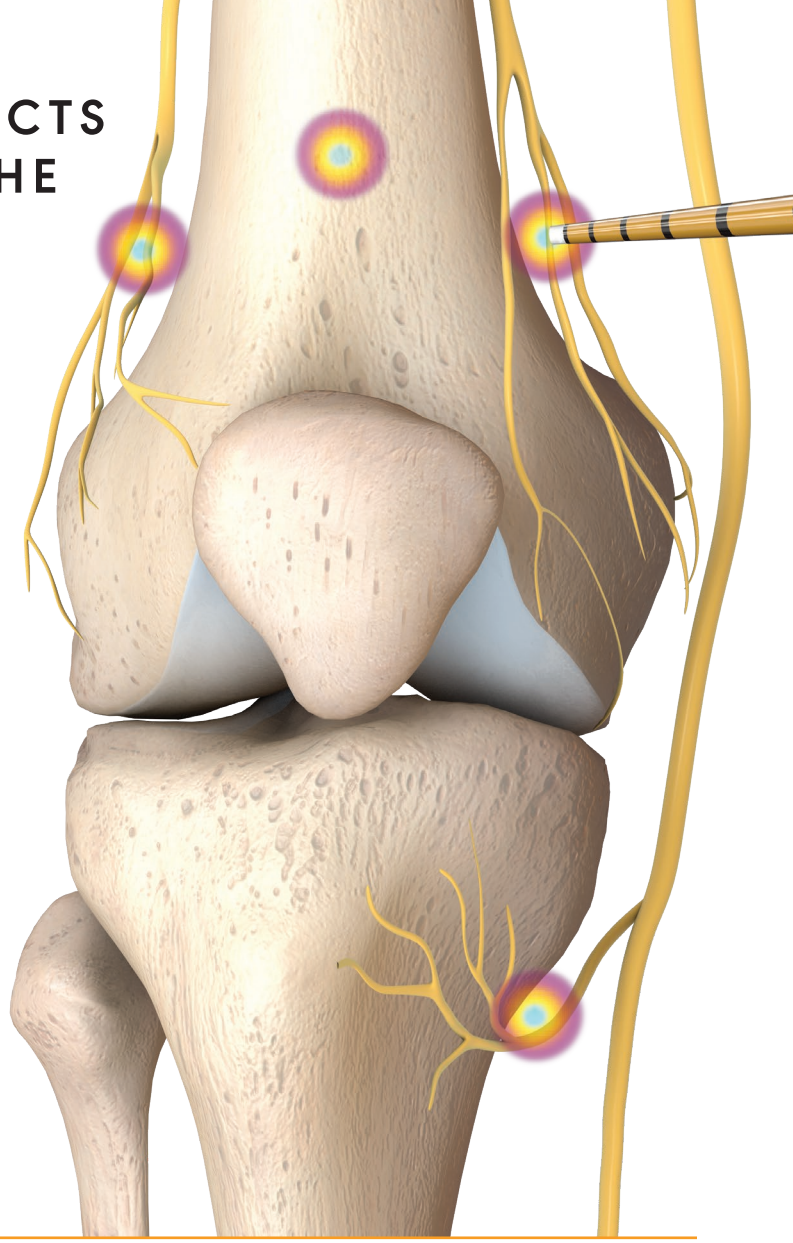
COOLIEF*
Cooled Radiofrequency Treatment

Uncovering the extended clinical durability of COOLIEF* Cooled Radiofrequency ablation compared to standard radiofrequency ablation

AVANOS

CHRONIC KNEE PAIN AFFECTS MILLIONS OF PEOPLE IN THE UNITED STATES



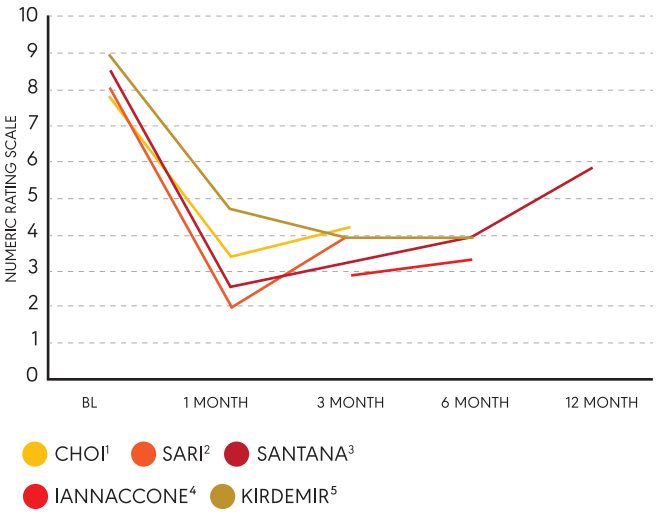
Non-operative procedures that help manage symptoms are an important part of the treatment paradigm.

COOLIEF* Cooled Radiofrequency ablation has demonstrated significant effectiveness and durability in the management of chronic knee pain caused by osteoarthritis.

COOLIEF* Cooled RF demonstrates extended clinical durability when compared to standard radiofrequency (Figure 1), suggesting that increased lesion size may not be the only driving factor of improved patient outcomes.

Several active preclinical research projects at Avanos exploring technological improvements have uncovered distinct differences between standard and cooled radiofrequency procedures.

STANDARD RADIOFREQUENCY STUDIES



COOLIEF* COOLED RADIOFREQUENCY STUDIES

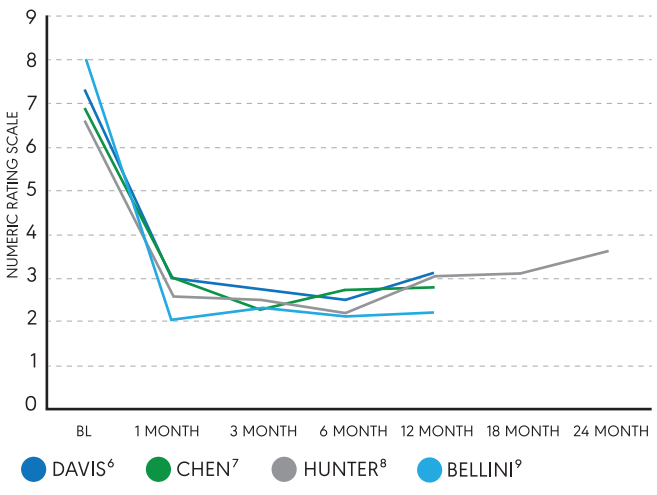


Figure 1
Comparison of Numeric Rating Scale (NRS) pain scores following radiofrequency ablation procedures

MORE ENERGY DELIVERED THROUGH WATER COOLING

With standard radiofrequency probes, temperatures at the tissue-tip interface reach 80°C. At these temperatures, desiccation can occur in the adjacent tissues. This can lead to charring of the tissue at the tissue-tip interface, which creates an insulated barrier, limiting delivery of radiofrequency energy.

Cooled radiofrequency probes are able to overcome the limitations inherent to standard radiofrequency probes by circulating cooled water through the probe. Heat is drawn away from the tissue-tip interface, preventing charring and allowing more energy to reach the nervous tissue.

By effectively managing the temperatures at the tissue-tip interface, cooled radiofrequency probes are able to deliver significantly more energy than standard radiofrequency probes. Cooled radiofrequency probes deliver up to 3.7 times more energy to the nerve and surrounding tissue than standard radiofrequency probes in a perfused tissue rodent model (Figure 2).

Furthermore, when the duration of a standard radiofrequency procedure is extended to 6 minutes, it still does not deliver as much energy as a 2.5-minute procedure with a cooled radiofrequency probe (Figure 3).

ENERGY AS A FUNCTION OF PROBE SIZE

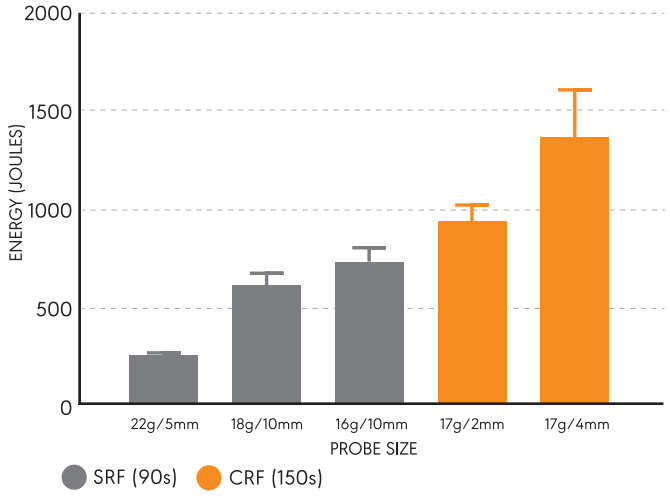


Figure 2
Energy delivered by various standard and cooled radiofrequency probe sizes

ENERGY AS A FUNCTION OF TIME

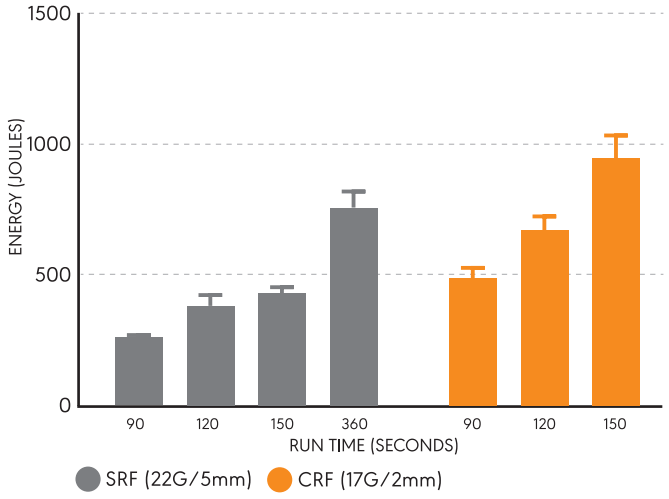
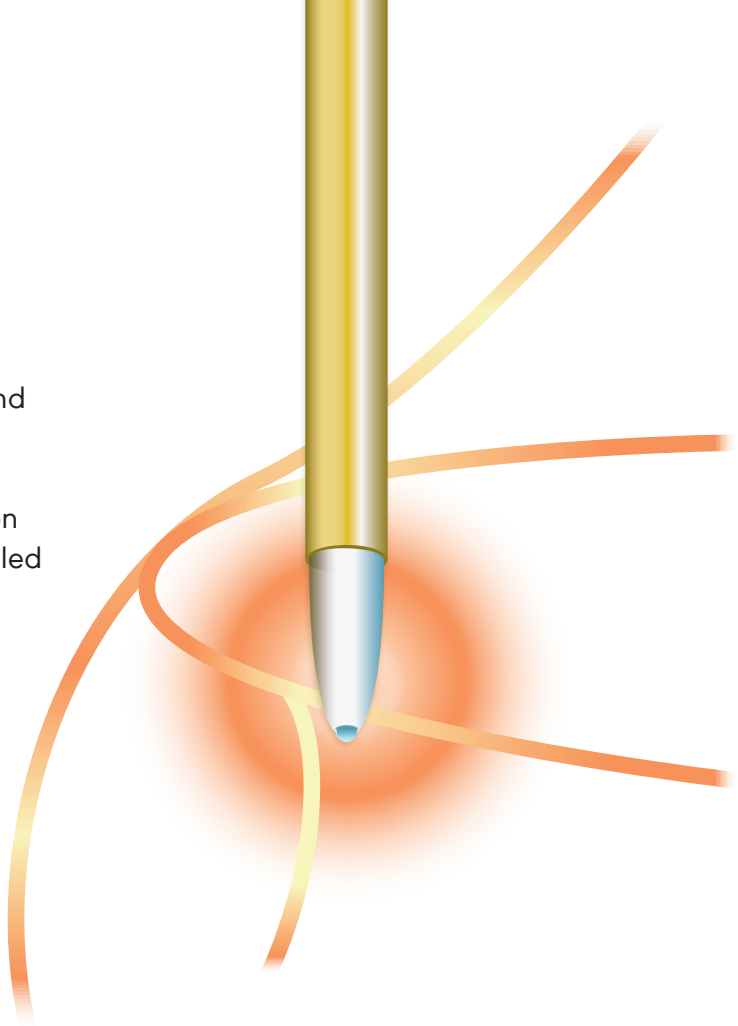


Figure 3
Energy delivered by radiofrequency probes with extended runtimes

IMPACT OF GREATER ENERGY DELIVERY ON NERVE STRUCTURE



Histological analysis of nerves ablated with standard and cooled radiofrequency probes demonstrates the extent and thoroughness of the damage to nerve structure.

Blinded, third party histological analysis was conducted on rodent sciatic nerves ablated with both standard and cooled radiofrequency probes. Sham serves as a control for healthy nerve structure.

Longitudinal analysis of ablations performed with cooled radiofrequency probes show larger areas of damage compared to standard radiofrequency probes (Figure 3). Cross sectional analysis shows a more thorough disruption of the nerve structure at the cellular level created by cooled radiofrequency probes (Figure 4).

Nerves ablated with cooled radiofrequency probes show a more thorough disruption to the nerve structure in general. Furthermore, lesions created with CRFA show distinct areas of thermal damage correlating with 80°C.

REPRESENTATIVE LONGITUDINAL NERVE SECTIONS

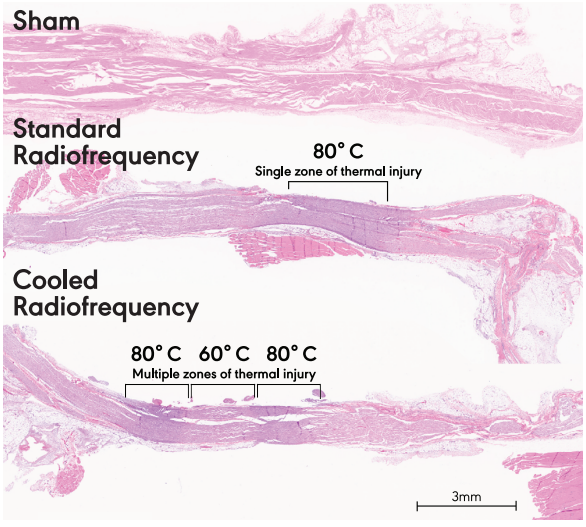


Figure 3
Longitudinal histological analysis

REPRESENTATIVE CROSS-SECTIONAL NERVE SECTIONS

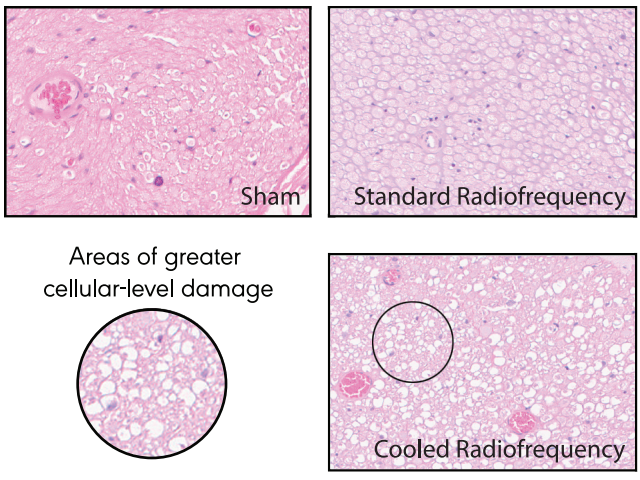


Figure 4
Cross-sectional histological analysis

SIGNIFICANT DELAYS IN THE RETURN OF NERVE FUNCTION IN RODENT STUDIES

Optimized rodent studies have demonstrated that cooled radiofrequency ablation provides a more thorough and extensive disruption to sciatic nerve function. Experimental protocols involved performing standard radiofrequency ablation and cooled radiofrequency ablation of the sciatic nerve of rodents. Nerve function was measured at 2-week intervals by electromyography (EMG), a tool which allows for the quantitative evaluation of a motor or mixed nerve's function. A lower signal response (or greater reduction from baseline) is indicative of greater level of nerve function impairment.

Rodents treated with cooled radiofrequency ablation showed a greater decrease in nerve function, which lasted longer than standard radiofrequency ablation, thus demonstrating the physiological impact of more extensive lesioning (Figure 5).

Results from this study closely mirror the extended clinical durability of cooled radiofrequency ablation and suggest that cooled radiofrequency ablation creates more extensive lesions to the nerve, which are able to interrupt pain signals for longer periods of time.

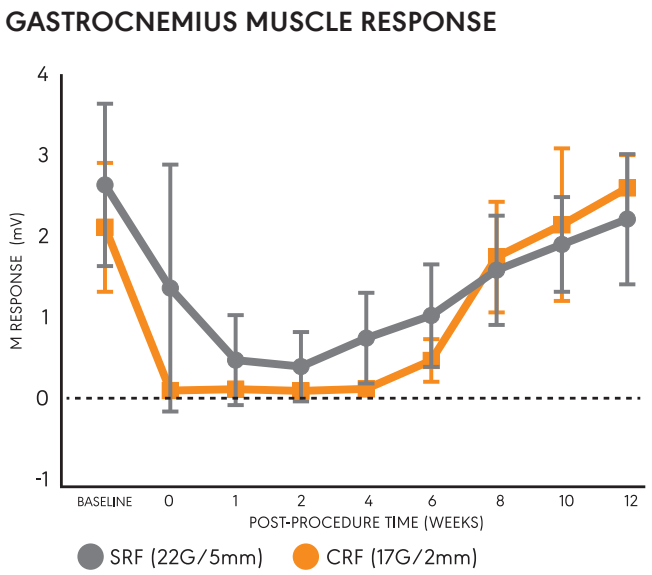


Figure 5
Return to function of the gastrocnemius nerve following ablation procedure

COOLIEF* Cooled RF delivers up to 3.7x more energy than standard RF

COOLIEF* Cooled RF's greater energy delivery leads to more extensive cellular disruption of the nerve as shown by histology

COOLIEF* Cooled RF decreases nerve function more and for a longer period of time than standard RF as assessed by EMG

For more information about COOLIEF* Cooled RF, please visit www.avanospainmanagement.com or call 1-844-4AVANOS.

REFERENCES

1. Choi W-J, Hwang S-J, Song J-G, et al. Radiofrequency treatment relives chronic knee osteoarthritis pain: A double-blind randomized clinical trial. Pain, 152, 481-487 (2011).
2. Sari S, Aydin ON, Turan Y, et al. Which one is more effective for the clinical treatment of chronic pain in knee osteoarthritis: radiofrequency neurotomy of the genicular nerves or intra-articular injection? International Journal of Rheumatic Diseases, Oct;21, 1772-1778 (2018).
3. Santana Pineda MM, Vanlinthout LE, Martin AM, et al. Analgesic Effect and Functional Improvement Caused by Radiofrequency Treatment of Genicular Nerves in Patients With Advanced Osteoarthritis of the Knee Until 1 Year Following Treatment. Regional Anesthesia and Pain Medicine, 42(1), 1-7 (2017).
4. Iannaccone F, Dixon S, Kaufman A. A Review of Long-Term Pain Relief after Genicular Nerve Radiofrequency Ablation in Chronic Knee Osteoarthritis. Pain Physician 20:E437-E444 (2017).
5. Kirdemir P, Catav S, Alkaya SF. The genicular nerve: radiofrequency lesion application for chronic knee pain. Turkish Journal of Medical Science, Feb 27;47(1), 268-272 (2017).
6. Davis T, Loudermilk E, DePalma M, et al. Twelve-month analgesia and rescue, by cooled radiofrequency ablation treatment of osteoarthritic knee pain: results from a prospective, multicenter, randomized, cross-over trial. Regional Anesthesia & Pain Medicine, 44(4), 499-506 (2019).
7. Chen AF, Khalouf F, Zora K, DePalma M, et al. Cooled Radiofrequency Ablation Demonstrates Greater Effectiveness and Equivalent Safety Compared to a Single Injection of Hyaluronic Acid for Chronic Knee Pain Management: Twelve Month Results from a Prospective, Multi-Center, Randomized, Clinical Trial. Journal of Arthroplasty. *In Press* (2020).
8. Hunter C, Davis T, Loudermilk E, Kapural L, DePalma M. Cooled Radiofrequency Ablation Treatment of the Genicular Nerves in the Treatment of Osteoarthritic Knee Pain: 18 and 24-Month Results. Pain Pract. October :papr.12844 (2019).
9. Bellini M, & Barbieri, M. (2015). Cooled radiofrequency system relieves chronic knee osteoarthritis pain: the first case-series. Anaesthesiology Intensive Therapy 47(1):30-33 (2015).

AVANOS