

MINIMALLY INVASIVE SURGERY FOR PAIN

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Radiofrequency Ablation Using a Novel Multitined Expandable Electrode: Device Description and Research Study

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Abstract: Durable pain remission using radiofrequency thermal neurotomy (RTN) requires thoughtful patient selection and a lesion of optimal size and position. Success necessitates complete ablation of approximately 8-10 mm of the targeted neural pathway. Technical failure may result if anatomic variations in the targeted pathway are not incorporated into the lesion and if the electrode is not positioned optimally relative to the target nerve. This paper presents an improvement in RF electrode design intended to improve RTN outcomes.

Keywords: Radiofrequency thermal neurotomy, pain management

INTRODUCTION

In the three decades since Bogduk and Long published accurate targets for lumbar zygapophyseal joint denervation, radiofrequency thermal neurotomy (RTN) has emerged as a useful interventional pain management technique. RTN relieves pain by inducing thermal coagulation of a segment of the afferent nociceptive pathway, effectively interrupting pain signal transmission. Historically, various techniques have been described for delivering the ideal lesion to the target neural pathway. Nonetheless, there is the inherent challenge posed by anatomical variation [2-7], as well as operator-dependent concerns such as the scope and extent of operator training and experience as well as individual kinesthetic skill.

In this paper we present the first multitined expandable radiofrequency electrode specifically designed for the field of interventional pain management. The electrode was developed to consistently, efficiently, and safely produce a lesion of such size and shape that predictable afferent nociceptive pathway ablation (including anatomic variation) could be readily accomplished using technically straightforward, easily mastered techniques.

BACKGROUND

Neurodestructive procedures have been a part of the pain management armamentarium since the early 20th century. Various techniques have been described for interrupting afferent nociceptive transmission along a well-defined neural pathway including open surgical neurectomy, chemical neurolysis, cryoneurotomy, and radiofrequency thermal neurotomy.

Of these techniques, Radiofrequency Thermal Neurotomy (RTN) has emerged as the neurodestructive modality of choice. It is the technique most frequently used by modern pain medicine interventionalists. Support for the use of RTN in the treatment of diverse spinal and non-spinal pain syndromes is well documented in the medical literature [2-9].

HISTORY

The scientific basis for RTN dates back to the late 1800s when the French physicist Henri Becquerel first demonstrated electrocautery by passing direct current (DC) electricity through a wire embedded in human tissue to cauterize bleeding. In 1891, Jacques-Arsene d'Arsonval discovered that high frequency alternating electric current could be passed through the body without an electric shock. Specifically, frequencies of 20 kHz or higher could create heat in tissue without causing neuromuscular excitation. In the early 1900s K.F. Nagelschmidt, a German physician introduced the concept of diathermy to explain how high frequency electrical current generated heat in the body through ionic agitation of molecules. In addition to adding the term diathermy to the medical lexicon, he developed the original machines capable of fulguration, desiccation, and cutting.

In 1928, Harvey Cushing, an American neurosurgeon, and William T. Bovie, an American physicist, developed the first electrocautery device. This scientific history

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is relevant because the general biophysical principles underlying electrocautery and radiofrequency thermal ablation are similar. It is, however, important to bear in mind that the power and frequency ranges used for RTN are not intended to burn or oxidize the target tissue but instead are optimized to produce in-situ controlled tissue coagulation.

Early reports of pain management via thermal ablation include the publication of Kirschner in 1932, who used electrocoagulation of the Gasserian ganglion to treat trigeminal neuralgia [2]. Three decades later, in 1965, Mullan described a technique he developed to treat malignant pain by using direct current to create a thermal lesion for percutaneous unilateral cordotomy [2]. Rosomoff modified this technique, using alternating RF current to obtain a more predictable, circumscribed lesion relative to direct current [2]. In 1974, Sweet reported that RF treatment of the Gasserian ganglion was among the most effective interventions when conservative treatment of trigeminal neuralgia failed [2]. Shealy introduced RF ablation into the field of spinal pain management in 1973 with descriptions of its use for zygapophyseal joint pain [3].

The modern era in generator technology commenced with the first commercial radiofrequency (RF) lesion generator built in the early 1950s by Cosman, Aronow, and Wyss [2]. A significant technological and safety milestone was achieved in the 1970s with the introduction of thermocouple technology for direct monitoring of the temperature at the tip of the electrode while lesioning. Most recent refinements in RF generator technology have occurred around simplifying the user interface, and developing simultaneous multi-lesion capability.

Perhaps the most notable advance in electrode technology occurred several decades ago with the development of a 16 gauge solid electrode with imbedded thermocouple by Charles D. Ray and Eric R. Cosman. The RRE-TC, as marketed, is the historic reference standard electrode, and has been used in many critical studies validating the clinical effectiveness of RTN [2, 3, 9].

Various single lumen monopolar cannulas have been developed since the 22-gauge electrode was introduced in 1980 (SMK-system). Today, the 18 and 20 gauge single lumen monopolar electrodes are still commonly available and widely used.

In 1997 Goldberg et al. reported on the internally irrigated cooled-tip RF probe. Initially developed with the goal of providing larger volume lesions for treatment of metastatic disease in the liver, the technology has been applied to treating various spinal pain syndromes since 2005 [2-4].

BIOPHYSICS

Biological tissue has impedance, or resistance to current flow. When low energy high frequency (100-500 kHz) current is passed through tissue, electromagnetic energy is converted to resistive heating around the RF electrode

delivering the current. This tissue heating is driven by the rapid oscillation of charged molecules. When dipolar water molecules in the tissue attempt to align with the rapidly alternating field heat is produced from the strain on covalent bonds [2]. Alherts et al. demonstrated that frequencies higher than 250 kHz produce the most uniform lesions with modern RF generators typically delivering 450kHz – 500 kHz frequencies [2]. A thermocouple inside the RF device positioned proximally to the active electrode tip measures the temperature of the tissue at the tissue/electrode interface, and provides feedback to the RF generator, which regulates power output to achieve the desired target ablation temperature. A tissue temperature of 45°C is required to initiate the microscopic cellular changes consistent with neuroablation [2], whereas a temperature greater than 100°C will result in boiling, steam formation, cavitation, and undesired tissue damage. A temperature of 60°C is associated with soft tissue coagulation and is appropriate for RF thermal neurotomy. Achieving this temperature threshold in tissues not in direct contact with the electrode requires tolerating 80-90°C at the electrode/tissue interface. The RF induced zone of coagulation (lesion size) is determined primarily by; current density, the duration of heat cycle (time), the temperature maintained at the electrode/tissue interface, size (length/gauge) of the active electrode surface, and surrounding tissue impedance.

Tissue heating is related directly to the current density (I) and inversely to the fourth power of the radius (R) from the electrode ($T=IR^{-4}$) with temperature dropping quickly as distance from the active electrode surface increases. Based on the current density distribution most thermal coagulation extends radially around the circumference of the exposed shaft of the electrode, with minimal propagation distal to the tip of the electrode. For the conventional monopolar electrode the lesion assumes the shape of a prolate ellipsoid, not unlike an American football, that forms around the active tip of the RF electrode with most coagulation occurring along the exposed shaft and little distal projection of the lesion off the tip of the electrode. The RF lesion propagates from the active surface of the electrode as dictated by current density distribution until rising resistance in the coagulated tissue limits further coagulation. Impedance “roll-off” occurs after approximately 90 seconds at a thermocouple temperature of 80°C, with neither additional time nor increased temperature resulting in further lesion propagation. This predictable rise in tissue resistance places a reliable upper limit on the diameter of an RF induced lesion with the radius of the resulting lesion equal to 1-2 times the diameter of the electrode.

Neurostimulation is commonly used in conjunction with imaging for neurophysiological confirmation of a safe and effective electrode placement. Sensory stimulation involves sending a low voltage, low frequency (less than 0.5 V at approximately 50 Hz) electrical signal into the tissue. Some clinicians find sensory stimulation useful for approximating the electrode to the target pathway. If the patient experiences a referred sensation (paresthesia)

IMPACT OF ACTIVE TIP POSITION RELATIVE TO TARGET NERVE (RED)

Active tip of the RF cannula placed parallel and adjacent to the largest nerve.



10mm thermal disruption of nociceptive pathway. Technically successful result.

Active placed perpendicular to the target nerve.



Point or "spot" lesion. Technically unsuccessful result.

Target nerve outside of the diameter of active coagulation.



Suboptimal placement or unrecognized anatomic variation. Technically unsuccessful result.

Figure 1. Impact of Active Tip Position Relative to Target

STRATEGY FOR INCREASING LESION VOLUME

Technique	Limitations
Large Gauge Solid Electrode – Ray Cosman 16 Gauge	Tissue trauma. No Lumen for anesthetic injection. Spherical lesion formation with collateral tissue injury. Heat cycles / target required. Non-disposable.
Multiple contiguous placements of an 18 – 20 gauge monopolar RF cannula	Operator-dependent number of placements introduces inherent variability in technique. Repositioning RF cannula after local anesthetic has been injected and stimulation cannot be repeated decreases safety. Meticulous cases using multiple placements/ lesions require long OR time and high X-ray exposure.
Bipolar RF	Second cannula required per target. Inter-cannula spacing is known to be critical, but definitive research in a variety of tissue types is not available. Width of coagulated strip of tissue is unlikely to be larger than the diameter of each cannula. 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
Fluid Injection during Monopolar or Bipolar RF	Difficult to extrapolate the ex-vivo model to in vivo anatomy. In-vivo effect likely to be significantly more variable than the lesion model studied. Does not change the requirement to place the monopolar RF cannula parallel and adjacent to target nerve.
Internally Irrigated Cooled-Tip RF Probe	Cannot verify active tip placement with motor or sensory stimulation. No active temperature monitoring at probe tip. Spherical lesion may cause unintended collateral tissue damage. Requires additional equipment to accomplish.

Table 1. Strategy for Increasing lesion volume.

into the area of their typical pain at low voltage then the electrode is likely placed in close proximity to the target nerve pathway. Conversely motor stimulation is a means of ensuring that the electrode is sufficiently far enough away from a motor nerve to cause no harm during the active heating cycle. The process of motor stimulation involves pulsing an electrical signal of 1.5V - 2 V at 2 Hz into the tissue in contact with the active tip. The absence of muscle contractions during motor stimulation indicates that the active surface of the RF electrode is positioned sufficiently far enough away from the nerve so as to not create unintended thermal damage during the lesioning process. A negative motor stimulation test means that the nerve of concern is a greater distance from the electrode than a >1.5 V 2Hz signal can travel. As described previously, the RF lesion is limited and predictable in propagation length and does not extend into the tissue farther than the motor stimulation signal travels. Hence, motor stimulation performed before lesioning can play a significant role in procedural safety.

The principal advantages of RTN over other neurodestructive techniques include:

- Predictable, reproducible and repeatable lesion size and shape;
- Ability to monitor tip temperature to maintain tissue temperatures within a safe and effective range (45 -100°C)
- Pre-lesion motor/sensory stimulation to optimize safety and efficacy.

Any contemplated novel electrode technology should at a minimum preserve these features.

EVOLVING RF TECHNIQUES AND TECHNOLOGY

High-grade pain relief following RTN depends on thorough destruction of the targeted nociceptive pathway. Duration of relief correlates with the length of nerve coagulated. Heuristically, a 10 mm interruption in the pain transmitting pathway is desired.

A fundamental technical challenge to successful RTN is the requirement for producing an RF lesion of optimal volume and orientation. Specifically, the lesion (zone of tissue coagulation) resulting from the RF technique not only must be of sufficient size to encompass anatomic variation in the afferent nociceptive pathway but also oriented to optimize the length of the neural pathway coagulated. Simply stated, the location, volume, and orientation of the RF lesion relative to the target nerve pathway collectively determine whether any given RF ablation procedure will provide the requisite anatomical interruption for a favor-

The effectiveness of RTN is currently limited by available electrode technology. Commonly used 16-20 gauge monopolar electrodes with 5-10 mm active tip all create the prolate ellipsoid lesion described previously. They differ only in regard to tissue volume treated per heat cycle. This lesion geometry is suboptimal in terms of shape and volume.

Firstly, the active tip of the electrode must be parallel and adjacent to the targeted neural pathway to achieve a length of neurotomy that corresponds to the length of the active tip. Any angle of incidence off the parallel plane will decrease the length of neurotomy, with perpendicular placement resulting in the least effective "point-lesion". It is important to remember that the duration of clinical response correlates with the length of nerve coagulated. For even the most experienced practitioner, ideal parallel adjacent placement of the active tip is difficult to consistently achieve. For some anatomical targets optimal placement is simply not achievable with current electrode designs.

The second major limitation of the conventional monopolar cannula is that a single lesion rarely if ever incorporates the variation in anatomy of the nociceptive pathway. Technical failure may result if anatomical variations in the targeted pathway are not incorporated into the lesion and if the electrode is not positioned optimally relative to the target nerve [8]. Cadaver studies demonstrate anatomic variability in the innervation of all common spinal targets, with extreme variability observed in the lateral branches innervating the sacroiliac joint and the thoracic posterior column [2]. Table 1 broadly summarizes active tip placement relative to target nerve.

Over the past two decades, various strategies have been proposed for reproducibly creating adequately sized target-specific RF lesions [2]. These include large gauge solid electrodes, multiple placements of a single lumen monopolar RF electrode, bipolar RF circuit, simultaneous parallel RF lesions, infusion of fluid concurrently with RF lesion, and an internally cooled RF probe [2]. Research in this area suggests widespread awareness that larger lesions are clinically desirable [32]. Although all of these techniques act to increase lesion volume, their efficacy varies. The limitations of each technique are summarized in Table 1.

In response to the prevailing consensus in the field of interventional pain management that a larger volume lesion, optimally shaped, and approximating an 8-10 mm diameter, is desirable and useful, a novel RF electrode was developed. The intent was to incorporate the beneficial features of the current state of the art device, while minimizing its limitations.

The following design performance requirements were set for the new device:

1. Optimal 8-10 mm lesion diameter
2. Lesion offset from central axis of cannula to allow directed lesioning of target to better spare collateral tissue

3. Capable of meaningful motor and sensory stimulation
4. Contains lumen for injection
5. Robust, simple, mechanical design, compatible with existing RF generators.
6. No additional equipment requirement.
7. Cost-effective manufacture promoting widespread adoption.
8. Efficient with short heat cycle/target.

The device was designed using deployable 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 resulting in an enlarged ablation zone relative to a standard monopolar cannula. The tines are deployed and retracted from the distal central cannula by a simple helical rotation of the hub (figure 2). When deployed, the tines function as antennae, expanding and concentrating the current density and predictably enlarging the lesion. They are unilaterally offset from the axis of the central cannula creating a directional lesion that facilitates selective targeting of the nociceptive pathway with decreased collateral tissue damage. The current density and heat concentrate along the shaft of the tines with little extension distal to the tips. Additionally, the distance the lesion will propagate from any active electrode surface is limited, predictable, and governed by the same biophysical principles seen with conventional monopolar cannula. This characteristic of the lesion is critical and allows meaningful sensory and motor stimulation. For enhanced 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 is incorporated for insertion of a standard thermocouple as well as for anesthetic or medication injection prior to lesion.

PRECLINICAL TESTING

Extensive safety, reliability, and technical efficacy testing of the new device began in 2009. In addition to medical device testing mandated by international and domestic regulatory agencies further studies were performed [2].

EX-VIVO VISIBLE TISSUE COAGULATION

Following proof-of-concept testing using egg-white medium to observe coagulation, the initial priority 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 made using both muscle tissue (chicken, tuna), and organ tissue (liver). Heating cycles intended to replicate clinical practice were performed using commonly available RF generators

(range 60 seconds – 240 seconds / 65°C. – 90°C.) and lesion size was measured. Tissue samples with embedded electrodes were sectioned along multiple planes parallel to the central axis of the cannula, or along multiple planes at 90 degrees to the central cannula. In samples sectioned perpendicular to the central cannula the lesion length toward the tines was differentiated from the lesion length away from the tines to establish the directional nature of the lesion (Figure 3).

No evidence of anomalous heating such as boiling, charring, or cavitation was observed or measured. Data were compiled for all heating cycles. Minimal variance in lesion size was noted beyond a 75°C/80 second threshold. The fully mature lesion required these parameters, but additional time and/or temperature did not have a noticeable effect on lesion progression. The lesion was highly reproducible and consistently directional. Calculated volume averaged 467 +/- 71 mm³/lesion. Topography was elongate spheroid and offset from the central axis toward tines. A representative graphic was generated (Figure 4).

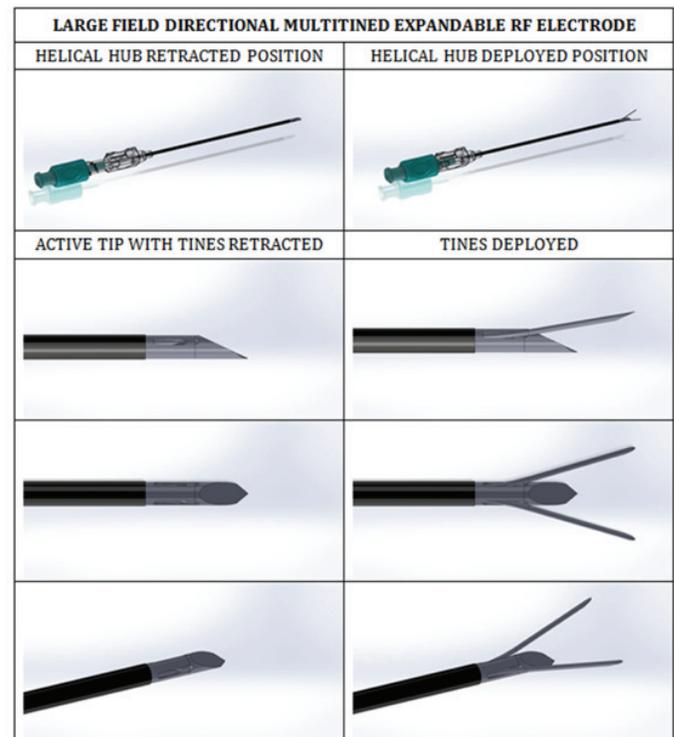


Figure 2 . Large Field Directional Multitined Expandable RF

EX-VIVO THERMAL MAPPING

After ascertaining that the electrode consistently produced a large volume directional lesion based on visible coagulation, testing was repeated using thermal imaging. A surface tissue contact model, illustrated in Figure 7, and a calibrated Flir T-400 color thermal camera monitored the full lesion cycle. The objective of this testing was to qualitatively monitor the evolution of the heat signature through to the mature lesion phase. Any thermal evidence of hot-spots, asymmetric tine activation, or unstable isotherms

therms was sought. The correlation between actual infrared measured peak lesion temperature and the thermocouple reported temperature was documented. An RF generator with graphic display of power and impedance was used for additional documentation of the stability of the multitined electrode construct.

In all samples the activation of the tines was symmetrical with smooth progression from initial coagulation around distal tine tips to consolidation at the central cannula. All lesions demonstrated thermally balanced isotherms without hot spots or anomalies. The mature lesion demonstrated a 55°C. isotherm closely matching the observed visible coagulation profile. There was close correlation in peak temperature measurements between the IR instrument and the RF generator. Power and impedance ramping was smooth, stable, and consistent with values observed with the reference monopolar cannula.

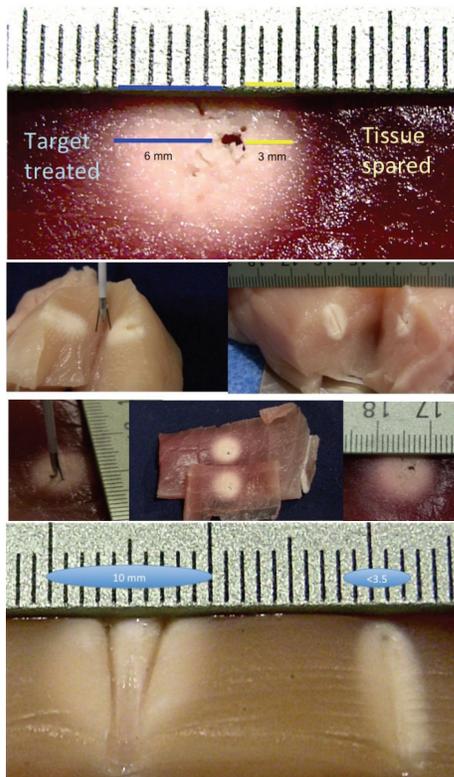


Figure 3. Tissue Samples with embedded electrodes.

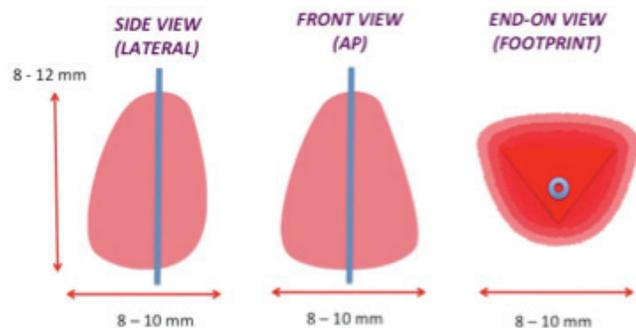


Figure 4. Representative Graph, Lesion Progression.

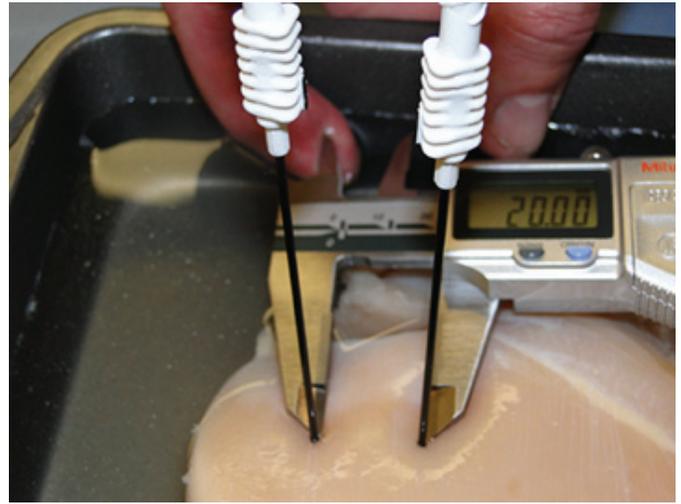


Figure 5. Electrodes Placed 20mm Apart Create a Well-Defined Bipolar Lesion.

IN-VIVO THERMAL MAPPING

The visible coagulation and thermal imaging studies documented the formation of consistent lesion geometry with a predictable thermal signature. No device safety concerns were identified, and the electrodes functioned within design specifications. Though the results of bench testing were compelling, it is well understood that thermal therapies may perform quite differently when tested in-vivo.

The in-vivo thermal mapping method consisted of placing the novel 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 facile “down-the-beam” or “gun barrel” technique was used, as described for diagnostic medial branch blocks. The consistent appearance of an optimally shaped 10 mm lesion footprint in all visible coagulation studies suggests that this technique will result in a technically superior lumbar medial branch neurotomy.

Once positioned the tines were deployed in a medial direction toward the SAP. A second separate electrode with 2 mm active tip was placed sequentially in the adjacent neural foramen near the lateral branch pathway at

the active electrode tip and onto the mammillary process of the SAP where anatomic variants of the medial branch can occur. Once temperature control 2 [TC-2] placements were obtained, heating of the primary multitined electrodes was accomplished with a Radionics RFG 3C RF generator set at 75°C for 80 seconds.

Average temperatures in were; 74.7°C at the active tip, 37.3 at adjacent spinal nerves, 37.7°C near the lateral branch, and 48.3°C at the mammillary process of target SAP.

The in-vivo temperature mapping demonstrated a safe and technically effective thermal profile consistent with ex-vivo results. Neurodestructive temperatures were achieved at the target tissue without undesirable heating of collateral structures or adjacent spinal nerves. The directional nature of the lesion was again demonstrated by documenting thermal bias toward the direction of the tines. For this target it is useful to cover the SAP up to the mammillary process as anatomic variants may arise anywhere along the SAP to the mammillary process [5].

Case Report: In-Vivo RF Thermal Medial Branch Neurotomy of the Lumbar Zygapophyseal Joint With EMG of the Segmental Multifidus

Following informed consent a 47-year-old male with established lumbar zygapophyseal joint pain (R L4/5) was treated. Using posterior oblique fluoroscopic guidance the RF electrode was advanced “down the beam” to the mid base of the right L4 superior articular pillar (SAP). The tines were then deployed medially toward the base of the SAP into the groove containing the L3 medial branch nerve. Placement was confirmed with both multi-planar fluoroscopy and neurostimulation (at 2 Hz, and 50 Hz, respectively). A Radionics RFG 3C RF generator was ramped to 75°C for 80 seconds. The procedure was repeated at L5 (L4 MB). Impedances were <250 ohms and power levels remained less than 10 watts. EMG evaluation of the L3-L5 lumbar multifidi was obtained at 20 days post-procedure. Follow-up at 30 days revealed an uncomplicated recovery and resolution of zygapophyseal-joint related pain. EMG demonstrated electrodiagnostic evidence of active and acute denervation of the right lumbar paraspinals at the L4, and L5 levels. Ipsilateral and contralateral L3 levels appeared normal. At 9 month follow-up the pain had not returned.

PRELIMINARY CLINICAL EXPERIENCE

The CE mark was obtained on June 18, 2012 and on September 21, 2012 the FDA approved the device for use in radiofrequency (RF) heat lesion procedures of relief of pain. With the scientific basis for safety and efficacy established by ex-vivo coagulation studies and reference in-vivo thermal mapping, the device was introduced to carefully selected centers in the USA, Canada, and Europe. The

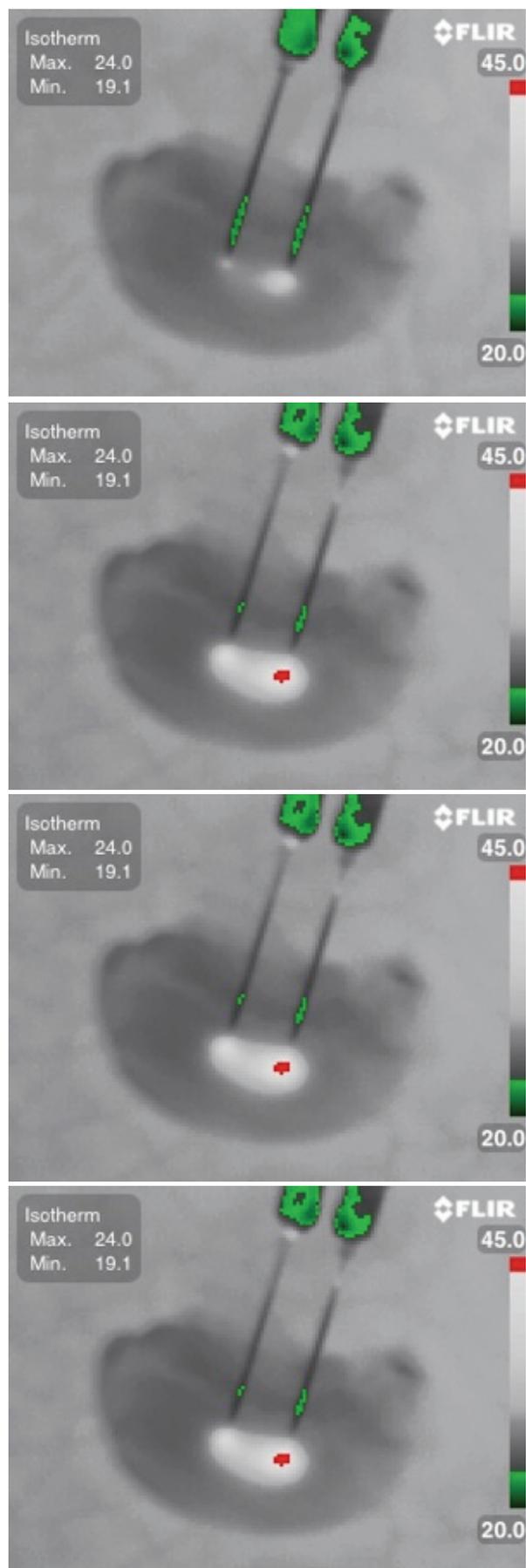


Figure 6. Surface thermography shows successive stages of lesion bipolar development

goals for the initial clinic experience were to: establish optimal techniques for the common spinal targets; prospectively track clinical response and document all complications related to the procedure; use these pilot study data to inform more extensive clinical studies and; arrive at a reasonable price for the device based on a procedural efficiency analysis.

CLINICAL APPLICATIONS

For purposes of pilot studies and early clinical experience sufficient anatomical and procedural literature exists for selected RF targets to allow extrapolation of the novel lesion geometry into a rational technique. Techniques continue to evolve as more clinical data become available. At the time of this publication more than 200 cases had been done worldwide without reported complication. Examples of cases from this initial group are presented.

COST

Today, even significant innovations must demonstrate measurable, consistent cost savings. The framework selected for evaluating the cost-effectiveness of the Nimbus device was a head to head comparison with conventional 18 gauge single lumen monopolar electrodes. The procedure was single level bilateral lumbar L5-S1 zygapophyseal joint denervation targeting the L4 medial branch and the L5 dorsal ramus. Four conventional electrodes were placed to target using the standard described “pillar-view” technique to ensure optimal parallel-adjacent placement of the active tip relative to the target nerve. Three lesions per nerve were made with the conventional electrode to create sufficient lesion volume to ensure ablation of target nerve pathway. A multilesion approach was used simultaneously activating the four conventional electrodes for each 80C x 110-second heat cycle. Total procedure time, and total X-ray exposure from the conventional technique were compared to a technique using a single Nimbus electrode placed sequentially onto target nerves using a “down-the-beam” technique advancing the central electrode cannula to the mid base of the superior articular process (SAP) at the juncture of the SAP and either transverse process or sacral ala in the case of the L5 dorsal ramus. Tines were directed to optimize target coagulation and spare collateral tissue damage. A single lesion was performed using an 80C x 110-second heat cycle. Total time of each procedure, total X-ray exposure from fluoroscopy, anesthesia time, and total cost of OR time were calculated for each technique.

The Nimbus technique was associated with greater than 40% savings in all variables tracked, thus enabling the same number of procedures to be performed at a significant savings in actual costs as well as X-ray related risks to the patient and OR team. In systems where a premium is placed on increasing the number of cases performed during a given work period, these data support significant

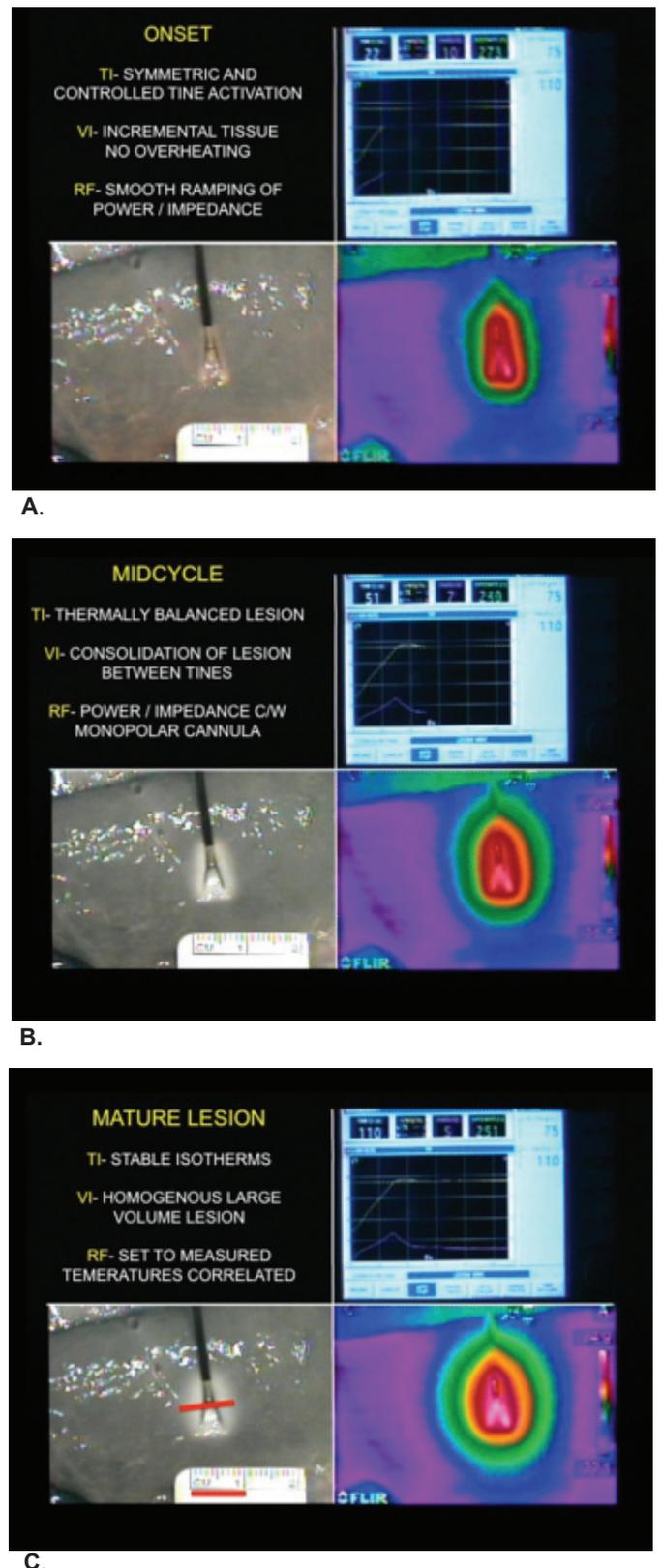
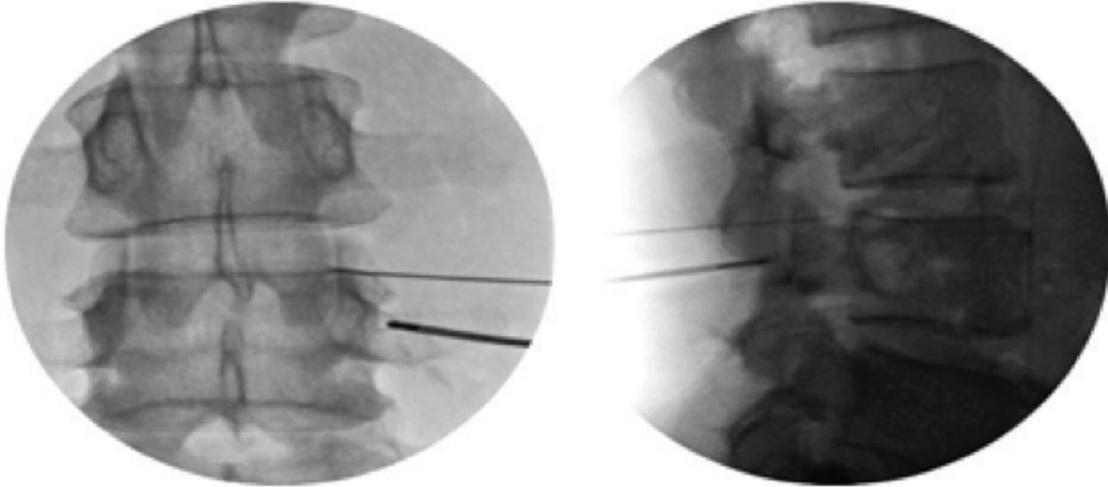
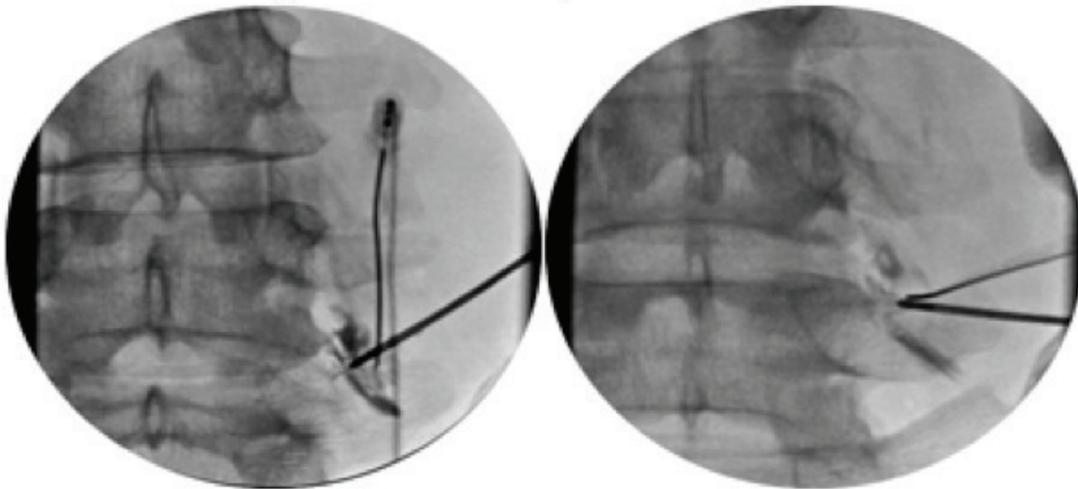


Figure 7. Surface Tissue Contact Model **A.** Onset **B.** Midcycle **C.** Mature Lesion

A.



B.



C.

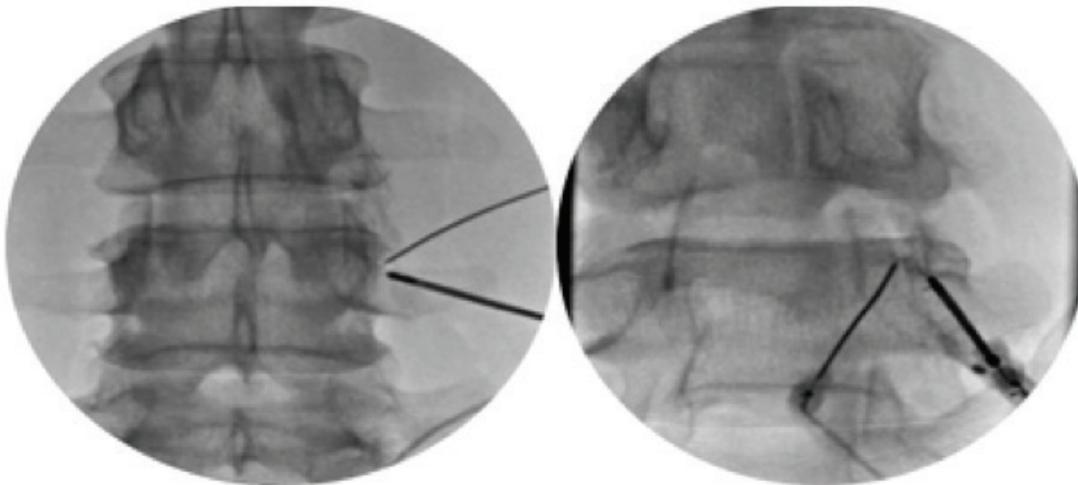


Figure 8. A. TC-2 recorded temperature at the adjacent exiting spinal nerve = 37.3°C. **B.** TC-2 recording temperature lateral to the electrode = 37.7°C. TC-2 recorded at active tip – 74.7°C (RF generator set for 75°C). **C.** TC-2 recording temperature at the base of the SAP = 63.5°C. TC-2 near the mammillary process (known location of anatomic variation) = 48.3°C.

gains in numbers of patients served. For example these efficiencies would permit a practice currently performing 500 RF procedures yearly to perform 700 cases/year.

Definitive assessment of the true value of the device will require factoring technical success and durability of pain relief into the quality-cost benefit analysis as these data become available. However, having established the scientific basis for the effectiveness of the device, it was deemed reasonable and conservative to use this framework to price this new technology. Given the realities of insurance reimbursement and prevalence of global fees, the price chosen for this technology was less than 20% of the price justified by a pure cost efficiency analysis.

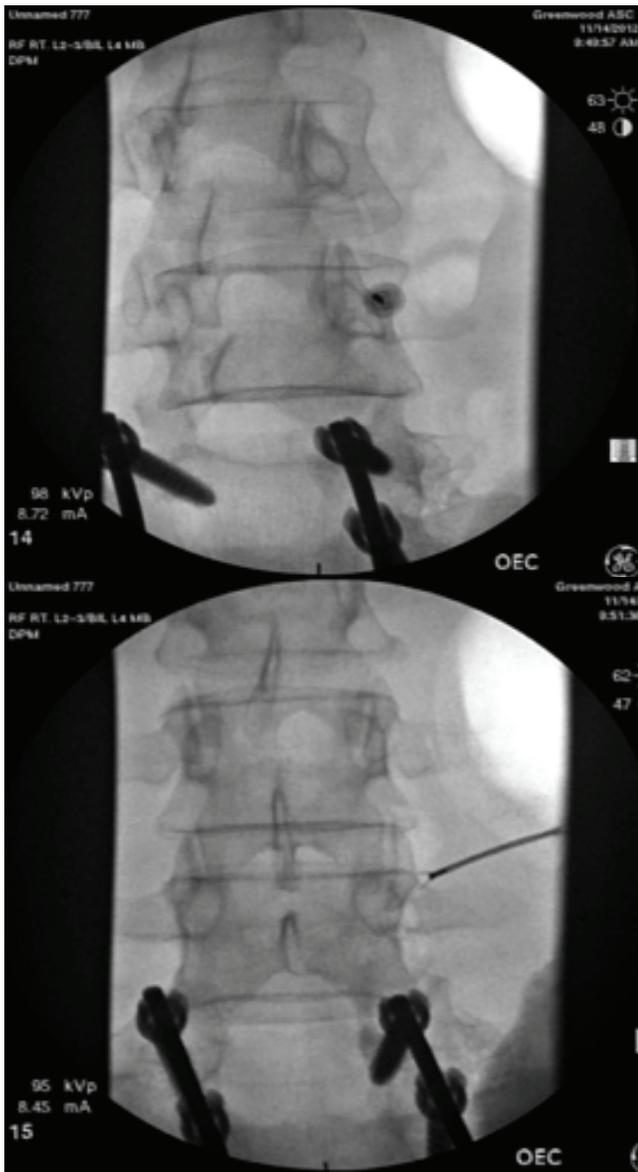


Figure 9. Lumbar MB Neurotomy "Down-the-Beam" Technique

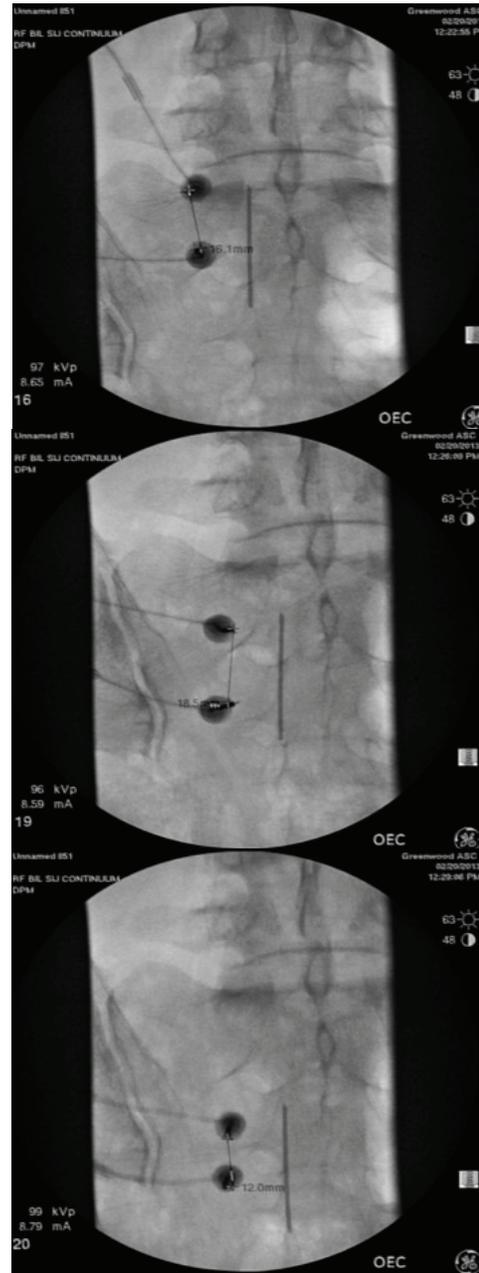


Figure 10. SJ Dorsal RF Denervation Bipolar Technique "Continuum".



Figure 11. Representative Axial MRI Image - Lesion Correlates

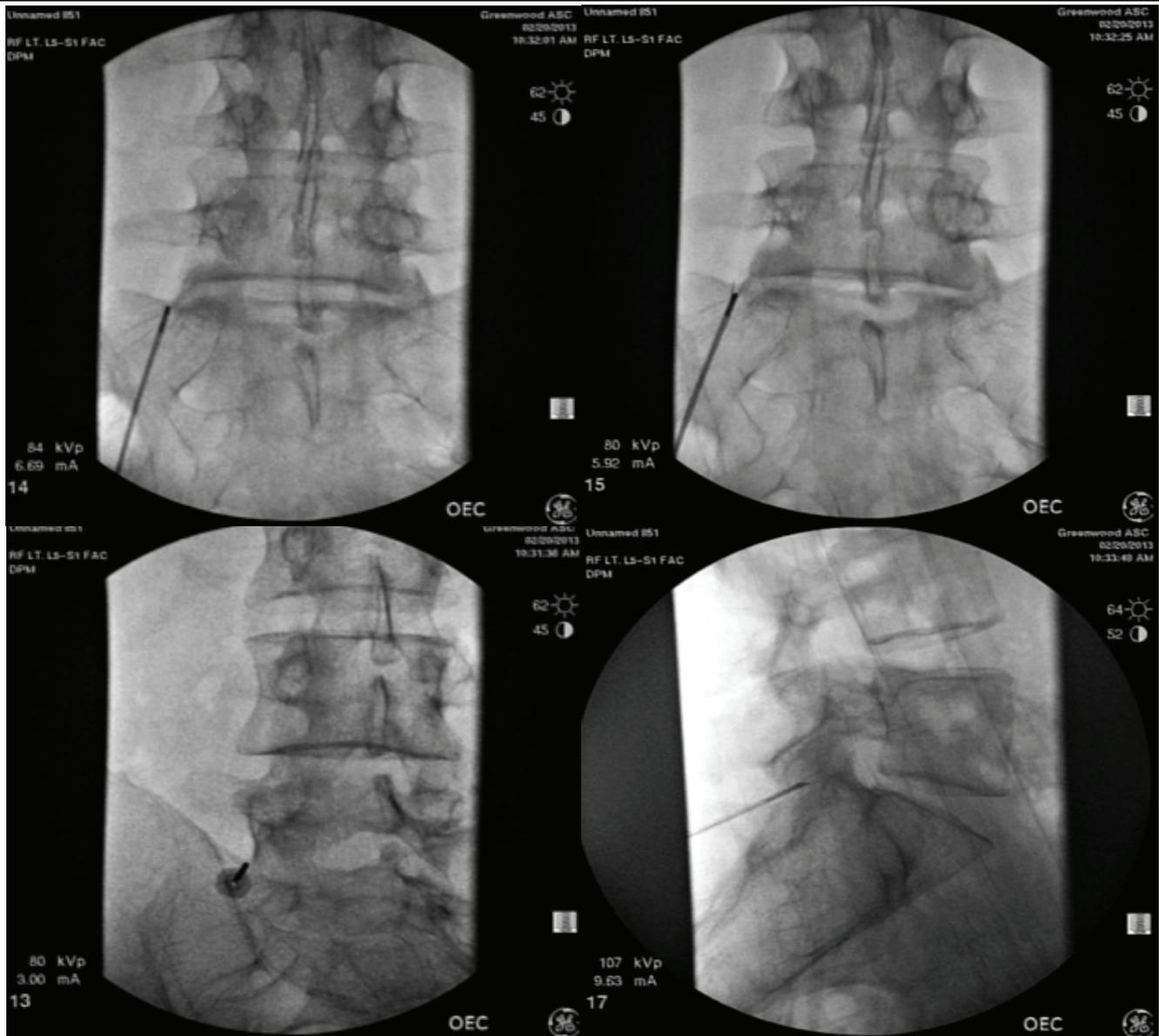


Figure 12. Slight Oblique With Caudal Decline – L5 Dorsal Ramus.

CONCLUSIONS

This is the first description of a multitined, expandable electrode designed for use in spinal radiofrequency procedures. It is manufactured by Nimbus Concepts, LLC in Austin, Texas. This novel radiofrequency 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 resulting geometry and stability of the tissue lesion are uniquely suited to safe, technically efficient, and effective interruption of nociceptive pathways. Detailed anatomical research into afferent pain pathways provided the basis for the electrode design and supports the premise that this device will enable practitioners to consistently achieve appropriate tissue ablation with fewer heat cycles and less

global tissue trauma compared to the various monopolar designs currently in use.

The advent of a technologically advanced radiofrequency electrode that produces 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. Furthermore, the multitined construct has the potential to configure future devices that will shape lesions even more precisely for additional specific thermal ablation targets heretofore not possible with current electrodes.

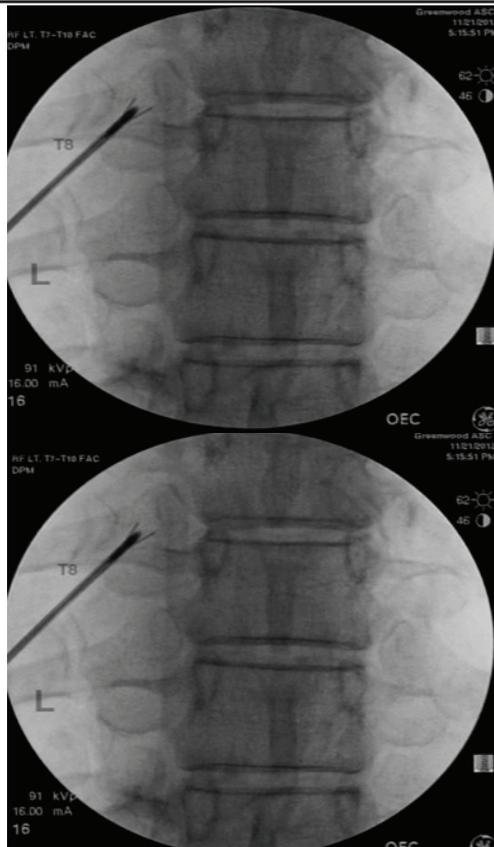


Figure 13. Thoracic MB Neurotomy – Superior Lateral Corner of Transverse Process, With Extension Into the Intertransverse Space for the T5-8 Medial Branch Nerves.

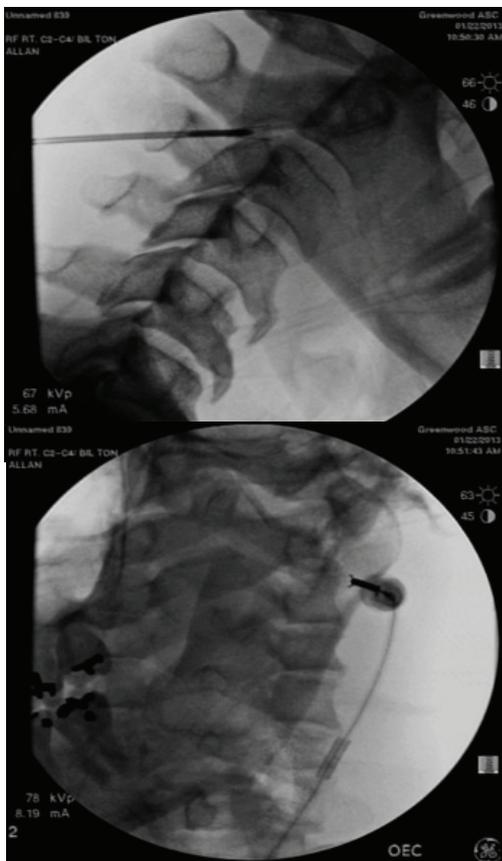


Figure 14. Cervical TON / MB Neurotomy - Posterior Parasagittal Approach.

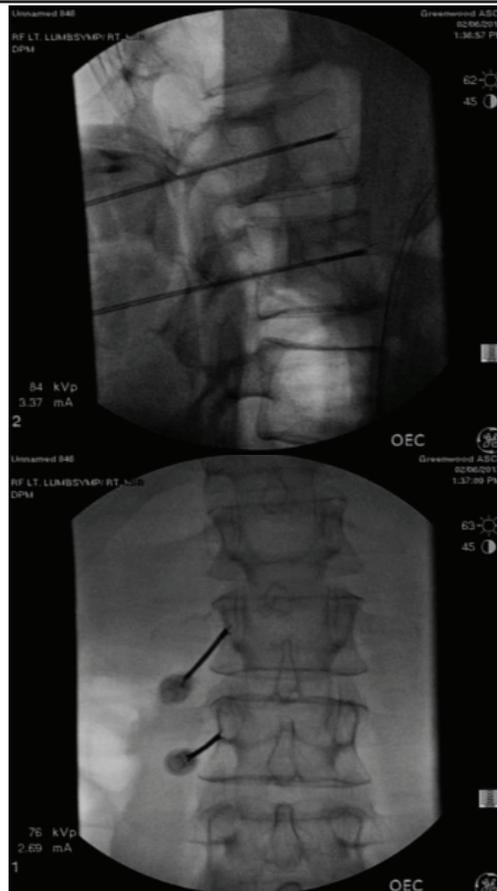


Figure 15. Lumbar Sympathetic Chain.



Figure 16. Thoracic sympathetic chain.

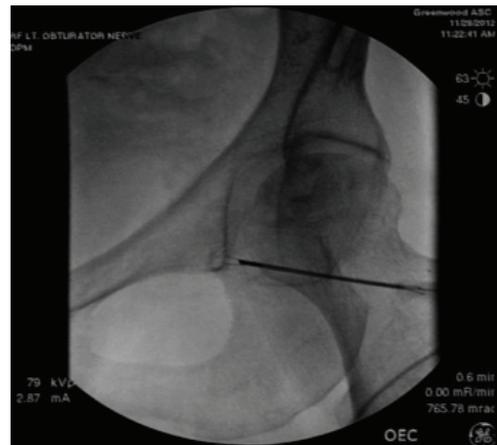


Figure 17. Obturator articular branches.

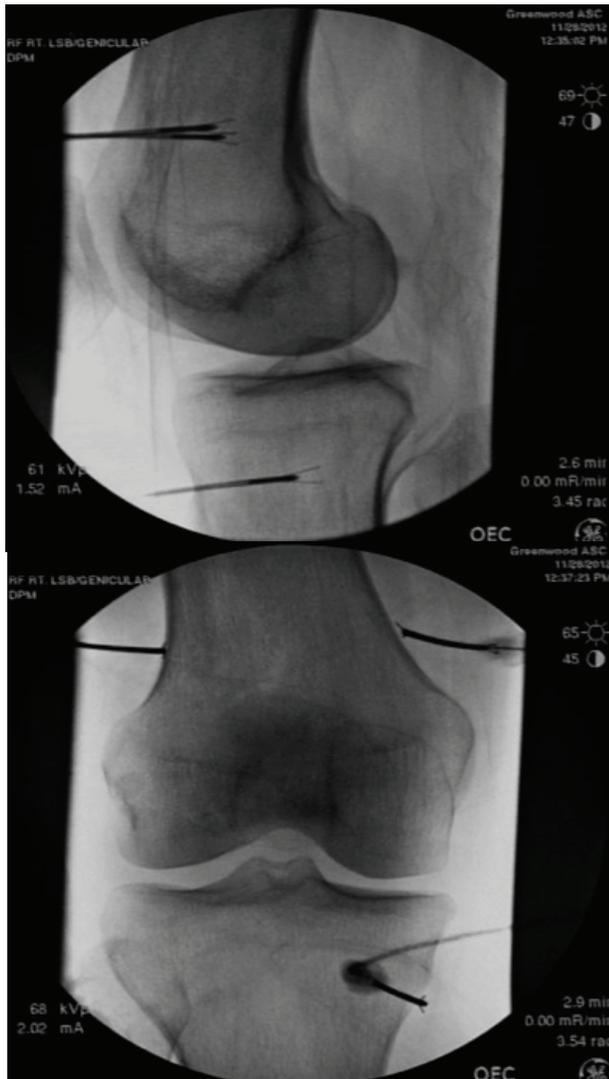


Figure 18. Genicular Nerves.

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Dr. Wright is the founder and Mr. Holley is the President and CEO of Nimbus Concepts, LLC. Drs. Wright, Allan, Kraft and Mr. Holley have significant financial interest in Nimbus Concepts, LLC.

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