AVANOS

COOLIEF
Cooled Radiofrequency Treatment

COOLED RADIOFREQUENCY ISN'T SO COOL

In the world of chronic pain management, not all treatments are created equal. For patients and providers alike, understanding the treatment options available is more important than ever, as the population dealing with chronic pain continues to grow. Approximately 100 million U.S. adults—more than the number affected by heart disease, diabetes, and cancer combined—suffer from chronic pain conditions. Patients who are constantly dealing with pain are often frustrated, and physicians are most satisfied when they can provide both effective and lasting pain relief for their patients.

As with everything in healthcare, it's important to ensure that the pain treatment provided best aligns with a patient's individual needs. The current treatment landscape is relatively sparse, and there is a heavy reliance on opioid medications, which have undesirable side effects. As such, there is great interest in using minimally invasive procedures in interventional pain management as they are non-opioid and can target the source of pain transmission.

One of those procedures is thermal radiofrequency (RF) ablation. There's more than one type of RF treatment option, and they're not created equal, either. This can mean the difference between continued suffering and long lasting pain relief for chronic pain patients.

There's more than one type of RF treatment option, and they're NOT CREATED EQUAL.

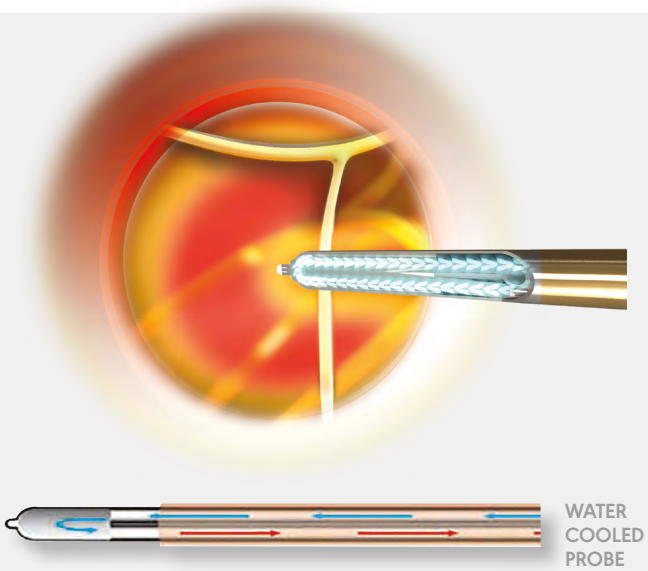
STANDARD RF AND ITS LIMITATIONS

One type, standard RF, generates heat to destroy specific nervous tissue to prevent transmission of pain signals. With standard RF, lesion size and shape are limited by the heat generated in the tissue adjacent to the electrode.[1] Specifically, the lesions are elliptical in shape and immediately adjacent to the active tip, with a diameter of approximately 4 millimeters.

Standard RF presents other limitations as well. With standard RF, compensating for nerve variabilities usually requires multiple lesions, which can mean longer procedure times and inconsistent clinical outcomes. Standard RF electrodes, including multiple-tined designs, require the electrode to be placed parallel to the nerve and in close proximity in order to achieve a maximum ablation zone. This can be challenging given the size, shape and lack of distal projection created by a standard RF probe. The nerves themselves can't be visualized, and the required parallel placement with standard and tined lesions can be challenging because of anatomical limitations. Because of this, proper placement becomes solely dependent upon the operator's comfort and experience in this technique, which can vary, potentially impacting outcomes.

Using Cooled RF for Common Sources of Chronic Pain

The large-volume lesions cooled RF helps create can make it a good option for treating several areas that are common sources of chronic pain:



USING WATER-COOLED TECHNOLOGY TO DELIVER MORE ENERGY

For those seeking another option, there is cooled RF technology, such as COOLIEF* Cooled RF. Cooled RF is not new—it is an established technology with many uses that is now being applied to pain management.

Using water-cooled technology allows the delivery of more RF energy, which results in:

- Large volume, spherically shaped lesions.
- The possibility of perpendicular, oblique or parallel approaches toward the target structure.
- Increased probability that target nerves with known nerve path complexity and variability will be successfully captured and ablated.

Up to 24 months of pain relief, improved physical functionality and reduced drug utilization for patients suffering from chronic pain.

CERVICAL PAIN:

Effective where anatomy and nerve path are variable.[2]

LUMBAR PAIN:

Using a perpendicular approach encompasses the medial branch nerve that requires only one pass[3] and mimics the approach utilized for the diagnostic blocks [WM1] [DB2] (familiar technique).

SACROILIAC JOINT PAIN:

Multiple anatomic dissections reiterate that this is an area with a tremendously variable nerve course, which requires a high number of lesions. The spherical shape of cooled RF ablation (CRFA) allows for a maximum ablation zone in three dimensions per lesion. Additionally, it ablates variable target neural structures between the posterior sacral foramina and sacroiliac joint.[4]

THORACIC FACET PAIN:

Variable medial branch paths in the thoracic region, particularly in midthoracic levels, make the clinical outcomes of standard RF ablation inconsistent. Cooled RF electrodes can achieve ablation of larger tissue volumes and may increase the probability of capturing the targeted thoracic medial branch nerves.[5]

DISCOGENIC BACK PAIN:

For intervertebral disc biacuplasty, bipolar probe placement straight into the disc is possible with COOLIEF* Cooled RF, which creates a large, reproducible lesion within significant volume of the disc. It enables placement of lesions in nervous and disc tissue without increased risk of damage to adjacent tissue.[6]

HIP JOINT PAIN:

Targets and treats sensory branches of the obturator and femoral nerves innervating the hip joint.[7] Nerve paths are complex and highly variable, and the anatomic landscape makes it nearly impossible to place standard RF probes parallel to the target nerves.[8] The distal projection and large spherical shape of the lesion made possible by cooled RF creates opportunities for successful procedures in the hip joint.

KNEE PAIN:

Cooled RF serves as a minimally invasive option for genicular nerve ablation that can decrease chronic pain and medication use for patients with chronic knee pain.[9] Additionally, because of the complexity and variability of the nerves in the knee, the larger cooled RF lesion may reduce technical failures that could be related to standard RF.

THE COOLED DIFFERENCE: THE COOLIEF* COOLED RF SYSTEM

The COOLIEF* Cooled Radiofrequency Pain Management System is the most advanced and comprehensive RF generator, with more application modalities than any other RF system. Minimally invasive and clinically effective, it is the only RF system that provides physicians with the flexibility to perform either standard or cooled RF.[10]

The cooled RF probe, which connects to the generator, circulates sterile water to cool the probe electrode, allowing for higher power delivery and larger volume of treated tissue with minimized risk of tissue adherence. The temperature sensor ensures the appropriate thermal gradient at the target. The standard RF and COOLIEF* Cooled RF multi-cooled RF module enables placement of up to four lesions in one operation.[11] This reduces procedure time, which can potentially improve operating room utilization.

HOW TISSUE TEMPERATURE CAN IMPACT OUTCOMES

Tissue temperature is the fundamental factor that determines the procedure's safety and the lesion's size. In standard RF, the hottest temperatures occur at the probe/tissue interface. But desiccation and charring can limit the amount of energy entering the tissue, resulting in smaller lesions. With cooled RF, the highest temperatures are recorded 2 mm from the electrode surface, and a higher temperature compared to conventional RF is maintained up to 4 mm from the electrode surface.[12]

With cooled RF, ideal lesion formation occurs at 60° C, while standard RF requires a temperature of 80° C be maintained for 90 seconds to attain an ideal lesion.[13] Despite a lower temperature setting, surrounding tissue still reaches temperatures of 80 to 90°C.[14] Heat is removed from the tissue adjacent to the electrode and slowly added to more distal tissues via increased RF energy output, so tissue temperatures (greater than 80° C) exceed what's required to coagulate tissue protein.[15] This is what creates lesions that are circular, rather than elliptical, with less size variability. By contrast, standard RF creates lesions that are relatively shallow in depth and narrow in width.[16] The use of cooled probes produces lesions from 8 to 10 mm in diameter using a 4 mm active tip. By comparison, standard RF typically produces lesions 3 to 4 mm in diameter.[17]

THE BENEFITS OF INCREASED RF ENERGY

With COOLIEF* Cooled RF, water-cooled electrodes enable more RF energy to be delivered than standard RF. This greater energy output has a number of benefits, including the ability to increase distal projection and reduce potential for charring or tissue adhesion after carbonization.

Cooled RF provides the ability to produce lesions that distally project more than 45% beyond the probe's tip. Specifically, a COOLIEF* Cooled RF Probe provides a lesion with an average distal projection of 47.18% with a 5.5 mm active tip, 45.53% with a 4 mm active tip and 52.22% with a 2 mm active tip. Additionally, between 20 and 70 watts, a cooled needle used in cooled RF is found to be significantly superior to a conventional needle in duration of ablation, delivered energy and lesion size.[18]

COOLIEF* Cooled RF provides significantly greater and longer-lasting pain relief, improved physical function and higher patient satisfaction than intra-articular steroid injections.

CLINICAL BENEFITS

The differences in lesion characteristics and energy delivery also seem to have an effect clinically. CRFA has shown in clinical studies consistent results for pain relief and functional improvement that last up to a year or longer.[19]

COOLIEF* Cooled RF is also a non-surgical, non-narcotic and effective pain management solution for appropriately selected patients with chronic osteoarthritis (OA) knee pain. Most patients with chronic knee pain have experienced notable pain relief with improved function for up to 12 months following cooled RF

treatment. In a recent OA study, 46.2% of the cooled RF group reported satisfactory joint function based on the Oxford Knee Score after 12 months. At baseline, 67.1% of the CRFA group reported symptoms of severe arthritis, but only 5.2% reported that severity at 6 months and only 11.5% reported that severity at 12 months based on the Oxford Knee Score. Moreover, based on the study results, 65.4% (34/52) of subjects who received the CRFA treatment maintained ≥50% improvement in pain relief from baseline through 12 months after treatment. For patients diagnosed with OA of the knee, study results conclude that COOLIEF* Cooled RF provides significantly greater and longer-lasting pain relief, improved physical function and higher patient satisfaction than intra-articular steroid injections.

OPINIONS IN THE INDUSTRY

In addition, several medical professional organizations have thrown their support behind cooled RF as a viable pain treatment option.

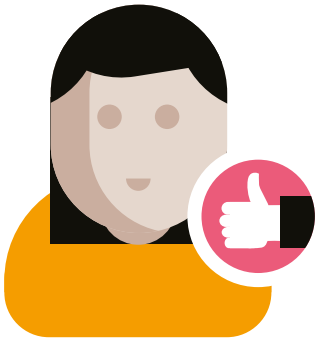
The Spine Intervention Society (SIS), is committed to "assuring that appropriate, effective and responsible treatments are preserved so that patients do not have to suffer or undergo more invasive and often unnecessary surgical procedures"[20] which is why it supports classification of cooled RF procedures as thermal ablative procedures.

The American Society of Interventional Pain Physicians (ASIPP), a non-profit organization consisting of 4,500 interventional pain physicians and other practitioners, cites a systematic review by Simopoulos et al that cooled RF has superior evidence of its durable relief compared to conventional RF, intraarticular steroid injections and other injections for the treatment of sacroiliac joint pain[21].

The American Academy of Physical Medicine and Rehabilitation (AAPM&R) is a national medical specialty organization representing more than 10,000 physicians who are specialists in physical medicine and rehab. AAPM&R physicians treat conditions affecting the brain, spinal cord, nerves, bones, joints, ligaments, muscles and tendons. The AAPM&R acknowledged that the "cooled" name creates misconceptions about the procedure, but verified that it is capable of producing thermal lesions greater than or equal to 80° C.[22]

CONCLUSION

When assessing the best course of treatment for certain patients suffering from chronic pain, thermal radiofrequency (RF) ablation can provide a minimally invasive, non-opioid option. However, not all RF technologies deliver the same results. While the name may suggest otherwise, using cooled RF technology provides the ability to deliver more energy into a larger area than standard RF technology. This results in larger, spherically shaped lesions, the ability to better target known nerve path complexity and variability, and–most importantly–clinically significant improvements in physical function for patients. Don't let the name fool you–using cooled RF technology can provide a superior method for treating patients suffering from chronic pain.



1. COOLIEF* Cooled Radiofrequency Pain Management System: A Revolution in Radiofrequency.
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13. Standard and Cooled Radiofrequency: Thermal Temperature and Lesion Characteristics; Technical Note.
14. Standard and Cooled Radiofrequency: Thermal Temperature and Lesion Characteristics; Technical Note.
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22. American Academy of Physical Medicine and Rehabilitation Position Statement.

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There are inherent risks in all medical devices. For more detail on indications, cautions, warnings and contraindications, click here.

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