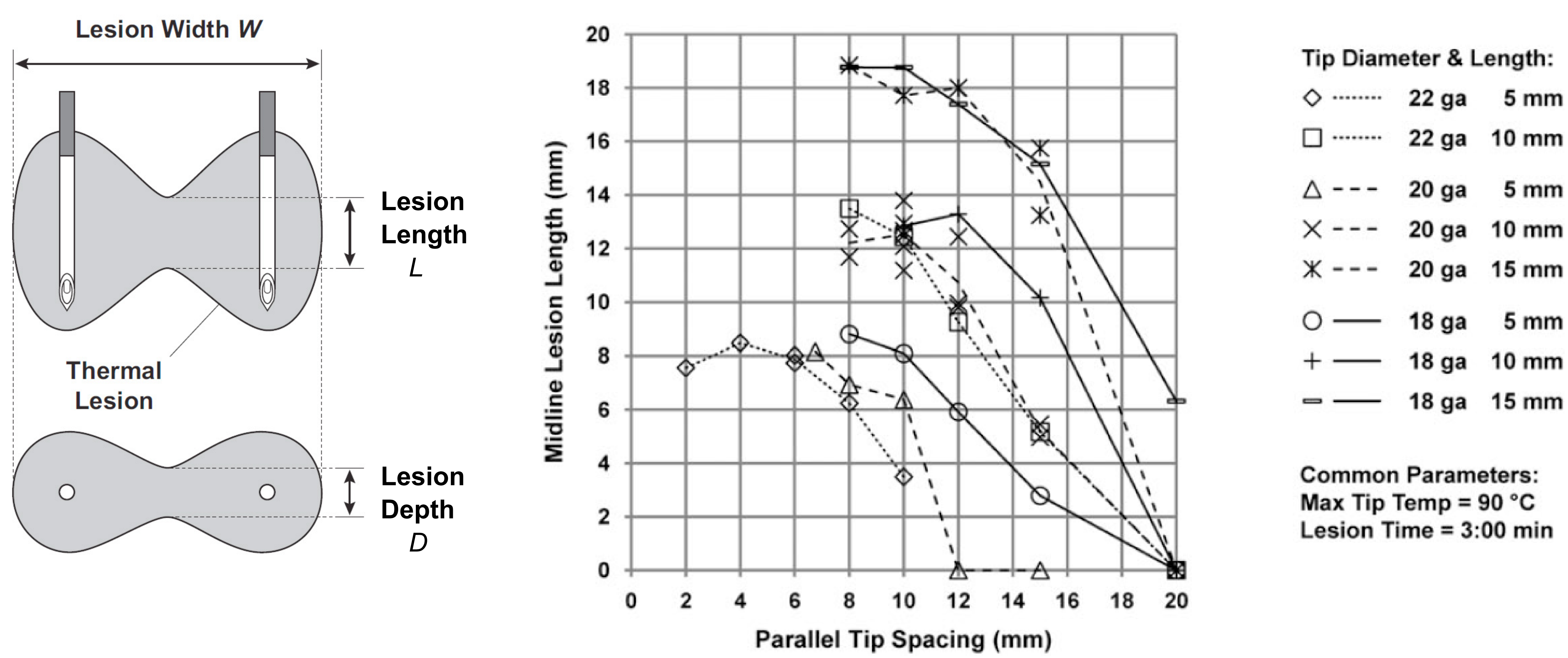


Cross-sectional photograph of bipolar lesions in ex vivo bovine liver show the lesion length and width produced by different parallel tip spacings and tip diameters (90°C tip temperature and 3-minute lesion time)

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.

- 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.



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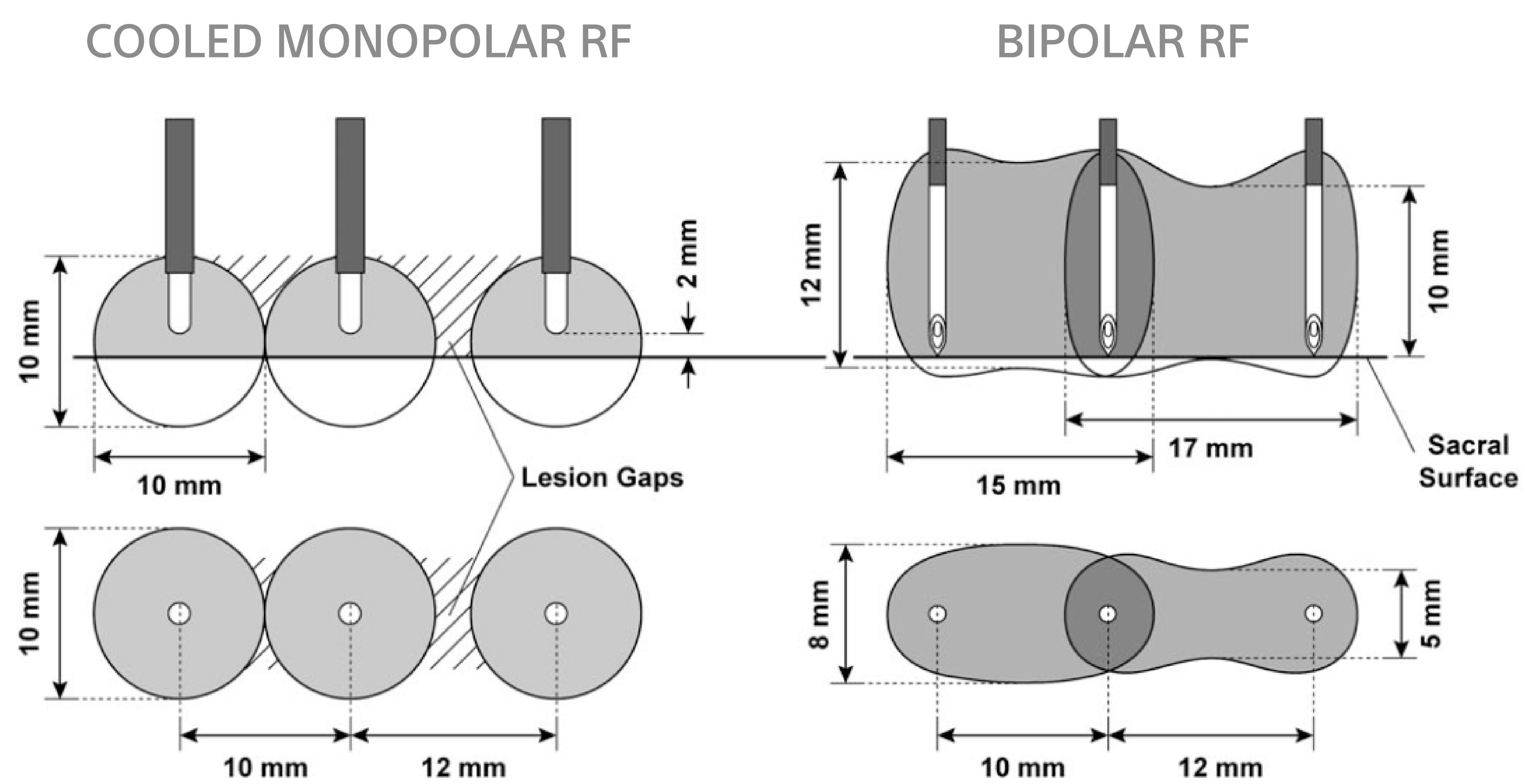

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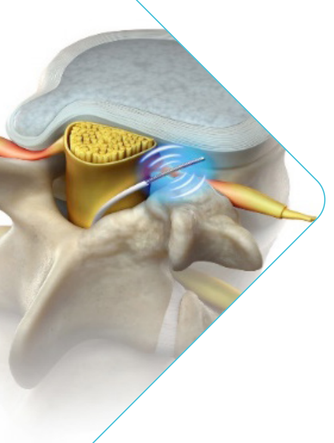
PULSED RADIOFREQUENCY FOR RADICULAR PAIN



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.

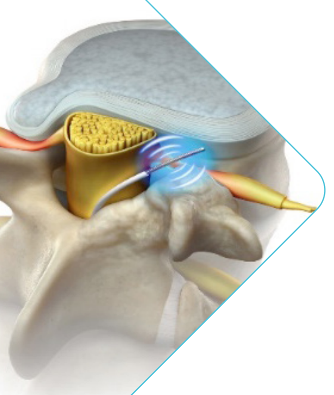
The underlying cause of radicular pain are lesions that either directly compromises the DRG (mechanical compression) or indirectly compromise the spinal nerve and/or its roots by causing ischemia or inflammation of the neuronal tracts (injury). Thereby, the most common causes of radiculopathy are disc herniation in the lumbar spine, failed back surgery syndrome (FBSS), and disc herniation and spondylosis in the cervical spine[1].

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, cancer[2].

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 complications[3].

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 al[4]; 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 Boxem 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.



EFFECTIVENESS OF ULTRASOUND-GUIDED PULSED RADIOFREQUENCY TREATMENT IN PATIENTS WITH REFRACTORY CHRONIC CERVICAL RADICULAR PAIN

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.

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

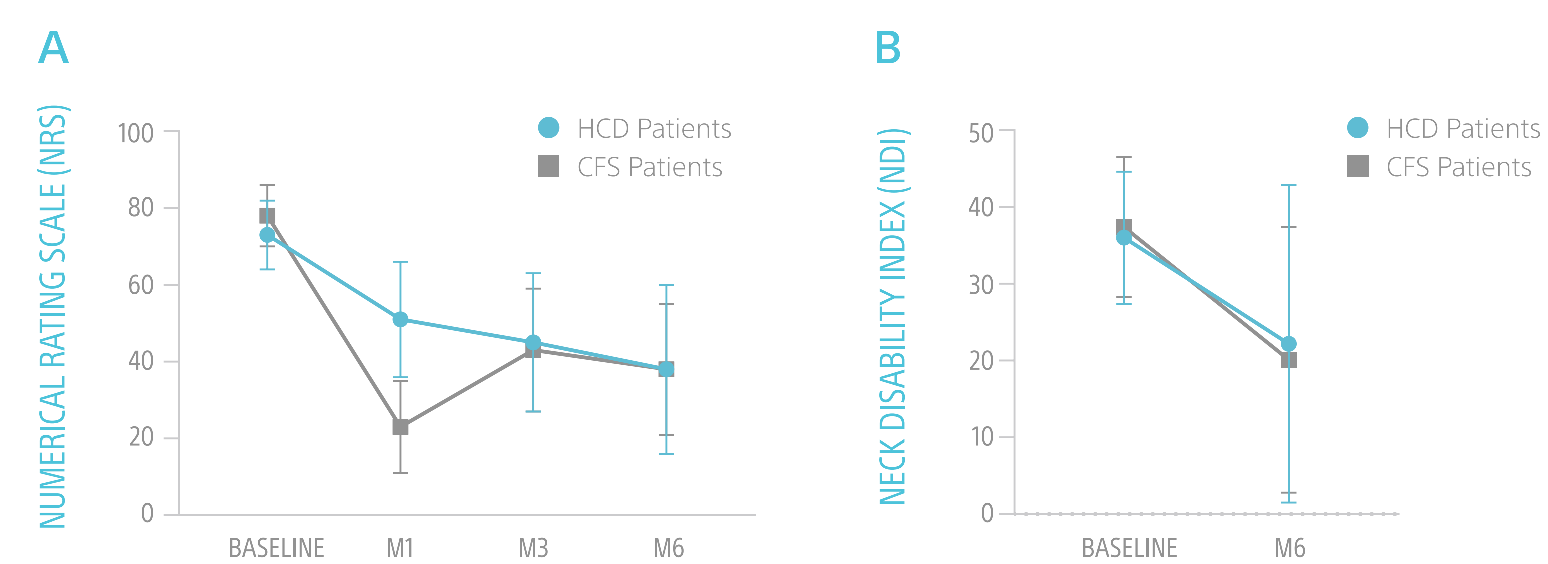
Patients: The study included 49 consecutive patients diagnosed with cervical radicular pain with, at least, 6 months history of segmental pain radiating to the arm. Patients were refractory to repeated TFESIs. 19 patients had HCD (herniated cervical disc) and 30 had CFS (cervical foraminal stenosis)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

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 (≥ 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).

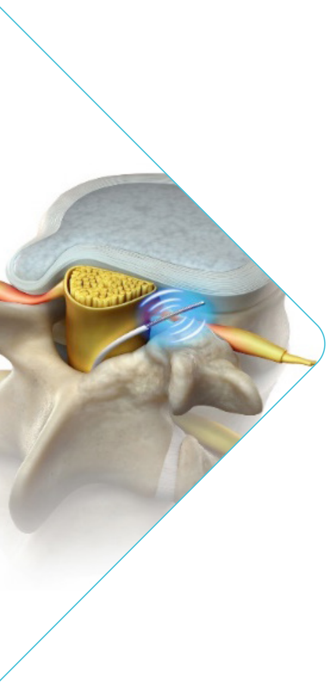


Changes in NRS-11 scores for cervical radicular pain. A. For the HCD group, NRS scores decreased from 7.3 before treatment to 3.8 at 6 months (6M) after PRF treatment. Similar results were found for CFS patients (7.8 before treatment to 3.8 at &M).
B. NDI scores decreased from 36 and 37.4 to 20.7 and 20.1 at 6 months after treatment for HCD and CFS, respectively.

AUTHOR'S CONCLUSIONS

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

Boston Scientific



CLINICAL STUDY OF SPINAL CORD STIMULATION AND PULSED RADIOFREQUENCY FOR MANAGEMENT OF HERPES ZOSTER-RELATED PAIN PERSISTING BEYOND ACUTE PHASE IN ELDERLY PATIENTS

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

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 ≥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)

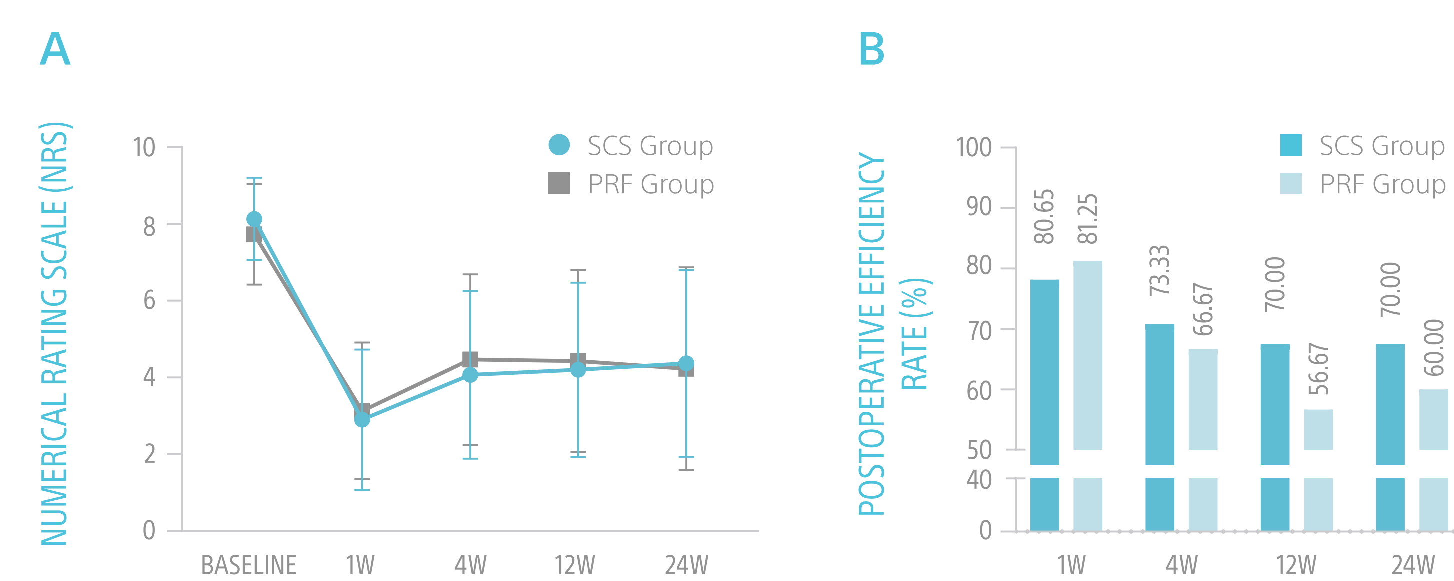
SCS parameters: Voltage 1-3 V; 1 Pulse width (PW) 20-210 ms; Frequency 30-60 Hz.

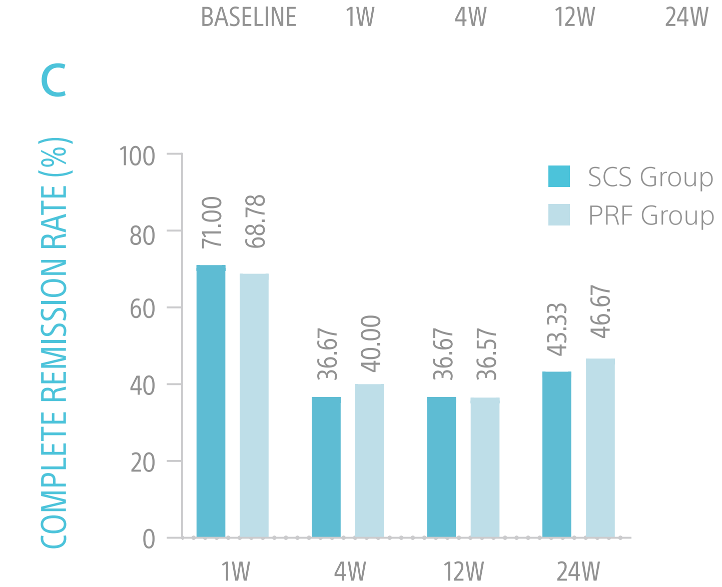
PRF procedure: The affected DRG was punctured with the RF needle under fluoroscopy guidance. A sensory test (50Hz and 0.3-06 V) was performed to confirm needle position and pain coverage. PRF treatment was performed with a Cosman G4 instrument.

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

RESULTS

- Pain scores in both SCS and RPF 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 ($p < .001$)

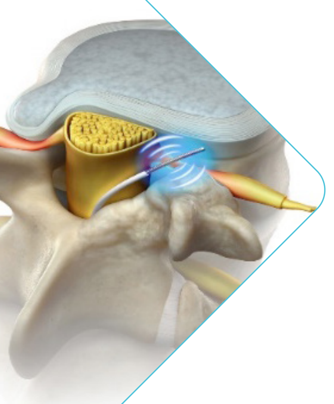




A. NRS-11 scores pre- and 1, 4, 12. and 24 weeks post-operation. The NRS-11 score in the SCS group decreased to 2.90 ± 1.83 (1W) and 4.37 ± 2.43 (24W), while that in the PRF group decreased to 3.13 ± 1.78 and 4.23 ± 2.64, respectively (compared with baseline) **B.** Postoperative efficiency rates (pain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

AUTHOR'S CONCLUSIONS

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



EFFECT OF BIPOLAR PULSED RADIOFREQUENCY ON CHRONIC CERVICAL RADICULAR PAIN REFRACTORY TO MONOPOLAR PULSED RADIOFREQUENCY

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

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 ≥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.

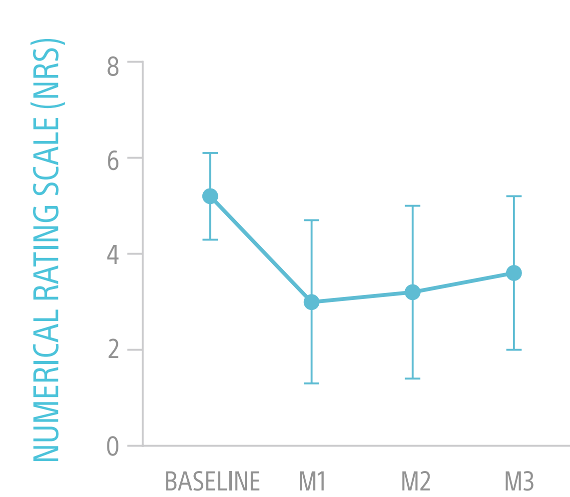
Bipolar PRF procedure: PRF stimulation of the cervical DRG was performed under fluoroscopy guidance as follows:

- 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.

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 (≥ 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.

A



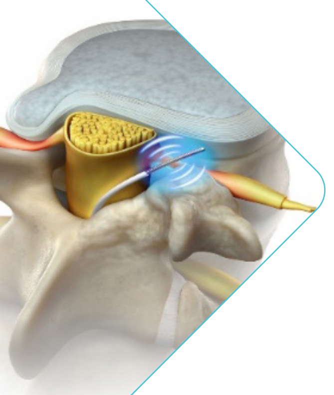
B

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' satisfaction with treatment.

AUTHOR'S CONCLUSIONS

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.



COMPARISON BETWEEN BIPOLAR PULSED RADIOFREQUENCY AND MONOPOLAR PULSED RADIOFREQUENCY IN CHRONIC LUMBOSACRAL RADICULAR PAIN

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

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).

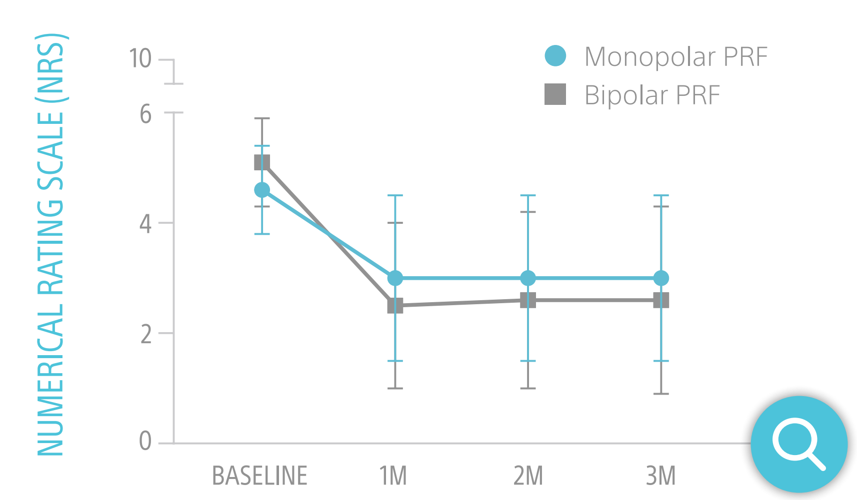
- All patients had a longer than 6-months history of lumbar or sacral segmental pain radiating from the back toward the leg.
- Imaging findings confirmed either herniated lumbar disc or lumbosacral stenosis in the patients.
- Pain intensity was assessed by a blinded investigator using a numeric rating 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.

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.

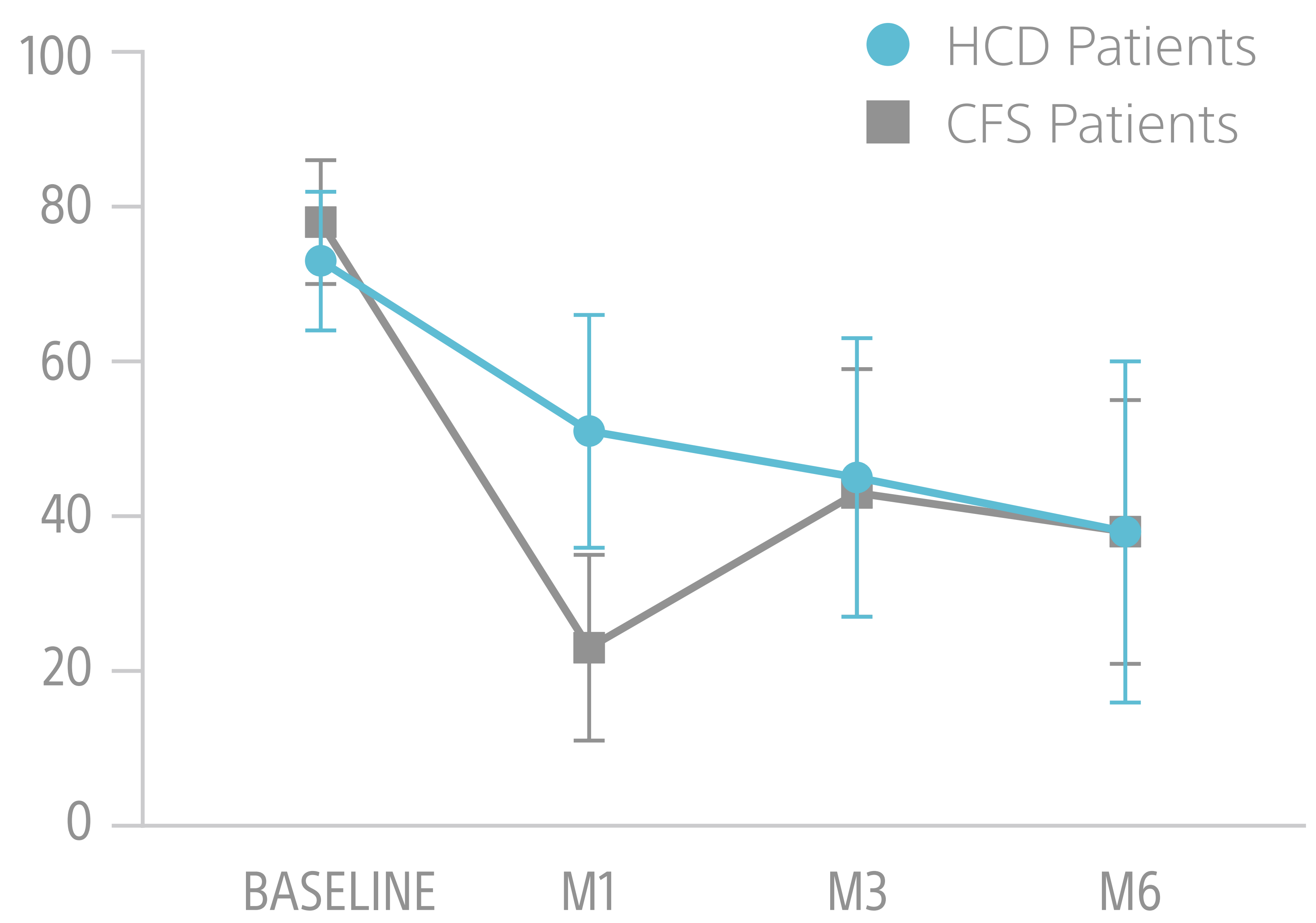


Changes in pain score. The NRS-10 score in the bPRF group decreased from 5.1±0.8 (baseline) to 2.6±1.7 (3M), whereas in the mPRF group decreased from 4.6±0.8 (baseline) to 3.0±1.5 (3M). NRS score was significantly lower in the bPRF group than in the mPRF group.

AUTHOR'S CONCLUSIONS

- 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.

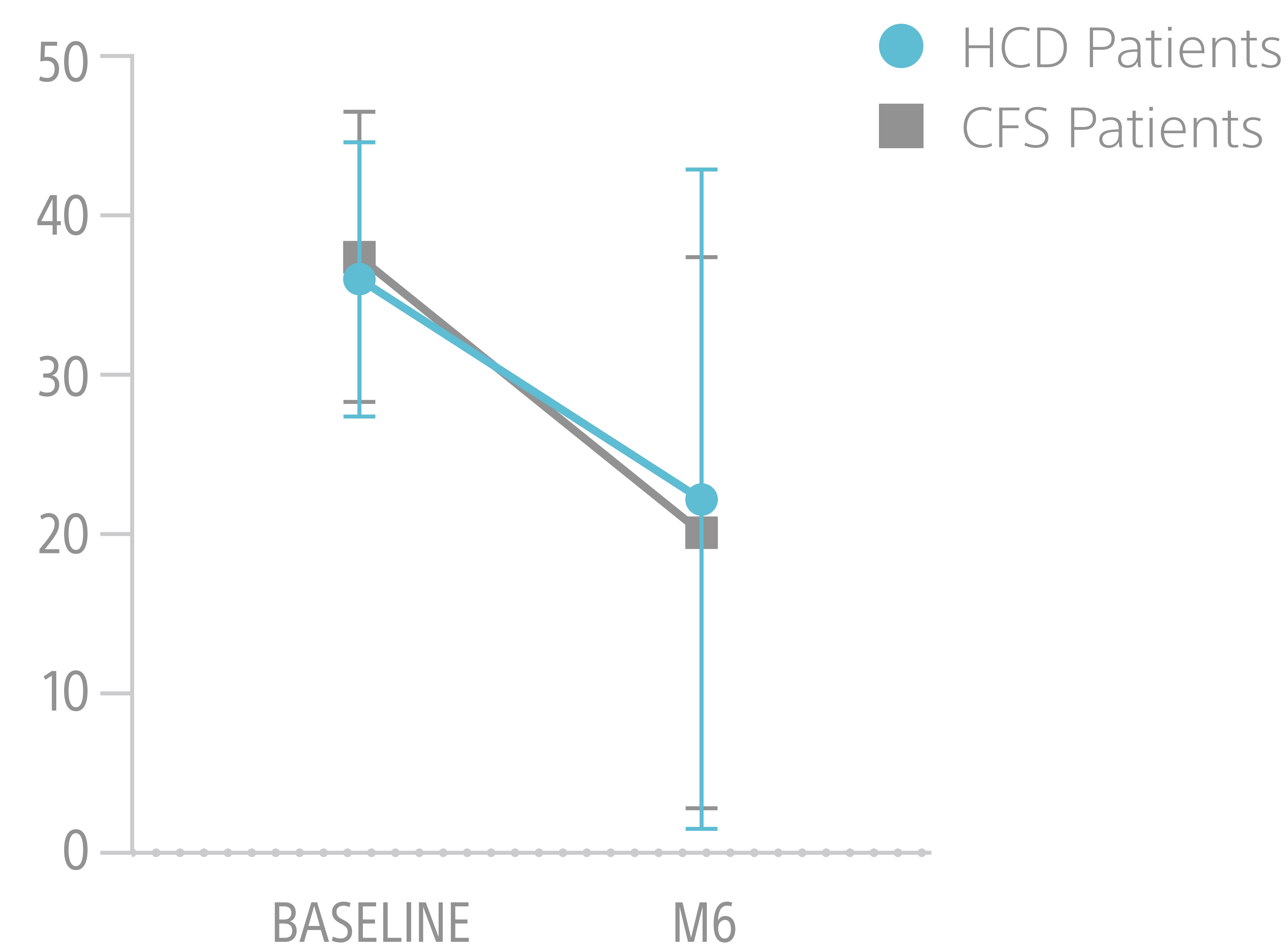
NUMERICAL RATING SCALE (NRS)



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 &M).

A B

NECK DISABILITY INDEX (NDI)

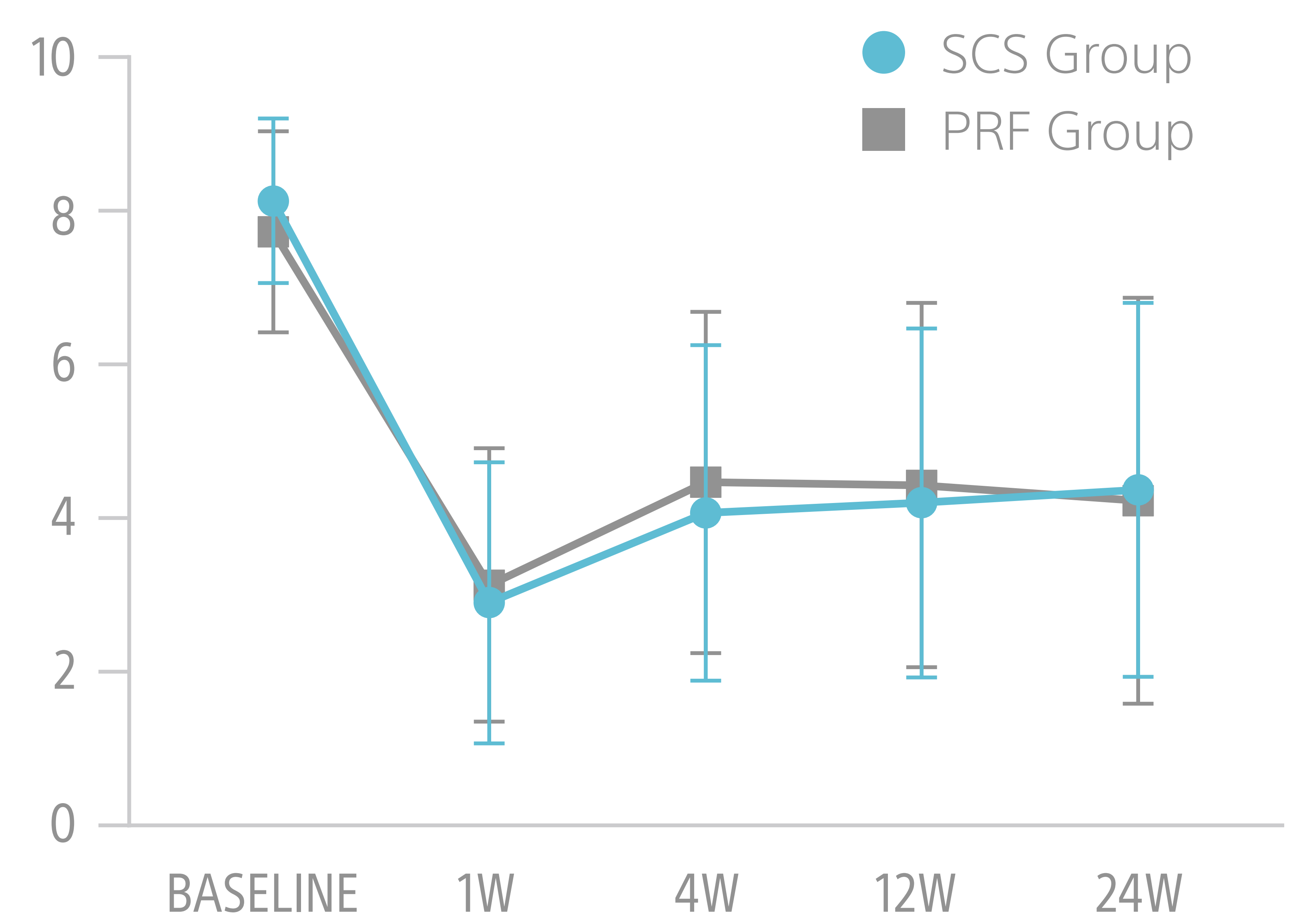


Changes in NRS-11 scores for cervical radicular pain.
NDI scores decreased from 36 and 37.4 to 20.7 and 20.1 at 6 months after treatment for HCD and CFS, respectively.

A B

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)

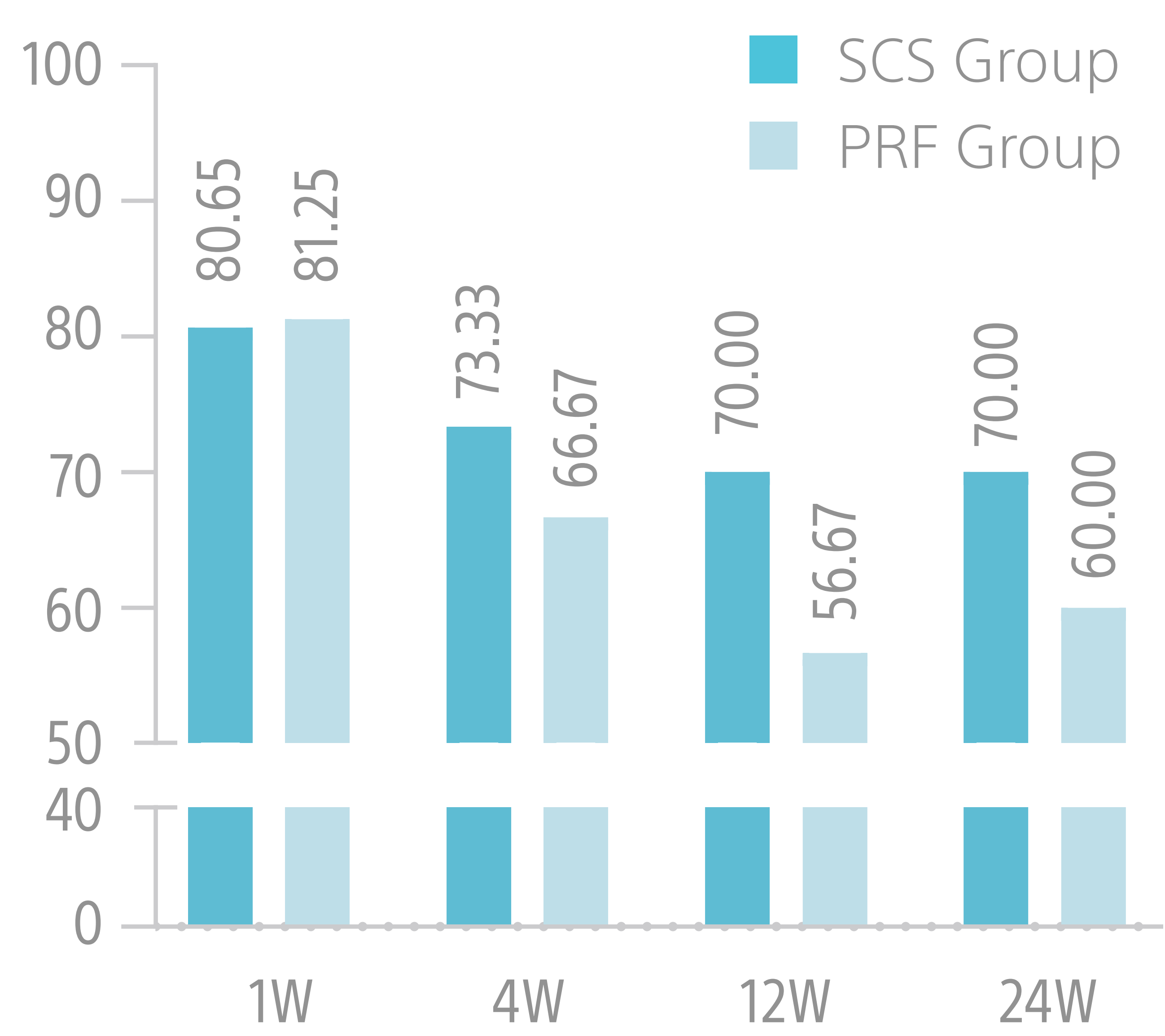
A B C

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.*

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

POSTOPERATIVE EFFICIENCY RATE (%)



Postoperative efficiency rates (pain relief ≥50%).

A B C

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.*

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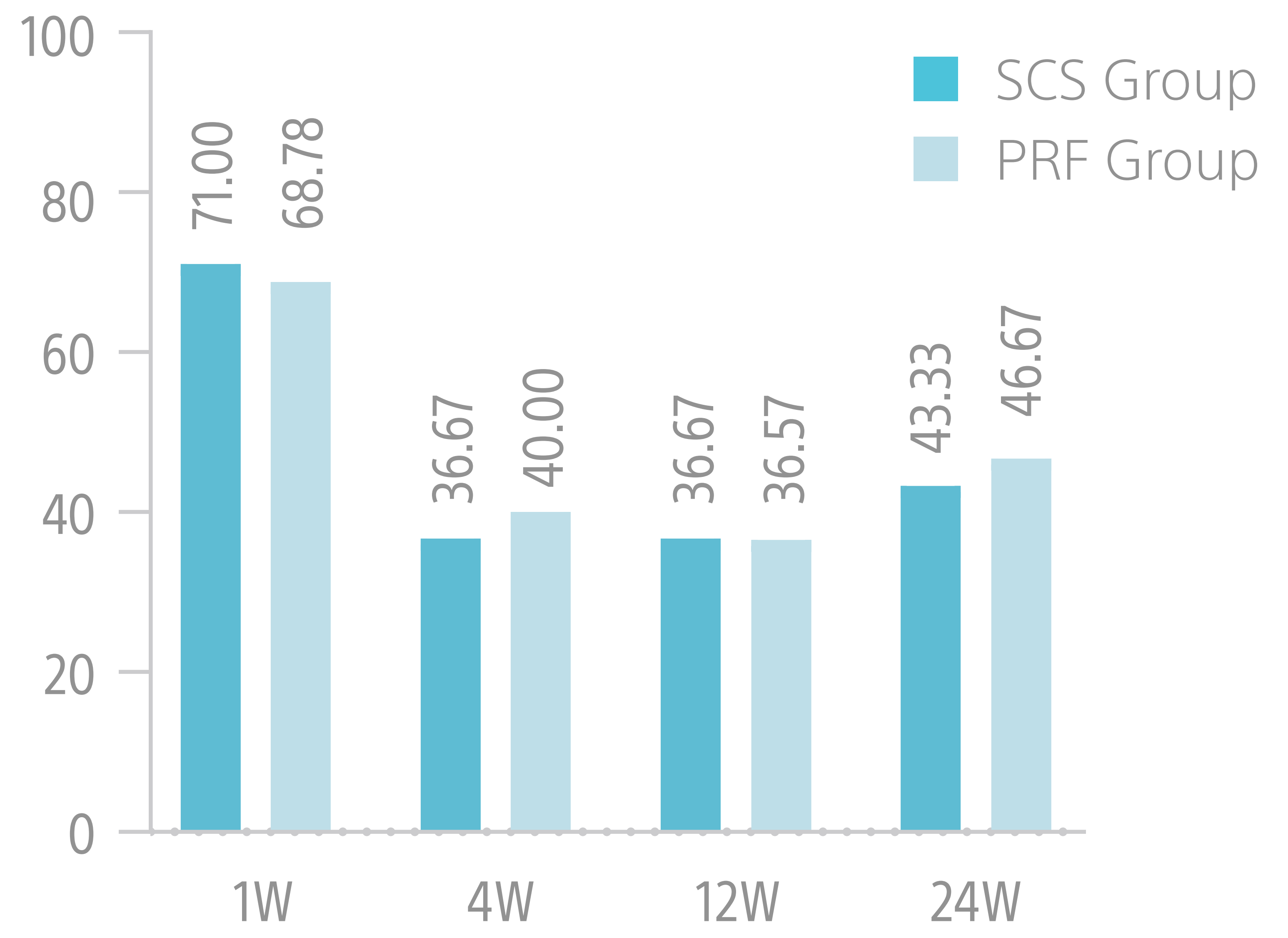
COMPLETE REMISSION RATE (%)



Complete remission rates (pain score ≤ 3)

A B C

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.*

AUTHOR'S CONCLUSIONS

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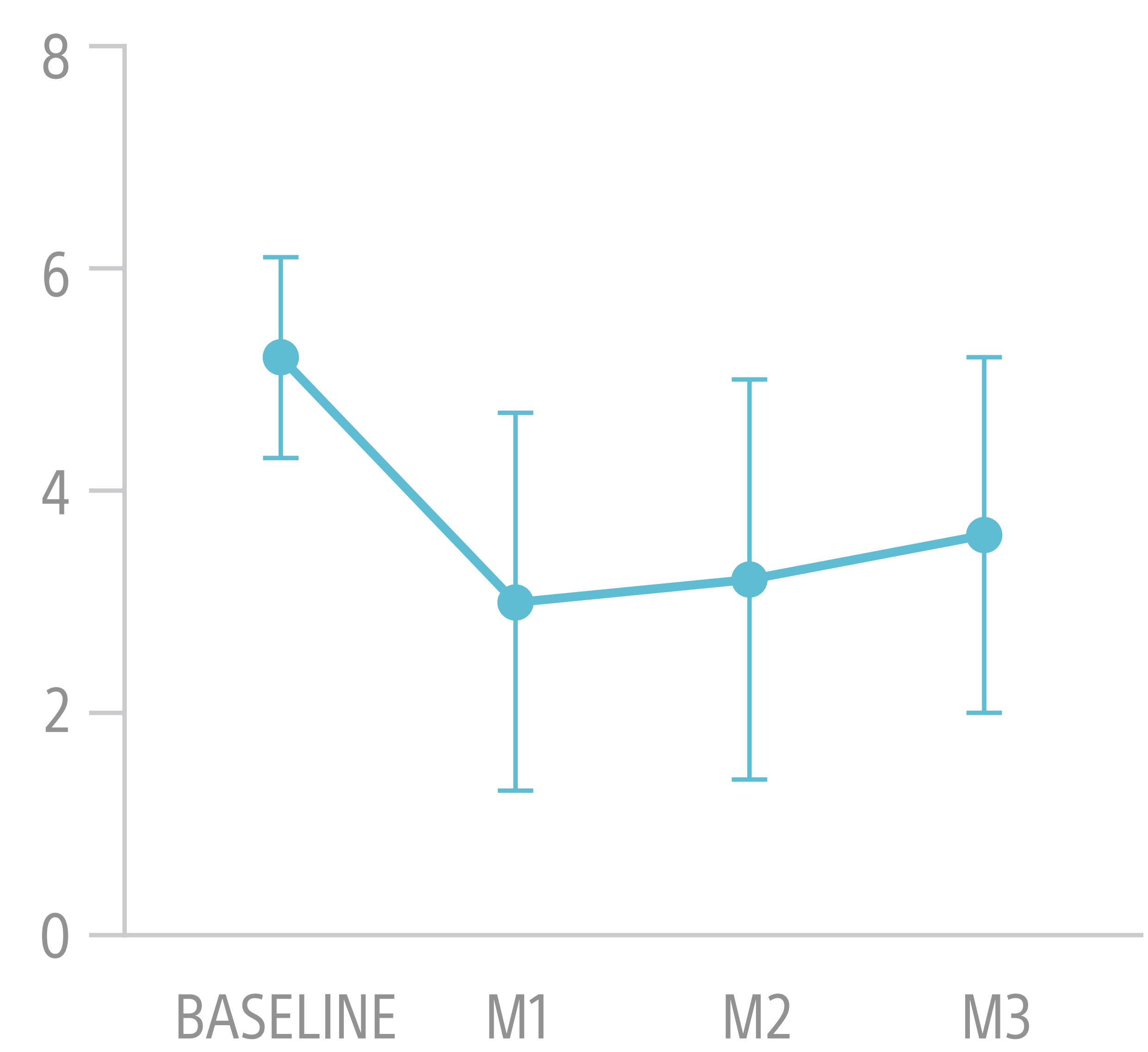

Changes in NRS scores for cervical radicular pain.
Average NRS scores declined from 5.2 at baseline to 3.0 at 1 month, 3.2 at 2 months, and 3.6 at 3 months after bipolar PRF treatment.

A B

- Sensory stimulation with a PRF generator (Cosman G4 Medical™) until the patient reported a tingling sensation and/or dysesthesia at <0.3V.

AUTHOR'S CONCLUSIONS

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.

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. Global perceived effect according to a Likert scale to assess patient' satisfaction with treatment.

A B

• Sensory stimulation with a PRF generator (Cosman G4 Medical™) until the patient reported a tingling sensation and/or dysesthesia at <0.3V.

AUTHOR'S CONCLUSIONS

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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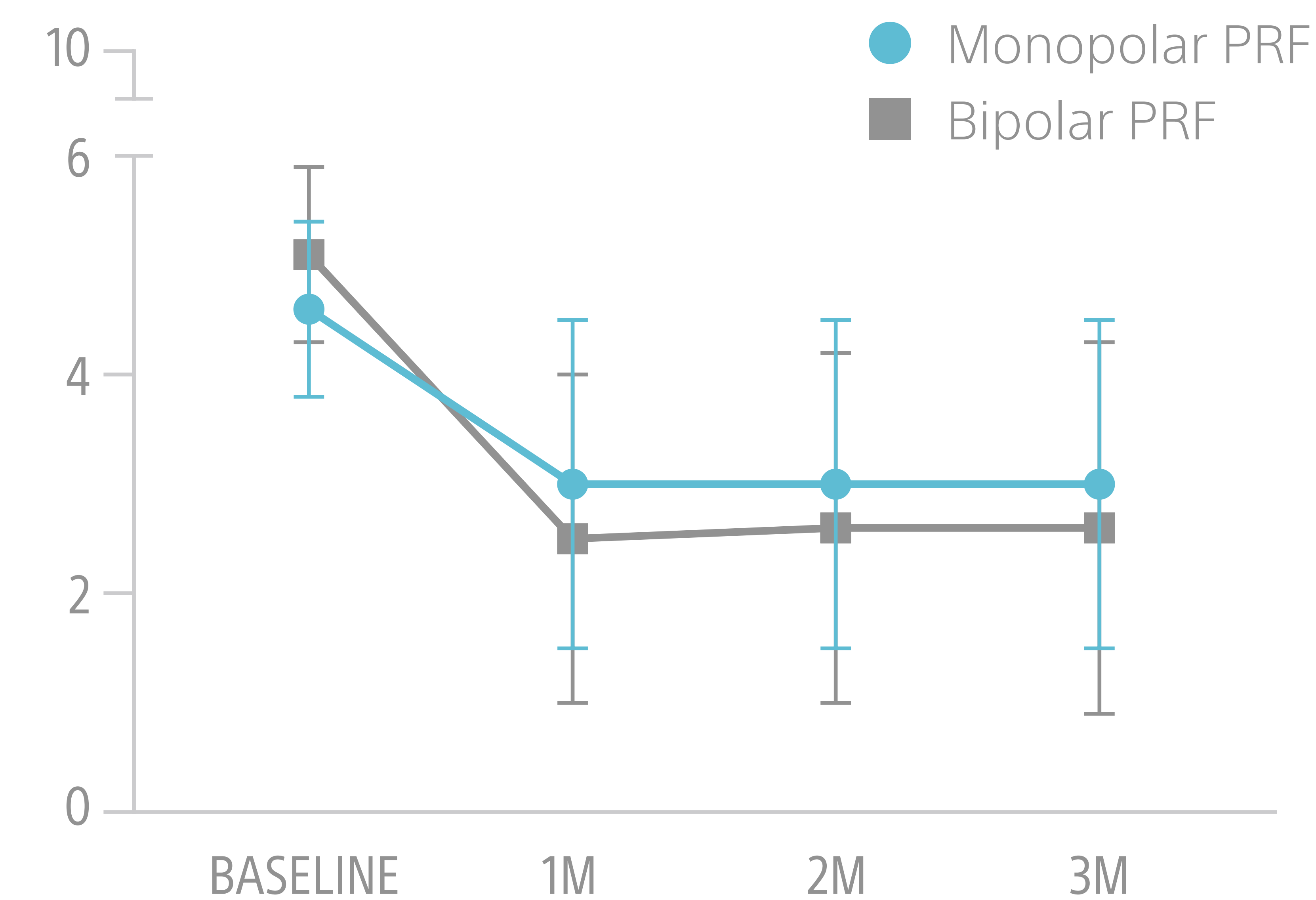

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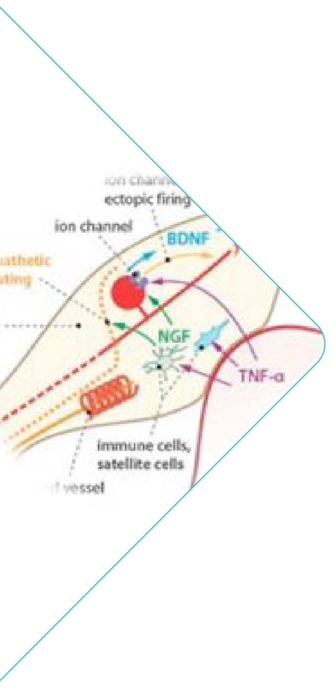
PRF procedure: The affected DRG was punctured with one (mPRF) or two (bPRF) catheter needles (active tip electrodes) under fluoroscopy guidance. A sensory test was performed using an RF Generator (Cosman G4) until the patients reported a tingling sensation or dysesthesia, at less than 0.3V.

technique for chronic refractory lumbosacral radiculopathy.
- Bipolar PRF is a more effective method for managing chronic lumbosacral radicular pain compared to monopolar PRF.

Radiofrequency Clinical Compendium – Supporting publications.
This summary is created by Boston Scientific and is intended to consolidate the paper for educational use only.

PULSED RADIOFREQUENCY MECHANISM OF ACTION

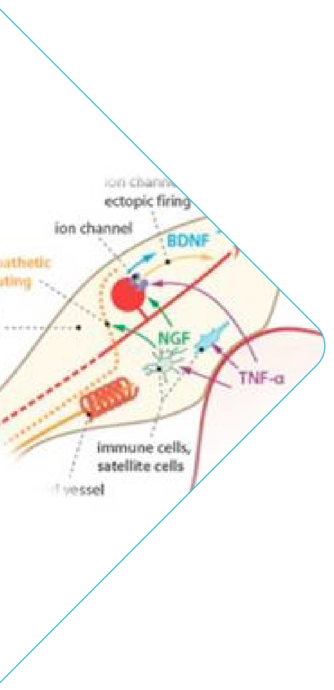


INTRODUCTION

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 analyses[1-2].

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 horn[3]. The effect of PRF on neurotransmission appears to act **selectively on small-diameter axons (C and Aδ pain fibers); hence explaining the analgesic effect of PRF, without interfering with sensory input**[2].

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.



PATHOPHYSIOLOGY OF RADICULAR PAIN: THE RADICULAR PAIN CASCADE

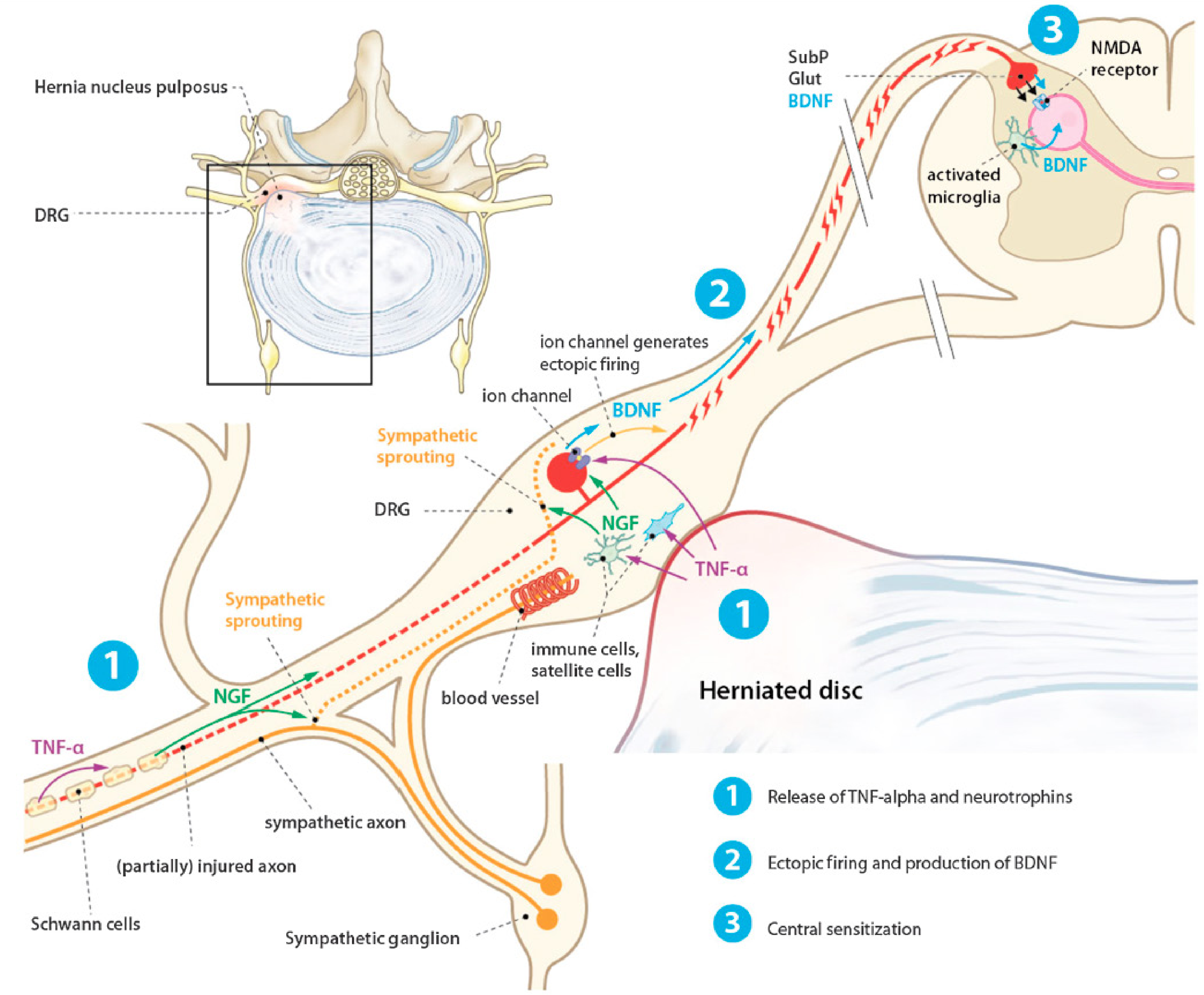
Radicular pain is characterized by the spreading of the nociceptive input in combination with complex cellular and molecular processes (at the axon and the DRG) that initiate and maintain the increased nociceptive signal input.

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)

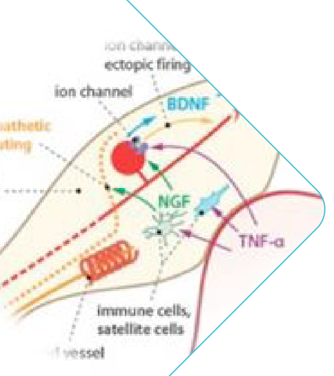
2. Ectopic or abnormal neuronal firing at the DRG driven by neurotrophins
Once **TNF-α** reaches the DRG, the production of the neurotrophic factor **NGF** (nerve growth factor) in the surrounding inflamed tissue is stimulated.
NGF triggers the production of another neurotrophic factor: **BDNF** (brain-derived 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 indices **microglia activation**



Schematic representation of the inflammatory cascade starting from herniated disc and/or degenerating nerve.

Figure reproduced with permission from Copyright Clearance Center (Van Boxem K et al. Reg. Anesth. Pain Med. 2014;39:149–159).



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 sensitization[1-2].

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 EEAs 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 applications[1].

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 serotoninergic inhibitory pathways;** which are involved in the modulation of neuropathic pain[1].

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

References
1. Van Boxem K et al. Regional Anesthesia and Pain Medicine. 2014; 39:149–159.
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3. Napoli A et al. Expert Review of Medical Devices. 2020; 17:2, 83-86.
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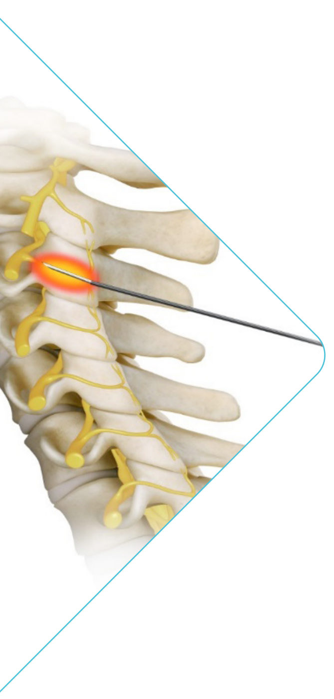
RADIOFREQUENCY ABLATION FOR CERVICAL PAIN



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 symptoms[1].

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 al[3]. 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 metanalyses 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.
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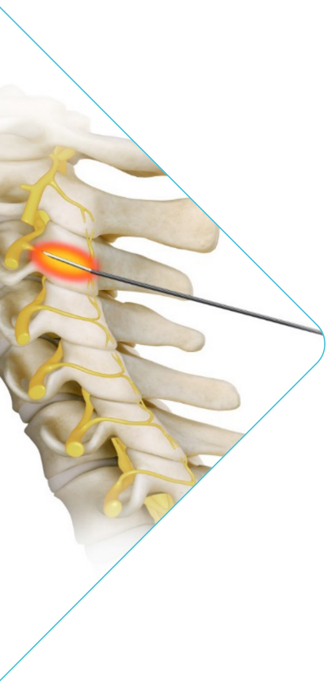


CERVICAL MEDIAL BRANCH RADIOFREQUENCY NEUROTOMY IN NEW ZEALAND

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

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.

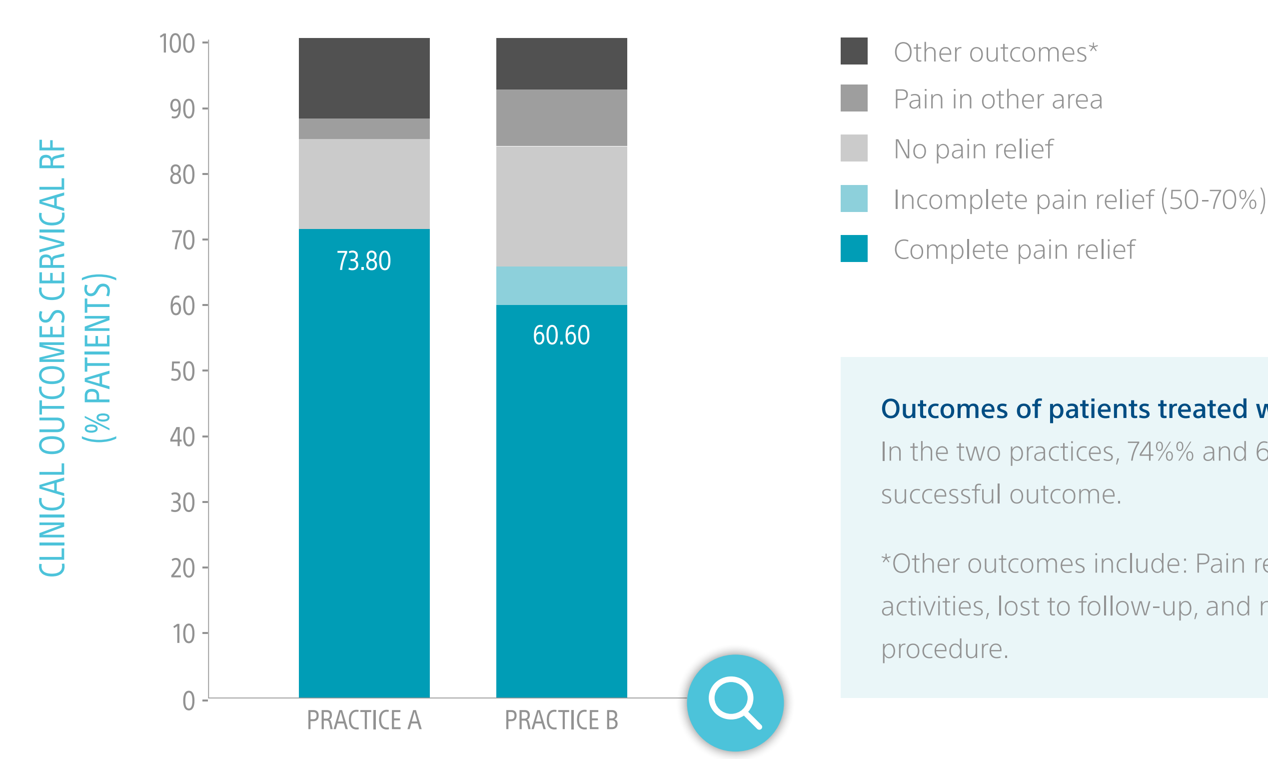
- Patient's VAS and NRS pain scores, as well as daily living activities were recorded before treatment and during follow-up visits post-procedure.
- Data recording and analysis were performed in a double-blind setup.
- Complete pain relief, for at least 6 months, accompanied by complete restoration of daily living activities and no need for any other health care intervention, was adopted as the cardinal criterion for a successful outcome.

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

- 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.

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.

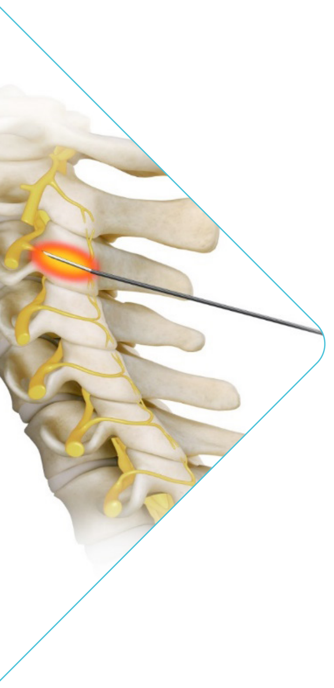


Outcomes of patients treated with cervical medial branch RFN. In the two practices, 74%% and 61% of patients achieved a successful outcome.

*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 CONCLUSIONS

- 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.



CLINICAL EFFECTIVENESS OF INTRA-ARTICULAR PULSED RADIOFREQUENCY COMPARED TO INTRA-ARTICULAR CORTICOSTEROID INJECTION FOR MANAGEMENT OF ATLANTO-OCCIPITAL JOINT PAIN

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

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.

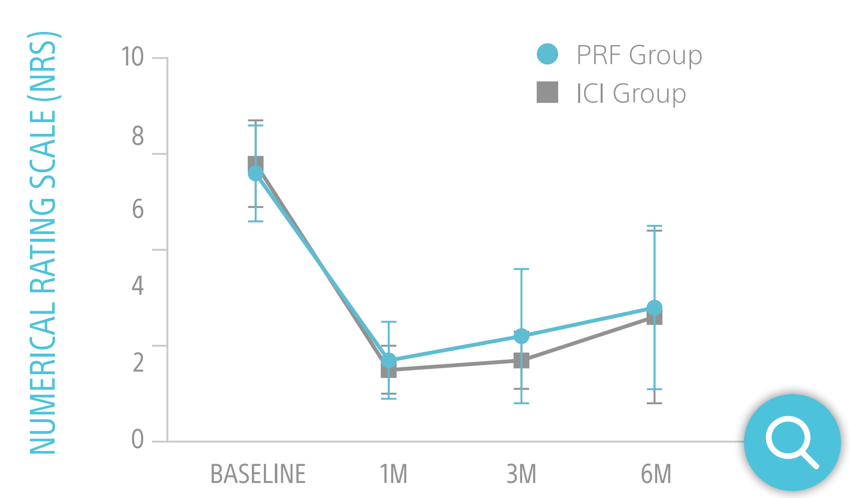
- A Numeric Rating Scale (NRS) score was used to evaluate pain severity before treatment and 1,3, and 6 months after the procedure. Successful pain relief was defined as ≥50% reduction in baseline NRS score at 6 months.

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.

RESULTS

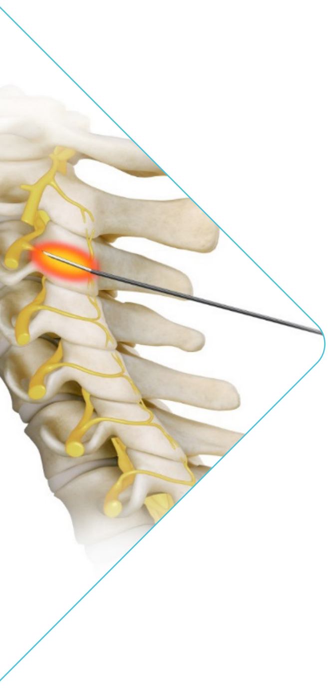
- Chronic joint pain severity (mean NRS scores) was significantly reduced at 1, 3, and 6 months after each procedure ($P<0.001$).
- Successful pain relief was achieved in 66.7% (8/12) of patients in the PRF group and 63.6% (7/11) of the patients in the ICI group.
- The extent of pain reduction between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



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 CONCLUSIONS

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.



MANAGEMENT OF REFRACTORY CHRONIC MIGRAINE USING ULTRASOUND-GUIDED PULSED RADIOFREQUENCY OF GREATER OCCIPITAL NERVE

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

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.

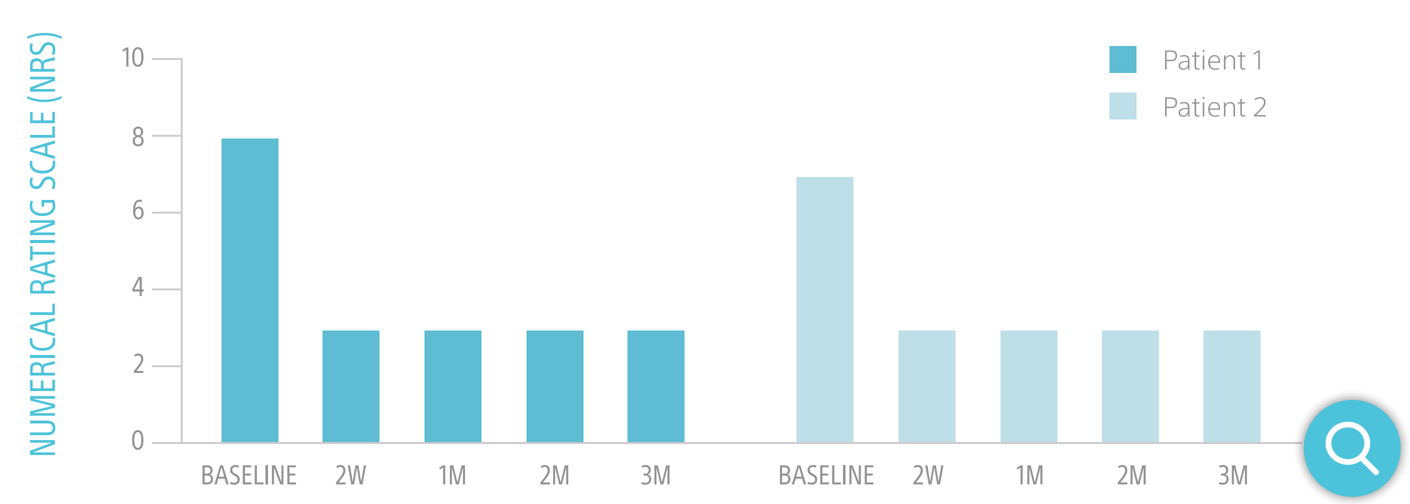
	PATIENT 1	PATIENT 2
Age and Sex	33 y/o - Men	34 y/o - Woman
Year of migraine onset	15 years	14 years
Frequency of headaches	Daily	Daily
Duration of headache attacks	12 to 48 hours	12 to 48 hours

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.

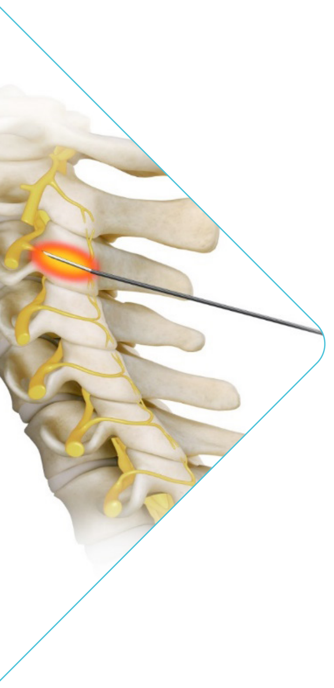
RESULTS

- 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.



AUTHOR'S CONCLUSIONS

- 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.



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 efficacy**[1-2]

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 procedure[2]

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 safety[3]

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.

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2. Wu H et al. J Pain Res. 2019; 18;12: 423-441.
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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 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.

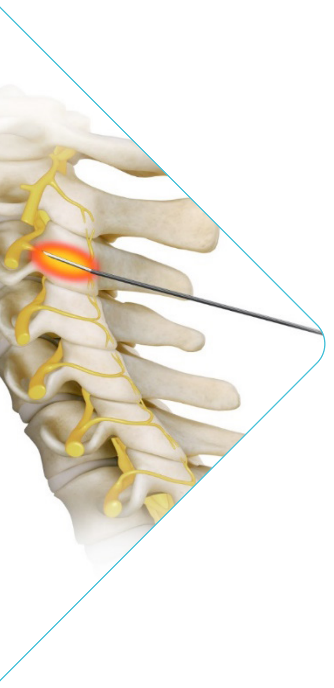
Primary outcome: Complete sensory block of the V3. Secondary outcomes: Presence of residual pain, recurrent pain, and adverse clinical effects.

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.

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.



IMPROVING SAFETY AND EFFICACY OF RADIOFREQUENCY TRIGEMINAL RHIZOTOMY OF THE FORAMEN OVALE: PROCEDURAL TECHNIQUES TO OPTIMIZE TARGET LOCALIZATION AND CANNULATION

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 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).

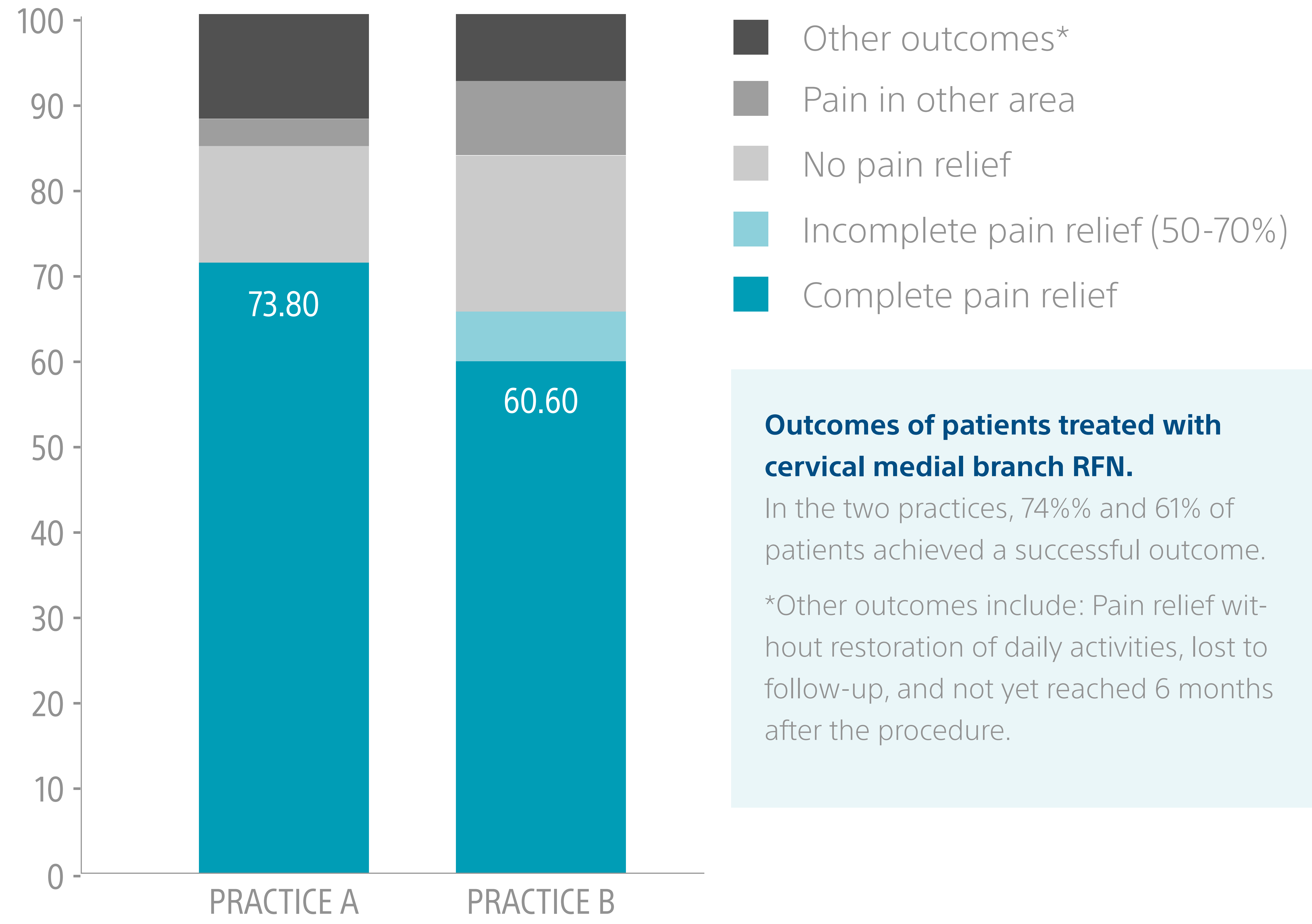
Clinical outcomes: Pain severity pre- and post-treatment and the occurrence of postoperative complications. Patients were followed up for 2-8 years via outpatient visits or phone interviews.

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.

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.

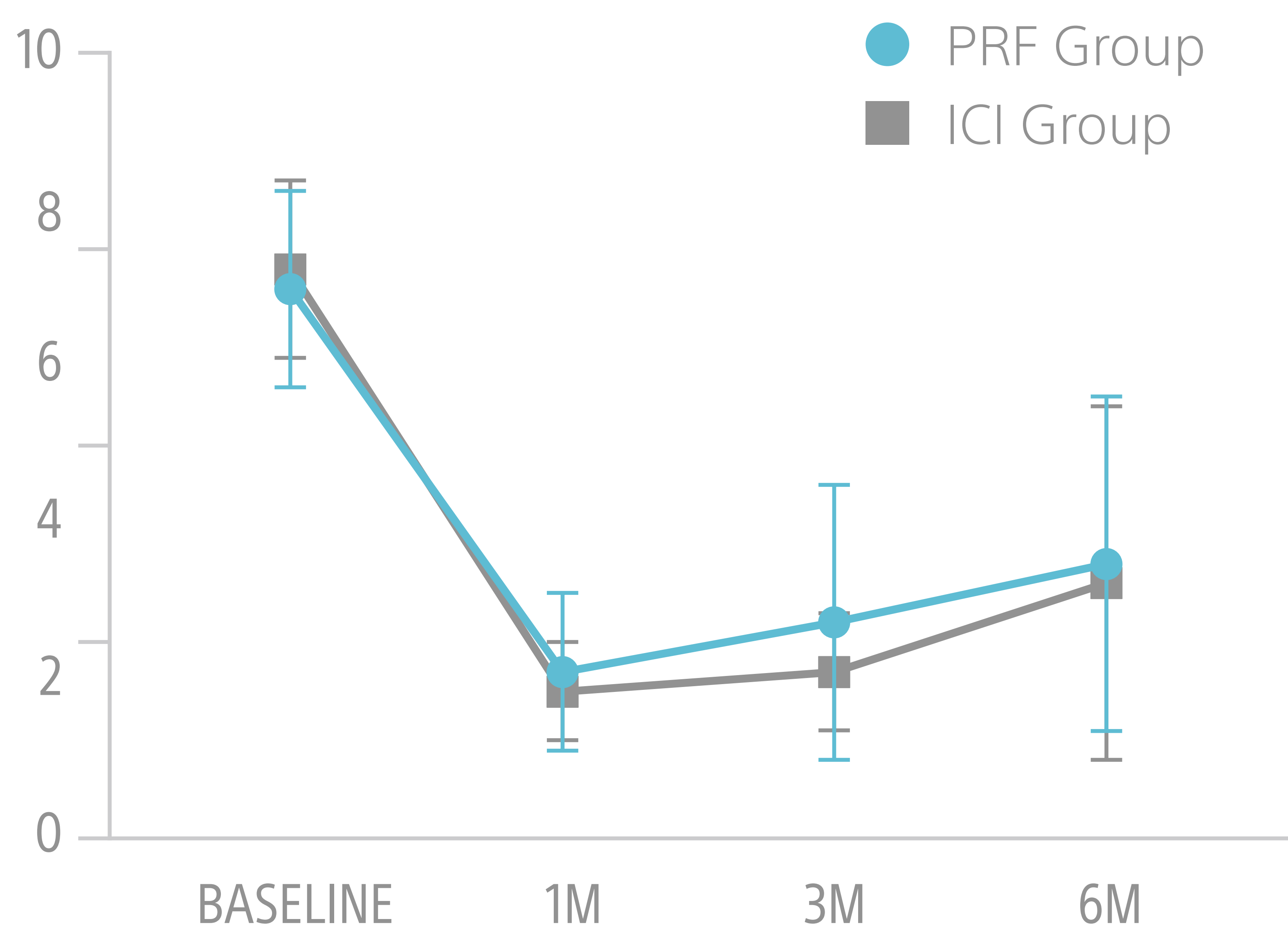
CLINICAL OUTCOMES CERVICAL RF (% PATIENTS)



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 wit-hout restoration of daily activities, lost to follow-up, and not yet reached 6 months after the procedure.

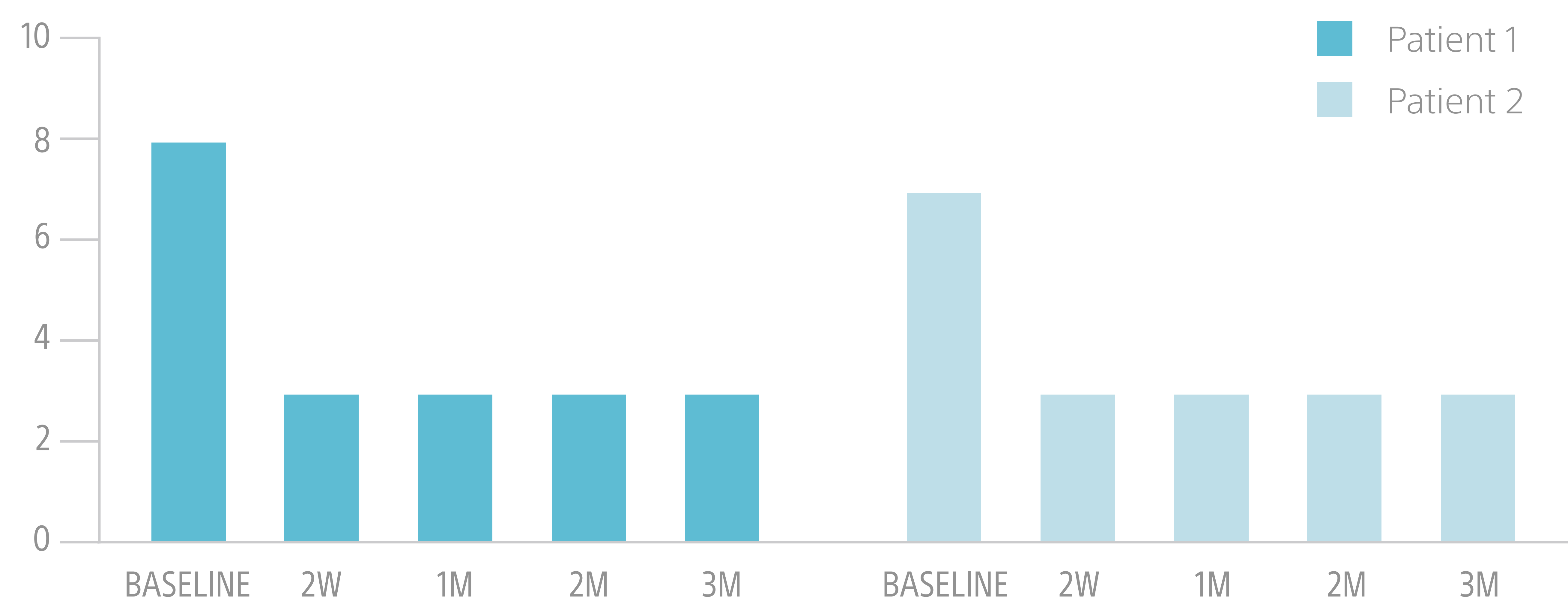
NUMERICAL RATING SCALE (NRS)



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.

(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.

NUMERICAL RATING SCALE (NRS)



- 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.

- Further studies involving more patients are still needed to confirm a positive therapeutic response to ultrasound-guided PRF of the GON.

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ACRONYMS

AO	Atlanto-Occipital	**GPE**	Global Perceived Effect	**PRF**	Pulsed Radiofrequency
bRFA	Bipolar Radiofrequency	**GON**	Greater Occipital Nerve	**RCT**	Randomized Clinical Trial
bPRF	bipolar Pulsed Radio Frequency	**HCD**	Herniated Cervical Disc	**RFN**	Radiofrequency Neurotomy
CFS	Cervical Foraminal Stenosis	**IA**	Intra-Articular	**RF-TR**	Radiofrequency Trigeminal Rhizotomy
cRFA	Cooled Radiofrequency	**ICI**	Corticosteroid Injection	**SIJ**	Sacroiliac Joint
CSF	Cerebro Spinal Fluid	**LBP**	Low back pain	**SCS**	Spinal Cord Stimulation
CT	Computed Tomography	**mRFA**	monopolar Radiofrequency	**TFESI**	Transforaminal Epidural Steroid Injections
DRG	Dorsal Root Ganglion	**mPRF**	monopolar Pulsed Radio Frequency	**TN**	Trigeminal Neuralgia
FO	Foramen Ovale	**MRI**	Magnetic Resonance Imaging	**US**	Ultrasound
GG	Gasserian Ganglion	**NRS**	Numeric Rating Scale	**VAS**	Visual Analog Scale