

# Treatment of Painful Diabetic Neuropathy with 10KHz SCS 24 month Outcomes of an RCT

Kasra Amirdelfan, M.D.  
Director of Clinical Research  
V.P. Business Development  
IPM Medical Group, Inc.  
Walnut Creek, CA

# Disclosures

- Consultant:
  - Medtronic
  - Boston Scientific
  - Nevro
  - Nalu
  - Saluda
  - Presidio
  - Biotronik
- Minor Options:
  - Nalu
  - Presidio

# Senza PDN Randomized Controlled Trial (RCT)

To determine whether high frequency 10-kHz Therapy improves outcomes for patients with refractory PDN.

- 216 subjects with diabetes
- $\geq 5$  on pain VAS
- A1c  $\leq 10\%$
- BMI  $< 45$
- 18 US centers randomized 216 subjects 1:1
- Crossover at 6 months with 24-month follow-up (93% of those eligible crossed over from CMM)

## Treatments

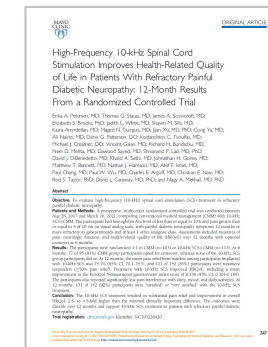
- CMM vs. 10 kHz Therapy + CMM.



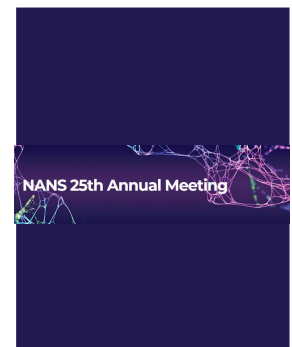
6-month<sup>1</sup>  
JAMA Neurology  
Apr 2021



12-month<sup>2</sup>  
Diabetes Care  
Nov 2021



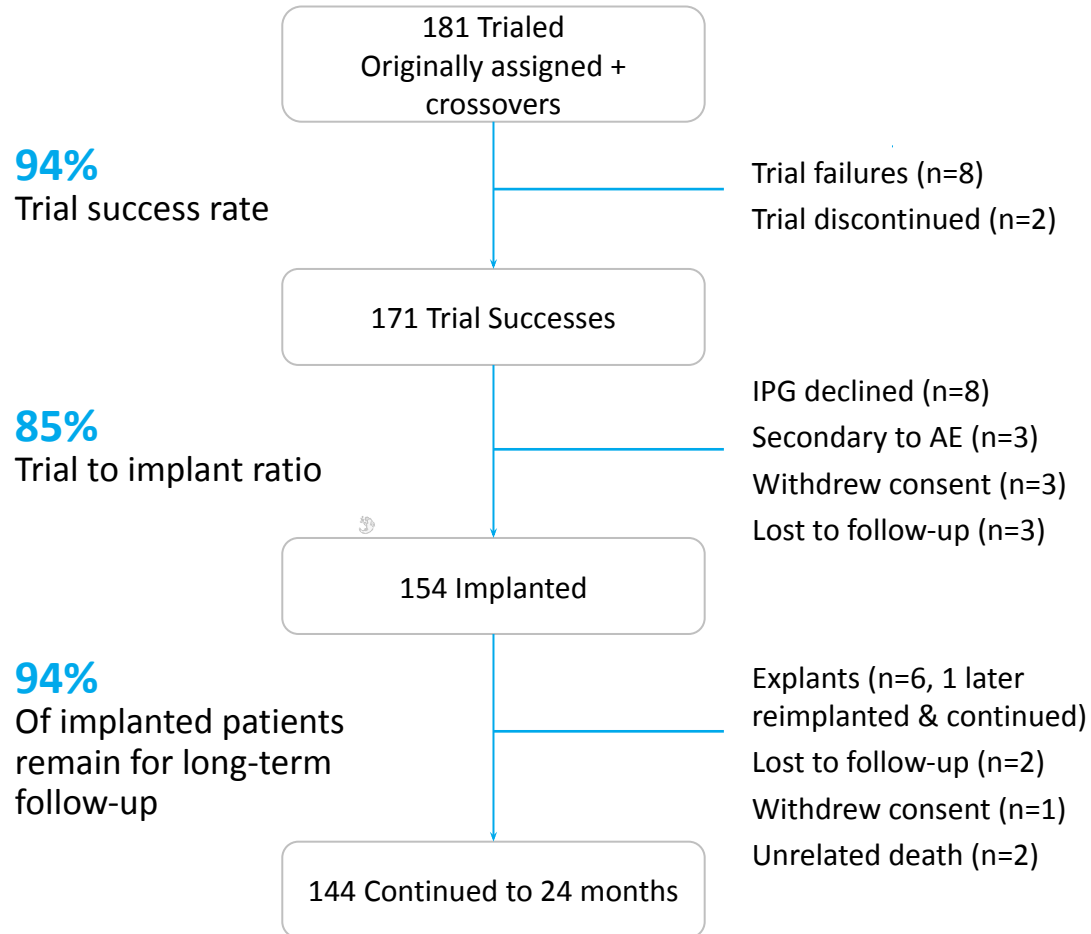
12-Month<sup>3</sup>  
Mayo Clinic Proceedings  
Jul 2022



18-month<sup>4</sup>  
Presented at NANS  
Jan 2022

1. Petersen E. et al. Effect of high frequency (10-kHz) spinal cord stimulation in patients with painful diabetic neuropathy: a randomized clinical trial. *JAMA Neurology* Apr 2021
2. Petersen E. et. al. Durability of high-frequency 10 kHz spinal cord stimulation for patients with painful diabetic neuropathy refractory to conventional treatments. *Diabetes Care*, Nov 2021.
3. Petersen E. et al., High-Frequency 10-kHz Spinal Cord Stimulation Improves Health-Related Quality of Life in Patients With Refractory Painful Diabetic Neuropathy: 12-Month Results From a Randomized Controlled Trial. *Mayo Clinic Proceedings*, Aug 2022.
4. Petersen E. et. al. Durability of 10 kHz spinal cord stimulation for painful diabetic neuropathy: 18-month results. NANS, Jan 2022.

# Subject Disposition: 10 kHz SCS



## Safety

No stimulation-related neurological deficits

No explants for loss of efficacy

8 procedure-related infections (5.2%)





3 resolved with antibiotics

5 required explant (3.2%, 1 patient reimplanted)

1 explant as a precaution for an unrelated infection

# Inclusion criteria and baseline characteristics

## SENZA-PDN RCT Inclusion criteria:

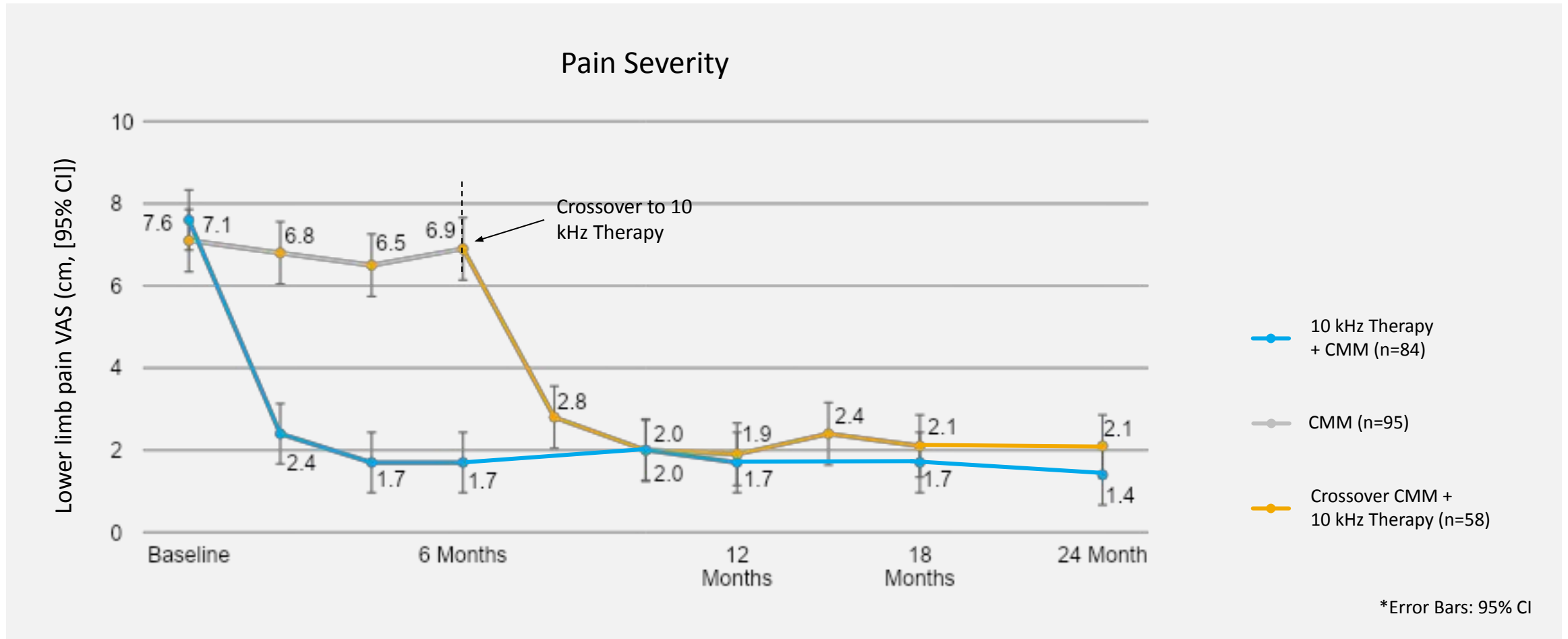
-  PDN diagnosis with symptoms for 12 months or more
-  Refractory to 2 or more pharmacologic treatments (gabapentin or pregabalin and at least 1 other class of analgesic)
-  Lower limb pain intensity of 5 cm or more on a 10-cm visual analogue scale (VAS)
-  Appropriate surgical candidate

Effect size index (Cohen's d):

- ≥ 0.20 = small
- ≥ 0.50 = medium
- ≥ 0.80 = large

Baseline Characteristics	CMM n = 103	10 kHz SCS + CMM n = 113	Standardized Difference*
Age in years, mean (SD)	60.8 (9.9)	60.7 (11.4)	0.01
Male, n (%)	66 (64%)	70 (62%)	0.04
Race			
White, n (%)	85 (82.5%)	87 (77.0%)	0.14
Black or African American, n (%)	13 (12.6%)	18 (15.9%)	
Native Hawaiian or other Pacific Islander, n (%)	1 (1.0%)	3 (2.7%)	
American Indian or Alaska Native, n (%)	0 (0.0%)	2 (1.8%)	
Asian, n (%)	1 (1.0%)	1 (0.9%)	
Other, n (%)	3 (2.9%)	2 (1.8%)	
Diabetes			
Type 1, n (%)	3 (3%)	8 (7%)	0.19
Type 2, n (%)	100 (97%)	105 (93%)	
Duration in years			
Diabetes, mean (SD)	12.2 (8.5)	12.9 (8.5)	0.09
Peripheral neuropathy, mean (SD)	7.1 (5.1)	7.4 (5.7)	0.06
Lower limb pain VAS in cm, mean (SD)	7.1 (1.6)	7.5 (1.6)	0.22
< 7.5 cm, n (%)	57 (55%)	54 (48%)	0.15
≥ 7.5 cm, n (%)	46 (45%)	59 (52%)	
HbA1c, mean (SD)	7.4% (1.2%)	7.3% (1.1%)	0.11
< 7.0%, n (%)	40 (39%)	46 (41%)	0.04
≥ 7.0%, n (%)	63 (61%)	67 (59%)	
BMI, mean (SD)	33.9 (5.2)	33.6 (5.4)	0.06

# Pain Relief over 24-Months



Partial 24-month data for original 10 kHz arm. Complete 24-month data will be analyzed and published at a later date.

# 24 Month Individual Pain Relief

**84%** Responders (119/142)

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**77%** Average Pain Relief

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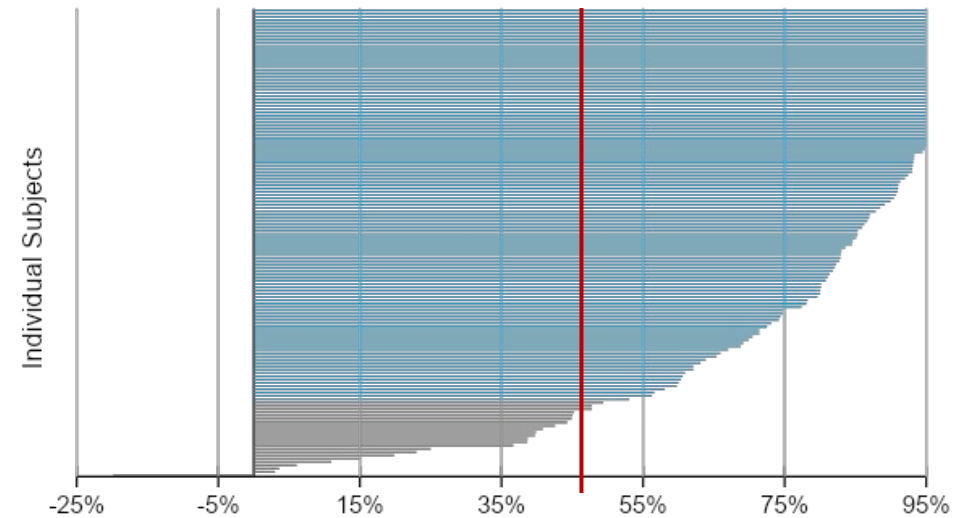
**61%\*** Profound Responders (87/142)

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**1.3** Number Needed to Treat

Partial 24-month data for original 10 kHz arm. Complete 24-month data will be analyzed and published at a later date.

Implanted Patients at 24 Months

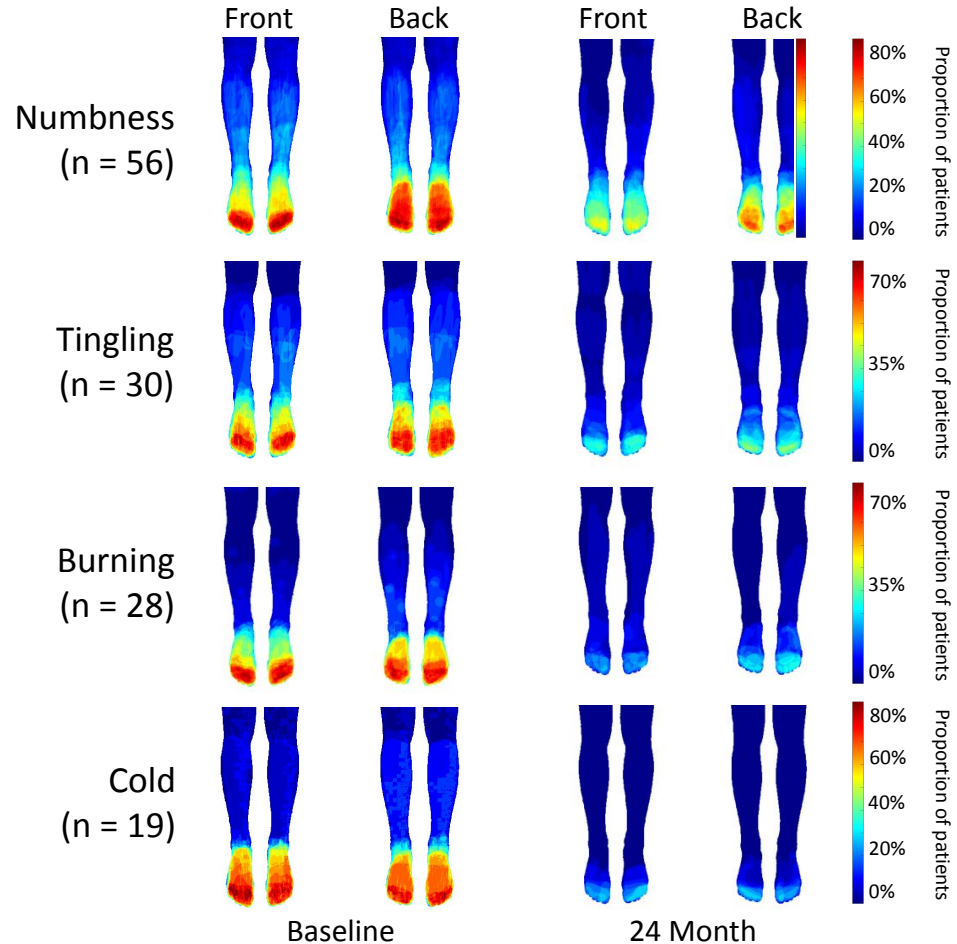


Improvement from baseline pain VAS

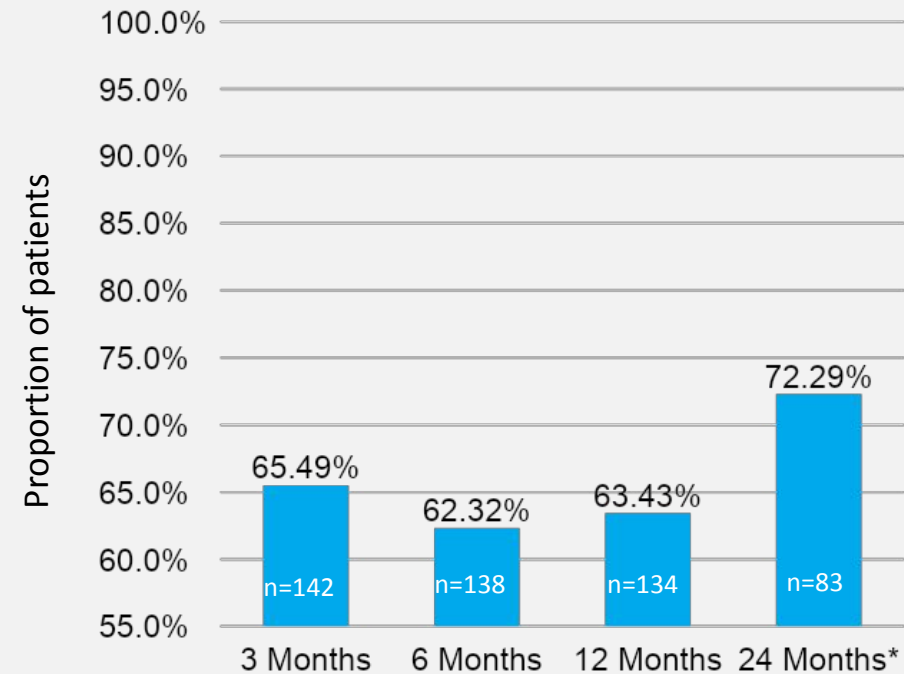
\*Profound responder defined as  $\geq 80\%$  pain relief

# Neurological Improvement with 10 kHz SCS

## Patient-reported reductions in dysesthesias



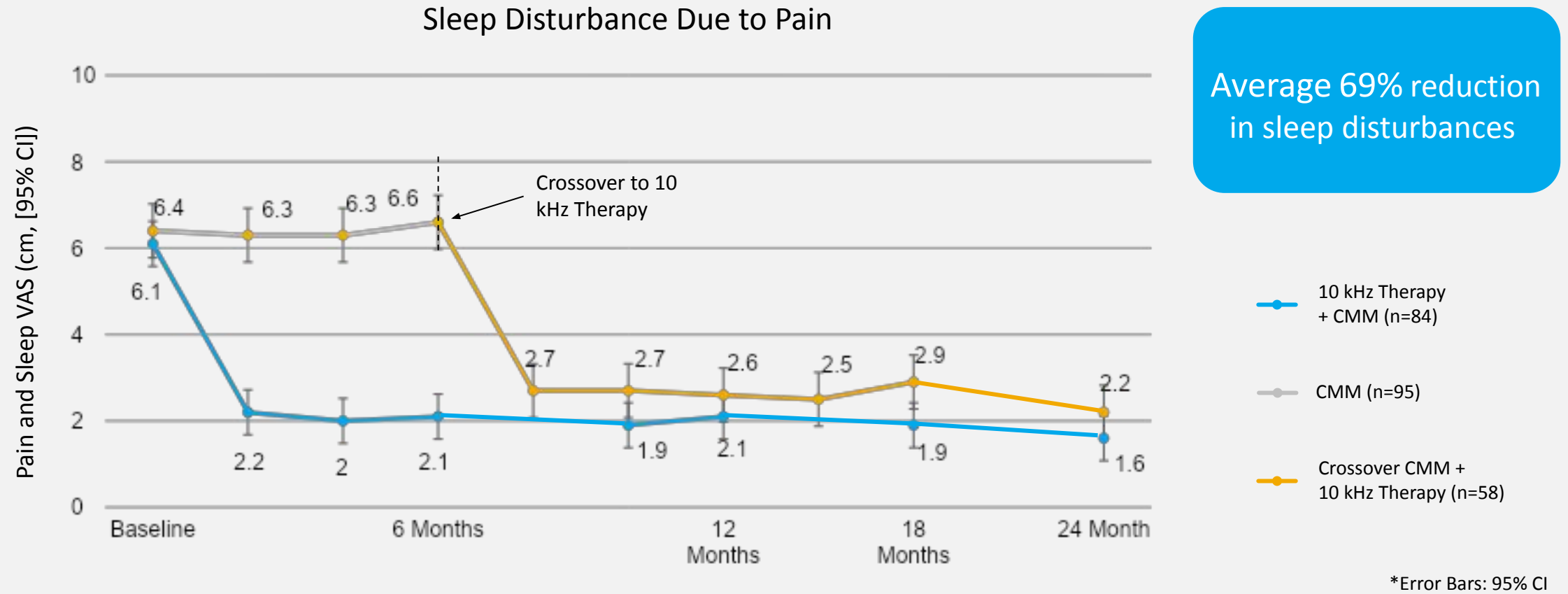
Did the investigator note improvement compared to baseline in motor, sensory, or reflex function, without deterioration in any category?



\*Partial 24-month data for original 10 kHz arm. Complete 24-month data will be analyzed and published at a later date.



# Reduction in Sleep Disturbance



Partial 24-month data for original 10 kHz arm. Complete 24-month data will be analyzed and published at a later date.

# Conclusions

- First FDA approved indication outside of trunk and limb in 50 years
- Largest SCS RCT performed to date
- 24 month data shows long-term efficacy
- Paresthesia free SCS proven to be best strategy for PDN
- Real world/registry data needed to further validate