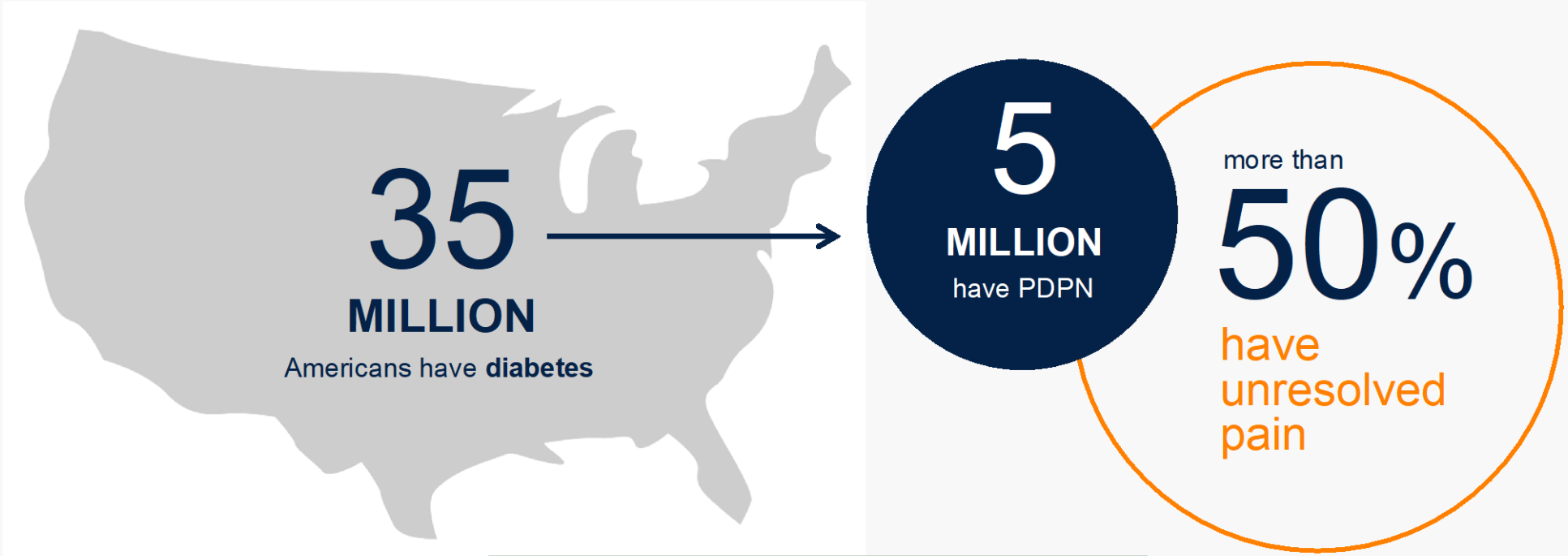
PATRICK FITZSIMMONS, MD
INTERVENTIONAL PAIN
OCHSNER CLINIC

DPN Management Updates

Disclosures:

- None

35 million Americans have diabetes, 5 million have PDPN, and more than 50% of patients with PDPN have unresolved pain with first-line pain therapies[1-4]



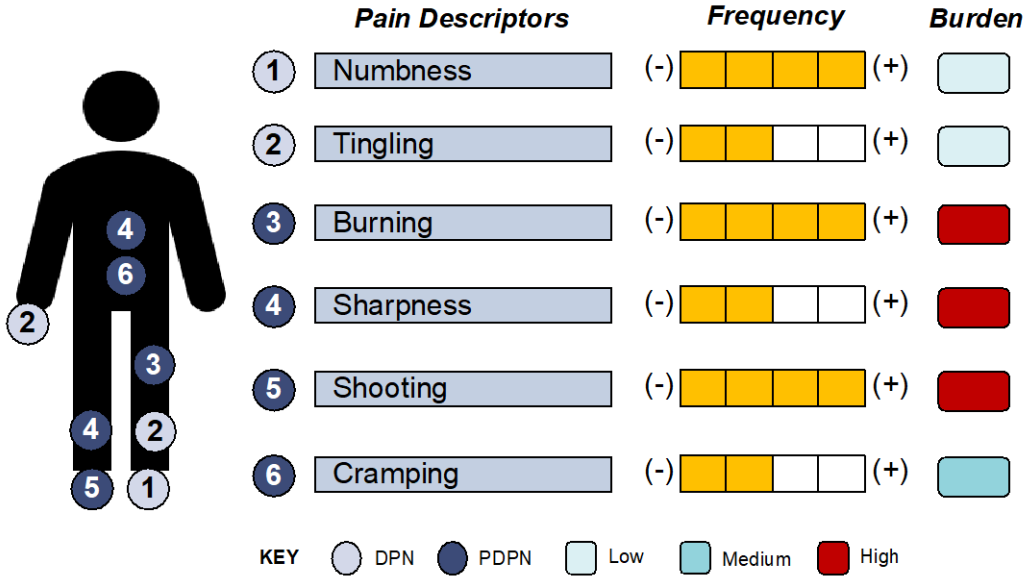
Unresolved PDPN can result in higher opioid use, loss of employment, and higher healthcare resource use such as surgical interventions[1,5-7]

Sources: 1 Gore M. et al. 2005; **2** International Diabetes Foundation 2019; **3** Gore M. et al. 2006; **4** Iqbal Z. et al. 2018; **5** Javed S. et al. 2015; **6** Sloan G. et al. 2018; **7** Veves A. et al. 2008

DPN Is A Significant Clinical Problem: Pain Is A Debilitating Feature Of DPN Resulting In Significant Morbidity[1]

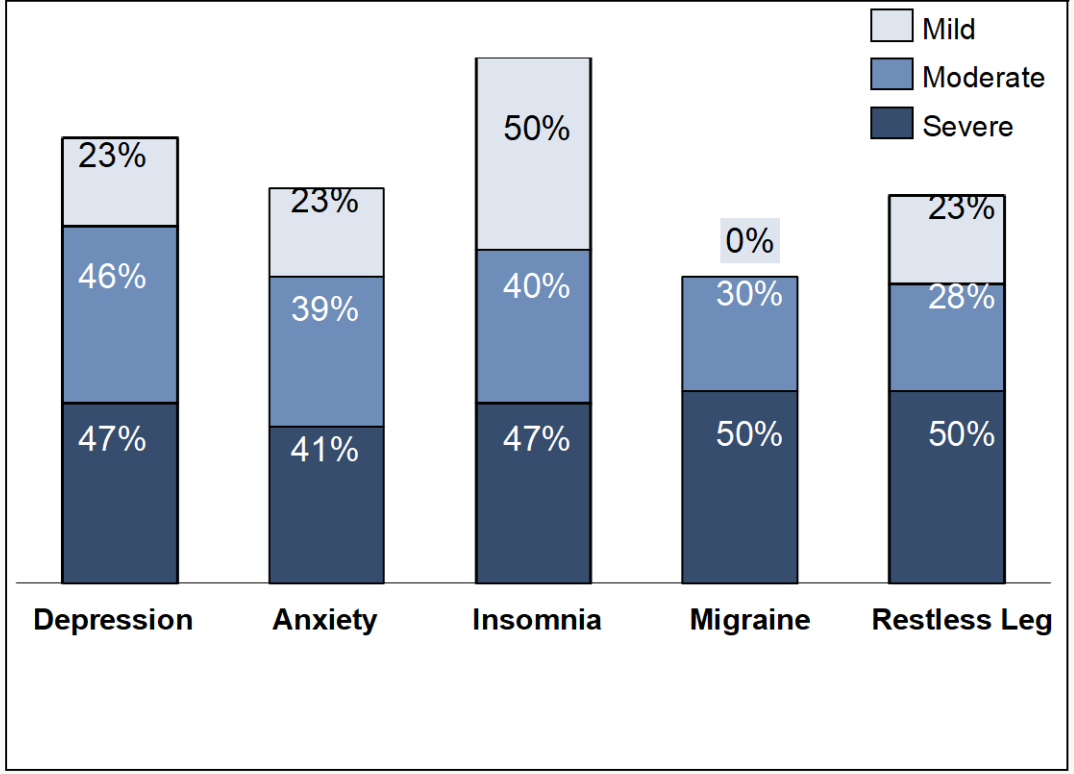
Painful DPN (PDPN) can be severe, chronic, & disabling, leading to substantial limitations, particularly with increasing severity

Clinical Presentation[1]



- Patients often use descriptors for their pain during diagnosis[3,4]
- The classic presentation of PDPN is pain or tingling in the feet that can be described as “burning” or “shooting” [3,4]

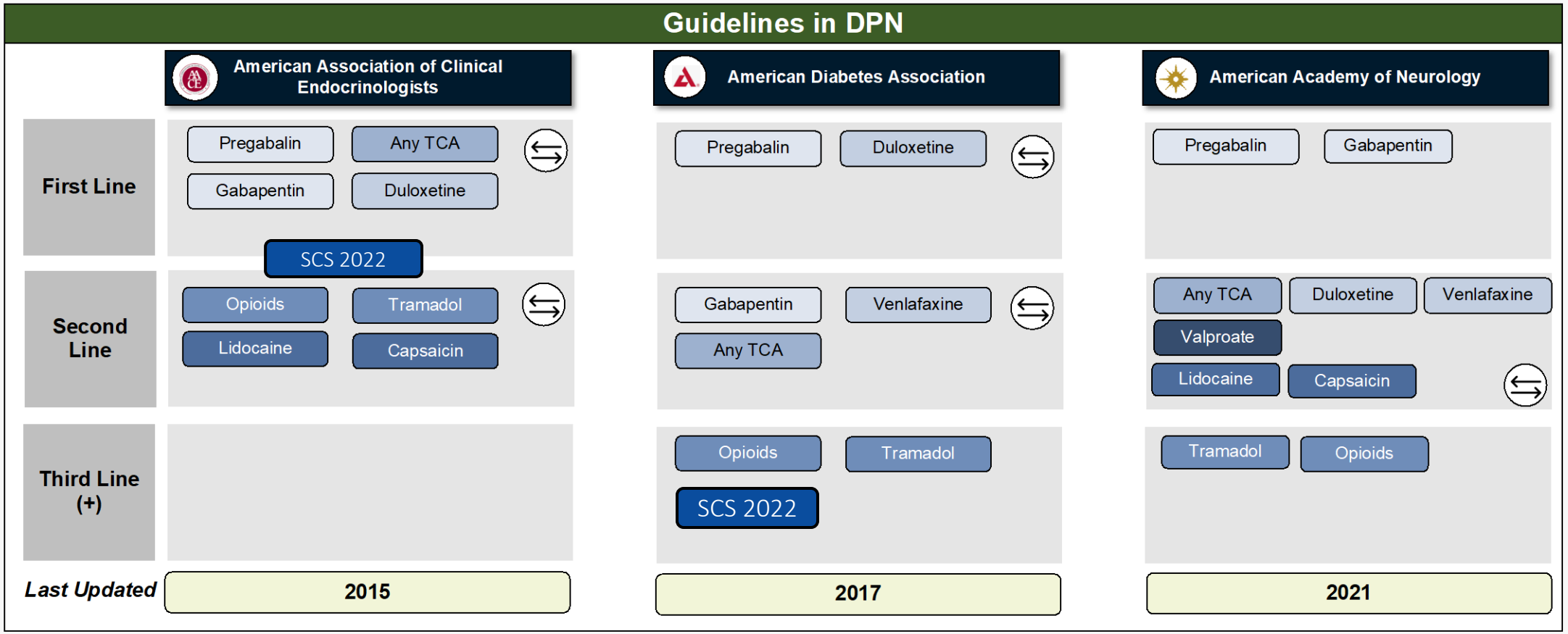
PDPN Is Associated With Additional Comormidities[2,5]



Sources: **1** Colloca, L. et al. 2017; **2** Sadosky, A. et al. 2013; **3** Eichholz, M. et al. 2017; **4** Jensen, T.S. et al 2006; **5** Schadina, S. & Toth, C. 2013

Three Major US Guidelines In DPN Have General Consensus On The Treatment Algorithm

American professional bodies advocate for anticonvulsants or antidepressants in the first line[1,2,3]



Sources: **1** Pop-Busui, R. et al. 2017; **2** American Academy of Neurology 2021; **3** Boulton, A. et al. 1998

Common Rx Perspectives

Treatment Class	Specific Drug	NNT	NNH
TCAs	Amitriptyline	1.3	4.6-16
SNRIs	Duloxetine	5.8	15
Gabapentinoids	Gabapentin	5.9	7.5
	Pregabalin	4.3	4-113
Opioids	Tramadol	4.4	8.2

Duehmke RM, Derry S, Wiffen PJ, Bell RF, Aldington D, Moore RA, 2017, Tramadol for neuropathic pain in adults, Cochrane Database Syst Rev, DOI: 10.1002/14651858.CD003726.pub4, PMID: 28616956, PMCID: PMC6481580.
Saarto T, Wiffen PJ, 2005, Antidepressants for neuropathic pain, Cochrane Database of Systematic Reviews, DOI: 10.1002/14651858.CD005454, PMID: 16034979
Saarto T, Wiffen PJ, 2007, Antidepressants for neuropathic pain (update), Cochrane Database of Systematic Reviews, DOI: 10.1002/14651858.CD005454.pub2, PMID: 17943857, PMCID: PMC10576544
Wiffen PJ, Derry S, Bell RF, Rice AS, Tölle TR, Phillips T, Moore RA, 2017, Gabapentin for chronic neuropathic pain in adults, Cochrane Database Syst Rev, DOI: 10.1002/14651858.CD007938.pub4, PMID: 28597471, PMCID: PMC6452908
Moore RA, Wiffen PJ, Derry S, Toelle T, Rice AS, 2014, Gabapentin for chronic neuropathic pain and fibromyalgia in adults, Cochrane Database Syst Rev, DOI: 10.1002/14651858.CD007938.pub3, PMID: 24771480, PMCID: PMC6464253
Moore RA, Wiffen PJ, Derry S, McQuay HJ, 2011, Gabapentin for chronic neuropathic pain and fibromyalgia in adults, Cochrane Database Syst Rev, DOI: 10.1002/14651858.CD007938.pub2, PMID: 21412914, PMCID: PMC4171034
Sultan A, Gaskell H, Derry S, Moore RA, 2008, Duloxetine for painful diabetic neuropathy and fibromyalgia pain: systematic review of randomised trials, BMC Neurol, DOI: 10.1186/1471-2377-8-29, PMID: 18673529, PMCID: PMC2529342
Biegstraaten M, van Schaik IN, 2007, [Pregabalin in the treatment of neuropathic pain], Ned Tijdschr Geneeskd, PMID: 17715763

Continued

Odds ratios for efficacy and withdrawal, numbers needed to treat (NNT) and numbers needed to harm (NNH)

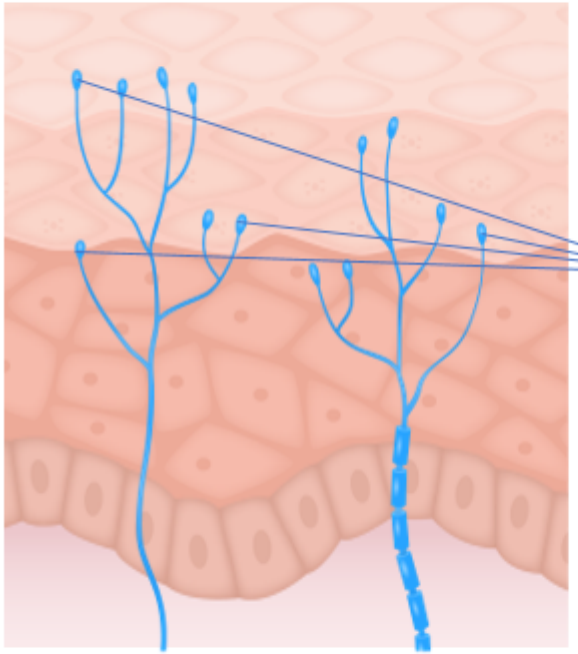
Drug class	Odds ratio – efficacy	Odds ratio – withdrawal (2ry to AE)	NNT	NNH
Tricyclics	22.2 (5.8–84.7)	2.3 (0.6–9.7)	1.5–3.5	2.7–17.0
Duloxetine	2.6 (1.6–4.8)	2.4 (1.1–5.4)	5.7–5.8	15.0
Traditional anticonvulsants	5.3 (1.8–16.0)	1.5 (0.3–7.0)	2.1–3.2	2.7–3.0
New generation anticonvulsants	3.3 (2.3–4.7)	3.0 (1.75–5.1)	2.9–4.3	26.1
Opioids	4.3 (2.3–7.8)	4.1 (1.2–14.2)	2.6–3.9	9.0

Vinik AI, Casellini CM. Guidelines in the management of diabetic nerve pain: clinical utility of pregabalin. Diabetes Metab Syndr Obes. 2013;6:57-78. doi: 10.2147/DMSO.S24825. Epub 2013 Feb 22. PMID: 23467255; PMCID: PMC3587397.

Capsaicin

- Potent TRPV1 agonist
  - Preferentially expressed on sensory (nociceptive) nerve fibers – mainly C and Aδ fibers
  - Important in pain perception – provides integrated responses to heat, acidic conditions, and endogenous inflammatory substances
  - Detects harmful stimuli and conveys this information to CNS

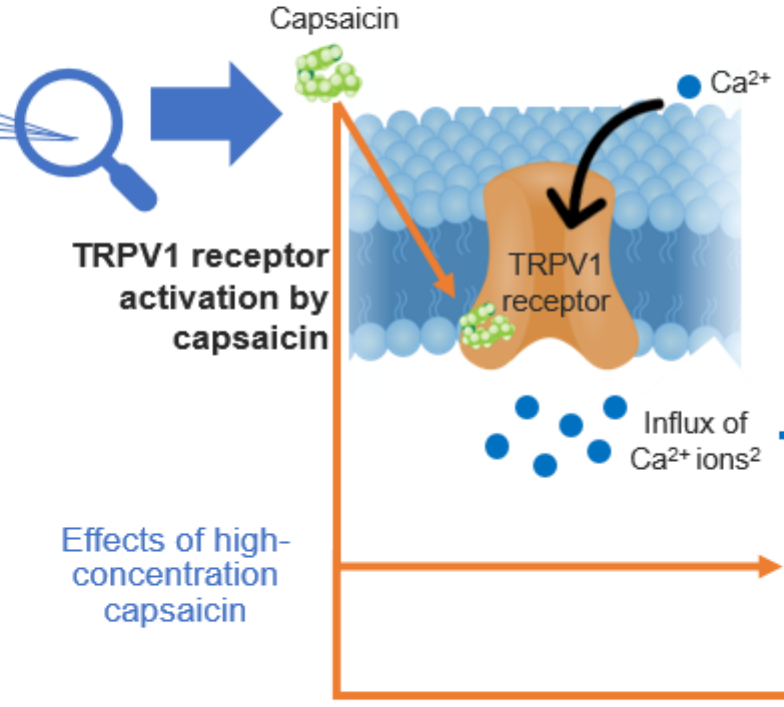
Activation of TRPV1 receptor by high concentration capsaicin → neurolysis of nociceptive nerve terminals



C fiber **Aδ fiber**

Heat-sensitive C and Aδ fibers located in the epidermis express TRPV1 receptors[1]

Capsaicin is a selective agonist and directly binds to TRPV1 receptors[2]



Defunctionalization → ablation of TRPV1-expressing nociceptors[2] → **ANALGESIA**

Ca2+ overload[2]

Release of intracellular Ca2+ ions[2]

Impairment of mitochondrial function[2]

Regeneration and restoration of function of TRPV1-expressing nociceptors[3,4]

May result in more normalized ENFD[3,4]

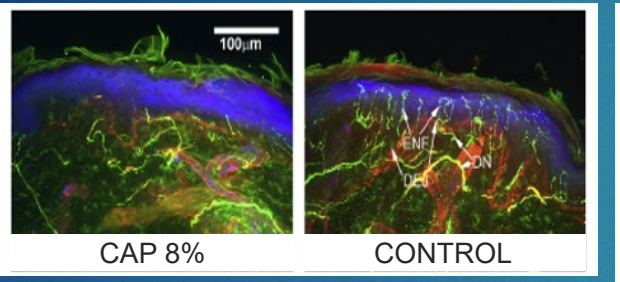
1. Üçeyler N & Sommer C. *Pain Ther*. 2014;3:73–84. 2. Anand P & Bley K. *Br J Anaesth*. 2011;107:490–502.
3. Anand P et al. *Front Neurol*. 2022;13:998904. 4. Sendel M et al. *Pain*. 2023;164:534–42.

Ca, calcium; ENFD, epidermal nerve fiber density; TRPV1, transient receptor potential vanilloid subtype 1.

Adapted from Anand & Bley. *Br J Anaesth*. 2011.[2]

Capsaicin MOA continued

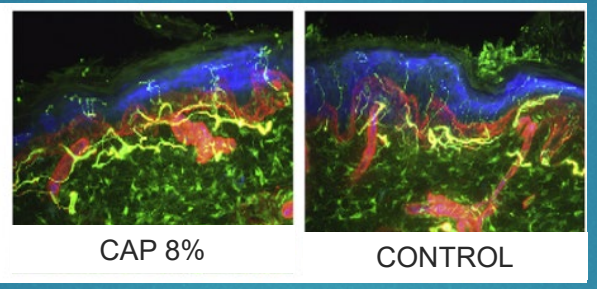
Week 1



CAP 8% CONTROL

Nerve fiber reduction (80%)

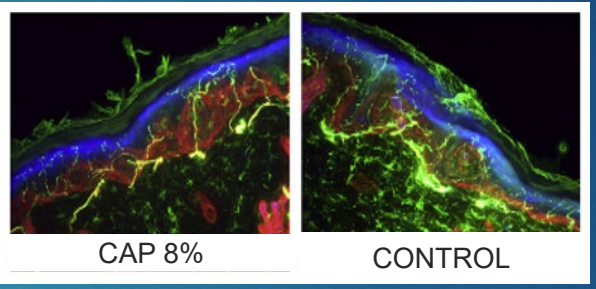
Week 12



CAP 8% CONTROL

Partial regeneration

Week 24



CAP 8% CONTROL

Recovery (93%)

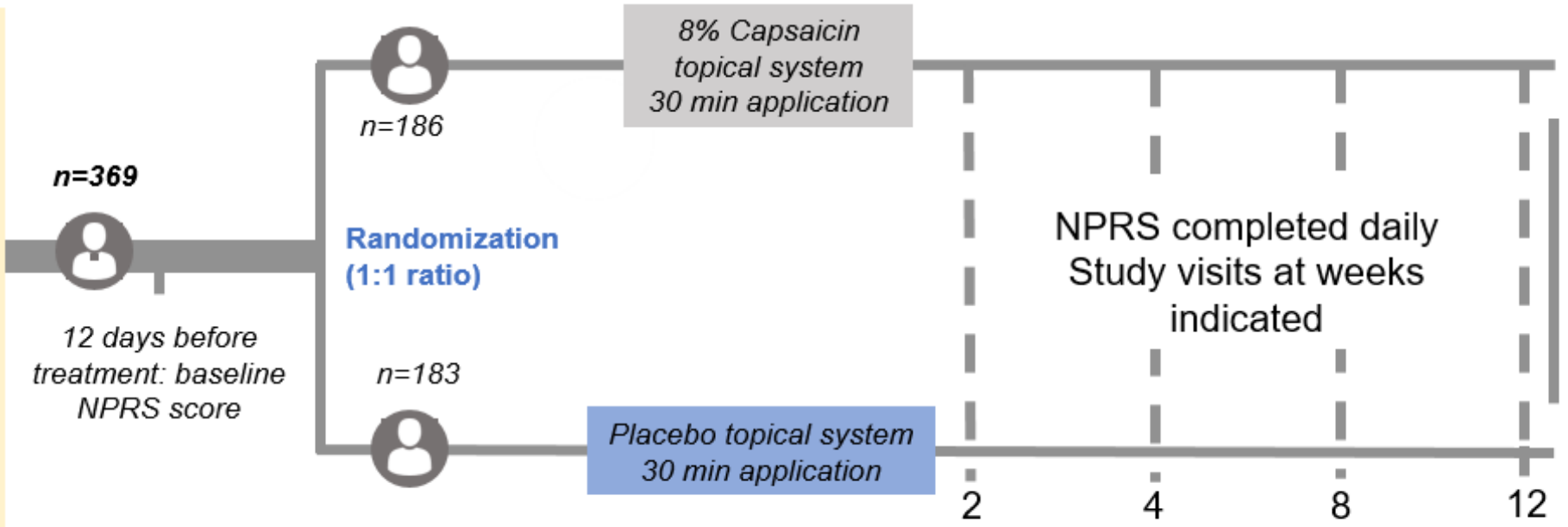
ENF and dermal nerves = **yellow** or **green**
Basement membrane at the dermal-epidermal junction and around blood vessels = **red**
Epidermis = **blue**

STEP Trial

In this Phase 3 study, 369 PDPN patients were randomized 1:1 to receive either Capsaicin 8% or placebo 30-min. topical system application to painful areas of the feet, with daily NPRS reports and other evaluations over for 12 weeks:

Key inclusion criteria:

- Aged ≥18 years with a diagnosis of PDPN for at least 1 year
- HbA1c ≤11% at screening and 3–6 months pre-screening
- Stable doses of pain medication >4 weeks before screening*
- Average NPRS score over the last 24 hours of ≥4 during the screening period



Primary EP: Percentage change in NPRS over the previous 24 hours in question 5 of the Brief Pain Inventory-Diabetic Neuropathy

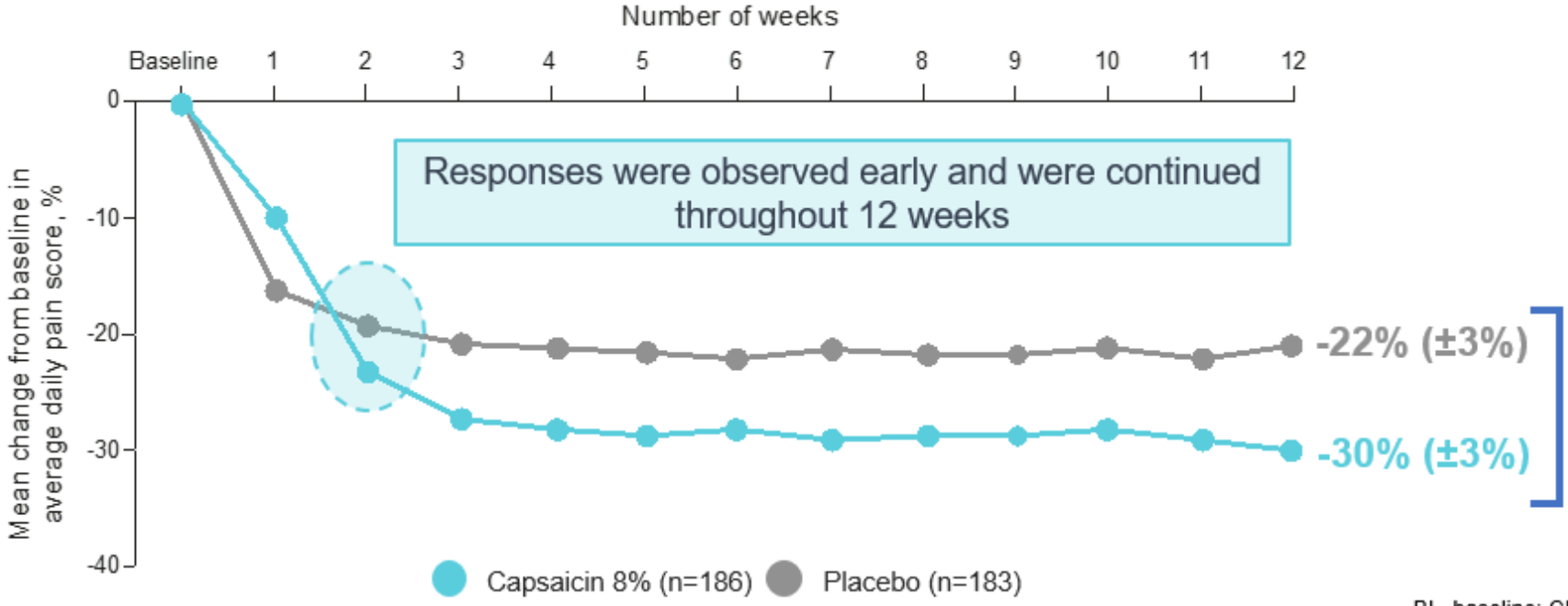
NPRS, numeric pain rating scale; PDPN: Painful Diabetic Peripheral Neuropathy

Simpson DM *et al*. J Pain. 2017;18:42–53.

STEP Trial: a single application of capsaicin 8% topical system reduced average daily pain from PDPN of the feet for up to 3 months

Phase III, randomized, double-blind trial; Capsaicin 8% vs placebo; one 30-minute application to feet; 12-week follow-up

Mean percentage change from BL in average daily pain score (NPRS) (ITT)



Patients treated with Capsaicin 8% achieved a **statistically significant reduction** in average daily pain between baseline and weeks 2–8 (primary outcome)...[1]

...and a **statistically significant reduction** in average daily pain between baseline and week 12[2]

Least-squares mean change in NPRS score with Capsaicin 8% vs placebo: –1.92 vs –1.37.
Least-squares mean difference: –0.56 (95% CI, –0.98, –0.14)

BL, baseline; CI, confidence interval; ITT, intent-to-treat; NPRS, Numeric Pain Rating Scale; PDPN, painful diabetic peripheral neuropathy.

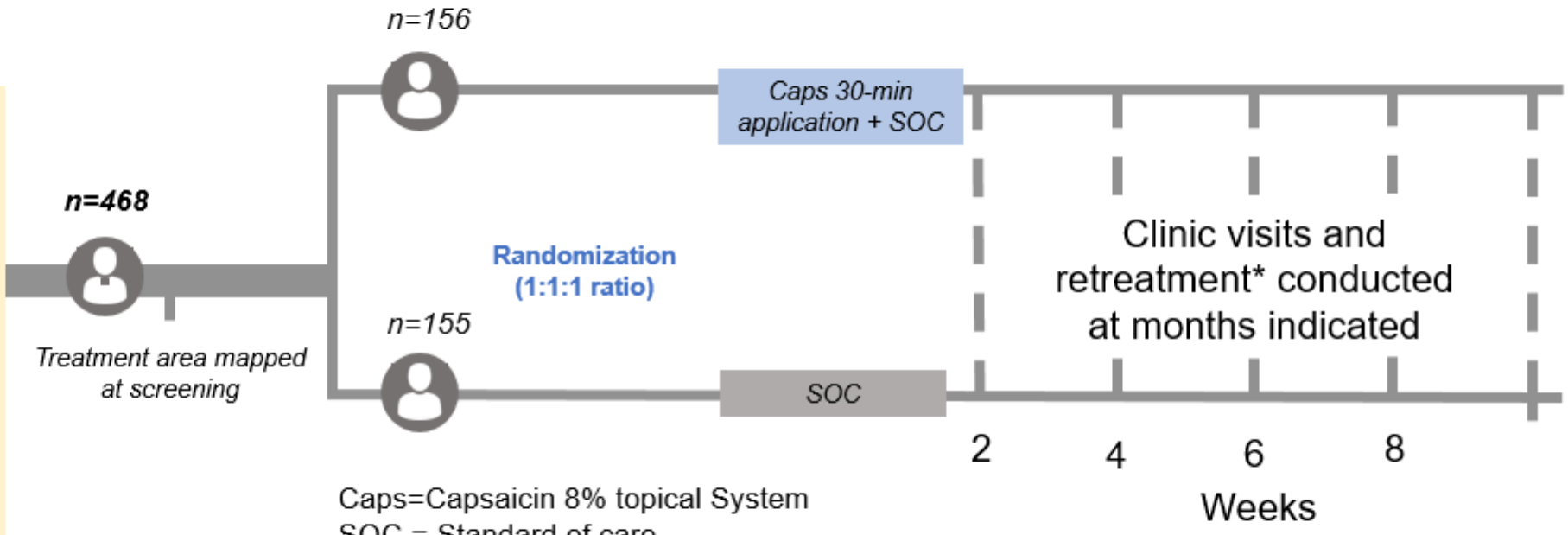
1. Simpson DM et al. *J Pain*. 2017;18:42–53.
2. QUTENZA® [prescribing information]. Morristown, NJ: Averitas Pharma, Inc.

PACE Trial Design

Phase III, open-label, long-term safety study – Capsaicin 8% topical system 30-minute repeated applications* to feet + SOC vs. SOC alone

Key Inclusion Criteria

- Aged ≥18 years with a diagnosis of PDPN confirmed by a score of ≥3 on the MNSI
- HbA1c ≤9% at screening and 3–6 months
- Stable glycemic control for ≥6 months
- Average daily pain score over the last 24 hours of ≥4 (question 5 of BPI-DN) at screening and baseline



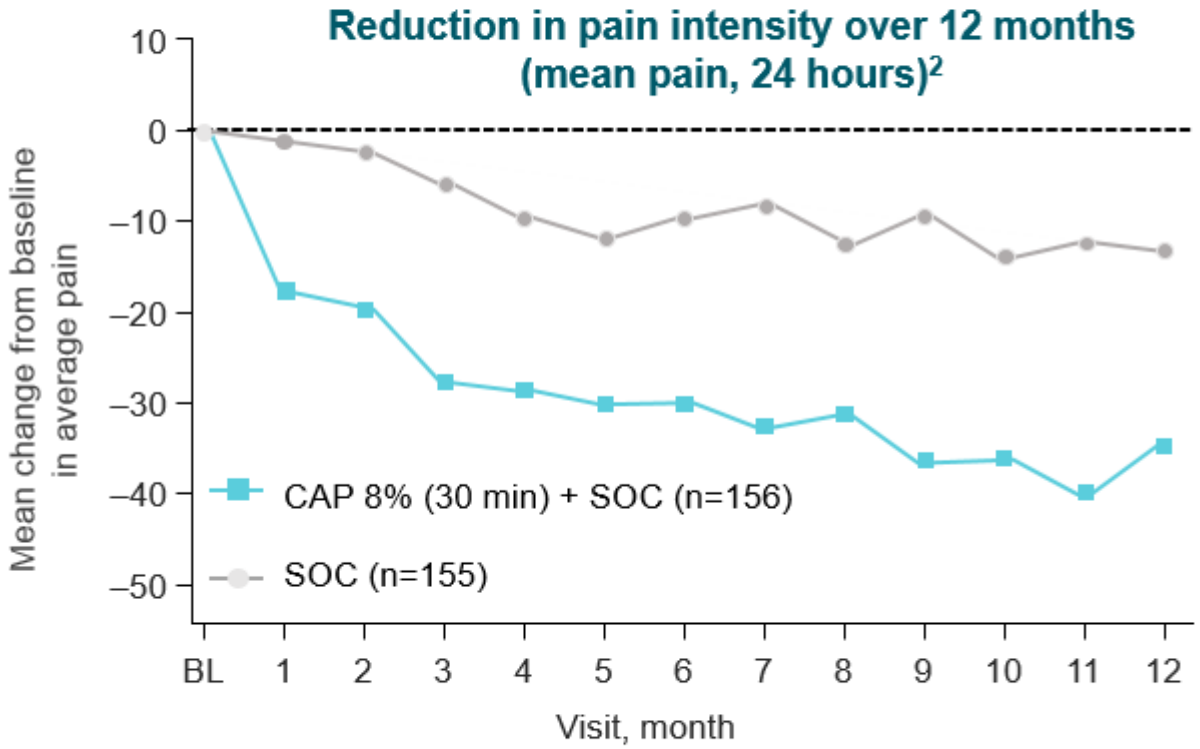
Caps=Capsaicin 8% topical System
SOC = Standard of care

The primary objective was safety, assessed by changes in Norfolk Quality of Life-Diabetic Neuropathy (QOL-DN) total score from baseline to end of study at 52 weeks

*Retreatment possible with minimum treatment interval of 8 weeks.
The PACE study also included a 60-min treatment application to fully evaluate safety but only 30-min application data is included for consistency with US label

Vinik AI, et al. BMC Neurol. 2016;16:251–65

PACE Trial
Efficacy: Repeated applications of Capsaicin 8% lead to progressive benefit over 52 weeks[1]



A **reduction in average pain** (measured by the **BPI-DN**) with Capsaicin 8% + SOC vs SOC alone was observed **as early as 1 month** and **continually improved** to end of study[2]

*1–7 treatments with ≥8-week intervals. SOC was optimized for each patient at the discretion of each investigator and was assessed at clinic visits and on days 1 to 5 post treatment, by completion of a rescue pain medication diary.

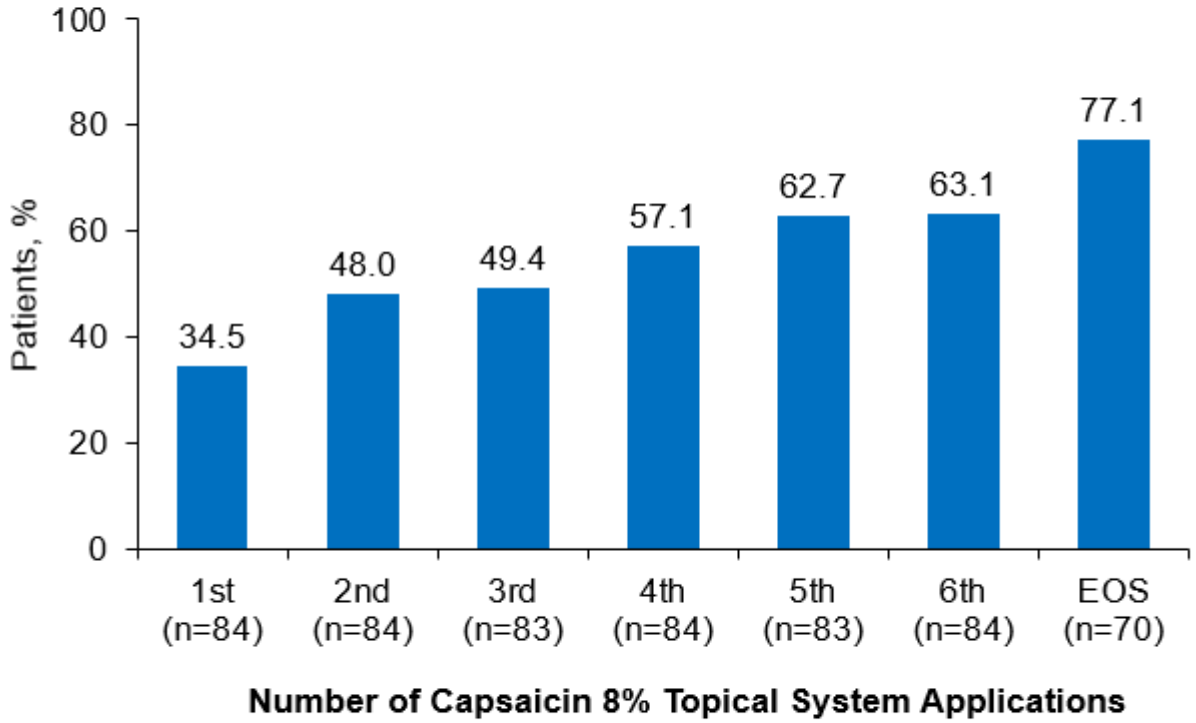
BL, baseline; BPI-DN, Brief Pain Inventory–Diabetic Neuropathy; CAP 8%: capsaicin 8%; SOC, standard of care.

Limitations of the study included no calculation of p-values to supplement 90% CIs, lack of quantitative sensory testing, last observation carried forward (LOCF) imputation, possible confounding with concomitant opioid use and that the patient population was 99% Caucasian

1. Vinik AI et al. *BMC Neurol*. 2016;16:251.
2. Vinik AI et al. *J Curr Med Res Opin*. 2019;2:388–401.

PACE Trial
Efficacy: Proportion of 30% responders over baseline with seven repeated capsaicin 8% topical system treatments

Number of treatments:	30% Responder rate 2 months after treatment:
1	34.5%
2	48.0%
3	49.4%
4	57.1%
5	62.7%
6	63.1%
7	77.1%



In a post-hoc analysis of all subjects who received seven applications of capsaicin 8% topical system, the 30% responder rate increased steadily

Limitations of the study included no calculation of p-values to supplement 90% CIs, lack of quantitative sensory testing, last observation carried forward (LOCF) imputation, possible confounding with concomitant opioid use and that the patient population was 99% Caucasian

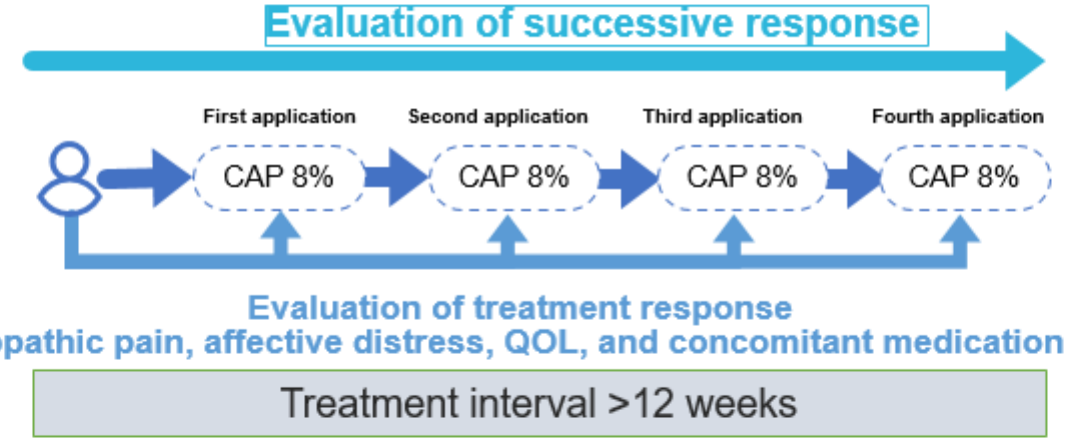
Vinik AI, et al. *JCMRO.* 2019;12:388–401

CASPAR Trial
Non-Interventional, Real-World Study of Capsaicin 8% Topical System

CASPAR is an exploratory, non-interventional, retrospective, longitudinal, single-cohort study using depersonalized data from a patient registry

Data from **2,577** patients in the **German Pain e-Registry** (Jan 2015 – Dec 2021)

Subpopulation of **365** patients with PDPN who were treated with ≥1 application of Capsaicin 8% to the feet
Patients were followed for 12 months regardless of number of Capsaicin 8% applications



Outcomes

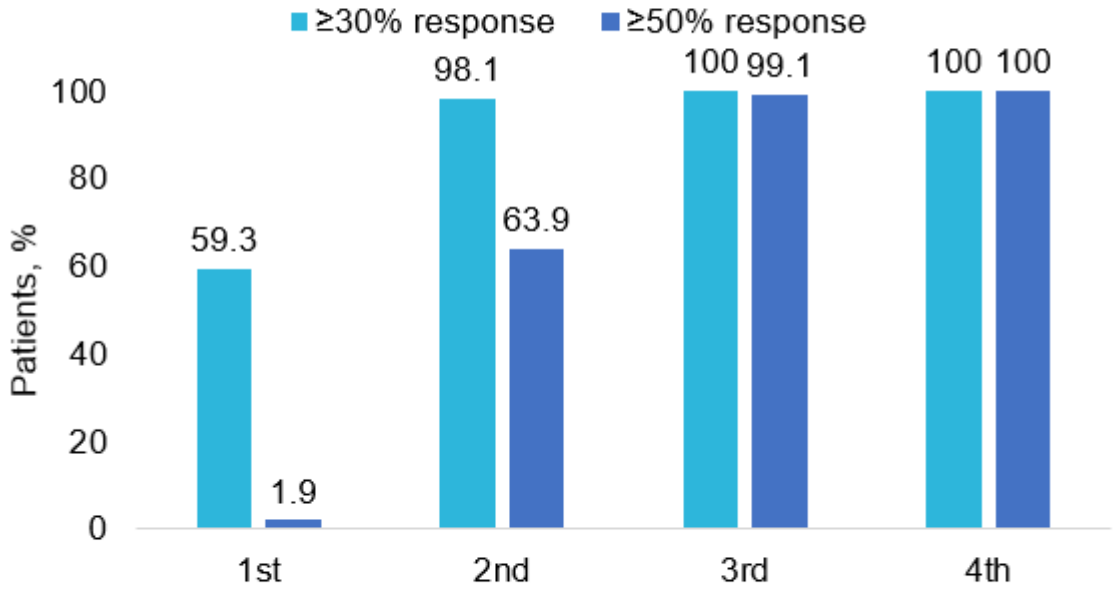
- Assessments were taken at baseline and at each 3-month timepoint up to 12 months
- Effectiveness assessments included:
  - Pain intensity and disability
  - Mental and physical QOL
  - Affective distress
  - Change in concomitant pain medications
- Primary outcome measure: % of patients with response to repeat Capsaicin 8%
- Tolerability was also assessed

Überall MA et al. ASPN 2024 [poster 1856478].

PDPN, painful diabetic peripheral neuropathy; QOL, quality of life

CASPAR Trial
Efficacy: Response rate following 4 Capsaicin 8% treatments

Percentage of patients achieving clinical response in average 24-h pain intensity vs baseline among those who received 4 Capsaicin 8% treatments (n=108)



By the 4th treatment, 100% of patients (n=108) achieved ≥50% reduction in pain

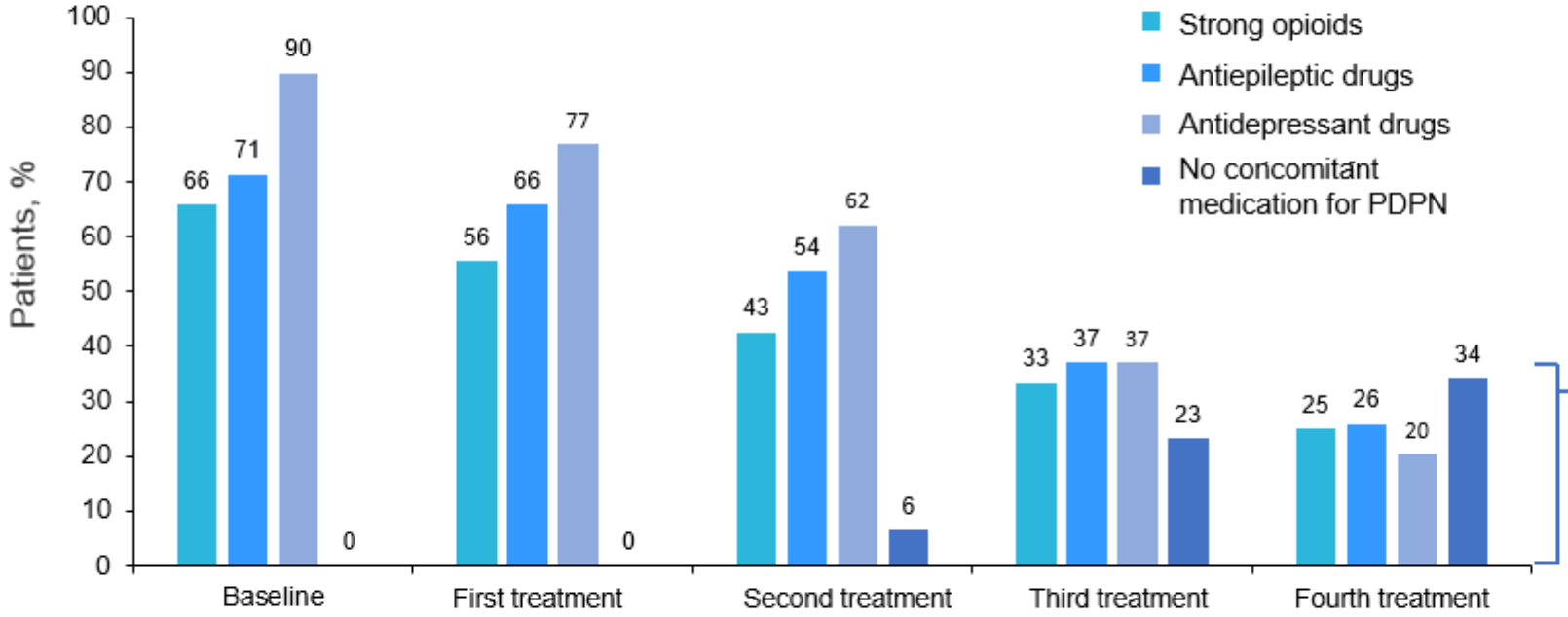
Limitations: CASPAR was an uncontrolled, observational study; therefore, results should be interpreted with caution as there may be confounding factors. Only 30% of the patients at baseline continued with Capsaicin 8% and received 4 applications. Reasons for patients not continuing with Capsaicin 8% are unknown and could include lack of efficacy or tolerability. No conclusions can be drawn from these data.

1. Data on file. Averitas Pharma, Inc. August 2024.

Real-World Observational Trial; Limitations may include missing data, lack of randomization, unobserved confounders, and susceptibility bias

CASPAR Trial:
Changes in the percentage of patients taking concomitant medications

Concomitant pain medications among patients (n=108) who received four Capsaicin 8% applications



The percentage of patients taking **strong opioids**, **antiepileptics**, or **antidepressants** decreased over time with repeated CAP 8% treatments

The percentage of patients taking no concomitant pain medications increased over time

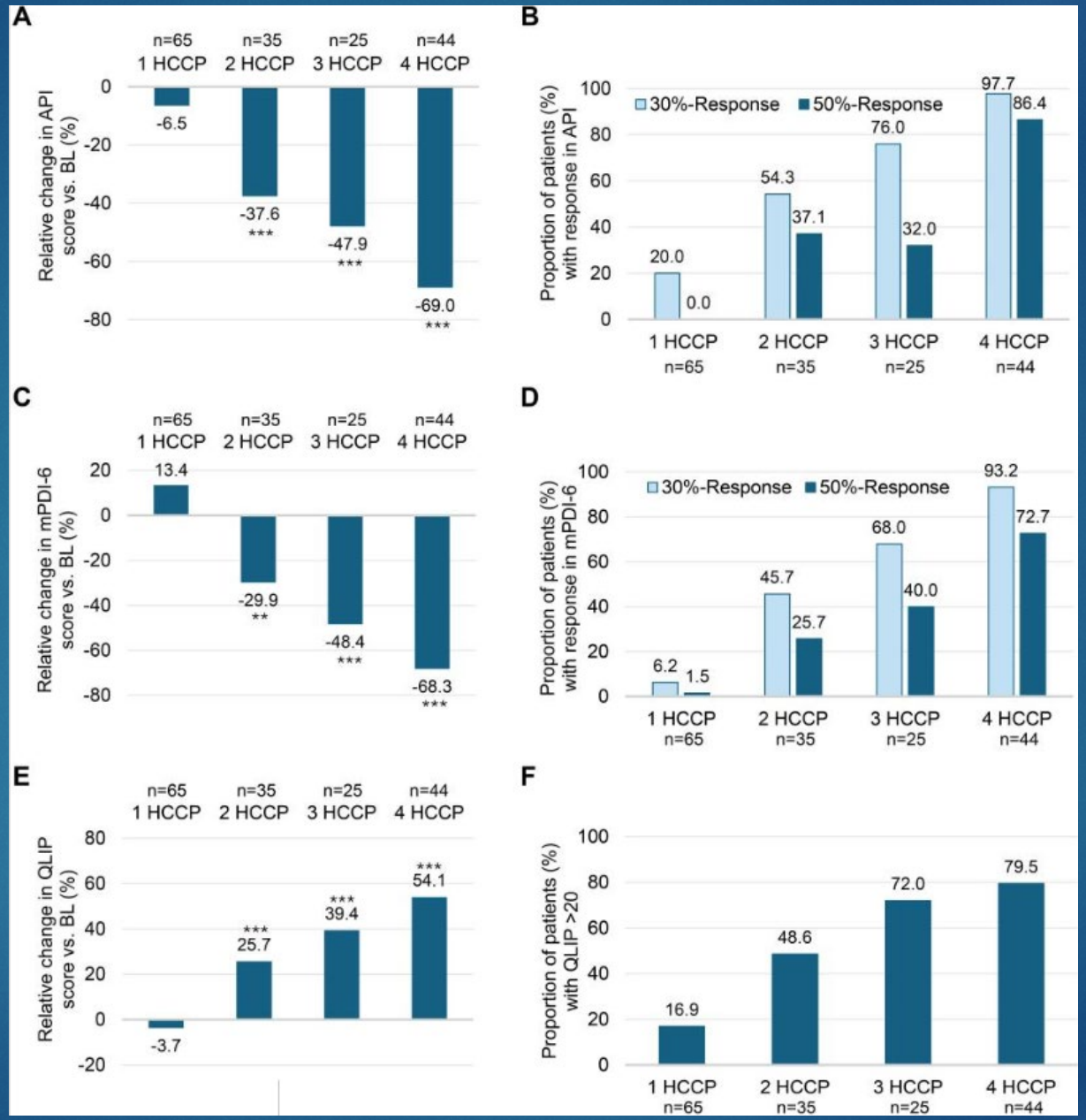
At 1 year, 34.0% of patients who received four applications stopped all concomitant pain medications

Percentages do not sum to 100% because patients could take >1 pain medication.

Limitations: CASPAR was an uncontrolled, observational study; therefore, results should be interpreted with caution as there may be confounding factors. Only 30% of the patients at baseline continued with Capsaicin 8% and received 4 applications. Reasons for patients not continuing with Capsaicin 8% are unknown and could include lack of efficacy or tolerability. No conclusions can be drawn from these data.

PDPN, painful diabetic peripheral neuropathy; CAP 8%, Capsaicin 8%.

1. Überall MA et al. ASPN 2024 [poster 1856478].
2. Averitas Pharma Inc. Data on file



Überall MA, Sabatowski R, Lux MP, Heine M, Garcia Guerra L, Eerdekens M, Quandel T. Real-world 12-month outcomes of repeated high-concentration capsaicin patch in chemotherapy-induced peripheral neuropathy: results from the CASPAR study. Front Oncol. 2025 Dec 4;15:1711597. doi: 10.3389/fonc.2025.1711597. PMID: 41426310; PMCID: PMC12711474.

Capsaicin 8% in painful DPN of the feet: conclusions

Capsaicin 8% topical system has a patented matrix technology creating forced diffusion of capsaicin into the epidermis/dermis within a 30-minute treatment[1–3]

High concentration capsaicin reversibly ablates sensory nerve fiber terminals, which leads to an analgesic effect[4,5]
The nerve fibers then regenerate within 1–3 months[4,5]
These regenerated fibers may be healthier (less hyperactive) and this change contributes to the analgesic effect[4]

CLINICAL IMPLICATIONS

A single application may provide sustained relief from the debilitating pain of DPN for up to 3 months[6]

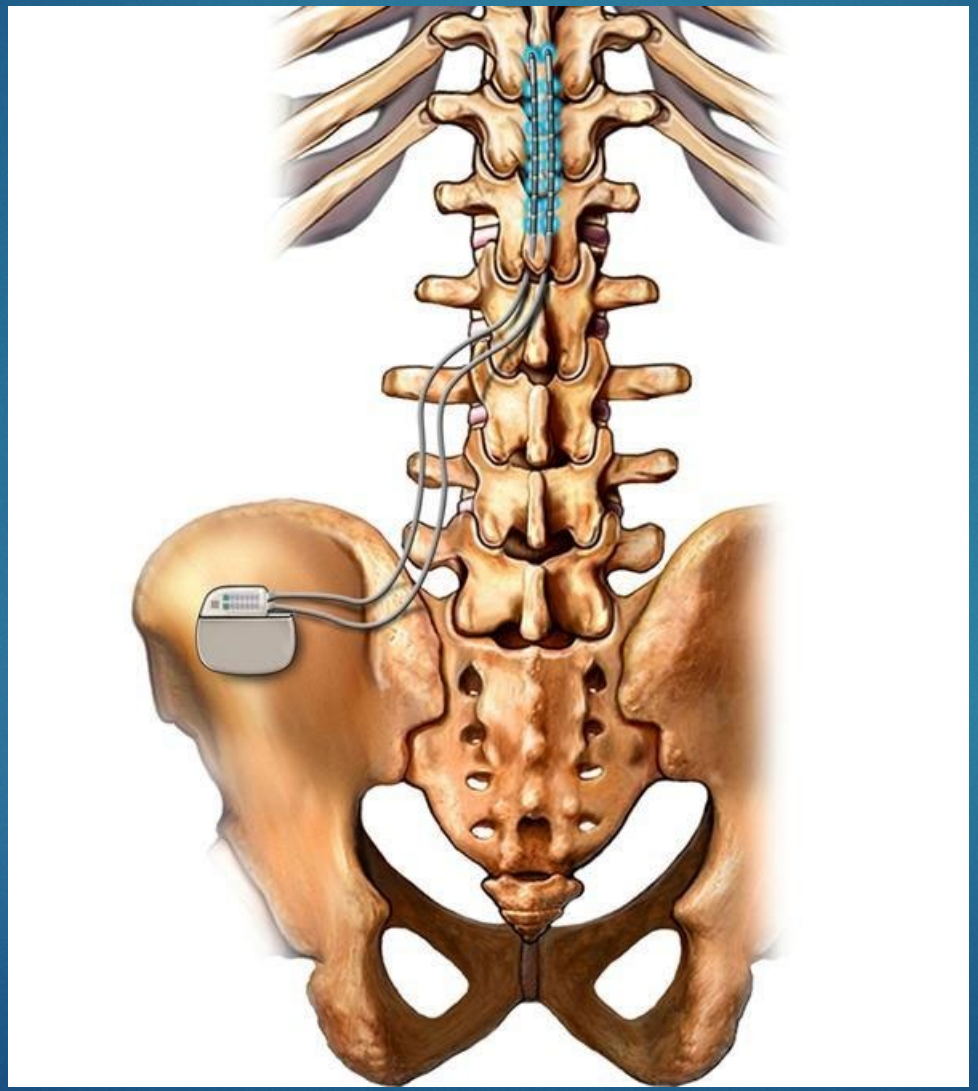
Progressive benefit in sensory function is associated with repeated application (recommended in chronic conditions like DPN)[7,8]

Acts directly on the painful area; therefore, limiting systemic AEs associated with oral therapies.[9] Capsaicin 8% is primarily associated with application-site reactions[9]

1. PubChem. Therapeutic patch for transdermal delivery of capsaicin. Patent: US-8821920-B2. 2014. https://pubchem.ncbi.nlm.nih.gov/patent/US-8821920-B2. Accessed December 1, 2023. 2. Anand P & Bley K. *Br J Anaesth*. 2011;107:490–502. 3. Wohlrab J et al. *Skin Pharmacol Physiol*. 2015;28:65–74. 4. Sendel M et al. *Pain*. 2023;164:534–42. 5. Anand P et al. *Front Neurol*. 2022;13:998904. 6. Simpson DM et al. *J Pain*. 2017;18:42–53. 7. Vinik AI et al. *BMC Neurol*. 2016;16:251. 8. Katz N et al. PAINWeek 2023 [poster presentation]. 9. Huygen F et al. *J Pain Res*. 2020;13:2585–97.

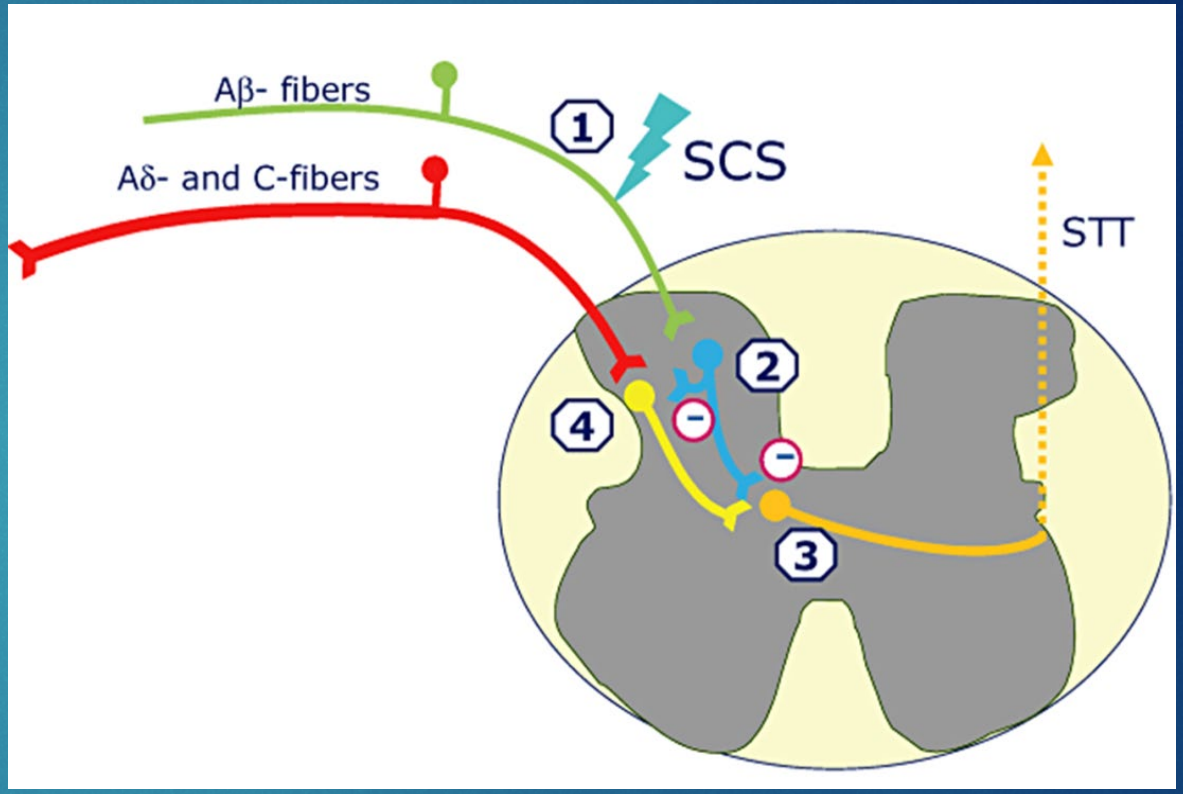
AE, adverse event;
DPN, diabetic peripheral neuropathy.

Spinal Cord Stimulation



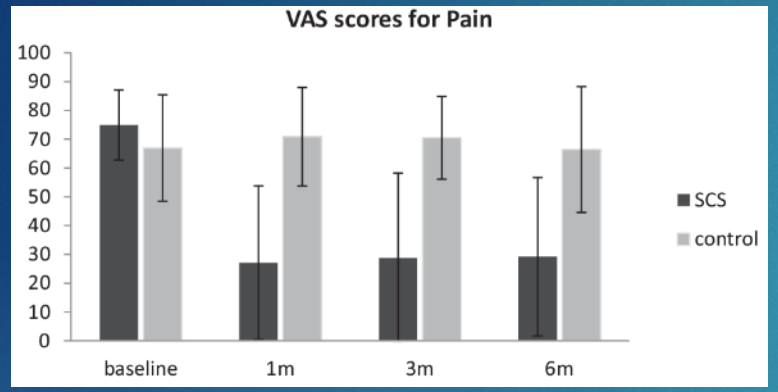
Gate Theory

- In the dorsal horn (where pain signals relay), there is a '**gate**' that opens and closes to allow pain signals up to the brain.
- C and A delta fibers are small pain fibers. When their signals get to the brain, you feel pain
- A beta fibers are larger fibers that carry non painful signals (vibration, light touch, etc)
- When A beta fibers are stimulated, they 'close the gate', and signals from the smaller pain fibers cannot get up to the brain



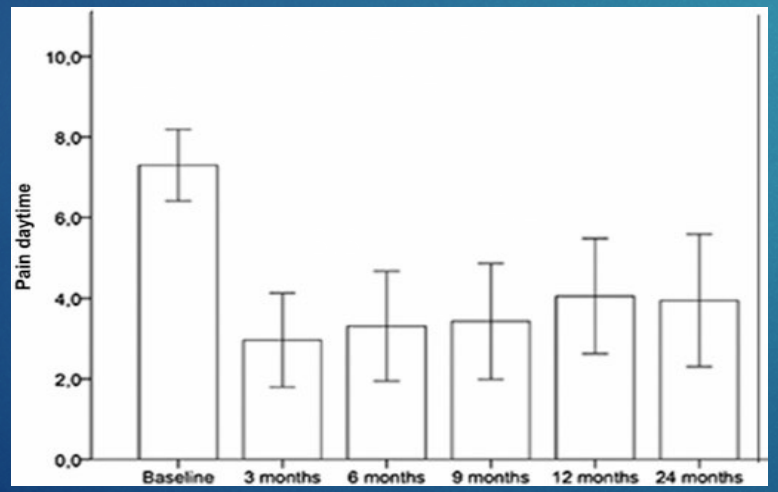
Low-frequency SCS for PDN

- Two prior RCTs demonstrated 50%-69% pain responders to LF-SCS at 6 months



- Prospective, multicenter RCT comparing LF-SCS+CMM to CMM alone
- 60 subjects randomized 2:1, 6-month follow-up
  - 36 LF-SCS subjects at 6 months
  - 69% pain responders (25/36)
  - No report of neurological improvements

de Vos et al. *Pain* 2014



- Prospective, two-center RCT comparing LF-SCS+CMM to CMM alone
- 36 subjects randomized 3:2, 24-month follow-up
  - 16 LF-SCS subjects at 6 months
  - 56% pain responders daytime (9/16)
  - 50% pain responders nighttime (8/16)
  - No report of neurological improvements

Slangen et al. *Diabetes Care* 2014
van Beek et al. *Diabetes Care* 2015

PDN Randomized Controlled Trial (RCT)

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

- 216 subjects with diabetes
- ≥5 on pain VAS
- A1c ≤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

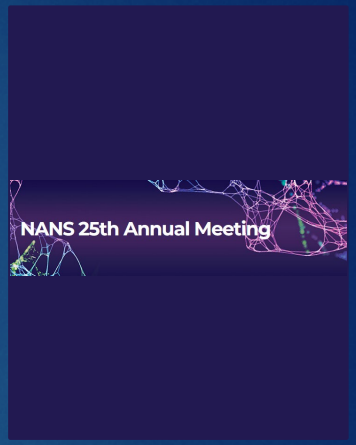
- CMM vs. 10 kHz Therapy (Nevro Corp.) + CMM.


Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy
A Randomized Clinical Trial

6-month[1]
JAMA Neurology
Apr 2021


Durability of High-Frequency 10-kHz Spinal Cord Stimulation for Patients With Painful Diabetic Neuropathy Refractory to Conventional Treatments: 12-Month Results From a Randomized Controlled Trial

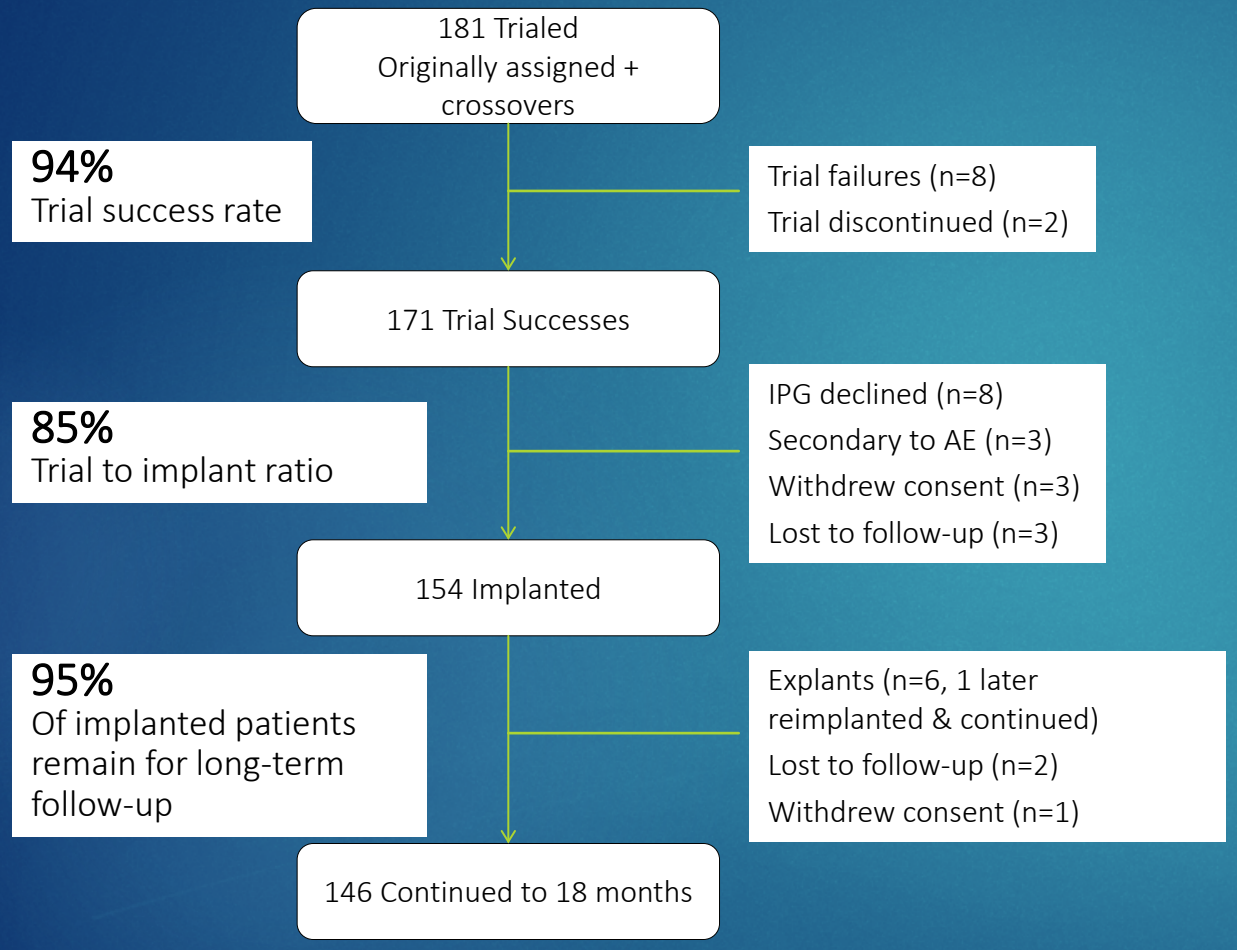
12-month[2]
Diabetes Care
Nov 2021



18-month[3]
Presented at NANS
Jan 2022

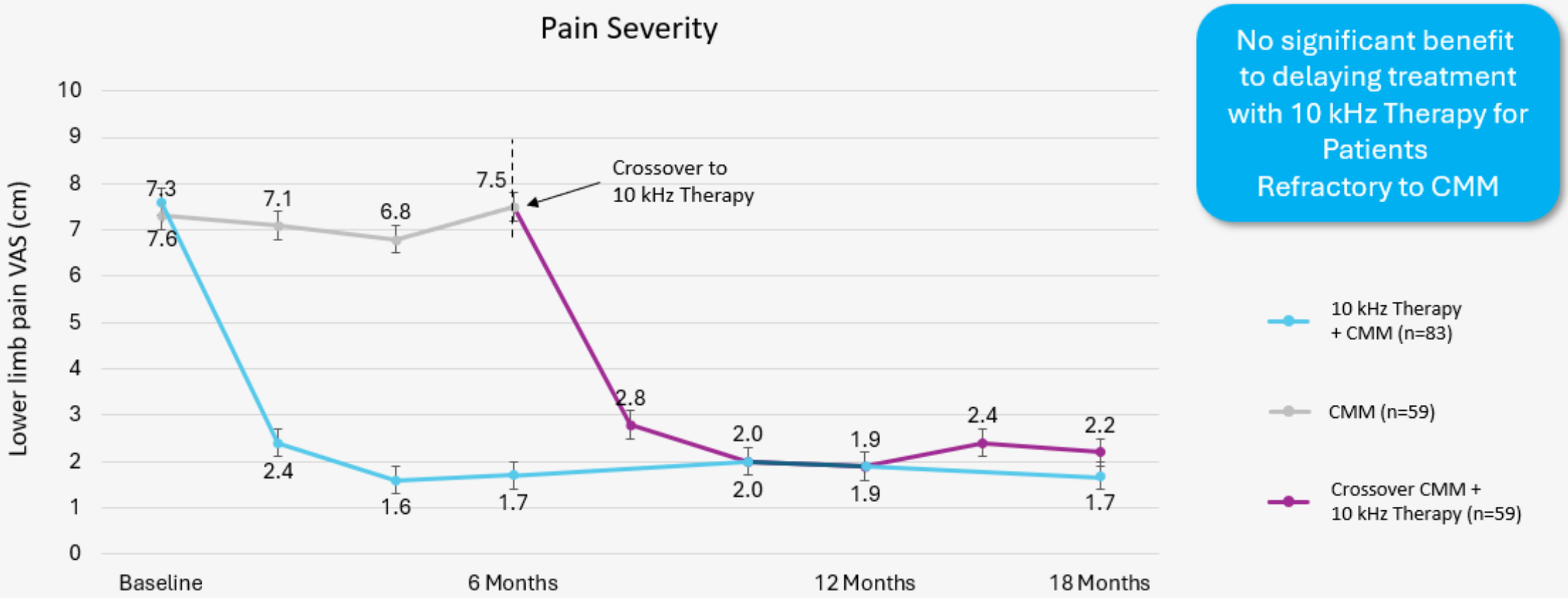
1. Petersen E. et al. Effect of high frequency (10-kHz) spinal cord stimulation in patients with painful diabetic neuropathy: a randomized clinical trial. JAMA Neurology Apr 2021
2. Petersen E. et. al. Durability of high-frequency 10 kHz spinal cord stimulation for patients with painful diabetic neuropathy refractory to conventional treatments. *Diabetes Care*, Nov 2021.
3. Petersen E. et. al. Durability of 10 kHz spinal cord stimulation for painful diabetic neuropathy: 18-month results. NANS, Jan 2022.

SENZA PDN RCT Subject Disposition: 10 kHz SCS

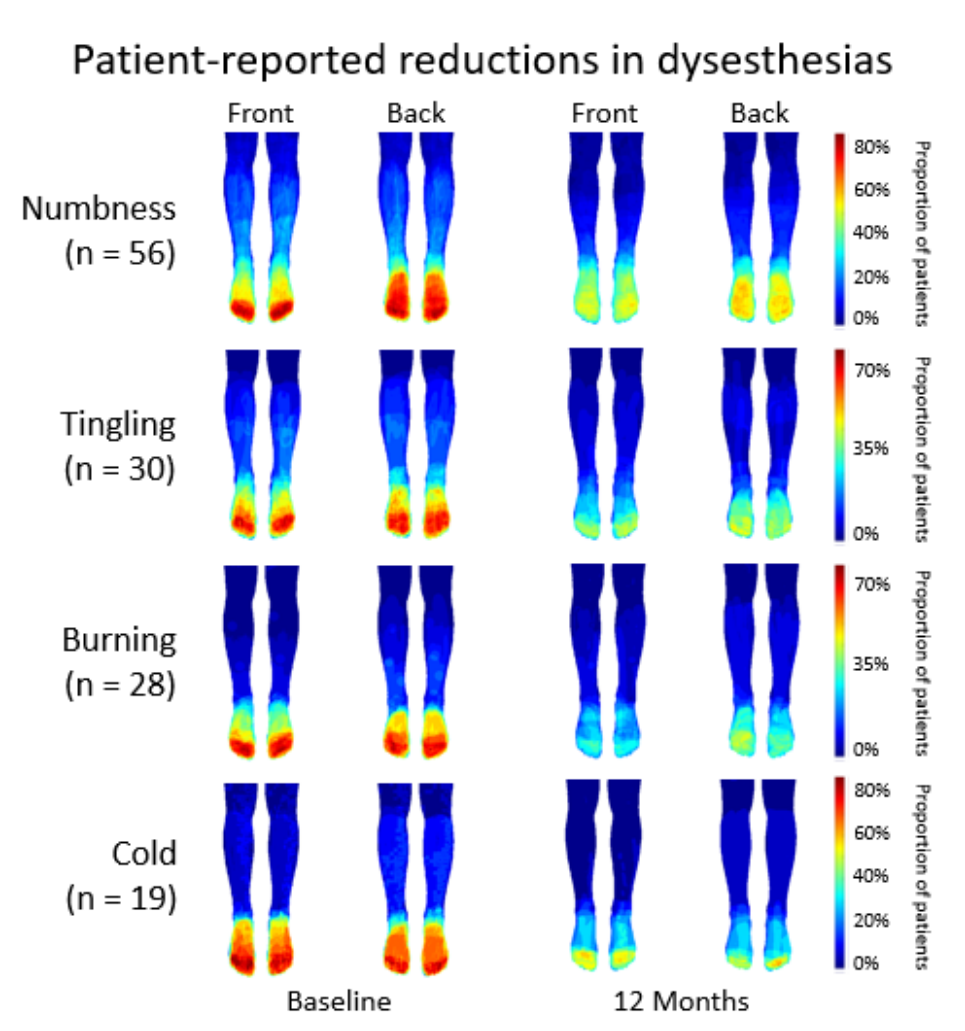


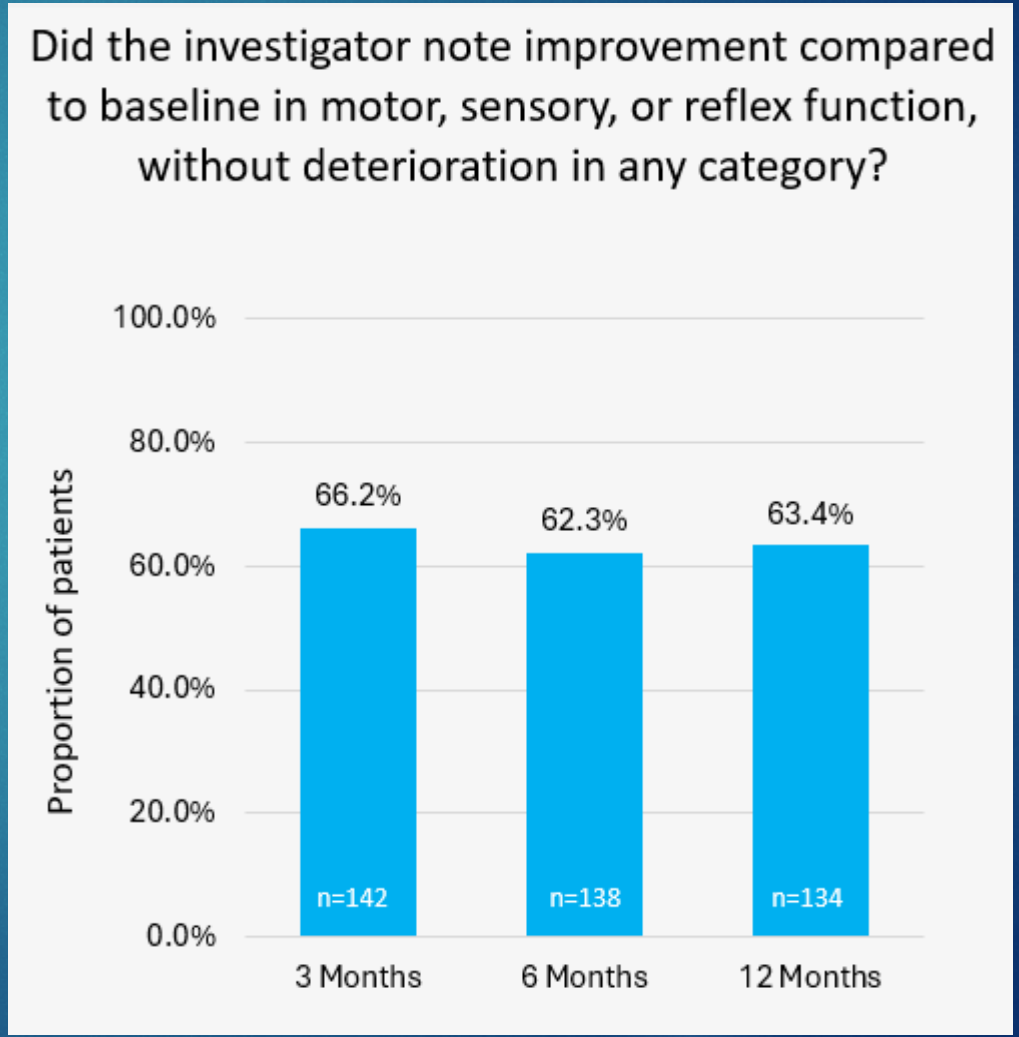
Safety
No stimulation-related neurological deficits
No explants for loss of efficacy
8 procedure-related infections (5.2%) 3 resolved with antibiotics 5 required explant (3.2%, 1 patient reimplanted)
1 explant as a precaution for an unrelated infection
3 IPG revisions (1.9%)
1 IPG replacement (0.6%)
1 lead revision (0.6%)

SENZA PDN RCT | Pain Relief Over 18 Months

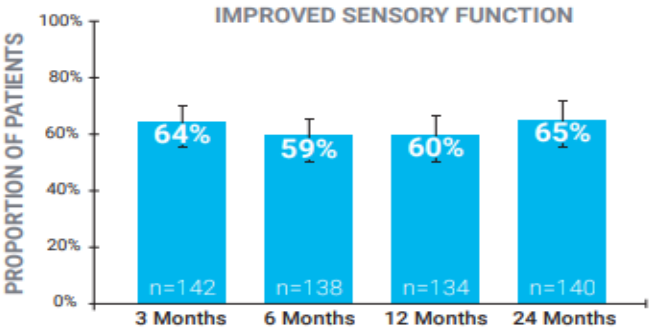


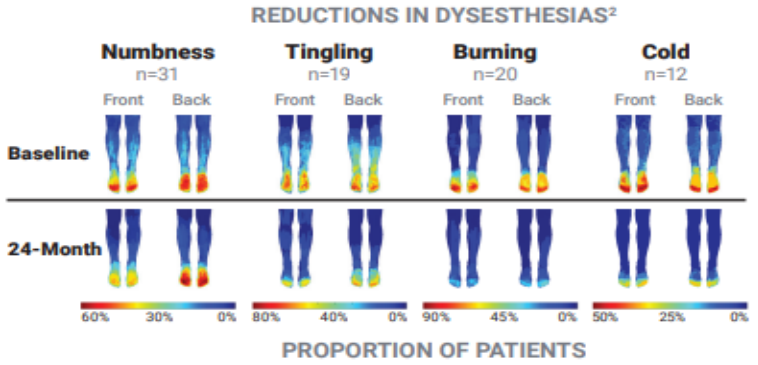
SENZA PDN RCT | Neurological Improvement with 10 kHz SCS





The majority of HFX patients in the SENZA PDN RCT reported sensory improvements[1]

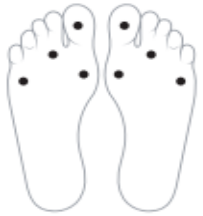




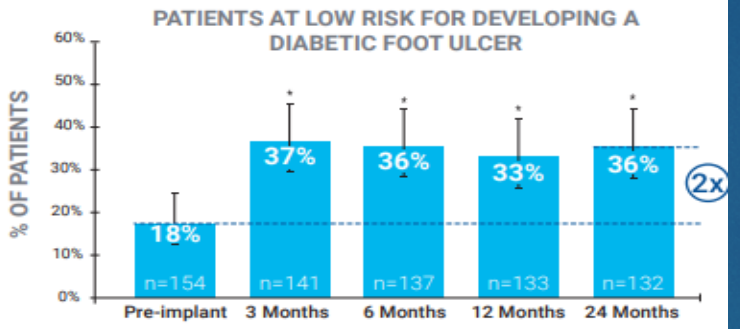
Durable improvement in protective sensation[3]

Foot ulceration risk assessment of participants in the SENZA PDN RCT

- Monofilament screening for loss of protective sensation (LOPS)
- Low-risk category = Sensate at all 8 locations



2X the number of patients at low risk of developing a diabetic foot ulcer at 24 months.

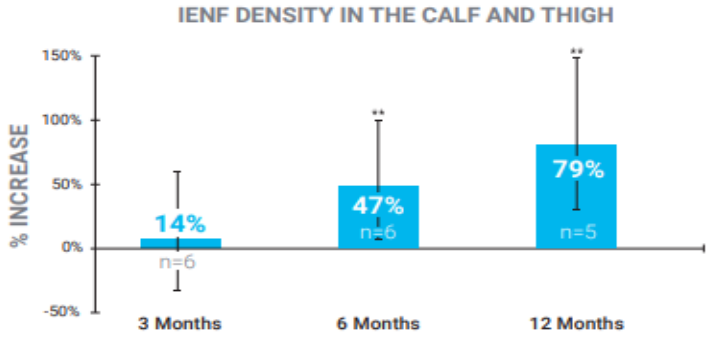


*p≤0.006

10 kHz SCS significantly increased intra-epidermal nerve fiber (IENF) density at the calf and thigh[4]

- Standard clinical diagnostic skin biopsies taken at the lower calf and upper thigh and analyzed for nerve fiber density
- Anatomic site was not a significant factor, so results were pooled across sites

79% increase in IENF density at 12 months, suggesting enhanced nerve regeneration accompanies the improvements in sensory function.



**p≤0.025

1. Petersen, E., et al. (2023). Long-Term Efficacy of High-Frequency (10 kHz) Spinal Cord Stimulation for the Treatment of Painful Diabetic Neuropathy: 24-Month Results of a Randomized Controlled Trial. *Diabetes Research and Clinical Practice*, 110865. 2. SENZA-PDN RCT. Data on file. 3. Argoff, C.E., et al. (2024) Improvement in Protective Sensation: Clinical Evidence From a Randomized Controlled Trial for Treatment of Painful Diabetic Neuropathy With 10 kHz Spinal Cord Stimulation. *Journal of Diabetes Science and Technology*. 4. Chen, J.C., et al. (2023). High frequency spinal cord stimulation (10 kHz) alters sensory function and nerve fiber density in painful diabetic neuropathy: A pilot prospective open label study. *Pain Medicine*. *13*;24(Supplement_2):S33-S40.

Sensory Improvements Demonstrated with 10kHz Spinal Cord Stimulation: A Randomized Controlled Trial Evaluating Treatment for Refractory Painful Diabetic Neuropathy with Sensory Dysfunction

Hurley et al 2025

Table 1: Primary and Secondary Endpoints and Results

	CMM Subjects (N=50)	10 kHz SCS + CMM (N=34)	P-value[4]
Primary Endpoint (mITT)			
Pain VAS Responder Rate[1,2]	0.0% (0.0%,7.4%)	84.4% (68.2%, 93.1%)	**<0.0001**
Secondary Endpoints			
Sensory Improvement Responder Rate[3]	25.0% (14.9%, 38.8%)	55.2% (37.5%, 71.6%)	**0.014**
Pain VAS Responder Rate at 3 Months	0.0% (0.0%,7.4%)	93.1% (78.0%, 98.1%)	**<0.0001**
Percentage Change in Lower Limb Pain[5]	-0.5 (-6.4, 5.5)	-83.1 (-90.2, -76.1)	**<0.0001**
Percentage Change in PSQ-3	11.3 (-15.2, 38.0)	-79.7 (-90.2, -69.2)	**<0.0001**
Mean Change in EQ-5D-5L	0.01 (-0.03, 0.05)	0.16 (0.09, 0.22)	**0.0001**
Mean Change in NeuroQol	-0.14 (-0.68, 0.4)	-5.4 (-6.6, -4.1)	**<0.0001**
Mean Change in Lower calf IENFD	-0.07 (-0.44,0.29)	0.58 (0.10, 1.06)	**0.027**
Mean Change in mTCNS	0.33 (-1.0, 1.7)	-5.4 (-8.4, -2.5)	**0.003**
Mean Change in HbA1c[6]	-0.68 (-1.72, 0.37)	0.03 (-2.93, 3.00)	0.55
Mean Change in Body Weight (lbs)[7]	-4.6 (-8.2, -0.9)	1.6 (-2.8, 6.0)	0.038

[1]Rates presented as % (95% Confidence interval (CI)). [2]Defined as ≥50% pain relief from baseline. [3]Defined as reduction in modified Toronto Clinical Neuropathy Scale (mTCNS) of ≥3 points from baseline (excluding changes in foot pain). [4]Statistically met endpoint indicated in **bold,** [5]Mean (95% CI), [6] Evaluated in subgroup with baseline HbA1c ≥ 8% and Type II diabetes, [7] Evaluated in subgroup with Type II diabetes

Abbreviations: mITT: modified intent-to-treat; VAS, Visual analog scale; PSQ-3, Pain-Sleep-Questionnaire-3 Item; EQ-5D-5L, Euroqol Health-related Quality of life – 5 item; NeuroQol, Neuropathy Related Quality of life; mTCNS, modified Toronto Clinical Neuropathy Score; IENFD, intraepidermal nerve fiber density.

DOI: 10.1111/papr.70023

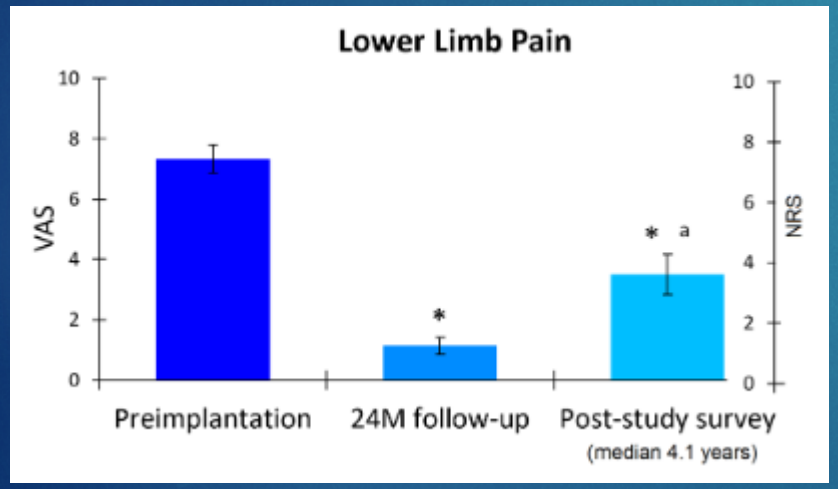
RESEARCH ARTICLE

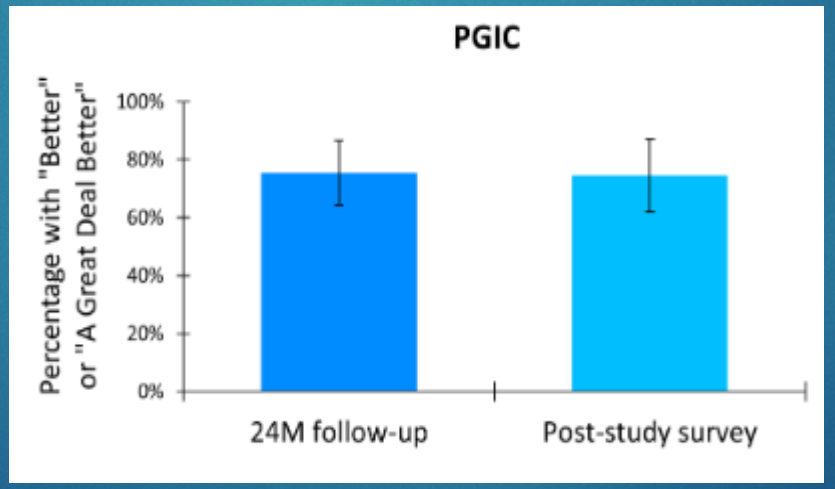
Long-term efficacy of 10 kHz spinal cord stimulation in managing painful diabetic neuropathy: A post-study survey

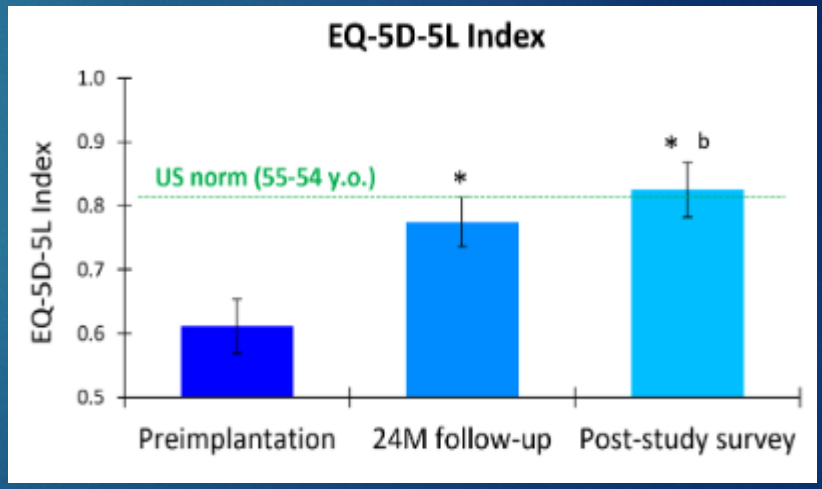
Erika A. Petersen MD[1] | Shawn M. Sills MD[2] | Thomas G. Stauss MD[3] | Rose Province-Azalde MS[4] | Michael J. Jaasma PhD[4] | Deborah R. Edgar PhD[5] | Judith L. White MD[6] | James A. Scowcroft MD[7] | Cong Yu MD[8] | Jijun Xu MD, PhD[9] | Maged N. Guirguis MD[10] | Kasra Amirdelfan MD[11] | David J. DiBenedetto MD[12] | Ali Nairizi MD[13] | Shivanand P. Lad MD, PhD[14] | Neel D. Mehta MD[15] | Dawood Sayed MD[16] | Khalid A. Sethi MD[17] | Sarah Benducci PhD[4] | Manish Bharara PhD[4]

Findings

- Post-study survey of PRO at a median of 4.1 years after implant
- 43/56 reported sustained meaningful pain relief
- 44/52 reported sustained QoL improvement







Thank you