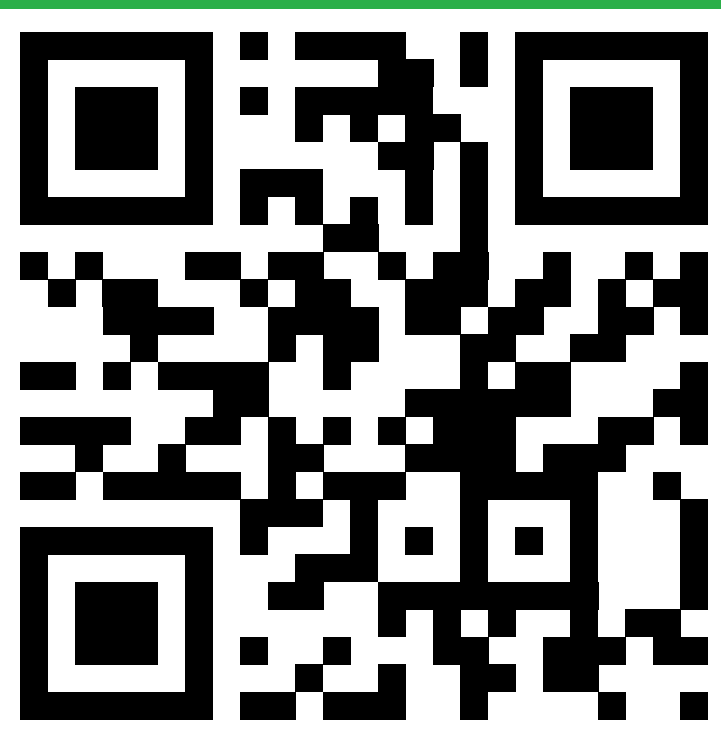




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Four-Year Follow-Up from a Prospective, Multicenter Study of 60-day Medial Branch Nerve Stimulation for the Treatment of Chronic Axial Back Pain

Christopher A. Gilmore, MD,¹ Timothy R. Deer, MD,² Mehul J. Desai, MD, MPH,³ Sean Li, MD,⁴ Michael J. DePalma, MD,⁵ Brandon D. Swan,⁶ Meredith J. McGee, PhD,⁶ Joseph W. Boggs, PhD⁶

¹Center for Clinical Research, ²The Spine and Nerve Center of The Virginias, ³International Spine, Pain & Performance Center, ⁴Premier Pain Centers, ⁵Virginia iSpine Physicians, ⁶SPR Therapeutics, Inc.

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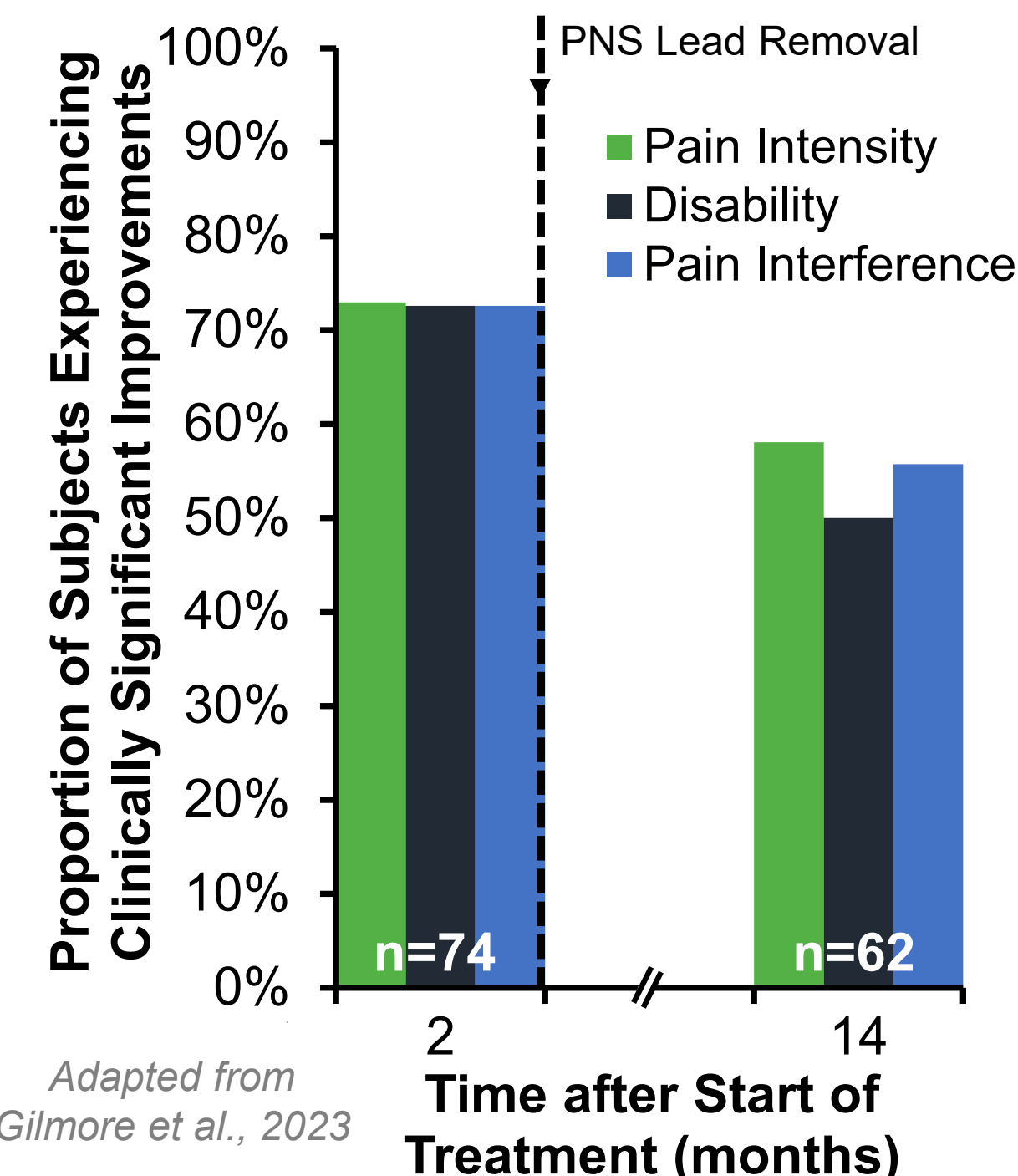
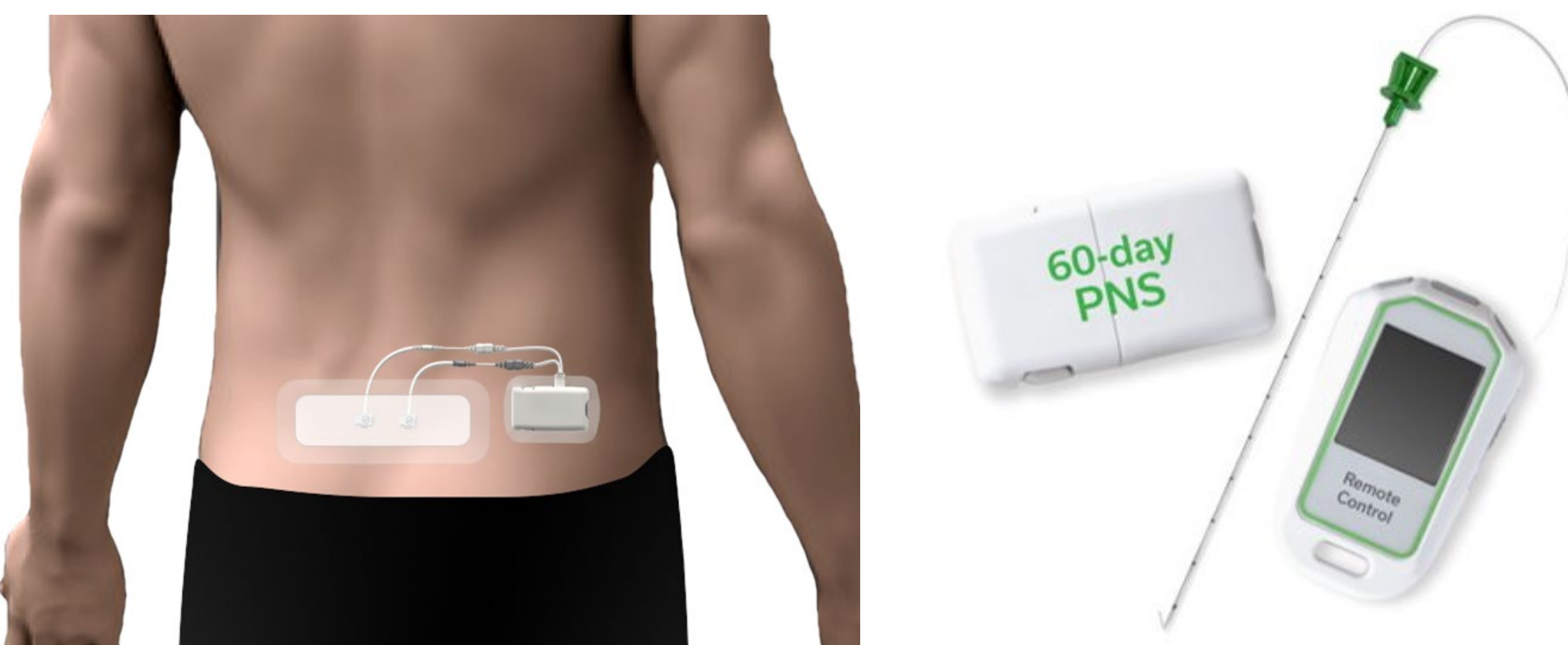
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Introduction

Short-term, 60-Day percutaneous PNS treatment has demonstrated sustained reductions in pain and disability at least one year after treatment in patients with chronic low back pain (LBP) patients.^{1,2}

- *Prior Prospective Multicenter Study Results:* 14 Months after starting treatment, 77% of subjects (n=48/62) experienced clinically significant improvements in pain, disability, and/or pain interference.



Objective: Further explore the potential for long-term durability of relief following 60-day PNS for chronic axial LBP.

Methods

Long-term Follow-Up Survey Eligibility:

Subjects completing prior study were eligible to participate in the follow-up survey if they had clinically significant improvement(s) at final study visit 14 months after start of 60-day medial branch PNS with at least one of:

- $\geq 30\%$ reduction in pain intensity (BPI5)
- ≥ 10 -pt reduction in disability (ODI)
- $\geq 30\%$ reduction pain interference (BPI9)

Participating Clinical Sites:

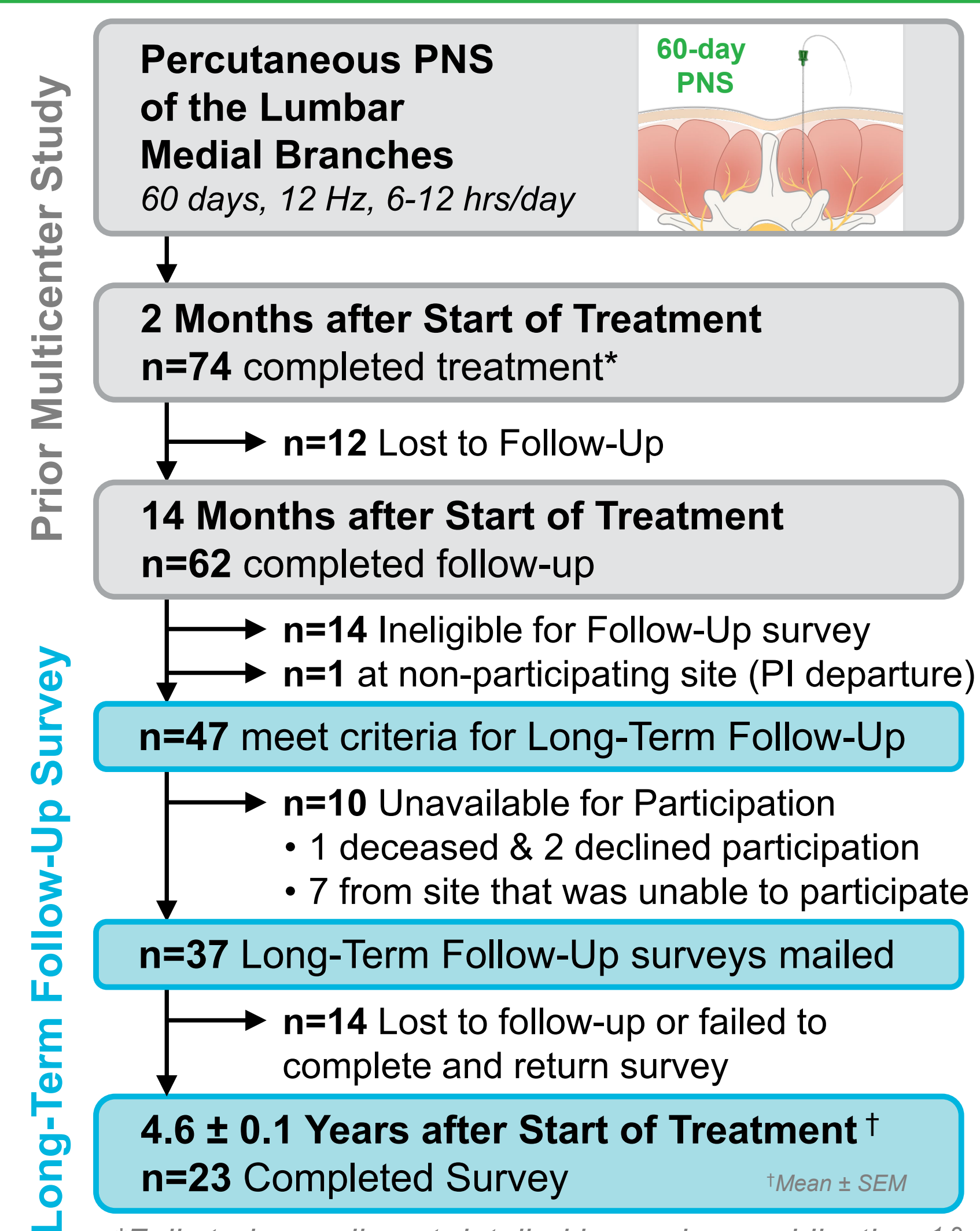
6 Sites from the prior study were invited to participate (sites with ≤ 1 subject meeting the survey eligibility criteria were not invited).

- 5 Sites participated (1 declined due to administrative bandwidth)

Survey Data Collection:

Subjects reported levels of pain relief, disability, pain interference, change in quality of life, LBP treatments used since last study visit, and satisfaction with PNS treatment.

- Safety outcomes were not assessed in survey.



Results

Survey Participant Demographics

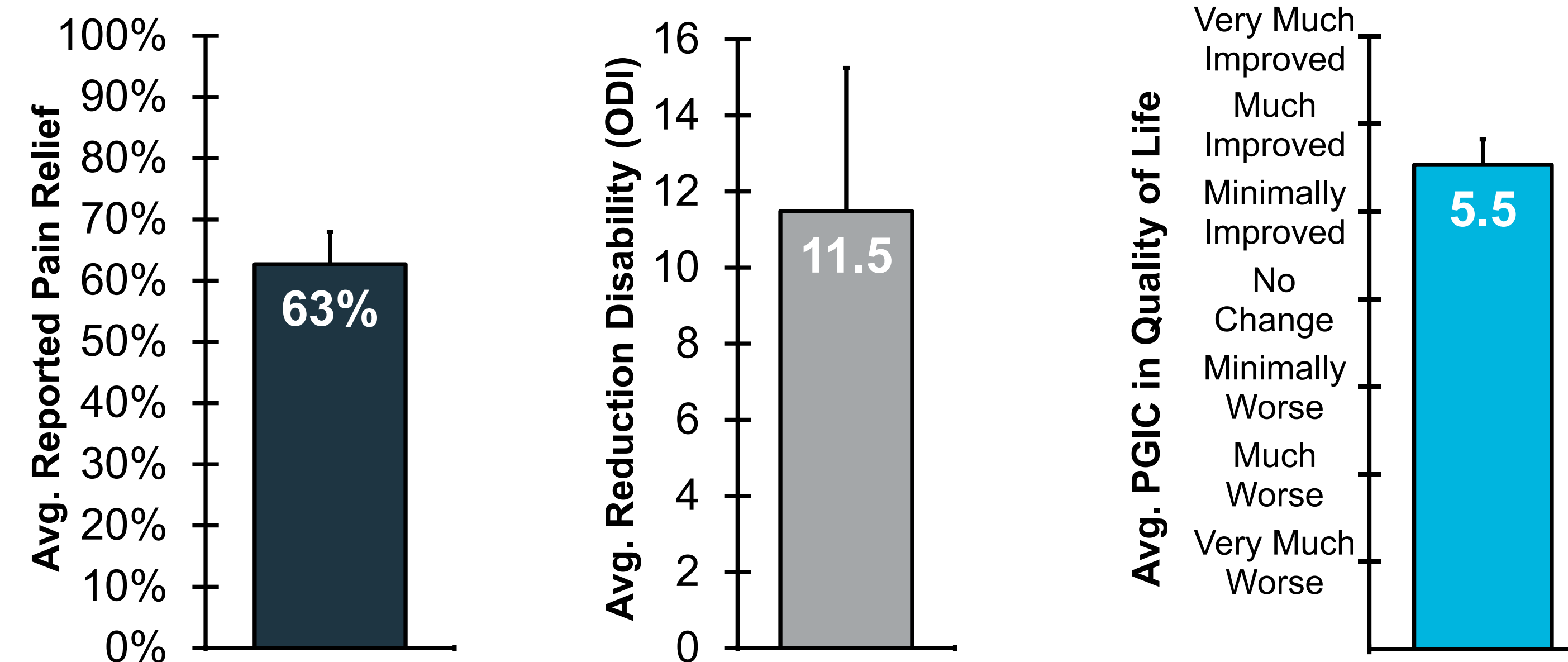
Participants Responding to Survey	23
Body Mass Index (BMI)	29.0 (4.9)
Age (years)	53.8 (13.4)
LBP Duration (years)	13.1 (13.9)
Sex (% Female)	65%
Average LBP Intensity at Baseline	6.6 (1.5)

Results are Mean (SD) unless otherwise stated

Majority of Survey Respondents Reported Relief 4+ Years after PNS:

- 65% reported clinically significant ($\geq 30\%$) relief of their LBP
- 70% reported highly clinically significant ($\geq 50\%$) pain relief and/or improvement in disability (≥ 10 -pt ODI)

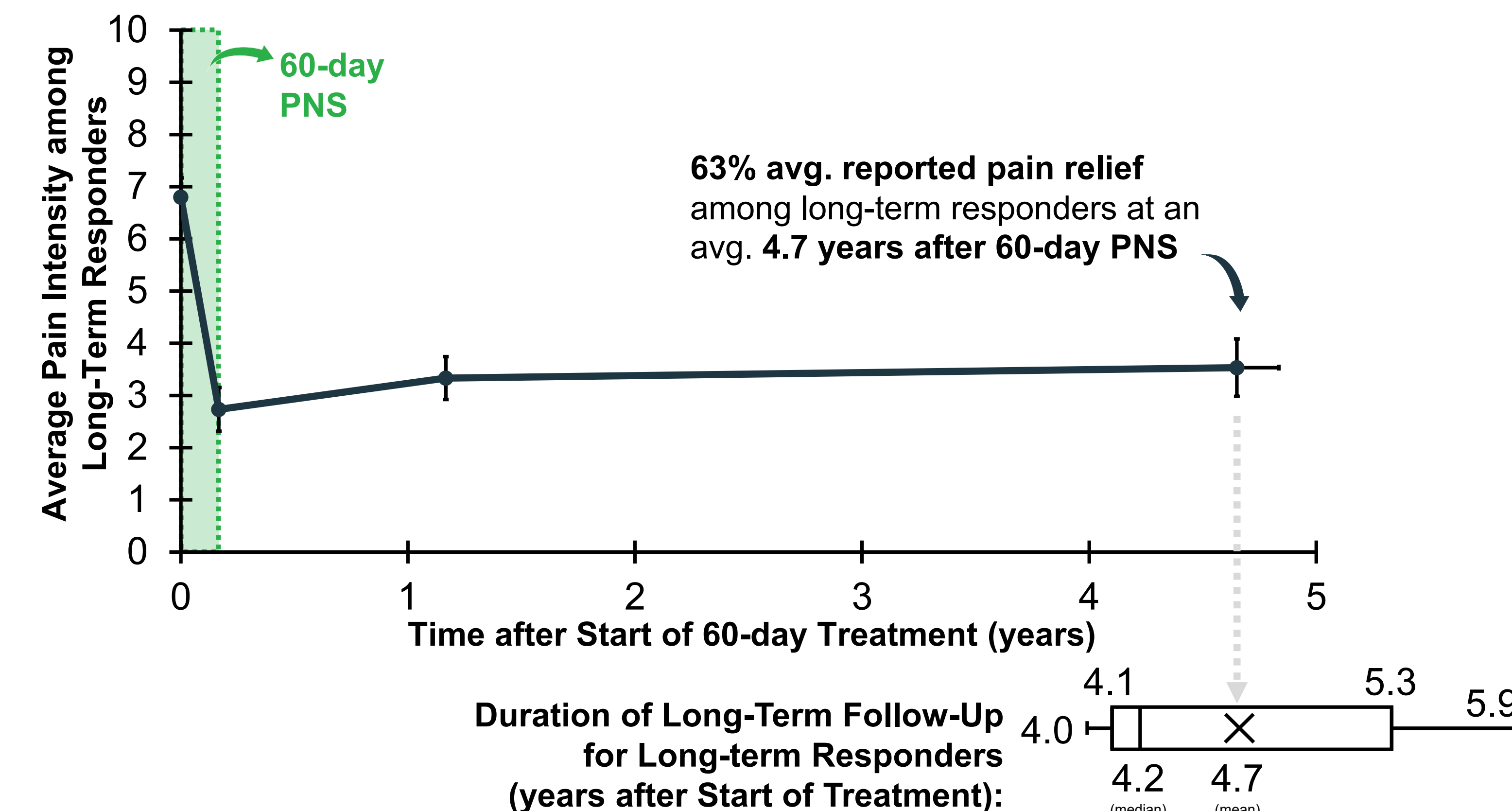
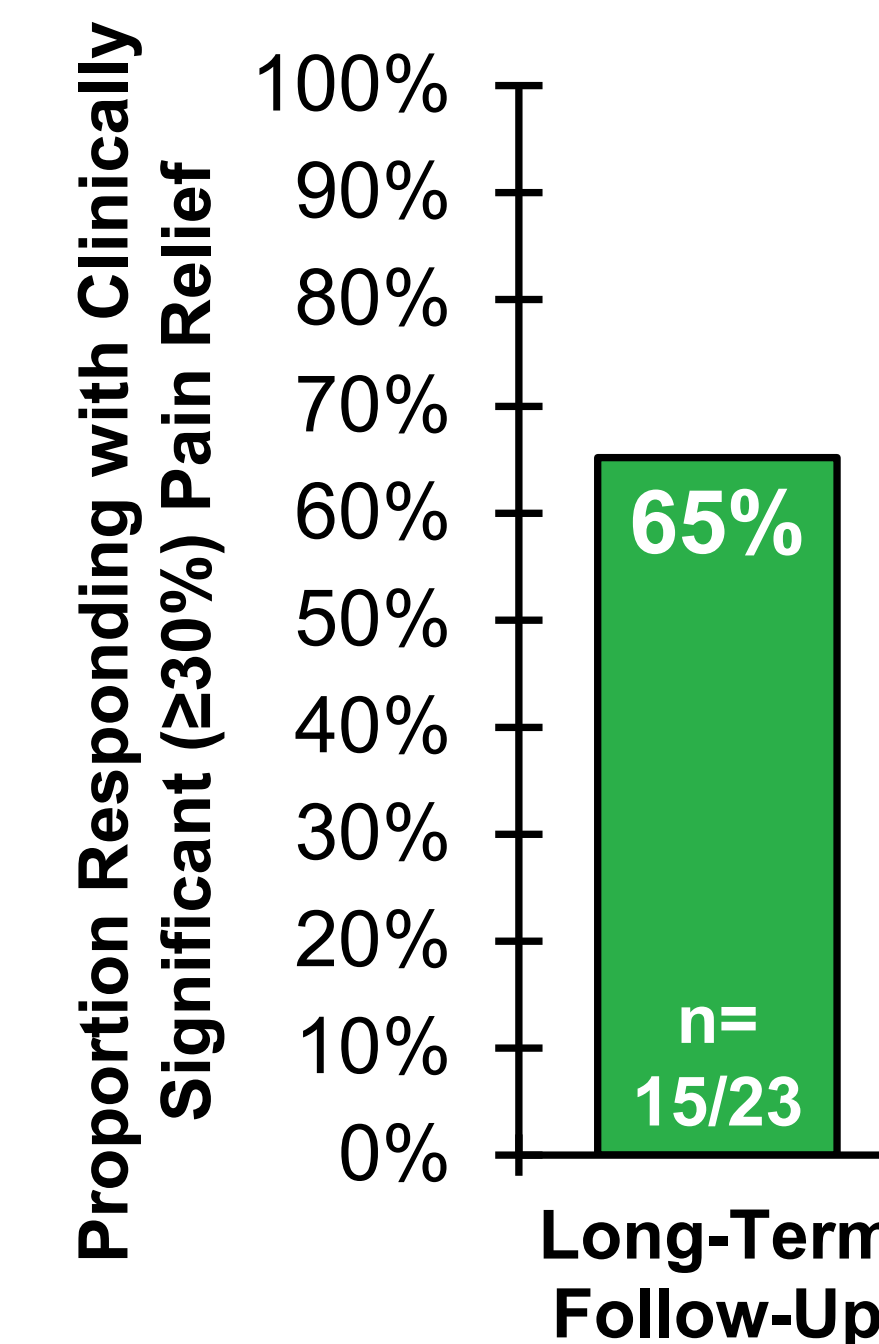
Improvements in Pain, Disability, and PGIC Quality of Life



Data plotted as Mean (SEM)

Results Among Long-term Responders at 4+ Years after 60-day PNS

Clinically significant pain relief 4+ years after receiving temporary, 60-day PNS



Long-term Healthcare Resource Utilization in Follow-Up

- 4.6+ years after 60-day PNS, a majority (70%, n=16/23) of survey respondents avoided progression to more costly, invasive, and/or destructive LBP pain interventions (i.e., radiofrequency ablation, neurostimulation implant, and/or lumbar surgery) in long-term follow-up:

- The rate of progression to interventions was 0.1 per subject per year of follow-up.

- Medication usage by survey respondents at long-term follow-up was most commonly mild analgesics (e.g., NSAIDs). 6 subjects reported weak opioid use.

Use of Other Interventions (i.e., RFA, Neurostim., Surgery) in Long-Term Follow-Up	0.1 procedures per subject · year
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Conclusions

- Percutaneous PNS treatment provided clinically significant pain relief and/or improvements in disability among a majority of surveyed respondents an average of more than four years after the treatment.
- These results demonstrate that percutaneous PNS can provide remarkably durable outcomes that are often sustained for multiple (4+) years after the 60-day treatment for LBP, which may mitigate the need for more invasive treatment interventions.

References:

- 1 Gilmore, Christopher A., et al. "Durable patient-reported outcomes following 60-day percutaneous peripheral nerve stimulation (PNS) of the medial branch nerves." *Interventional Pain Medicine* 2.1 (2023): 100243.
- 2 Gilmore, Christopher A., et al. "Treatment of chronic axial back pain with 60-day percutaneous medial branch PNS: Primary end point results from a prospective, multicenter study." *Pain Practice* 21.8 (2021): 877-889.

Acknowledgement:

- This study was funded by SPR Therapeutics.
- Gilmore, Deer, Desai, Li, and DePalma have research sponsored by SPR Therapeutics. Gilmore, Deer, Desai and Li are consultants for SPR. Swan, McGee, and Boggs are employees of SPR. Deer, Desai, McGee, and Boggs have stock options in SPR.
- Thank you to site research staff and the Clinical Affairs team at SPR, including Lauren Easley, Sara Anderson, and Rosemary Zang.