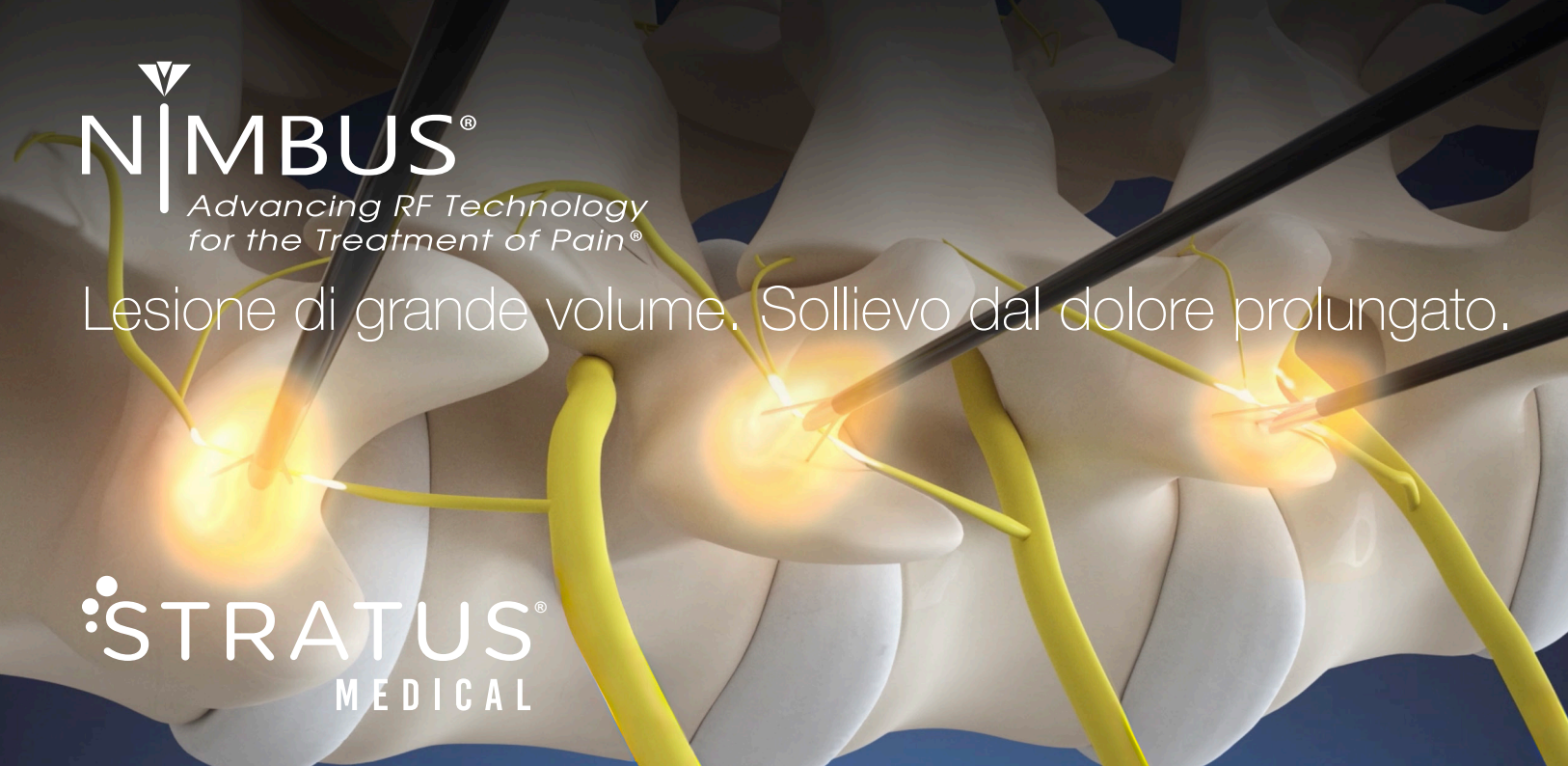
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MEDICAL

PERCHÉ I MEDICI ADOTTANO NIMBUS?

I pazienti hanno bisogno di un sollievo dal dolore più prevedibile e duraturo

- Lesione di grande volume[4,5]
  - Ridurre gli insuccessi e migliorare i risultati[17]
- Tecnica semplice e tempo di intervento più rapido del 50%.[2]
  - Messa a fuoco perpendicolare o parallela
- Compatibile e conveniente
  - Non è necessario un capitale aggiuntivo e spesso si ottengono risparmi significativi.[+]

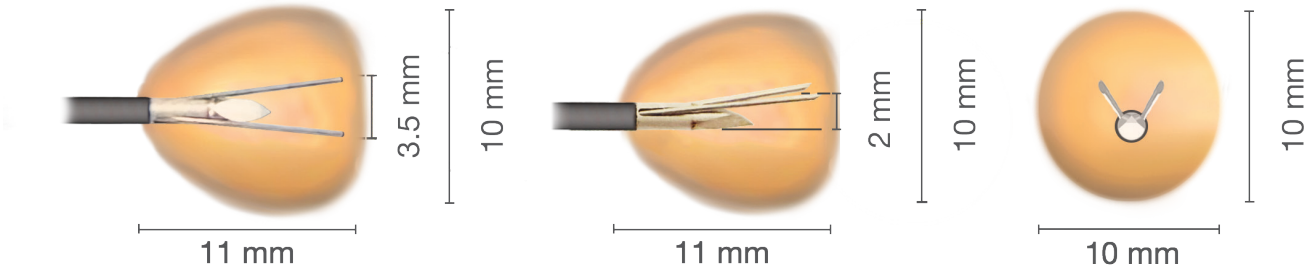
[+]Basato su 1.000 procedure all'anno

NIMBUS

Area di Lesione

Volume:

601 mm^3



La maggior parte della lesione è contenuta vicino alla punta distale ed è ideale per il posizionamento del fascio perpendicolare o verso il basso.[4,5]

AMPIO VOLUME DI LESIONE

Affrontare le variazioni anatomiche e l'area di superficie

L4 ANGOLO DI ENTRATA

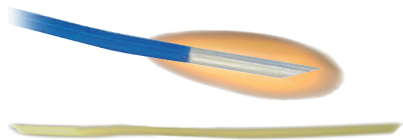
L'angolo medio di inserimento per un corretto posizionamento parallelo in L4 è di 31,04° +/- 1,83°.[17]

L5 ANGOLO DI ENTRATA

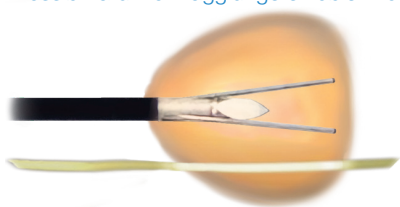
L'angolo medio di inserimento per un corretto posizionamento parallelo a L5 è di 40,74° +/- 1,86.[17]

[17]Patel A, Chang JL, Haffey PR, Mainkar O, Gulati A. Characterizing an angle of cannula insertion for lumbar medial branch radiofrequency neurotomy: a retrospective observation study. Pain Pract. 2021;21(7):747-758.

Posizionamento in parallelo

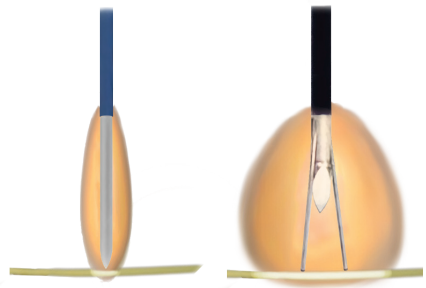


Possibilità di non raggiungere l'obiettivo



Neurotomia di 10 mm

Posizionamento perpendicolare



Lesione puntiforme di 3 mm

Neurotomia di 10 mm

LINEE GUIDA DI CONSENSO

Il dispositivo ablazione a radiofrequenza per grandi lesioni migliora la sua

LE LESIONI DI GRANDI DIMENSIONI RIDUCONO I FALLIMENTI

"…diminuire il tasso di fallimento tecnico aumentando le dimensioni della lesione dovrebbe essere un'impresa relativamente non controversa su cui la maggior parte delle persone può concordare."[13]

LIMITI DELLA CANNULE STANDARD

"Sulla base delle attuali limitazioni della RFA termica tradizionale e delle piccole dimensioni delle strutture mirate, la creazione di lesioni più grandi con una ridotta variabilità della lesione può aumentare la probabilità di catturare la struttura mirata."[13]

Special article

OPEN ACCESS

Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group

Steven P Cohen, Arun Bhaskar, Anuj Bhatia, Asokumar Buvanendran, Tim Deer, Shuchita Garg, W Michael Hooten, Robert W Hurley, David J Kennedy, Brian C McLean, Jee Youn Moon, Samer Narouze, Sanjog Pangarkar, David Anthony Provenzano, Richard Rauck, B Todd Sitzman, Matthew Smuck, Jan van Zundert, Kevin Vorenkamp, Mark S Wallace, Zirong Zhao

ABSTRACT

Background The past two decades have witnessed a surge in the use of lumbar facet blocks and radiofrequency ablation (RFA) to treat low back pain (LBP), yet nearly all aspects of the procedures remain controversial.

Methods After approval by the Board of Directors of the American Society of Regional Anesthesia and Pain Medicine, letters were sent to a dozen pain societies, as well as representatives from the US Departments of Veterans Affairs and Defense. A steering committee was convened to select preliminary questions, which were revised by the full committee. Questions were assigned to 4–5 person modules, who worked with the Subcommittee Lead and Committee Chair on preliminary versions, which were sent to the full committee. We used a modified Delphi method, whereby the questions were sent to the committee en bloc and comments were returned in a non-blinded fashion to the Chair, who incorporated the comments and sent out revised versions until consensus was reached.

Results 17 questions were selected for guideline development, with 100% consensus achieved by committee members on all topics. All societies except for one approved every recommendation, with one society dissenting on two questions (number of blocks and cut-off for a positive block before RFA), but approving the document. Specific questions that were addressed included the value of history and physical examination in selecting patients for blocks, the value of imaging in patient selection, whether conservative treatment should be used before injections, whether imaging is necessary for block performance, the diagnostic and prognostic value of medial branch blocks (MBB) and intra-articular (IA) injections, the effects of sedation and injectate volume on validity, whether facet blocks have therapeutic value, what the ideal cut-off value is for a prognostic block, how many blocks should be performed before RFA, how electrodes should be oriented, the evidence for larger lesions, whether stimulation should be used before RFA, ways to mitigate complications, if different standards should be applied to clinical practice and clinical trials and the evidence for repeating RFA (see table 12 for summary).

Conclusions Lumbar medial branch RFA may provide benefit to well-selected individuals, with MBB being more predictive than IA injections. More stringent selection criteria are likely to improve denervation outcomes, but at the expense of more false negatives. Clinical trials should be tailored based on objectives, and selection criteria for some may be more stringent than what is ideal in clinical practice.

INTRODUCTION

There are few conditions in interventional pain medicine as controversial as lumbar facet joint pain. Everything from incidence, to diagnostic criteria, patient selection for interventions and the effectiveness of treatment is a source of contention and scientific debate. Regarding prevalence, the cited frequency of lumbar facet joint pain ranges from as low as 4.8% in the multicenter National Low Back Pain Survey evaluating final diagnoses of 2374 patients with low back pain (LBP) referred to an orthopedic or neurosurgical spine surgeon, to over 50% in systematic reviews on prevalence studies using varying criteria for diagnostic blocks performed by interventional pain physicians.[1–4] The wide disparity in reported prevalence raises questions regarding the accuracy of diagnostic testing in the absence of any non-interventional diagnostic reference standard. The poor correlation between facet joint pathology on imaging and LBP further fuels debate.[5] For diagnostic criteria, research and review articles abound on the ideal cut-off for designating a block as positive, and the optimal number of blocks that should be performed before lumbar facet radiofrequency ablation (RFA) treatment, with no consensus emerging.[6–11]

Lumbar facet interventions comprise the second most common procedure performed in interventional pain practices, with millions per year being performed in the USA alone.[12] For lumbar RFA, a recent review of the Markerscan commercial claims and encounters databases from 2007 to 2016 demonstrated a 130.6% overall increase in utilization (9.7% annually).[13] Along with increasing utilization, there was also a reciprocal increase in cost,

To cite: Cohen SP, Bhaskar A, Bhatia A, *et al*. *Reg Anesth Pain Med* 2020;45:424–467.

► Additional material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/rapm-2019-101243).

For numbered affiliations see end of article.

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[13] Cohen S, Bhaskar A, Bhatia A, Buvanendran A, Deer T, et al. Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group. Pain Pract. 2021;21(7):747-758.

VALIDAZIONE CLINICA

NIMBUS Posizionamento perpendicolare Risonanza magnetica convalidata a 601 mm^3

RISONANZA MAGNETICA ESEGUITA SU 6 PAZIENTI PRE E POST TRATTAMENTO RF

La risonanza magnetica post ablazione con radiofrequenza della branca mediale è stata utilizzata da tre a sei settimane dopo la procedura per quantificare le dimensioni e la topografia della lesione.[5]

VOLUME DI LESIONE PRINCIPALE 601 mm^3

Per dimostrare l'efficacia e la sicurezza di NIMBUS con l'approccio perpendicolare è stata utilizzata la risonanza magnetica ablazione a radiofrequenza post-ramo mediale.[5]

[5]Bainbridge JS, Wright RE, et al. Technical efficacy of a direction specific radiofrequency device in the performance of lumbar medial branch neurotomies – an MRI and EMG confirmation study. Pain Med. 2015;16(8):1650.

Pain Medicine

PAIN MEDICINE
Volume 16 • Number 8 • 2015

INTERNATIONAL SPINE INTERVENTION SOCIETY – 2015
23RD ANNUAL SCIENTIFIC MEETING RESEARCH ABSTRACTS

Technical Efficacy of a Direction Specific Radiofrequency Device in the Performance of Lumbar Medial Branch Neurotomies – An MRI and EMG Confirmation Study (Interim Analysis)

J Scott Bainbridge, MD, jsb@denverbackpainspecialists.com[1,4], Robert E Wright, MD[2], C Dino Pappas, MD[3], Sara Light, BA, RC[2], R Brett McQueen, PhD[4], 1) Denver Back Pain Specialists, 2) Denver Pain Management, 3) Denver Spine Specialist, 4) University of Colorado Anschutz Medical Campus

Background/Objectives: Lesion position and geometry are cardinal in maximizing safety and efficacy when performing lumbar medial branch radiofrequency ablation (LMBRFA). Technical efficacy of a multi-tined expandable electrode (MIEE), with perpendicular approach, was demonstrated using a novel LMRI validation protocol and corroborated with parapsinous EMG (PEMG) findings in this IRB approved study.

Methods: Patients (n=6 MRI, n=5 EMG) chosen for LMBRFA underwent pre and post LMRI and PEMG[1]. Post-ablation LMRI using a previously described[2] protocol was obtained 7 days following RFA and used to quantify lesion size and provide lesion topography and anatomic relationship information. Post-LMBRFA EMG was obtained at 3-6 weeks. Monitoring of possible complications was carried out.

Results: Lesions were achieved, incorporating the target MB/SAP wall, in all cases*. Mean lesion volume was 601.7 mm^3 (n=40, 95%CI: 522.6, 680.8). No bony edema or complications were noted. EMG evidence of target medial branch ablation was achieved in 88%* (n=34, 95%CI: 77-99) of targets which compares favorably with EMG % ablation of Dreyfuss, et al [3] of 90.5%. *One subject underwent repeat procedure, adding one additional MRI/EMG positive ablation site – included in these results. There were no complications.

Comments: Post-MBRFA LMRI, supported by PEMG, was used to demonstrate technical efficacy and safety of a multi-tined expandable RF electrode, using a new technique (perpendicular approach) that simplifies this ablative procedure for this common target. This validation method is an extension of all ex-vivo RF work done to date, and may be used for future research, as well as being a useful tool for educational purposes.

References: 1) Haig, A.J., et al., Paraspinal mapping: quantified needle electromyography in lumbar radiculopathy. Muscle Nerve, 1993. 16(5): p. 477-84. 2) Wright, R., Bainbridge, JS, Allan, KJ, MRI Protocol for Analysis of Tissue Ablation Following Dorsal SIJ Radiofrequency Denervation, in ISIS ASM July, 2013 Poster Session. 2013. 3) Dreyfuss, P., et al., Efficacy and validity of radiofrequency neurotomy for chronic lumbar zygapophysial joint pain. Spine, 2000. 25(10): p. 1270-7.

VALIDAZIONE CLINICA

~57% di 495 pazienti riporta un esito positivo con NIMBUS per la RFA lombare a 12 mesi[10]

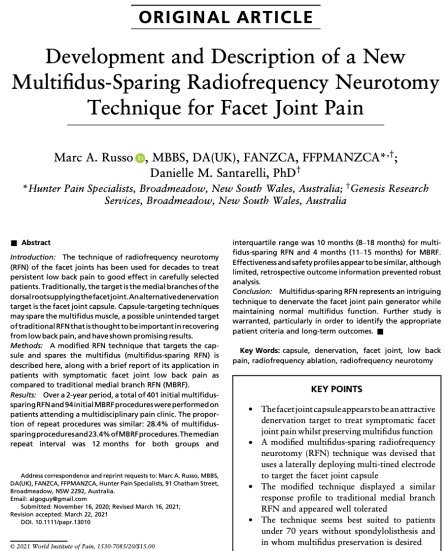
RFA LOMBARE A 12 MESI

"Il 58,5% delle procedure di RFA della branca mediale lombare e il 56,1% delle procedure di RFN con risparmio del multifido hanno avuto un esito positivo" a 12 mesi.[10]

ESITI DELLA RFA LOMBARE RIPETUTA A 12 MESI

"La maggior parte delle procedure ripetute sono state eseguite dopo un primo risultato positivo (86,4% delle ripetizioni di radiofrequenza della branca mediale lombare e 82,5% delle ripetizioni di RFN multifido)."[10]

[10]Russo MA, Santarelli DM. Development and description of a new multifidus-sparing radiofrequency neurotomy technique for facet joint pain. Pain Pract. 2021;21(7):747-758.



ORIGINAL ARTICLE

Development and Description of a New Multifidus-Sparing Radiofrequency Neurotomy Technique for Facet Joint Pain

Marc A. Russo, MBBS, DA(UK), FANZCA, FFPMANZCA*,†; Danielle M. Santarelli, PhD†

*Hunter Pain Specialists, Broadmeadow, New South Wales, Australia; †Genesis Research Services, Broadmeadow, New South Wales, Australia

■ Abstract

Introduction: The technique of radiofrequency neurotomy (RFN) of the facet joints has been used for decades to treat persistent low back pain to good effect in carefully selected patients. Traditionally, the target is the medial branches of the dorsal root supplying the facet joint. An alternative denervation target is the facet joint capsule. Capsule-targeting techniques may spare the multifidus muscle, a possible unintended target of traditional RFN that is thought to be important in recovering from low back pain, and have shown promising results.

Methods: A modified RFN technique that targets the capsule and spares the multifidus (multifidus-sparing RFN) is described here, along with a brief report of its application in patients with symptomatic facet joint low back pain as compared to traditional medial branch RFN (MBRF).

Results: Over a 2-year period, a total of 401 initial multifidus-sparing RFN and 94 initial MBRF procedures were performed on patients attending a multidisciplinary pain clinic. The proportion of repeat procedures was similar: 28.4% of multifidus-sparing procedures and 23.4% of MBRF procedures. The median repeat interval was 12 months for both groups and interquartile range was 10 months (8–18 months) for multifidus-sparing RFN and 4 months (11–15 months) for MBRF. Effectiveness and safety profiles appear to be similar, although limited, retrospective outcome information prevented robust analysis.

Conclusion: Multifidus-sparing RFN represents an intriguing technique to denervate the facet joint pain generator while maintaining normal multifidus function. Further study is warranted, particularly in order to identify the appropriate patient criteria and long-term outcomes. ■

Key Words: capsule, denervation, facet joint, low back pain, radiofrequency ablation, radiofrequency neurotomy

KEY POINTS

- The facet joint capsule appears to be an attractive denervation target to treat symptomatic facet joint pain whilst preserving multifidus function
- A modified multifidus-sparing radiofrequency neurotomy (RFN) technique was devised that uses a laterally deploying multi-tined electrode to target the facet joint capsule
- The modified technique displayed a similar response profile to traditional medial branch RFN and appeared well tolerated
- The technique seems best suited to patients under 70 years without spondylolisthesis and in whom multifidus preservation is desired

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Email: algogu@gmail.com

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DOI. 10.1111/papr.13010

VALIDAZIONE CLINICA

Esiti a 12 mesi in 182 pazienti consecutivi che hanno utilizzato NIMBUS per la RFA dell'articolazione sacroiliaca[15]

12 MESI DI SOLLIEVO DURATURO DAL DOLORE

NIMBUS fornisce una lesione bipolare anatomicamente accurata con una significativa riduzione del dolore a 12 mesi di follow-up.[15]

SIJ CON L4 MB E L5 DR

L'inclusione del ramo mediale di L4 e del ramo dorsale di L5 può fornire ulteriori benefici.[15]

[15]Wright RE, Block JE. Radiofrequency neurotomy for sacroiliac joint pain: twelve month outcomes and comparison between two techniques. Med Res Arch. 2023;11(12). doi:10.18103/mra.v11i12.4978.

Medical Research Archives

European Society of Medicine

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DOI https://doi.org/10.18103/mra.v11i12.4978

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REVIEW ARTICLE

Radiofrequency Neurotomy for Sacroiliac Joint Pain: Twelve Month Outcomes and Comparison Between Two Techniques

Robert E. Wright, M.D.[1], **Jon E. Block, Ph.D.**[2]*

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[2] Consultant, San Francisco, CA, USA

***Corresponding author:** jb@drjonblock.com

ABSTRACT

Background: Radiofrequency neurotomy (RFN) is an effective treatment option for patients with severe sacroiliac joint (SIJ) pain.
Aims: We evaluated the 12-month clinical outcomes between patients (n=93) having RFN of the lateral branches of S1-S3 compared to patients (n=89) undergoing the same procedure augmented with RFN of the L4 medial branch and L5 dorsal ramus.
Methods: This was a retrospective chart review. Following diagnostic intra-articular anesthetic injections and multi-site multi-depth lateral branch nerve blocks to establish SIJ pain, patients underwent bipolar ablation of the S1-S3 lateral branches using the Nimbus multitined electrode. The second group of patients underwent supplementary monopolar RFN of the L4 medial branch and the L5 dorsal ramus. Pain severity and global Pain Disability Quality of Life Questionnaire-Spine (PDQQ-S) scores were obtained prior to RFN and at 12 months.
Results: There were 61% and 59% average 12-month improvements in SIJ-related pain severity and global PDQQ-S scores, respectively, in the overall study group (P<0.001 for both comparisons). Efficacy was moderately better for patients with augmented ablation that captured the L4 medial branch/L5 dorsal ramus. For example, 12-month average pain reduction was 54% and 66%, and PDQQ-S improvement was 56% and 62% for patients treated with S1-S3 lateral branch RFN and the augmented RFN procedure, respectively. The percentage of patients exhibiting ≥ 50% improvement in pain severity at 12-months was 73% (68 of 93) and 88% (78 of 89) (P=0.016) for the same study groups.
Conclusion: RFN of the S1-S3 sacral lateral branches using an anatomically accurate bipolar strip lesion technique produced a sufficient lesion topography to provide highly significant pain reduction and improvement in PDQQ-S at 12-months follow-up. Including the L4 medial branch and L5 dorsal ramus in the RFN treatment protocol may offer more complete denervation of all afferent pain pathways and provide additional clinical benefit.

Keywords: radiofrequency, sacroiliac, pain, neurotomy, Nimbus, bipolar

VALIDAZIONE CLINICA

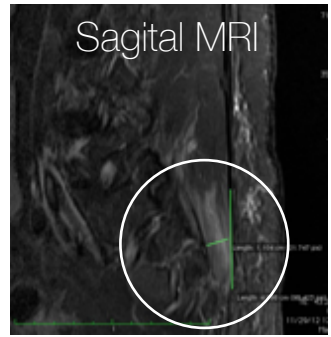
Caso clinico con protocollo di risonanza magnetica che convalida le dimensioni e la forma della lesione dell'articolazione sacroiliac[7]

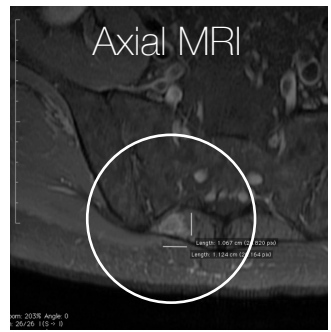
LESIONE DELLA STRISCIA BIPOLARE NIMBUS

Non siamo a conoscenza di nessun altro dispositivo RF che sia stato convalidato con prove di risonanza magnetica dopo la procedura RF. Ciò è correlato alle prove di dimostrazione dei tessuti inanimati di NIMBUS.[7]

RISONANZA MAGNETICA CONVALIDATA DELLA LESIONE SACRALE

"È stata dimostrata una lesione tubulare a strisce con un diametro medio di 11,7 mm per 4,99 cm. Il volume totale del cambiamento di tessuto era di 24,4 cm^3."[7]





[7]Wright RE, Weingardt J, Bainbridge JS, Allan KJ. MRI protocol for analysis of tissue ablation following dorsal SIJ radiofrequency denervation. Poster presented at: International Spine Intervention Society 21st Annual Meeting; July 2013; New York, NY.

ELETTRODO ESPANDIBILE MULTITUBOLARE NIMBUS

Lesione monopolare

Larghezza Lesioni

La lesione NIMBUS è stata valutata indipendentemente come larga 10 mm.[5]

Altezza Lesione

La lesione NIMBUS è stata valutata in modo indipendente con un'altezza di 11 mm.[5]

Lesione bipolare

I NIMBUS, distanziati di 15-20 mm l'uno dall'altro, forniscono una lesione bipolare di grande volume, 11 mm per 30 mm, ideale per l'applicazione della RFA dell'articolazione sacroiliaca.[7,15]

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	NIM-100-10BB	Lunghezza 100 mm, punta attiva da 10 mm
	NIM-100-10BB-CS*	Lunghezza 100 mm, punta attiva da 10 mm
	NIM-150-10BB	Lunghezza 150 mm, punta attiva da 10 mm

* solo per elettrodo bianco Avanos

Specifiche tecniche

Tipo di punta:	Smusso posteriore
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Diametro esterno punta:	1,47 mm
Lunghezza:	50-150 mm
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