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NIMBUS

Nimbus Electrosurgical RF Multi-tined Expandable Electrode

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Introduction

The Nimbus radiofrequency multi-tined expandable electrode aims to improve radiofrequency neurotomy outcomes. Radiofrequency thermal neurotomy (RTN) is recognized as a highly effective intervention for patients suffering from intractable pain. RTN relieves pain by inducing thermal coagulation of a segment of the afferent nociceptive pathway, effectively interrupting transmission of sensory information from a pain generator to the central nervous system and brain.

There is widespread support for the use of RTN in the treatment of a wide range of spinal and non-spinal pain syndromes in the medical literature.[1, 2, 3, 4, 5, 6, 7, 8] Indications range from sacroiliac (SIJ) zygapophyseal facet joint pain and trigeminal neuralgia to pain associated with metastatic disease.

RTN is the neuroablative procedure of choice because:

» It creates a lesion with a predictable size and shape

» The lesion produced is reproducible and repeatable

» It enables accurate lesion temperature feedback via a thermocouple, permitting tissue ablation within a safe and effective range (50°-100° C)

» The availability of motor and sensory stimulation optimizes safe and effective needle placement

Achieving Optimal Results is Challenging

To achieve optimal pain relief, the pain specialist performing RTN must produce the ideal lesion, parallel and adjacent to the target neural pathway.[9] The efficacy of pain relief following RTN hinges on complete destruction of the afferent nociceptive pathway, and the duration of relief is considered proportional to the length of nerve ablated.

> *"RF lesions must be parallel and adjacent to the target nerve to produce sufficient neurotomy for definitive and durable symptom relief."*
>
> (Bogduk N, Macintosh J, Marsland A. Technical limitations to the efficacy of radiofrequency neurotomy for spinal pain. Neurosurgery. 20(4) (1987) 529-35.)

Experience suggests that a 10 mm interruption of the pain-transmitting pathways is desired.

Although various techniques have been developed for delivering the ideal lesion to the target neural pathway, it is often technically challenging to produce an RF lesion of optimal volume and orientation. This is because the lesion resulting from the RF technique not only must be large enough to encompass anatomic variation in the afferent nociceptive pathway but also oriented to optimize the length of the neural pathway coagulated.

The location, volume, and orientation of the RF lesion relative to the target nerve pathway determine whether the RF ablation procedure will create the anatomical interruption necessary for an optimal clinical outcome. In addition to challenges posed by anatomical variation [10, 11, 12, 13, 14, 15] there are operator-dependent variables that influence clinical outcomes such as the scope and extent of the pain management specialist's training and experience as well as the clinician's innate kinesthetic skill.

Historically, the limits of instrumentation – specifically electrode technology – also have compromised RTN outcomes. Using the standard device, a single lumen 16-20 gauge cannula with monopolar electrodes, the clinician may be unable to position the electrodes parallel to the adjacent nerve. Worse still, conventional instrumentation is confounded by even slight anatomic variation in the afferent nociceptive pathway and may produce a lesion that completely misses its target.

> *"The technical accuracy of cervical medial branch neurotomy might be improved by developing superior radiofrequency electrodes."*
>
> (Lord S, McDonald G, Bogduk N. Percutaneous Radiofrequency Neurotomy of the Cervical Medial Branches: A Validated Treatment for Cervical Zygapophysial Joint Pain. Neurosurgery. 36(4) (1995) 732-9.)

The need for improved electrode technology has not gone unnoticed. In a 1995 landmark study, Percutaneous Radiofrequency Neurotomy of the Cervical Medial Branches: A Validated Treatment for Cervical Zygapophysial Joint Pain, Susan Lord, Gregory McDonald, and Nikolai Bogduk observe that, "The technical accuracy of cervical medial branch neurotomy might be improved by developing superior radiofrequency electrodes."

During the past two decades, several techniques have been proposed for reproducibly creating adequately sized target-specific RF lesions. While these techniques do serve to increase lesion volume, their efficacy varies. The limitations of each technique are summarized in the table below.

Figure 1

Strategies for Increasing Lesion Volume	
Technique	**Limitations**
Large Gauge Solid Electrode - Ray Cosman 16 Gauge	» Spherical lesion formation with collateral tissue injury » Multiple heat cycles » Non-disposable
Multiple Contiguous Placements of an 18-20 Gauge Monopolar RF Cannula	» Inherent variability in technique » Requires long OR time and high X-ray exposure
Bipolar RF	» Precise placement may be difficult to accomplish given anatomy and X-ray beam parallax
Simultaneous Parallel Lesions	» Second cannula required » Inter-cannula spacing is critical » Additional tissue trauma per target
Internally Irrigated Cooled-Tip RF Probe	» No active temperature monitoring at probe tip » Requires additional equipment to accomplish

Source: Wright RE, Allan KJ, Kraft M. Radiofrequency Ablation. Using a Novel Multitined Expandable Electrode: Device Description and Research Study. International Journal of Neural Systems. (2012) at press.

A Revolutionary New Design For The RF Electrode

The Nimbus, a novel RF electrode, was developed to produce a larger volume, optimally shaped lesion approximately 8-10 mm in diameter, to enable pain management specialists to more predictably target ablation, including anatomic variation, using technically simple, easily mastered electrode placement techniques. The Nimbus RF electrode increases the functional electrode surface area, spreads electrical current density and increases the volume of tissue heated resulting in a larger ablation zone.

The Nimbus RF electrode design specifications include:

- Optimal 8-10 mm lesion diameter
- Lesion offset from central axis of cannula to allow directed lesioning of target to better spare collateral tissue
- Capable of meaningful motor and sensory stimulation
- Down the beam, perpendicular approach to target nerves
- Contains lumen for injection
- Robust, simple, mechanical design, compatible with existing RF generators
- No additional equipment requirement
- Efficient with short heat cycle/target

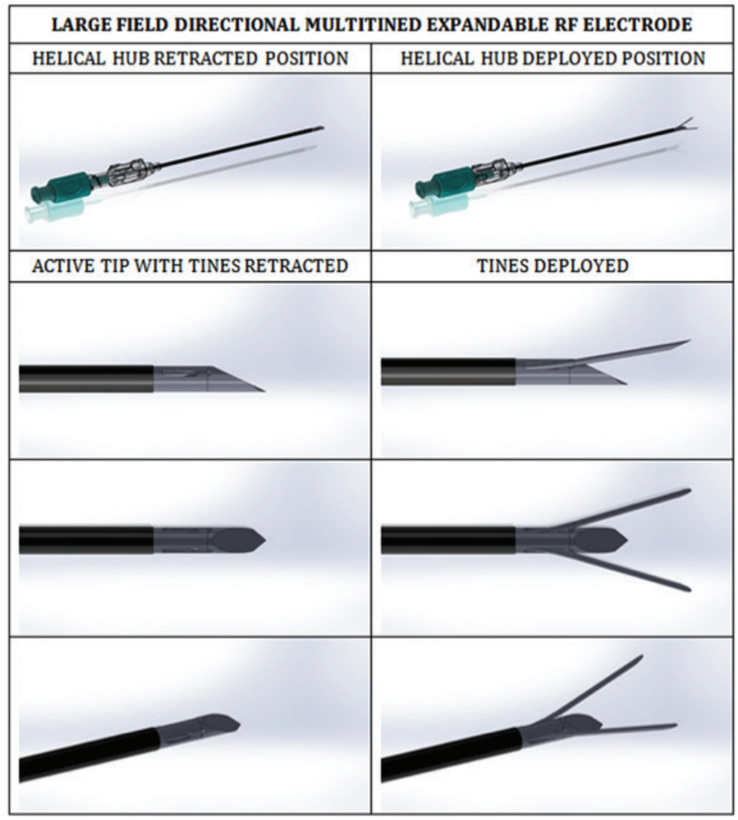
The device uses expandable metal tines to diffuse the RF current density in the target tissue thereby increasing the functional electrode surface area. Increased functional electrode surface area proportionately increases the volume of tissue heated producing a larger ablation zone compared to results from a standard monopolar cannula. The tines are deployed and retracted with a simple helical rotation of the hub. (See Figure 2)

When deployed, the tines function as antennae, expanding and concentrating the current density and predictably enlarging the lesion.

Because they are unilaterally offset from the axis of the central cannula they create a directional lesion that enables selective targeting of the nociceptive pathway with decreased collateral tissue damage.

Moreover, the distance the lesion propagates from any active electrode surface is limited and predictable. This attribute of the lesion is vitally important because it allows meaningful sensory and motor stimulation. To further ensure patient safety, the internal design of the device couples the tines and the central cannula with the inserted thermocouple permitting real-time monitoring of critical temperatures in the ablation zone. A central lumen allows insertion of a standard thermocouple and/or anesthetic or medication injection prior to lesion.

Figure 2



Source: Wright RE, Allan KJ, Kraft M. Radiofrequency Ablation. Using a Novel Multitined Expandable Electrode: Device Description and Research Study. International Journal of Neural Systems. (2012) at press.

PRECLINICAL TESTING

More extensive safety, reliability, and technical efficacy testing of the new device than required by U.S. and international regulatory agencies began in 2009.

> *"If novel electrodes are developed, their reliability and safety would need to be tested in the laboratory before their use in clinical research or practice."*
>
> Lord S, McDonald GJ and Bogduk N. Radiofrequency Neurotomy of the Cervical Medial Branches: A Validated Treatment for Cervical Zygapophysial Joint Pain. Neurosurgery Quarterly. 8 (1998) 288 308.

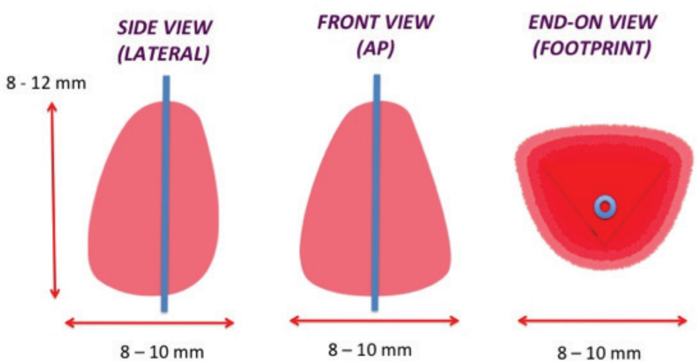
EX-VIVO VISIBLE TISSUE COAGULATION

Following proof-of-concept testing the initial aim was to estimate the size and reproducibility of the lesion shape based on visible coagulation of raw tissue. Electrodes were placed in surface contact with tissue samples and inserted into other tissue samples after all were equilibrated in a 37°C water bath. More than 100 lesions were created in muscle tissue and organ tissue.

Heating cycles intended to closely reproduce clinical practice were performed using commonly available RF generators (range 60 seconds -240 seconds / 65°-90°C) and lesion size was measured.

There was no evidence of anomalous heating such as boiling, charring, or cavitation. Data compiled for all heating cycles revealed minimal variation in lesion size beyond a 75°C/80 second threshold. The lesion produced was highly reproducible and consistently directional with an average volume of 467 +/- 71 mm3/ lesion. The lesions assumed an elongate spheroid shape and were offset from the central axis toward tines. A graphic showing the size and orientation of the lesion was created.

Figure 3



EX-VIVO THERMAL MAPPING

After determining that the electrode consistently produced a large volume directional lesion based on visible coagulation, testing was repeated using thermal imaging. Figure 4 shows the surface tissue contact model, which was calibrated by a Flir T-400 color thermal camera and monitored throughout the full lesion cycle. This testing was intended to qualitatively evaluate the evolution of the heat signature as the lesion matured and monitor its development for thermal evidence of hotspots, asymmetric tine activation, or unstable isotherms.

The correlation between the actual infrared measured peak lesion temperature and the thermocouple reported temperature was recorded. An RF generator with graphic display of power and impedance provided additional documentation of the stability of the multitined electrode design. All samples displayed symmetrical activation of the tines and even progression from initial coagulation around distal tine tips to consolidation at the central cannula.

All of the lesions showed thermally balanced isotherms with no hot spots or anomalies and mature lesions had a 55°C isotherm, consistent with the observed visible coagulation profile. Peak temperature measurements between the IR (infrared) instrument and the RF generator were closely correlated. Power and impedance ramping was smooth, stable, and consistent with values observed with the reference monopolar cannula. A graphical representation of a typical heat lesion formed with the electrode and a cross sectional diagram of representative isotherm distribution are shown in figures below.

Figure 4

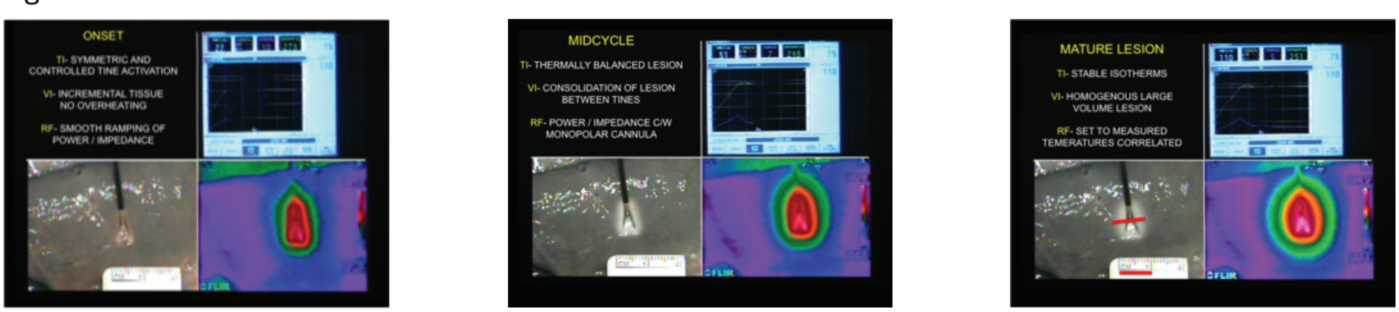


Figure 5

TC-2 recorded temperature at the adjacent exiting spinal nerve = 37.3 C.

TC-2 recording temperature lateral to the electrode = 37.7 C.
TC-2 recorded at active tip = 74.7 C. (RF generator set for 75 C.)

TC-2 recording temperature at the base of the SAP = 63.5 C.
TC-2 near the mammillary process (know location of anatomic variation) = 48.3 C.

IN-VIVO THERMAL MAPPING

Visible coagulation and thermal imaging studies documented the formation of consistent lesion geometry with a predictable thermal signature. In-vivo thermal mapping method was performed by placing the Nimbus large-field directional RF electrode at the base of the superior articular process (SAP) of L4 and L5 to target the course of the medial branch. A “down-the-beam” or “gun barrel” technique was used and consistently produced an optimally shaped 10 mm lesion, indicating that this technique will likely result in a technically superior lumbar medial branch neurotomy.

The in-vivo temperature mapping confirmed a safe and technically effective thermal profile consistent with the ex-vivo results. Importantly, neurodestructive temperatures were achieved in the target tissue without undesirable heating of collateral structures or adjacent spinal nerves. In addition, thermal bias toward the direction of the tines the directional nature of the lesion was reconfirmed.

CONCLUSIONS

The Nimbus multi-tined, expandable RF electrode was developed using dual deployable tines for electrical field diffusion and increased functional electrode surface area. The lesion it produces is geometrically predictable and thermally stable.

The innovative design of the electrode and the geometry and stability of the tissue lesion it produces are uniquely suited to safe, technically efficient and effective interruption of nociceptive pathways. Based on detailed anatomical research into afferent pain pathways, the innovative electrode design enables practitioners to consistently achieve appropriate tissue ablation with fewer heat cycles and less global tissue trauma compared to the current technology.

The advent of a technologically advanced RF electrode that creates directional and optimally-sized lesions for neurotomy holds great promise for interventional pain management. The design simplifies technique and readily adapts to various RF ablation targets including the cervical, thoracic and lumbar zygapophyseal joints, the sacroiliac joint, and other targets along the spinal sympathetic chain.

References

[1] Lord S, McDonald GJ and Bogduk N. Radiofrequency Neurotomy of the Cervical Medial Branches: A Validated Treatment for Cervical Zygapophysial Joint Pain. Neurosurgery Quarterly. 8 (1998) 288-308.

[2] Govind J, King W, Bailey B and Bogduk N. Radiofrequency neurotomy for the treatment of third occipital headache. J Neurol Neurosurg Psychiatry. 74 (2003) 88-93.

[3] Dreyfuss P, Halbrook , Pauza K, Joshi A, McLarty J and Bogduk N. Efficacy and validity of radiofrequency neurotomy for chronic lumbar zygapophysial joint pain. Spine. 25 (2000) 1270-7.

[4] Cohen SP, Hurley RW, Buckenmaier 3rd CC, Kurihara C, Morlando B and Dragovich A. Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain. Anesthesiology. 109 (2008) 279-88

[5] Zhou Y, Zhao Y, L Bi, et al. Meta-analysis of radiofrequency ablation versus hepatic resection for small hepatocellular carcinoma. BMC Gastroenterol. 10 (2010) 78.

[6] Manchikanti L. The role of radiofrequency in the management of complex regional pain syndrome. Curr Rev Pain. 4 (2000) 437-44.

[7] Rivera F, Mariconda C and Annaratone G. Percutaneous radiofrequency denervation in patients with contraindications for total hip arthroplasty. Orthopedics. 35 (2012) e302-5.

[8] Hansen H, Manchikanti L, Simopoulos TT, Christo PJ, Gupta S, Smith HS, Hameed H and Cohen SP. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. Pain Physician. 15(3) (2012)

[9] Bogduk N, Macintosh J, Marsland A. Technical limitations to the efficacy of radiofrequency neurotomy for spinal pain. Neurosurgery. 20(4) (1987) 529-35.

[10] Lord SM and Bogduk N. Radiofrequency procedures in chronic pain. Best Pract Res Clin Anaesthesiol. 16(4) (2002) 597-617.

[11] McDonald GJ, Lord SM and Bogduk N. Long-term follow-up of patients treated with cervical radiofrequency neurotomy for chronic neck pain. Neurosurgery. 45(1) (1999) 61-68.

[12] Chua WH and Bogduk N. The surgical anatomy of thoracic facet denervation. Acta Neurochir (WIEN). 136(3-4) (1995) 140-4.

[13] Lau P, Mercer S, Govind J and Bogduk N. The surgical anatomy of lumbar medial branch neurotomy (facet denervation). Pain Med. 5(3) (2004) 289-98.

[14] Burnham RS and Yasui Y. An alternate method of radiofrequency neurotomy of the sacroiliac joint: a pilot study of the effect on pain, function, and satisfaction. Reg Anesth Pain Med. 32(1) (2007) 12-9.

[15] Yin W, Willard F, Carreiro J, Dreyfuss P. Sensory stimulation-guided sacroiliac joint radiofrequency neurotomy: technique based on neuroanatomy of the dorsal sacral plexus. Spine. 28 (2003) 2419-25.

[16] Hansen H, Manchikanti L, Simopoulos TT, Christo PJ, Gupta S, Smith HS, HameedH and Cohen SP. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. Pain Physician. 15(3) (2012).

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