

Real-world outcomes of large lesions in radiofrequency ablation treatment for chronic low back pain using a new cannula with deployment design

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BACKGROUND

Radiofrequency (RF) techniques in chronic pain management are used to modulate sensory nerve transmission usually by producing thermal lesions. The aim is to lesion a targeted nerve that innervates a structure believed to be contributing to pain. To optimize the outcomes, and because the lesion is not selective to specific tissue types, RF needle technology and placement as well as RF parameters need to be carefully selected to optimize precise and complete coverage of the neural target.¹⁻² For lumbar facetogenic pain, consensus guidelines and clinical data indicate that larger lesions drive better outcomes.³ A new RF cannula was recently developed to produce larger lesions, up to 2x larger than a standard cannula, without the need for additional equipment or procedure time**. This cannula includes a unique deployment design that was engineered to help achieve larger lesions and reduce the need for multiple burns. We have conducted a real-world study to evaluate clinical outcomes when using this new cannula as per standard practice

RESULTS

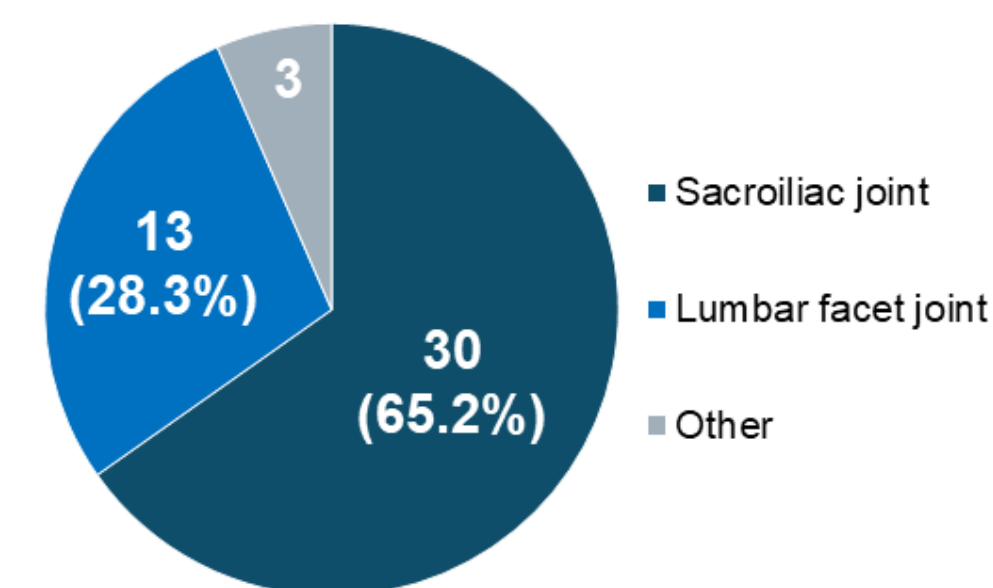
Baseline characteristics

Age (yrs.) - Mean (SD) n	65.6 (12.1) 46
Gender (Female) - % (n/N)	58.7% (27/46)
Pain location (%)	
Low back - % (n/N)	93.5% (43/46)
Low back and/or leg - % (n/N)	93.5% (43/46)
Lower limbs- % (n/N)	13.0% (6/46)
Baseline Overall Pain (NRS)- Mean (SD) n	8.2 (1.0) 46
Baseline Oswestry Disability Index (ODI) – Mean (SD) n	49.3 (12.7) 34
Follow-up duration (days)- Mean (SD) n	47.8 (131.6) 46

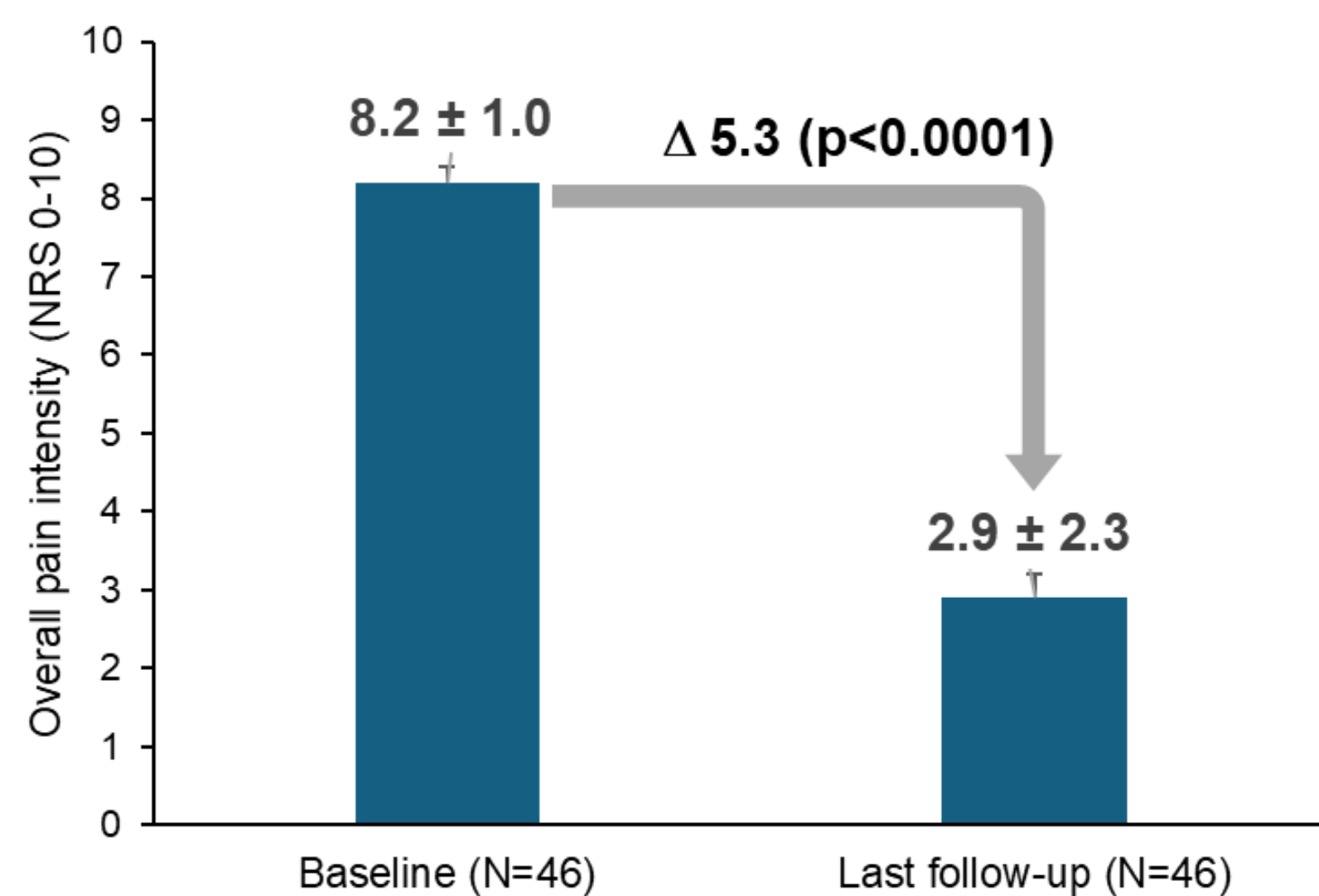
RF procedure

Procedure duration (minutes)- Mean (SD) n	14.9 (6.7) 45
Burn temperature (°C)- Mean (SD) n	83.6 (2.5) 45
Burn time (seconds)- Mean (SD) n	124 (40) 45

Nerve ablation target

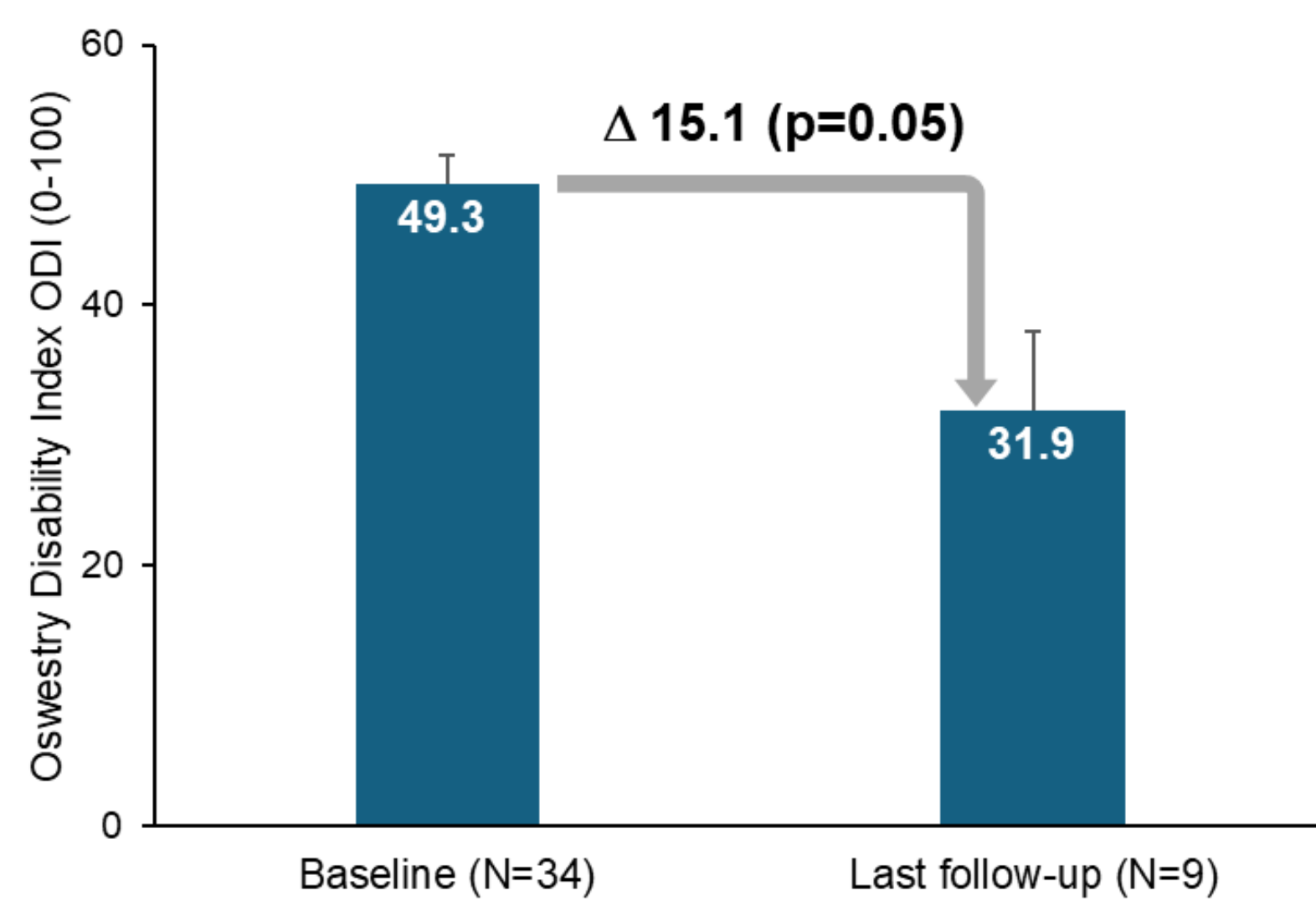


Pain relief at last follow-up (NRS)



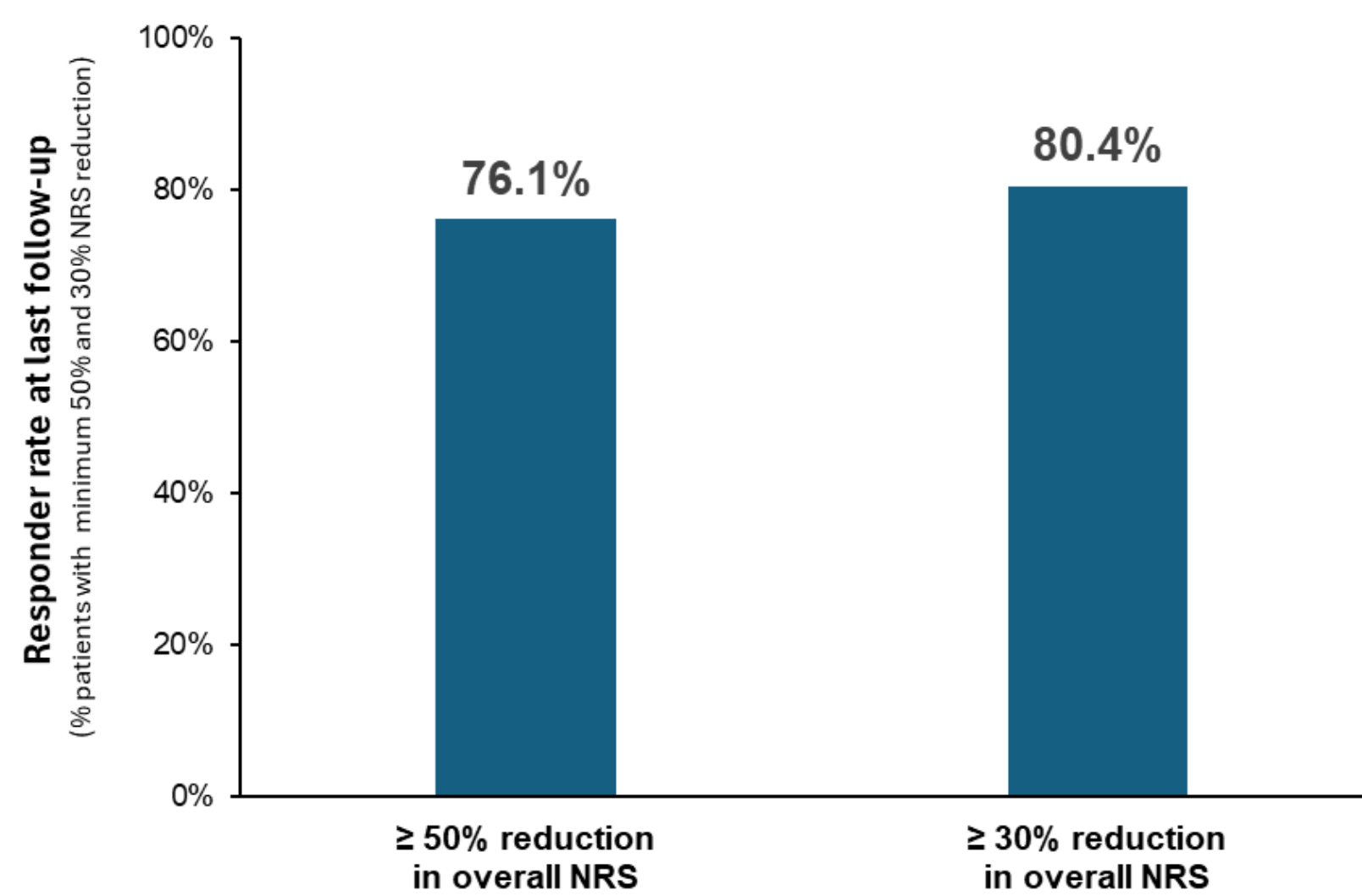
A significant **5.3-point** average reduction in overall pain was observed at last follow-up (N=46, p<0.0001)

Functional disability at last follow-up (ODI)



A significant **15.1-point** improvement in functional disability was observed at last follow-up (p=0.05)

Responder rate at last follow-up (N=46)



76% and 80% patients had their overall NRS pain score reduced by **≥ 50%** and **≥30%** respectively

CONCLUSIONS

Our preliminary results suggest that the use of a new cannula designed for producing larger lesions is effective for RF treatment. Our study included various target locations which may benefit from the use of larger ablation lesions, such as lumbar facet joints and sacroiliac joints.

- **Overall pain decreased by 5.3-points, from 8.2 to 2.9 (N=46, p<0.0001)**
- **Preliminary ODI results show a significant 15.1-point improvement**
- **Up to 80% of the patients reported clinically significant levels of pain relief at last follow-up**

Our study in ongoing and future analysis will be conducted to confirm these findings. Further studies are warranted to assess cost-effective outcomes and efficiency benefits of this novel RF cannula deployment design.

REFERENCES

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- ** SideKick Cannula (20ga/10mm), Mean +/- SD (n=8) extent of color change in porcine muscle ex vivo at 37°C, set temperature 80°C, set time 2:00 minutes, monopolar RF, Boston Scientific G4 generator, Ellipsoidal volume estimated from cross-sectional measurements. Ex vivo lesions may differ from clinical lesions

DISCLOSURES

Study Sponsored by Boston Scientific. Dr. Thomson has a consulting agreement with Boston Scientific. Edward Goldberg IS employee of Boston Scientific.