

Global, Multicenter Registry of Prospectively-Enrolled Patients Utilizing SCS for Chronic Pain: Long-Term Outcomes from a Sub-Cohort Diagnosed with Diabetic Peripheral Neuropathy

Anthony Berg¹, John Noles², Eric Loudermilk³, Joseph C. Hegarty⁴, Nathan Harrison⁵, Jeff B. Phelps⁶, Richard L. Rauck⁷, Julio Paez⁸, Albert Lee⁹, Louis Bojrab¹⁰, Jose Cid¹¹, Concepcion Perez, Brett Chandler¹³, Binit Shah¹⁴, Mayank Gupta¹⁵, Todd Turley¹⁶, Mahendra Sanapati¹⁷, Channing Willoughby¹⁸, Simon Thomson¹⁹, Stephen G. Smith²⁰, Nicolas Varela²¹, Anne Christopher²², Lilly Chen²³, Edward Goldberg²³

1. Spine Team Texas, Rockwall, TX USA 2. Spine and Pain Specialists, Shreveport, LA USA 3. Piedmont Comprehensive Pain Management, Anderson SC USA 4. Optim Health System – Tattnall Hospital, Reidsville, GA USA 5. Ochsner Health Center, Covington, LA USA 6. Spine Works Institute, North Richland Hills, TX USA 7. Carolinas Pain Institute, Winston-Salem, NC USA 8. South Lake Pain Institute, Clermont, FL USA 9. Tallahassee Neurological Clinic, Tallahassee, FL USA 10. Forest Health Medical Center, Ypsilanti, MI USA 11. Toledo Hospital Complex, Toledo, Spain 12. Hospital Universitario de La Princesa, Madrid, Spain 13. Pain Matrix, Geelong, VIC AUS 14. Carolinas Pain Center, Huntersville, NC USA 15. Kansas Pain Management & Neuroscience, Overland Park, KS USA 16. Advanced Spine and Pain, Phoenix, AZ USA 17. Pain Management Centers of America, Evansville, IN USA 18. Carolina Orthopaedic & Neurological, Spartanburg, SC USA 19. Basildon and Thurrock University, Basildon, UK 20. Ramos Center for Function Pain Medicine, Bradenton, FL USA 21. Clinica Universidad de Navarra, Pamplona, Spain 22. Saint Louis Pain Consultants, St. Louis, MO USA 23. Boston Scientific Neuromodulation, Valencia, CA USA

BACKGROUND

With the global rise in incidence of type-2 diabetes mellitus, there exists a growing population of those that will experience Diabetic Peripheral Neuropathy (DPN). Of those that experience DPN, a substantial will experience painful DPN (thought to occur in up to ~26%).¹ Patients diagnosed with DPN who suffer from associated chronic pain often display a complex array of clinical manifestations often requiring an extensive calibration of treatment regimen according to specific needs of patient.² Additionally, clinical outcomes using 1st and 2nd line therapies (e.g., drugs, lifestyle modification, physical therapy) are often suboptimal mainly due to occurrence of side effects and/or patient non-compliance.^{3,4} Furthermore, as a result of the burgeoning advances in neuromodulatory-based systems, interest has grown in reassessing this patient population when treated with implanted Spinal Cord Stimulation (SCS) devices. Accordingly, the American Diabetes Association now recommends referring DPN patients to interventional pain management care when pharmacological therapies have no meaningful effect.⁵ Here, we assessed real-world outcomes of those diagnosed with painful DPN as derived from a subset of patients participating in a global, multicenter SCS-patient registry who were implanted with contemporary neuromodulation systems capable of more advanced and highly customized approaches to therapeutic neurostimulation.

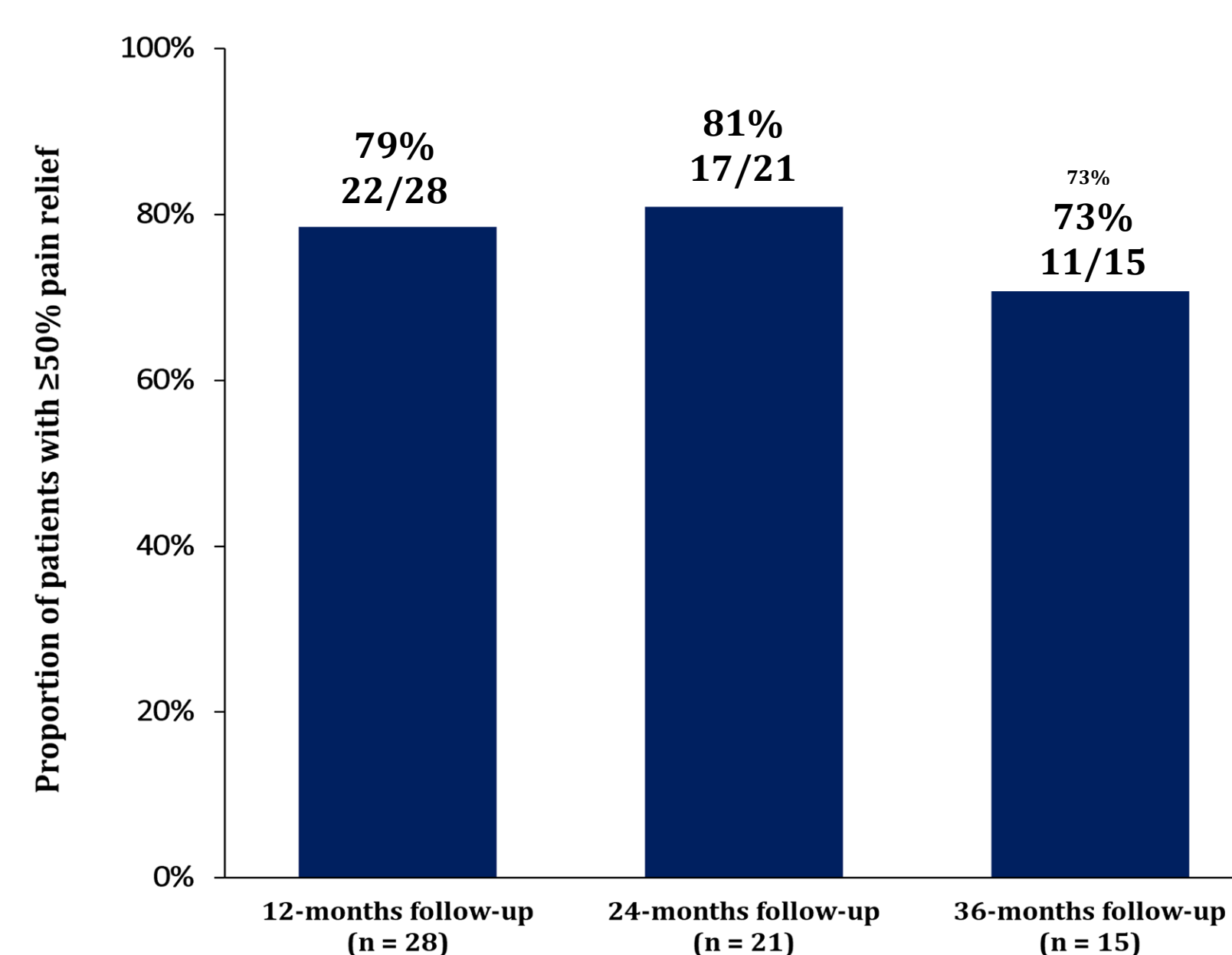
METHODS

Study Design	Prospective, multicenter registry (ClinicalTrials.gov: NCT01719055)
Study Device	Boston Scientific SCS Systems with multiple neurostimulative waveform programming: •Multiple Independent Current Control (MICC) •3D anatomically guided algorithms enabling precise neural targeting •Leads with tight contact spacing
Cohort	Diagnosis of Diabetic-Peripheral Neuropathy
Endpoints	•Responder Rate (% of patients reporting ≥50% targeted pain relief) ❖targeted pain: anatomical site intended to be treated using SCS •Quality-of-Life: EuroQoL-5D (EQ-5D) •Patient Global Impression of Change (PGIC) •Infection Rate (procedural)
Follow-Up	12-, 24-, and 36-months follow-up

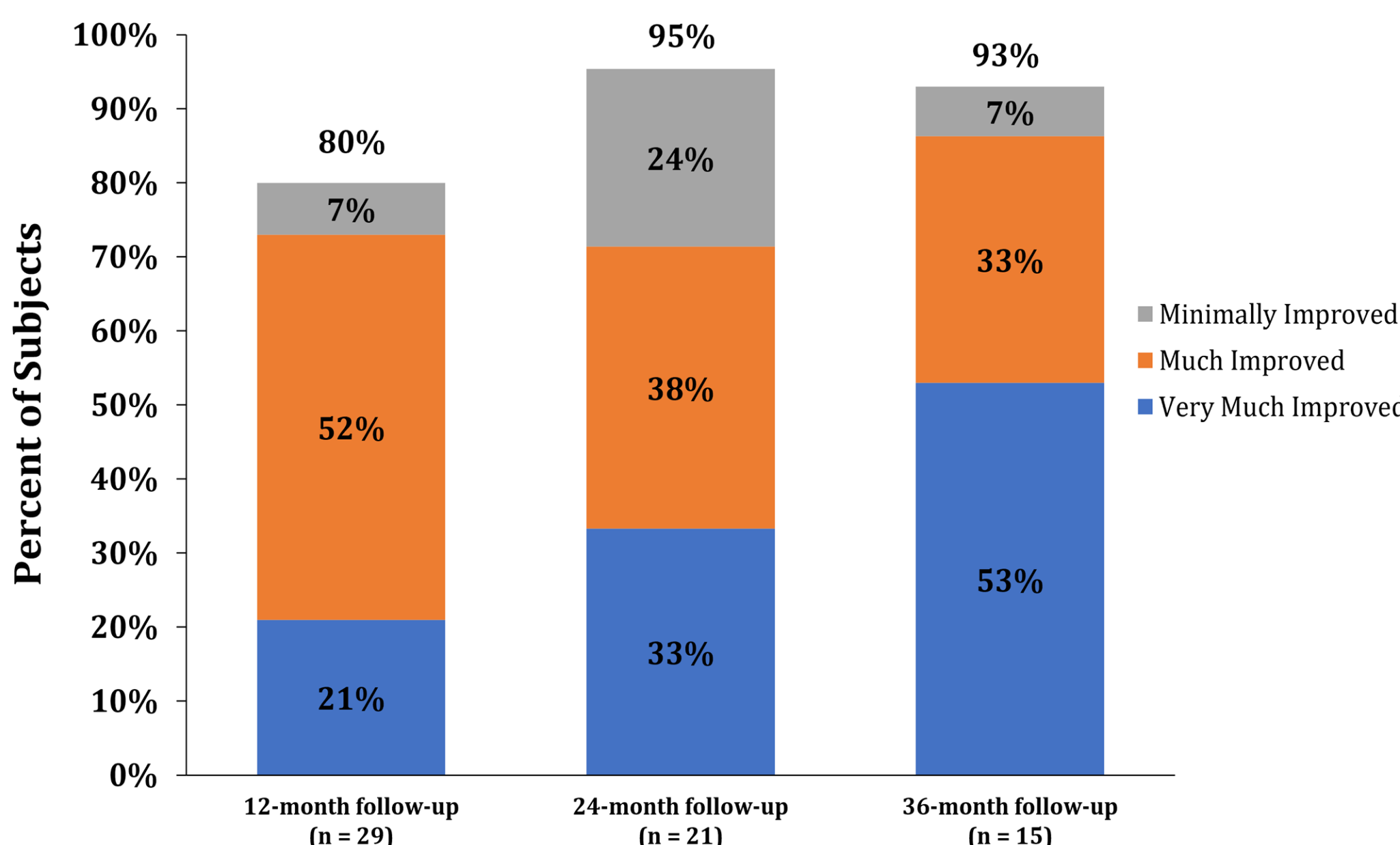
RESULTS

Baseline Demographics	
Gender (% male)	58.1% (25/43)
Age (years) – Mean (SD) n	66.2 (9.3) 43
Duration of time with chronic pain prior to device implant (yrs.) – Mean (SD) n	14.4 (13.6) 28

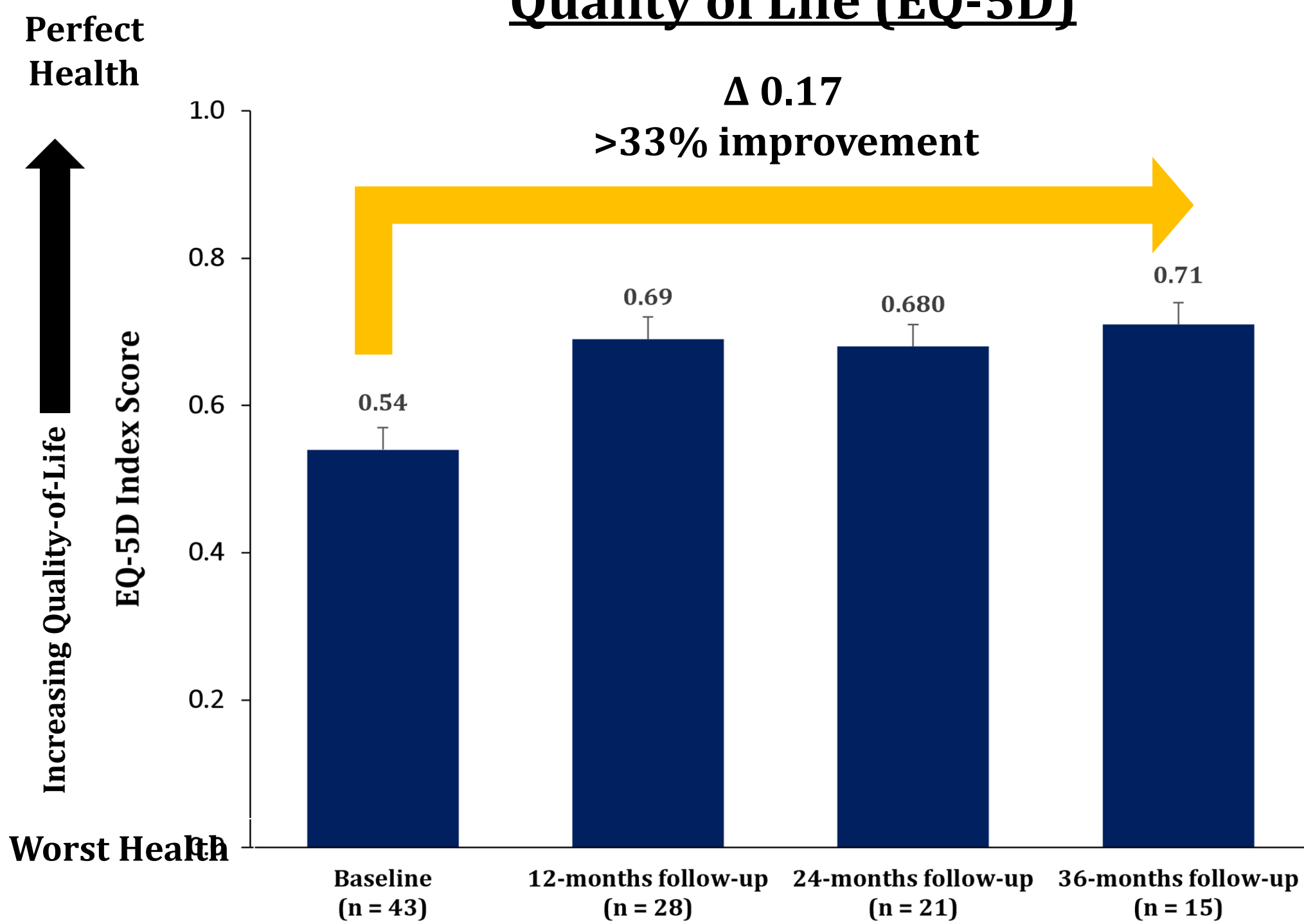
Treatment Responder Rates at Long-Term Follow-Up



Patient Global Impression of Change (PGIC)



Quality of Life (EQ-5D)



Safety Outcomes

Adverse Events (AE) related to device and/or procedure			
Adverse Event Term (n)	Non-serious AE	Serious AE	Outcome
Implant site pain (3)	X		resolved
Fever (1)	X		resolved
Headache (1)	X		resolved
Implant site infection (1)		X	resolved

All related non-serious and serious adverse events resolved.

- Low rate of procedural infection 4.7% (2/43)

CONCLUSIONS

- Real-world responder rate of up to 81% was noted when using an SCS system to treat chronic pain in patients diagnosed with DPN.

- Real-world clinical data from the global, multicenter, prospectively-enrolled RELIEF registry of a sub-cohort of DPN-diagnosed SCS patients demonstrated:

- At 12-months follow-up:

- ❑ Responder rate of up to 81% at 2-years
- ❑ Improvement in EQ-5D index (Quality of Life) of 3x minimally important difference (MID)⁶
- ❑ Consistent high level of satisfaction (up to 95% of patients reported improvement)
- ❑ Low rate of procedural infection 4.7% (2/43)

- This data supports the safety and efficacy of SCS in patients with chronic pain diagnosed with diabetic peripheral neuropathy

REFERENCES

1. Schreiber AK, Nones CF, Reis RC, Chichorro JG, Cunha JM. Diabetic neuropathic pain: Physiopathology and treatment. World J Diabetes. 2015 Apr 15;6(3):432-44.
2. Yang H, Sloan G, Ye Y, Wang S, Duan B, Tesfaye S, Gao L. New Perspective in Diabetic Neuropathy: From the Periphery to the Brain, a Call for Early Detection, and Precision Medicine. Front Endocrinol (Lausanne). 2020 Jan 17;10:929.
3. Finnerup NB, Attal N, Haroutounian S, McNicol E, Baron R, Dworkin RH, et al. Pharmacotherapy for neuropathic pain in adults: a systematic review and meta-analysis. Lancet Neurol. (2015)14:162–73.
4. Yang M, Qian C, Liu Y. Suboptimal Treatment of Diabetic Peripheral Neuropathic Pain in the United States. Pain Med. 2015;16(11):2075–83.
5. Pop-Busui R, Boulton AJM, Feldman EL, et al. Diabetic Neuropathy: A position statement by American Diabetes Association. Diabetes Care. 2017; 40(1): 136-154..
6. McClure NS, Sayah FA, Ohinmaa A, Johnson JA. Minimally Important Difference of the EQ-5D-5L Index Score in Adults with Type 2 Diabetes. Value Health. 2018 Sep;21(9):1090-1097.

DISCLOSURES

Study Sponsored by Boston Scientific. Drs. Berg, Rauck, and Thomson have consulting agreements with Boston Scientific. Lilly Chen and Edward Goldberg are employees of Boston Scientific..