LA NEUROPATHIE DIABÉTIQUE : QUELLES SOLUTIONS POUR SOULAGER?

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LIEN D'INTÊRETS

- Grünenthal
- Medtronic
- Boston
- Merz
- Esteve

LA POLYNEUROPATHIE DIABÉTIQUE (PNDD) DOULOUREUSE

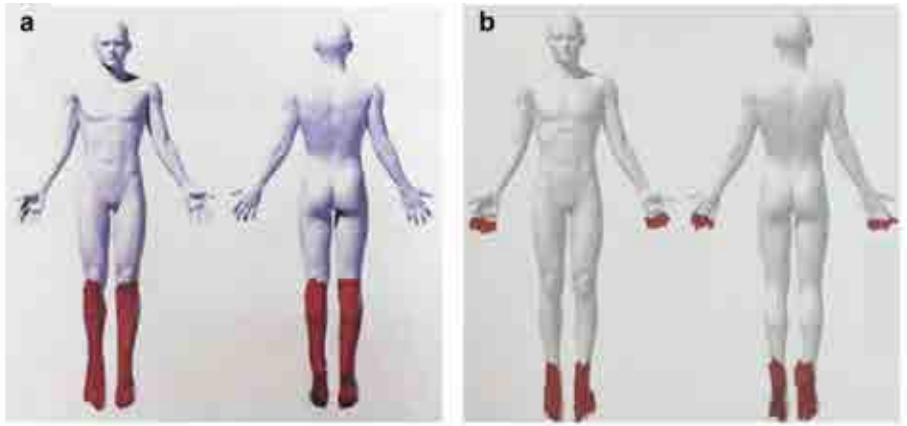
« *La neuropathie douloureuse concerne environ* ***20% des diabétiques de type 2 et 5% des diabétiques de type 1****.*

Elle doit être ***systématiquement cherchée par l'interrogatoire*** *car les patients n'en parlent pas spontanément.*

[…] Le ***questionnaire DN4*** *est un* ***outil diagnostique simple et validé*** *(pour le diagnostic de la neuropathie diabétique douloureuse).*

»

- PNDD – fibres de petits calibres non myélinisées, Aβ et Aα
- Brulûres, décharges , coup de couteau, paresthesies, picotement
- Dépense de soins > 7500 euros/an pour une PNDD / PN non douloureuse



Chen et al.; Journal of Diabetes Science and Technology 2022, Vol. 16(2) 282–288

Hartemann et al. Groupe International de travail sur le Pied Diabétique (IWGDF) *Diabetes Metab.* 2011

TRAITEMENTS DE 1ÈRE ET 2ÈME LIGNE

1ère ligne

Emplâtres de Lidocaïne
(1-3, 12h/j)

TENS
(≥30min/j)

Gabapentine (neurotin) (1200-3600mg/j)

Antidépresseurs (IRSN*, ATC**) (10-150mg/j)

2ème ligne

Patch de capsaïcine
(1-4 / 3mois)

Toxine botulique A
(50-300 unités / 3mois)

Prégabaline (lyrica) (150-600mg/j)

Tramadol
(100-400 mg/j)

Combinaison
(Antidépresseurs + gabapentinoïdes)

Colonne de droite : toute douleur neuropathique, périphérique ou centrale, focale ou diffuse

En cas d'échec des traitements de 1ère et 2ème ligne, la douleur de PND est considérée comme réfractaire.

Dans le cas de douleurs de PND réfractaires depuis au moins un an, la SFETD et la Haute Autorité de Santé recommandent le recours à la neurostimulation médullaire.

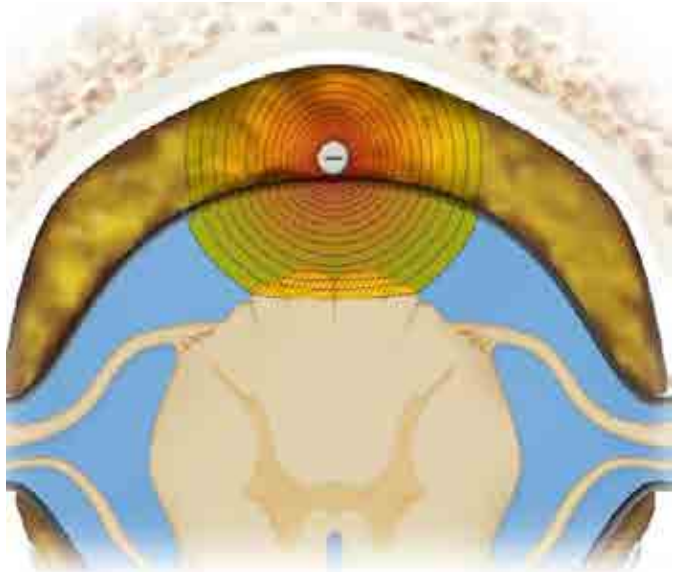
Moisset et al. Pharmacological and non-pharmacological treatments for neuropathic pain: Systematic review and French recommendations. *Rev Neurol.* 2020

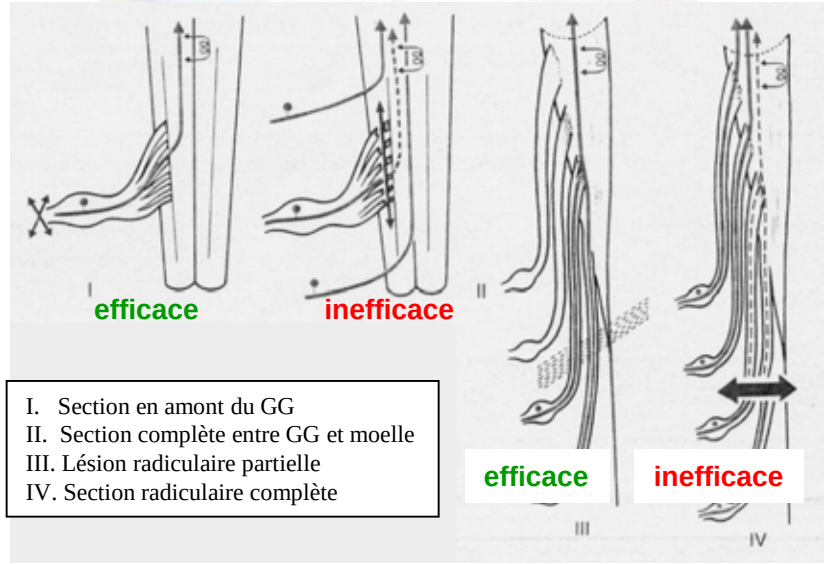
TENS : Stimulation électrique transcutanée | *IRSN : Inhibiteur de recaptage de la sérotonine et de la noradrénaline (Duloxétine 60-120mg/j ou Venlafaxine 150-225mg/j)
** ATC : Antidépresseur Tricyclique

Recommandations 2020 de la Société Française d'Étude et Traitements de la Douleur (SFETD)

PRINCIPE DE LA SCP

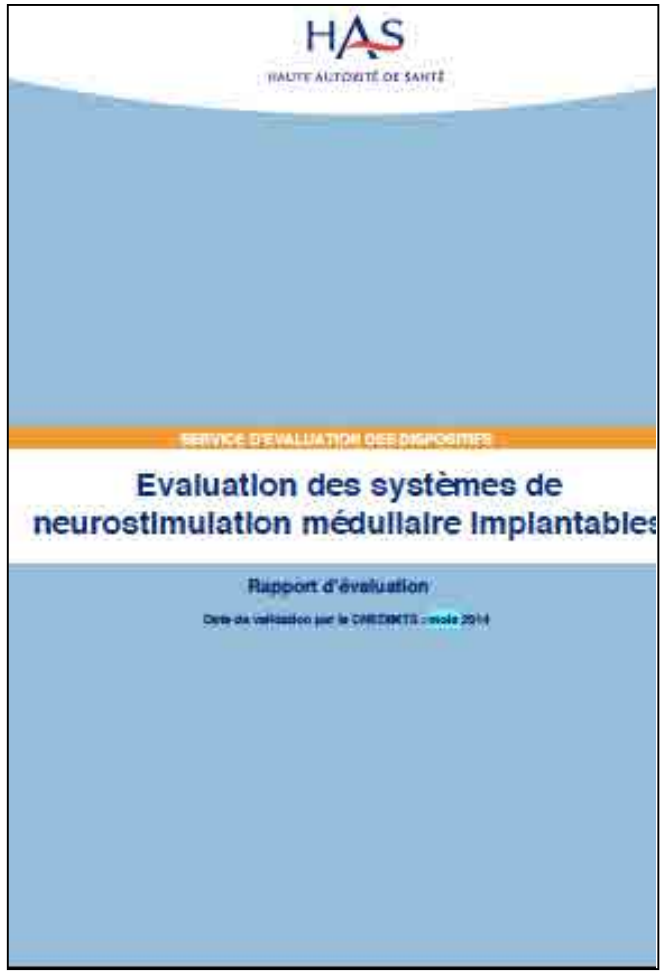
- Stimulation électrique chronique des cordons dorsaux via une électrode épidurale postérieure
  - visant à renforcer les contrôles physiologiques inhibiteurs de la douleur
- Neuromodulation, réversible non destructrice
- Induction de paresthésies perceptibles dans la zone douloureuse
- Electrode placée au niveau du segment médullaire situé à la limite supérieure du territoire douloureux
- Nécessite la préservation au moins partielle des fibres des cordons dorsaux
- Sélection des patients en équipe pluridisciplinaire + validation en RCP douleur/neuromodulation

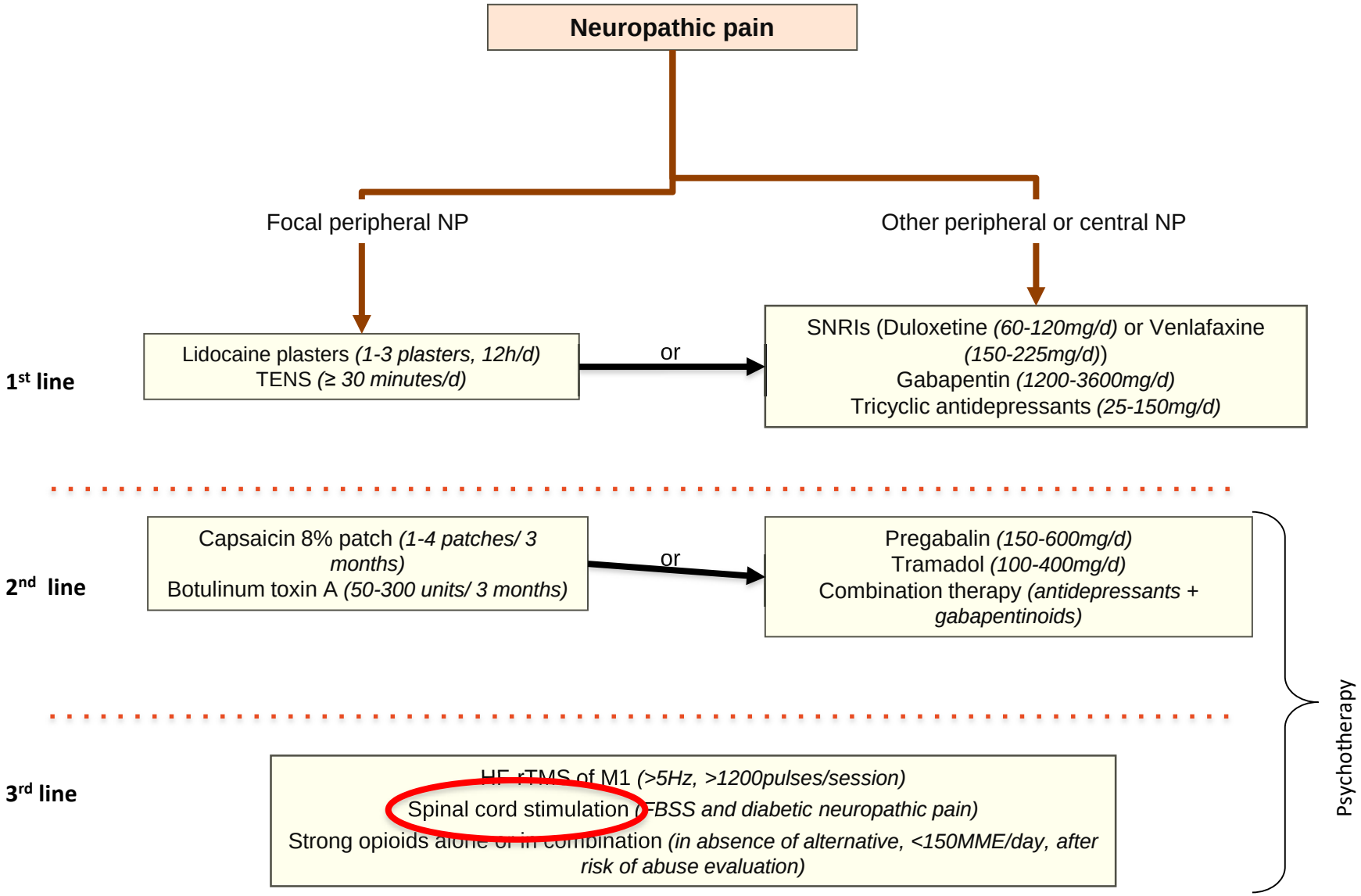




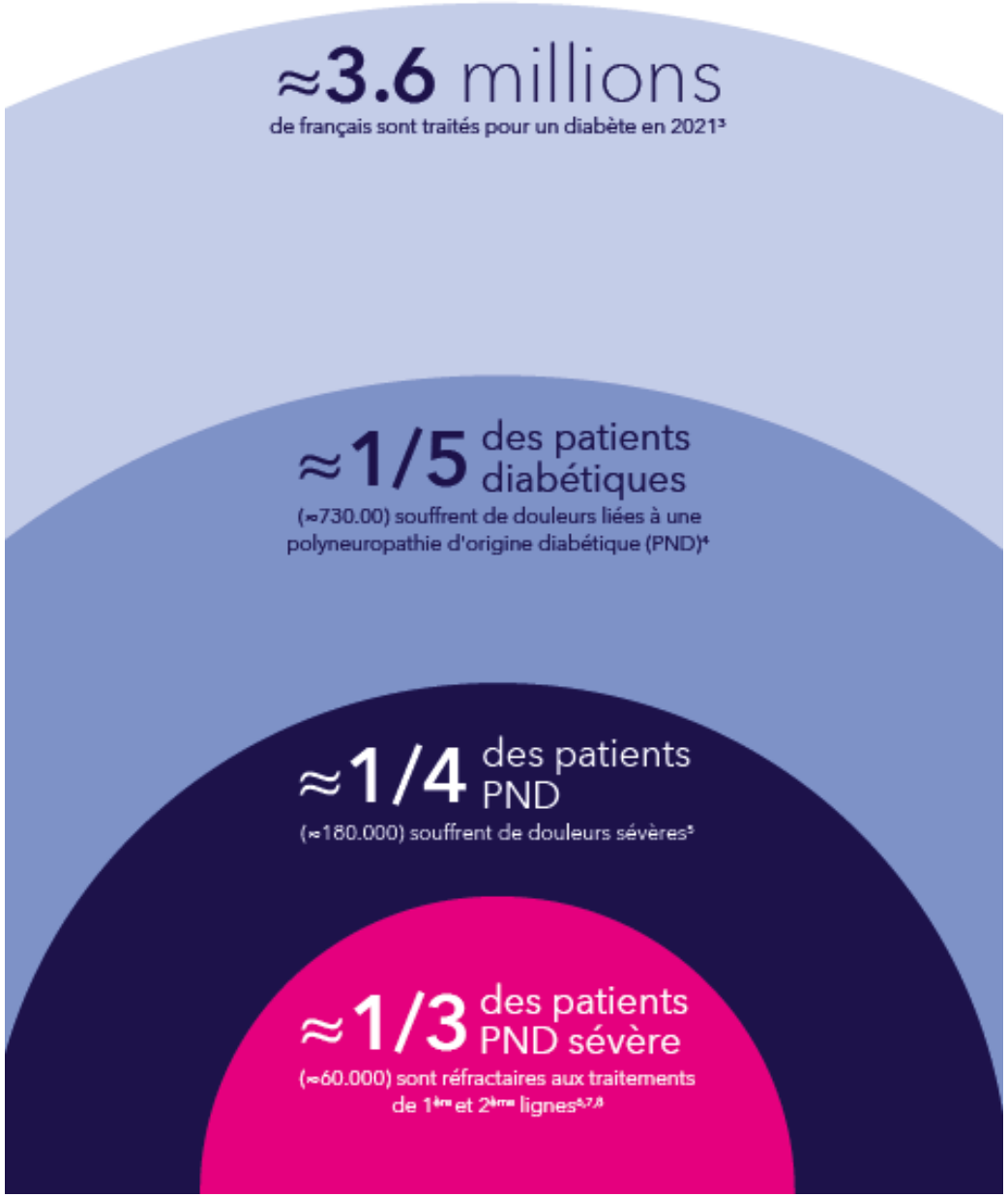
RECOMMANDATIONS HAS 2014

- « La CNEDiMTS considère que les systèmes implantables de neurostimulation médullaire ont une place dans la prise en charge des douleurs chroniques ayant les caractéristiques suivantes :
  - douleur chronique d'origine neuropathique, après échec des alternatives thérapeutiques, secondaire à:
    - un syndrome douloureux chronique radiculaire ou tronculaire d'origine diabétique, zostérienne, traumatique ou chirurgicale persistant depuis au moins 1 an ;
    - un syndrome douloureux régional complexe de type I ou II persistant depuis au moins 6 mois.
- Le plus souvent : FBSS et SDRC
- Les douleurs de la polyneuropathie diabétique rentrent parfaitement dans ce cadre
- La SCP est donc validée et remboursée dans cette indication





Pharmacological and non-pharmacological treatments for neuropathic pain: systematic review and French recommendations. X Moisset et al. *Rev Neurol 2020*



- < 20 patients traités pour PND en France chaque année
- beaucoup des médecins qui prennent en charge les douleurs de la PND ne connaissent pas (bien) la stimulation médullaire
- ceux qui connaissent la stimulation médullaire ne connaissent pas forcément ses résultats dans les douleurs de la PND
- beaucoup de ceux qui pratiquent la stimulation médullaire ne connaissent pas bien la PND
- et ne prennent pas en charge de patients PDN

PROCÉDURE

- Stimulation cordonnale postérieure
  - percutanée
  - sous AL / sédation
- Mini –invasif
- Phase de test de 7 jours
  - validation de l'implantation définitive

DONNÉES DE LA LITTÉRATURE

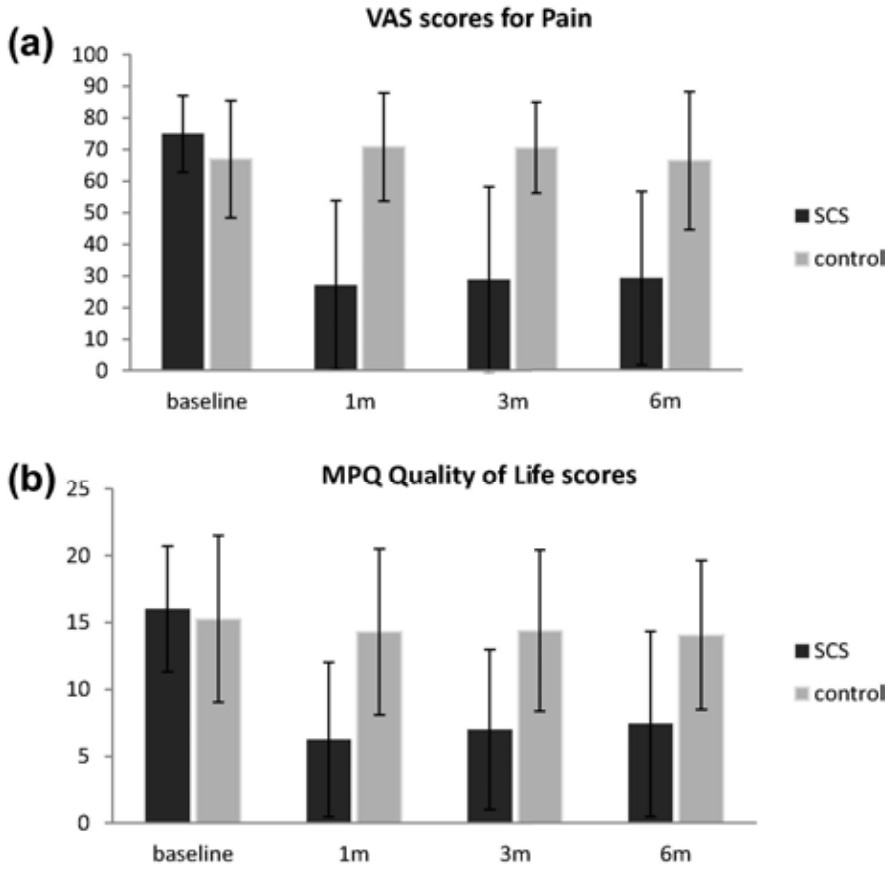
- 3 RCT
- Séries rétrospectives
- Séries prospectives

CRITÈRES D'INCLUSION/EXCLUSION

de Vos 2014	Slangen 2014	Petersen 2021
Inclusion criteria: • PDN symptoms >12 months • refractory to all conventional treatment • lower limb pain ≥ 5/10	**Inclusion criteria**: • PDN symptoms >12 months • refractory to drugs (guidelines) • lower limb pain ≥ 5/10	**Inclusion criteria**: • PDN symptoms >12 months • refractory to gabapentinoids + one other treatment • lower limb pain ≥ 5/10 • « medicaly suitable for SCS »
Exclusion criteria: • infection • pain related to atherosclerotic lesions • upper limb pain > 2/10 • anticoagulation • addiction, psychiatric issues	**Exclusion criteria**: • HbA1c >10% • upper limb pain > 3/10 • alcohol/drug abuse • insufficient cooperation • blood clotting disorder • peripheral vascular disease (bilat absence of distal pulses) • immune deficiency • life expectancy < 1 year • local infection	**Exclusion criteria**: • HbA1c >10% • BMI > 45 • opioïds > 120mg Morphin eq • upper limb pain > 3/10

RÉSULTATS RCP (1)

- SCS tonique + Trt Med / Trt Med seul
- 60 patients inclus dont 40 implantés
- A 1 mois SCP
  - réduction EVA 29%,
- A 6 mois
  - 25/40 réduction EVA > 50%
  - 16/40 réduction EVA > 75%
- Réduction de la description de la douleur échelle McGill
- Amélioration sommeil 40% des patients
- Complications reliées au matériel
  - repositionnement générateur 2
  - migration électrode 1
  - Infection test 1



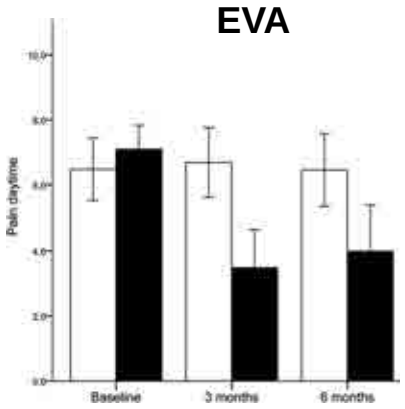
de Vos, et al. Pain 2014

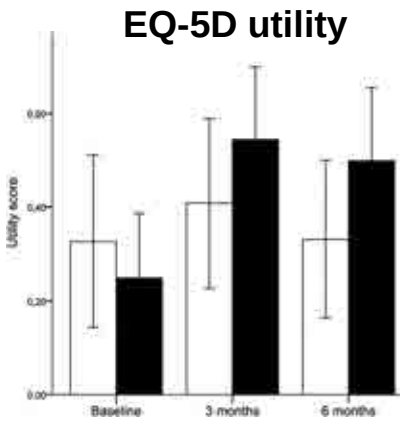
RÉSULTATS RCP (2)

- SCS + BMT / BMT seul
- 36 patients inclus dont 22 dans le groupe implanté
- SCS tonique

- évaluation à 6 mois:

	SCS n = 22	Contrôle n = 14
• amélioré >50%	59 %	7 %
• amélioration EVA	3,1	0
• EQ-5D utility	0,25 → 0,50	0,33 → 0,33
• diminution des trt	32%	0%

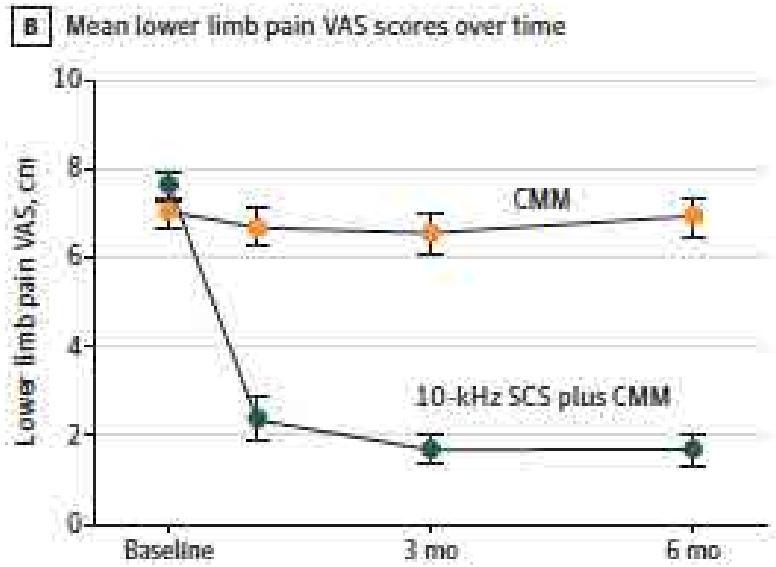


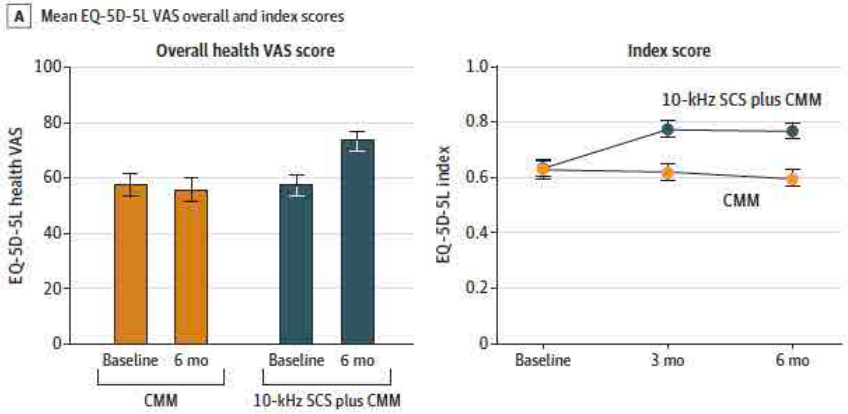


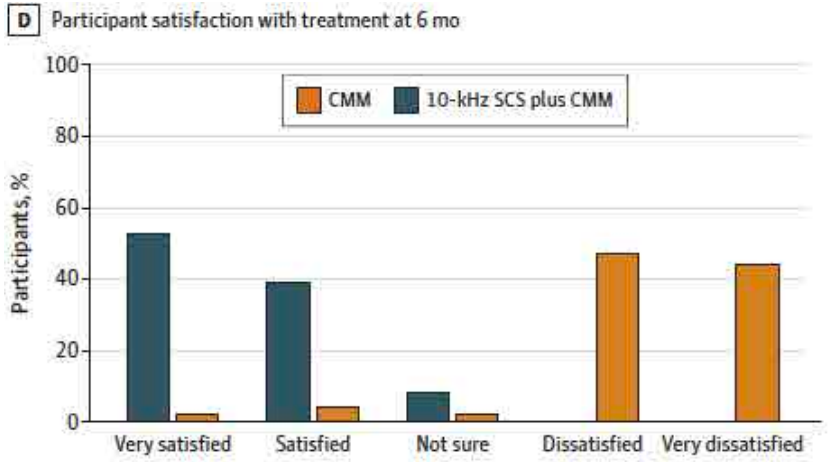
Slangen, et al. Diabetes Care 2014

RESULTATS RCP (3)

- 10 kHz stimulation vs CMM
- 216 patients randomisés,
- évaluation après 6 mois
- amélioration significative dans le groupe SCS
  - EVA: 7,6 →1,7 (SCS) vs 7 → 6,9 (CMM)
  - QoL
  - satisfaction patient







Petersen, et al. JAMA Neurol 2021

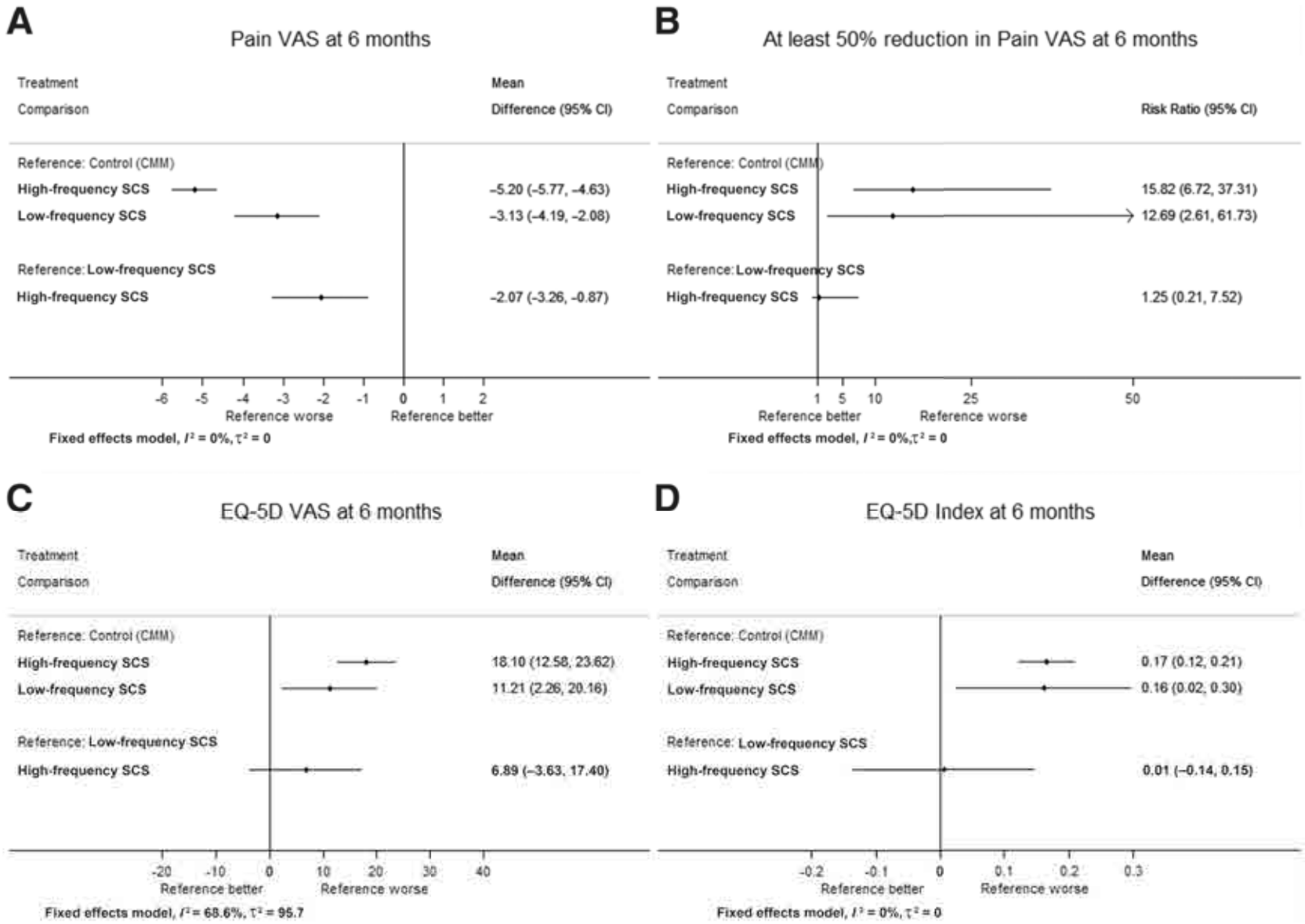


Figure 3—Direct treatment comparisons of LF- and HF-SCS vs. CMM and indirect treatment comparison of LF- vs. HF-SCS at 6 months for pain intensity (0–10 scale) (*A*), at least 50% pain reduction (0–100% scale) (*B*), EQ-5D VAS scale (0–100 scale) (*C*), and EQ-5D utility index (0–1.00 scale) (*D*).

Duarte et al.; Diabetes Care Volume 45, October 2022

IMPACT SUR LA QUALITÉ DE VIE

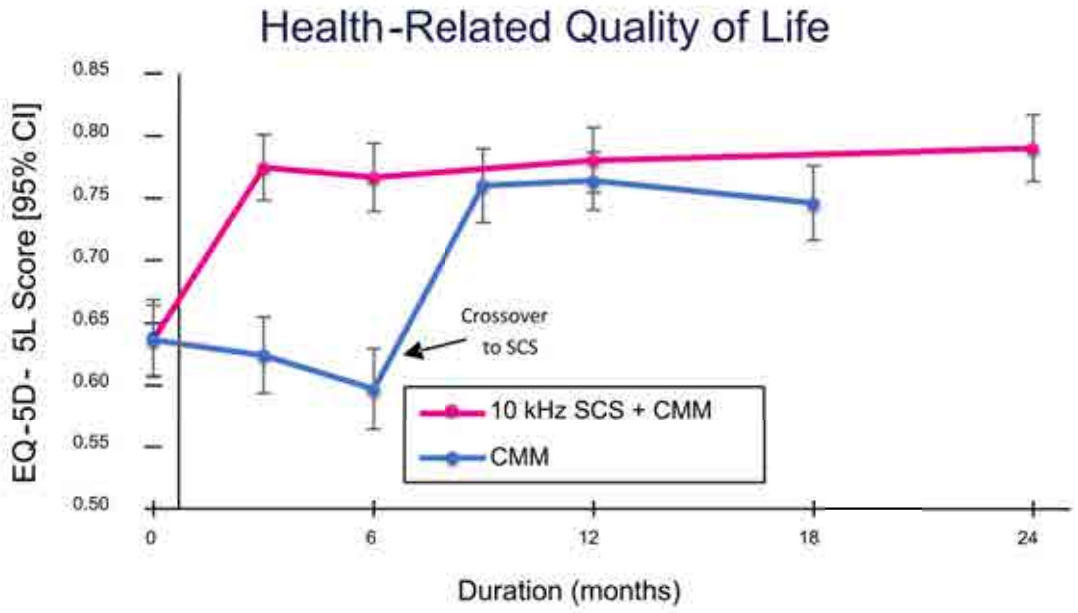


Fig. 3. SENZA-PDN change in EQ-5D index score over 24-months follow up in SCS and control PDN patients.

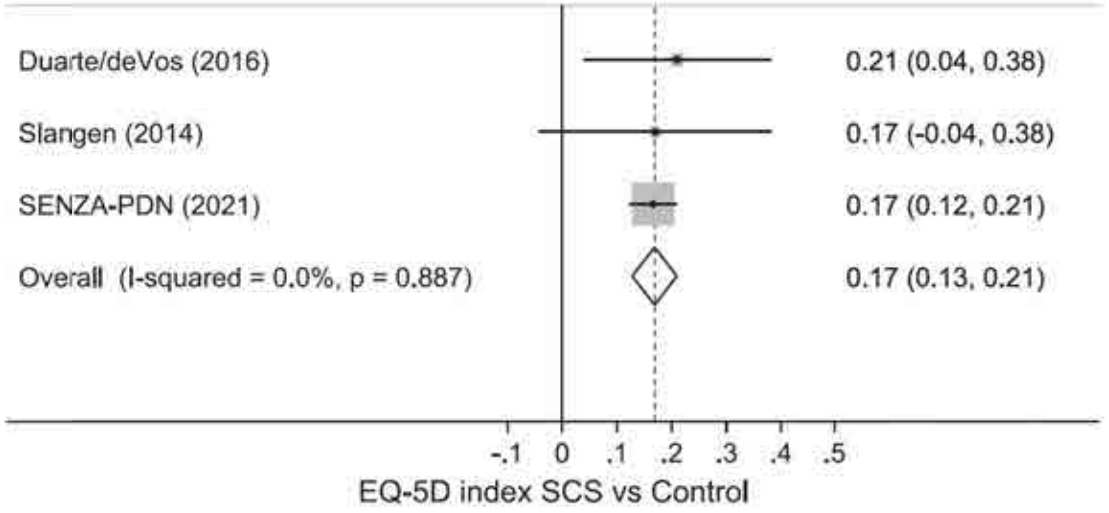
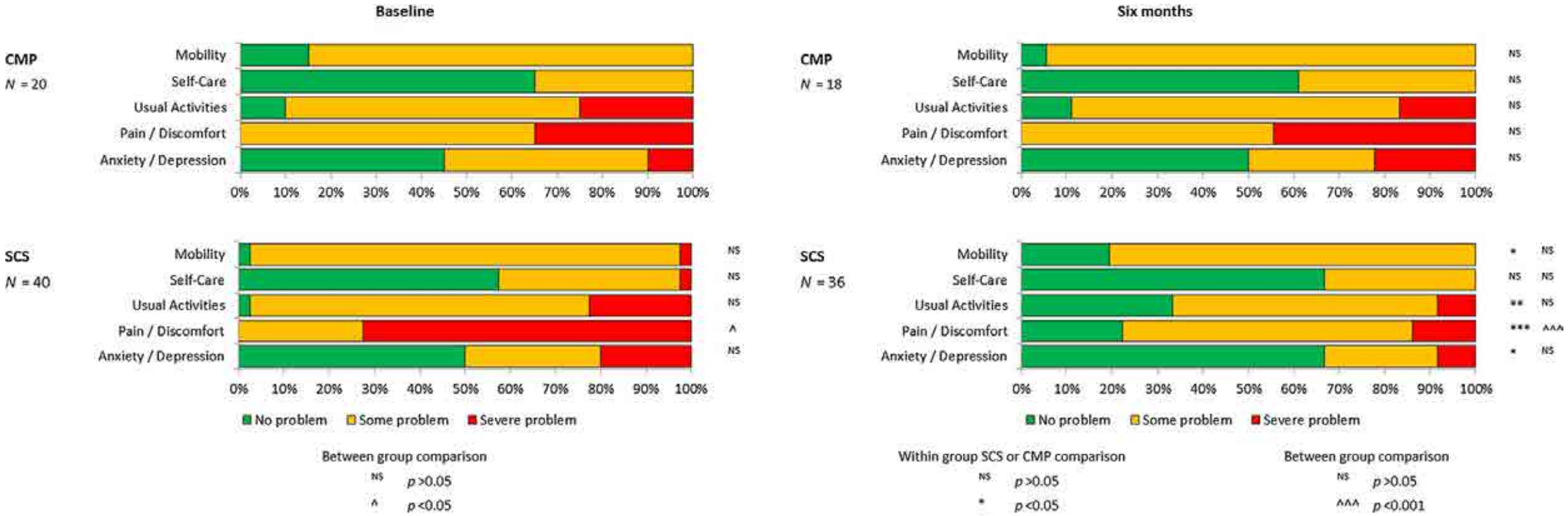


Fig. 1. Meta-analysis of RCTs of SCS for PDN – impact on EQ-5D index score at 6-months follow up. Studies pooled using a fixed effect *meta*-analysis model (I^2 = 0%).

Taylor, Diabetes Research and Clinical Practice 206 (2023) 110826

IMPACT SUR LA QUALITÉ DE VIE



Duarte et al.; Qual Life Res (2016) 25:1771–1777

ETAT DES LIEUX

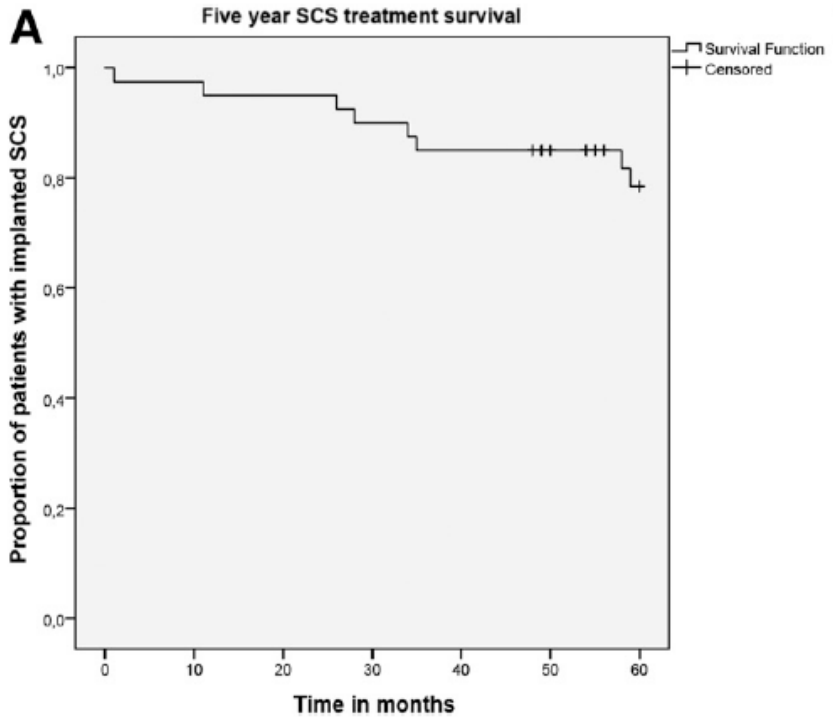
- **<u>Ce qui est amélioré:</u>**
- l'intensité des douleurs diurnes et nocturnes
- leur impact fonctionnel et émotionnel
- leur impact sur la qualité de vie

- **<u>Ce qui n'est pas amélioré</u>**
- l'évolution de la polyneuropathie
- les déficits neurologiques
- l'équilibre du diabète (HbA1c)
- l'altération de la qualité de vie qui n'est pas en rapport avec les douleurs

RÉSULTATS À LONG TERME

- 48 patients PDN suivis à 5 ans après SCS
  - 80% des patients continuent à utiliser la stimulation
  - 55% des patients encore stimulés sont améliorés > 50%

- NRS baseline moyen: 6,7
  - 1 an: 3,8
  - 3 ans: 3,8
  - 5 ans: 4,3



van Beek et al, Diabetes Care 2018

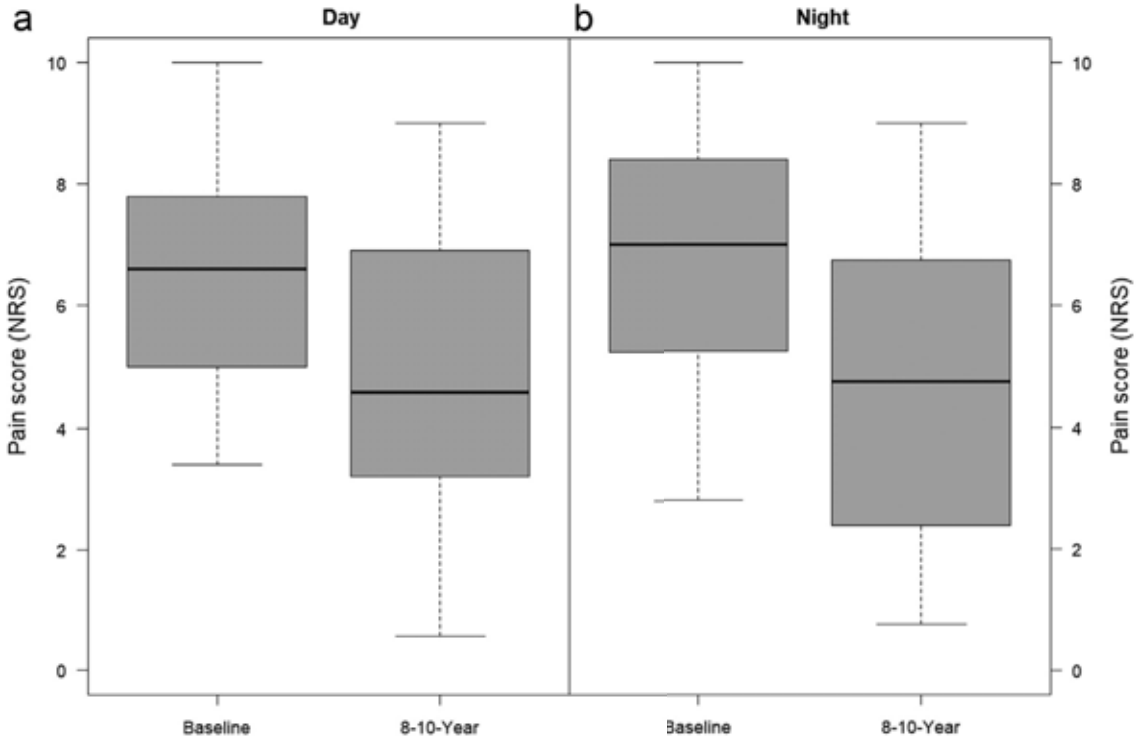
Neuromodulation: Technology at the Neural Interface

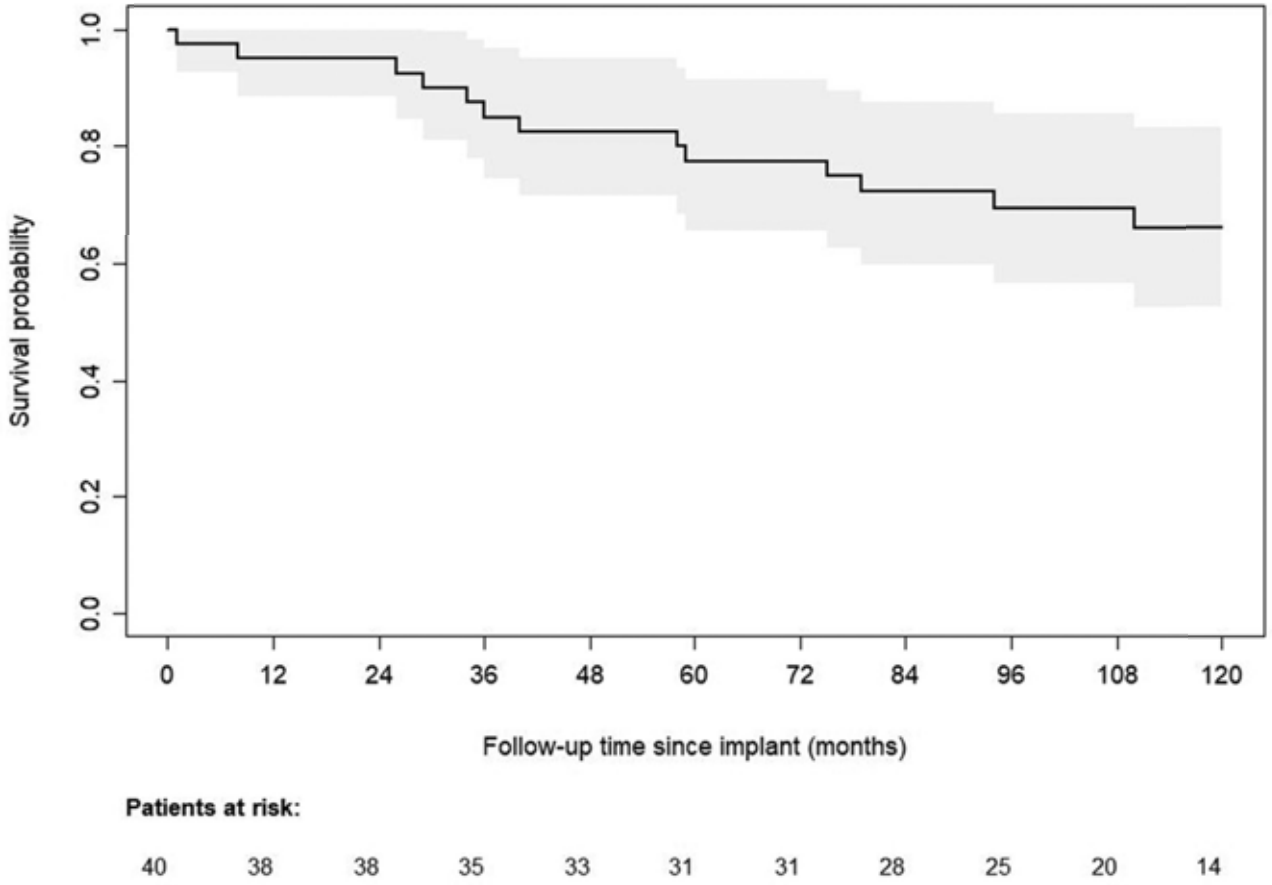
Received: August 30, 2022 Revised: November 5, 2022 Accepted: December 3, 2022

https://doi.org/10.1016/j.neurom.2022.12.003

Long-Term Evaluation of Spinal Cord Stimulation in Patients With Painful Diabetic Polyneuropathy: An Eight-to-Ten–Year Prospective Cohort Study

Xander Zuidema, MD[1,2]; Elke van Daal, MSc[1]; Iris van Geel, MSc[1]; Thomas J. de Geus, MSc[1,3]; Sander M.J. van Kuijk, PhD[4]; Bastiaan E. de Galan, MD, PhD[5,6,7]; Nelleke de Meij, PhD[1]; Jan Van Zundert, MD, PhD[1,8]





SCP EFFET PRÉVENTIF ?

- PND
  - douleur
  - perte de la sensibilité douloureuse
    - surface plantaire
    - X2 risque ulcération
    - X3 risque d'amputation

- Mortalité 5 ans diabétique amputé 5 ans

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
1–7
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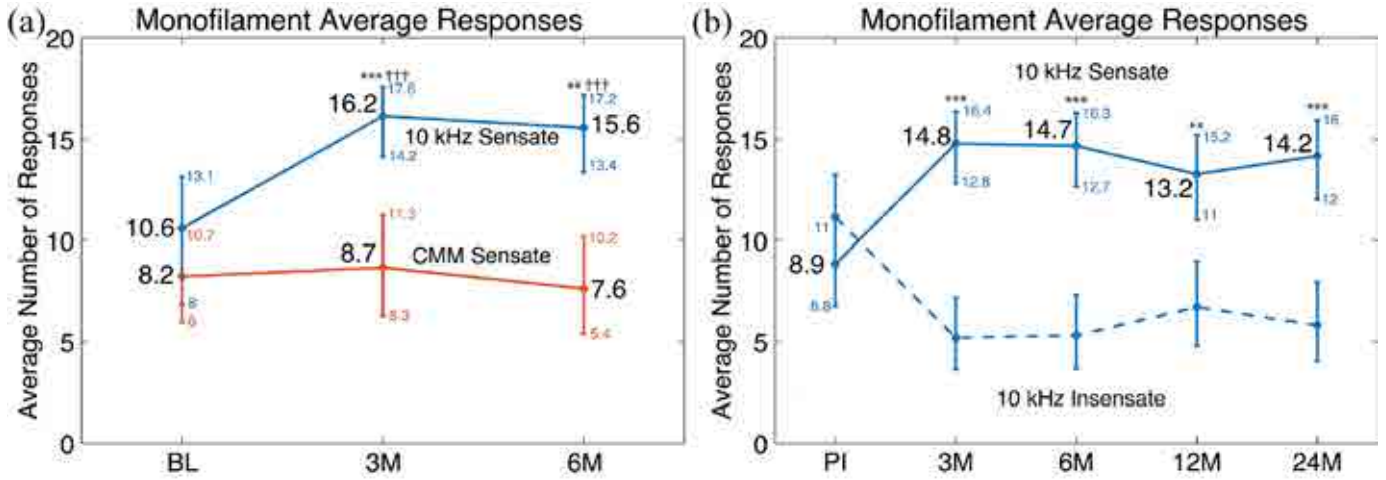
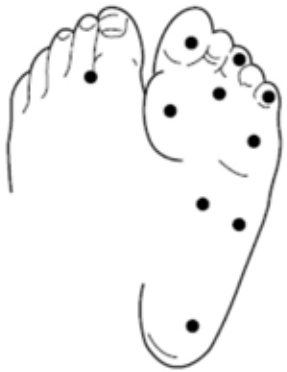
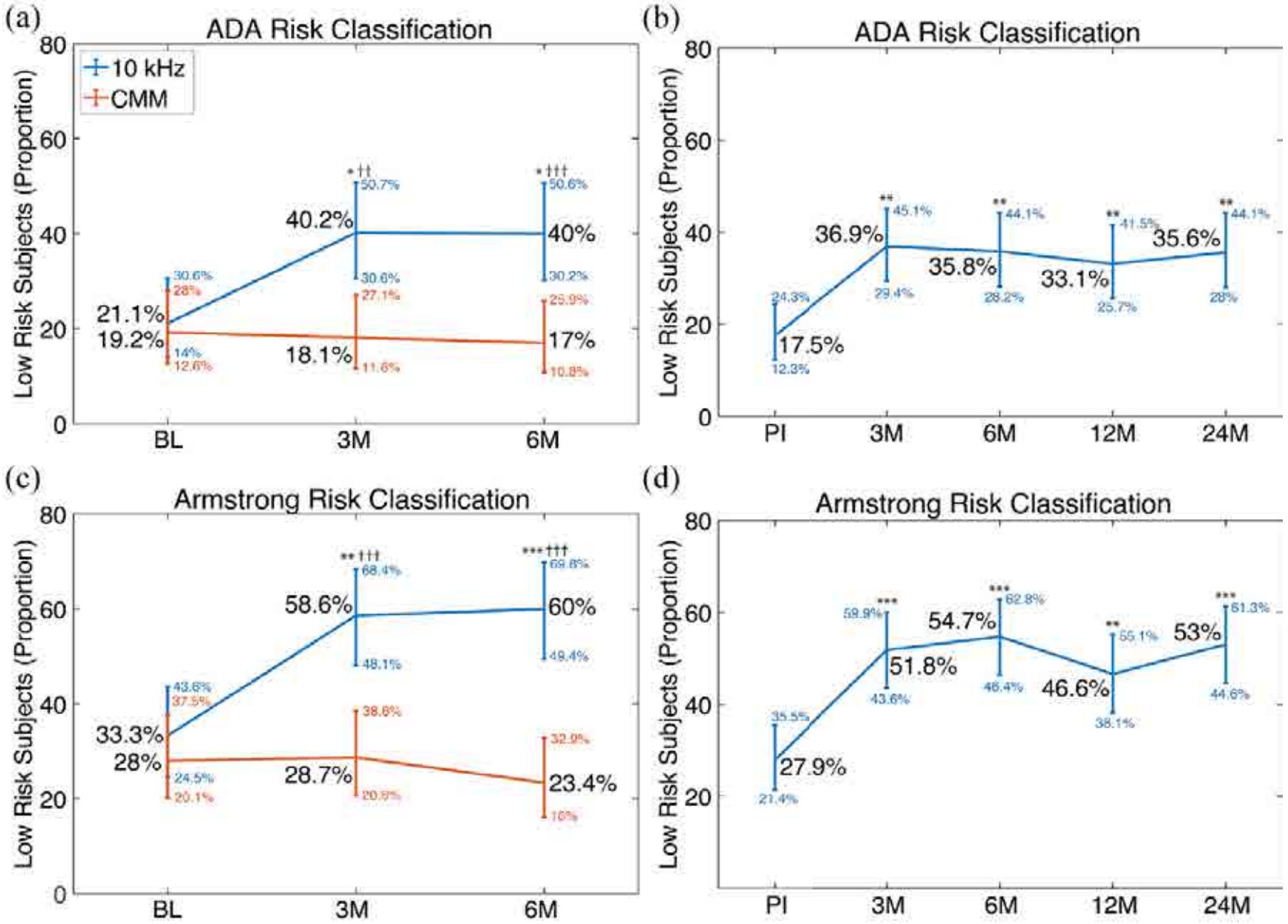
Charles E. Argoff, MD[1], David G. Armstrong, DPM, MD, PhD[2], Zachary B. Kagan, PhD[3], Michael J. Jaasma, PhD[3], Manish Bharara, PhD[3], Kerry Bradley, MS[3], David L. Caraway, MD, PhD[3], and Erika A. Petersen, MD[4] for Investigators






(a)
ADA Risk Classification
10 kHz
CMM
Low Risk Subjects (Proportion)
BL
3M
6M
21.1%
19.2%
40.2%
18.1%
40%
17%
(b)
ADA Risk Classification
Low Risk Subjects (Proportion)
PI
3M
6M
12M
24M
17.5%
36.9%
35.8%
33.1%
35.6%
(c)
Armstrong Risk Classification
Low Risk Subjects (Proportion)
BL
3M
6M
33.3%
28%
58.6%
28.7%
60%
23.4%
(d)
Armstrong Risk Classification
Low Risk Subjects (Proportion)
PI
3M
6M
12M
24M
27.9%
51.8%
54.7%
46.6%
53%

Pain Medicine, 24(S2), 2023, S33–S40
https://doi.org/10.1093/pm/pnad096
Original Research Article

High-frequency spinal cord stimulation (10 kHz) alters sensory function and nerve fiber density in painful diabetic neuropathy: a pilot prospective open-label study

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Abstract

Objective: Spinal cord stimulation at 10 kHz has provided effective pain relief and improved function in painful diabetic peripheral neuropathy. This study aims to confirm the clinical outcomes for 10-kHz spinal cord stimulation treatment of painful diabetic peripheral neuropathy and explore its impact on objective quantitative measures of nerve pathology and function.

Methods: This single-academic center, prospective, open-label, observational study examined the pain relief success of 10-kHz spinal cord stimulation in patients >18 years of age with diabetic peripheral neuropathy. Patients underwent skin biopsies to measure intra-epidermal nerve fiber densities and corneal confocal microscopy measurements before implantation and at the 3-, 6-, and 12-month follow-up visits. Numerical rating scale for pain, visual analog scale, neuropathy pain scale, Short Form-36, and Neuropen (pin prick and monofilament) assessments were also conducted.

Results: Eight patients met the criteria and were enrolled in the study. A successful trial was achieved in 7 subjects, and 6 completed the study. Significant pain relief ($P < .001$) was achieved at all follow-up visits. Neurological assessments showed reduced numbers of "absent" responses and increased "normal" responses from baseline to 12 months. Both proximal and distal intra-epidermal nerve fiber densities were higher at 12 months than at baseline ($P = .01$). Confocal microscopy measurements showed a steady increase in nerve density from baseline (188.8% increase at 12 months; $P = .029$).

Conclusions: We observed pain relief and improvements in sensory function after stimulation that were accompanied by increases in lower-limb intra-epidermal nerve fiber density and corneal nerve density. Further evaluation with a blinded and controlled study is needed to confirm the preliminary findings in this study.

Keywords: 10-kHz spinal cord stimulation; painful diabetic peripheral neuropathy; nerve fiber density

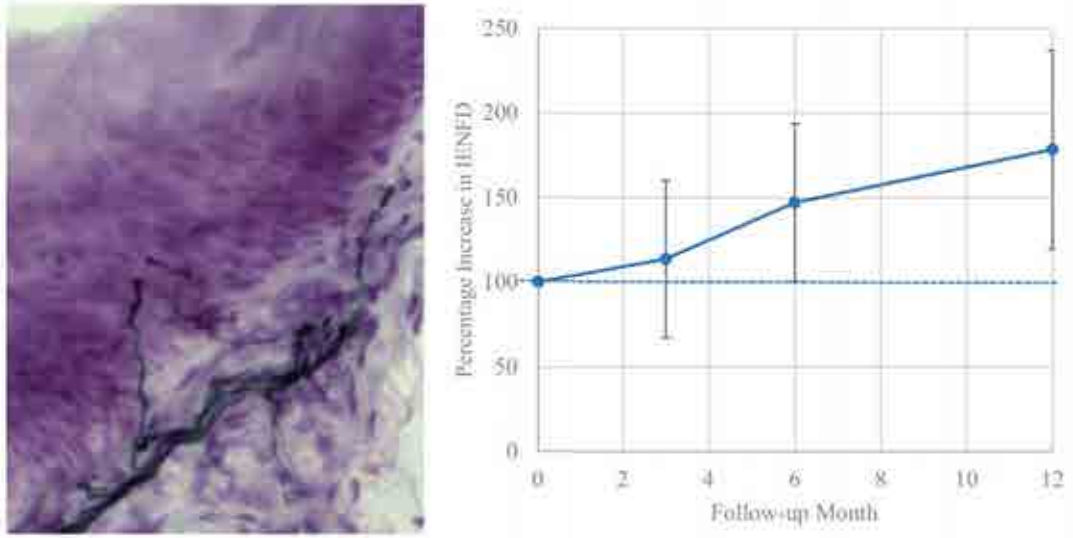
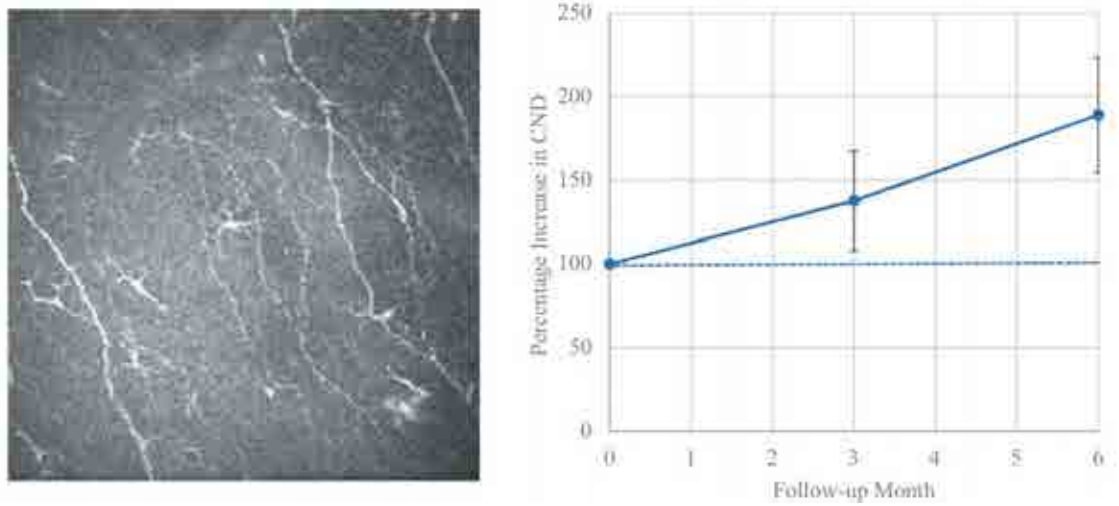
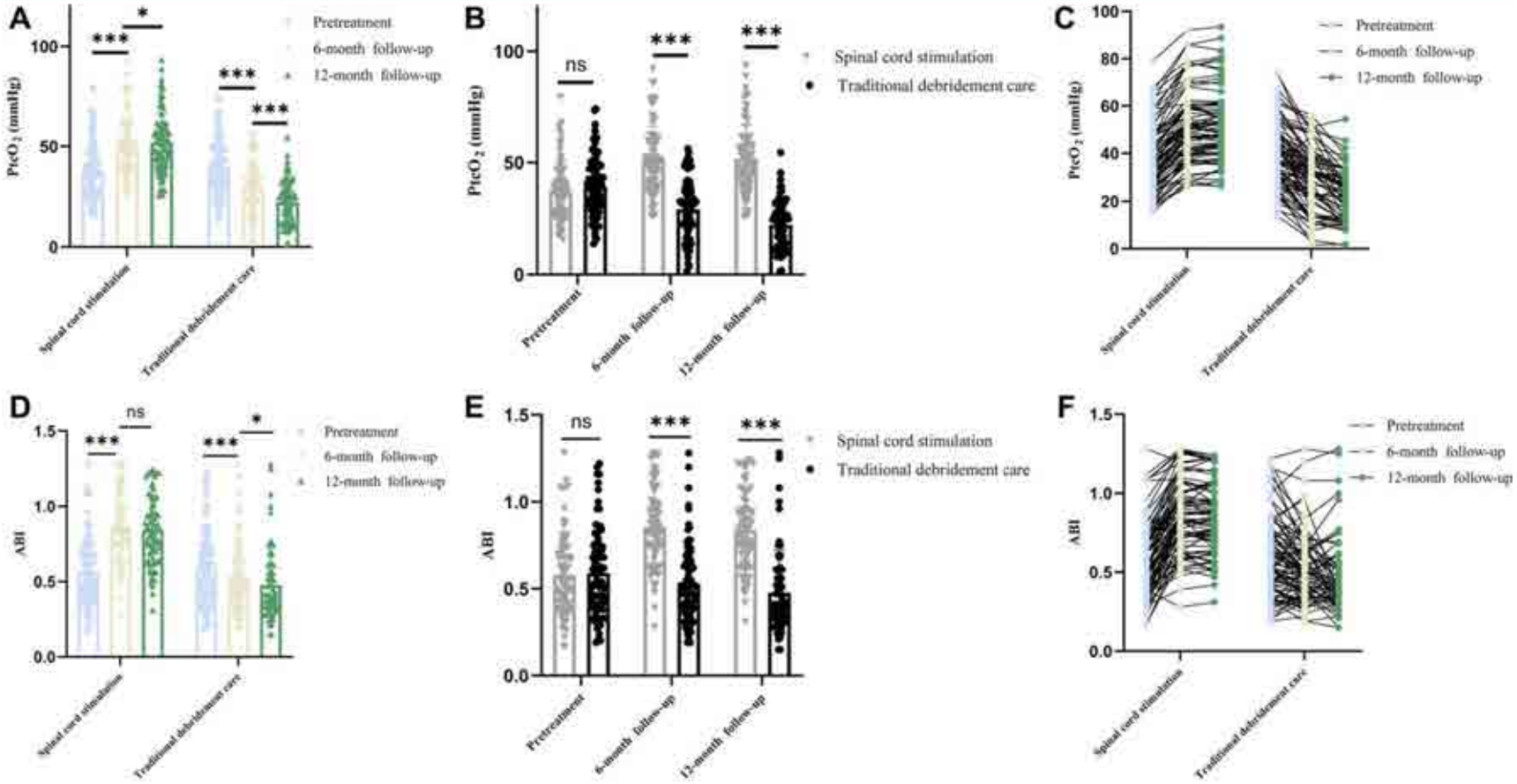


Figure 4. Representative image of nerve fibers crossing the dermal–epidermal interface in the skin of a study subject (left) and mean percentage increase from baseline in IENF density measurements (right). At 3 months, the average nerve density was 113.9% of the baseline value (a 13.9% increase), which was not a statistically significant change over baseline ($P = .42$). However, the increase became significant at 6 months, when the average ratio to baseline was 147% (95% CI: 108%–201%, $P = .024$), and it increased further at 12 months to 179% (95% CI: 129%–247%; $P = .002$). CI = confidence interval; IENF = intra-epidermal nerve fiber; IENFD = IENF density.



A 3 mois densité nerveuse augmentée de 113%

Sécrétion de facteurs de croissance



- Augmentation de la perfusion distale
  - réduction du tonus sympathique (vasodilatation)
- Guérison d'ulcère
- Reduction significative du risque d'amputation

TABLE 2. Comparison of Amputations in the SCS and TDC Groups

	6-Month follow-up			12-Month follow-up		
Type	SCS group (n = 84)	TDC group (n = 86)	OR (95% CI)	SCS group (n = 78)	TDC group (n = 63)	OR (95% CI)
Minor amputation, n (%)	5 (5.95%)	7 (8.14%)	0.71 (0.22-2.35)	7 (8.97%)	10 (5.87%)	0.52 (0.19-1.46)
Major amputation, n (%)	4 (4.76%)	11 (12.79%)	0.34 (0.10-1.12)	6 (7.69%)	24 (38.10%)	0.13 (0.05-0.36)
Total amputation, n (%)	9 (10.71%)	18 (20.93%)	0.45 (0.19-1.08)	13 (16.67%)	34 (53.97%)	0.17 (0.08-0.37)

OR, odds ratio; SCS, spinal cord stimulation; TDC, traditional debridement care.
OR > 1 indicates that SCS is a risk measure for amputation compared with TDC; OR = 1 indicates that there is no difference between SCS and TDC in their effect on amputation; and OR < 1 indicates that SCS is a protective measure for amputation compared with TDC.

Zhou et al.; Neurosurgery 2024

diabetesresearchandclinicalpractice 206 (2023) 110763

Contents lists available at ScienceDirect

Diabetes Research and Clinical Practice

journal homepage: www.journals.elsevier.com/diabetes-research-and-clinical-practice

Where does spinal cord stimulation fit into the international guidelines for refractory painful diabetic neuropathy? a consensus statement☆

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11. Conclusion

Globally, the use of opioids should rarely be recommended for refractory, severe PDN. Based on increasing clinical evidence, SCS, especially HF-SCS, should be considered as a treatment for PDN not responsive to first- or second-line monotherapy/dual therapy.

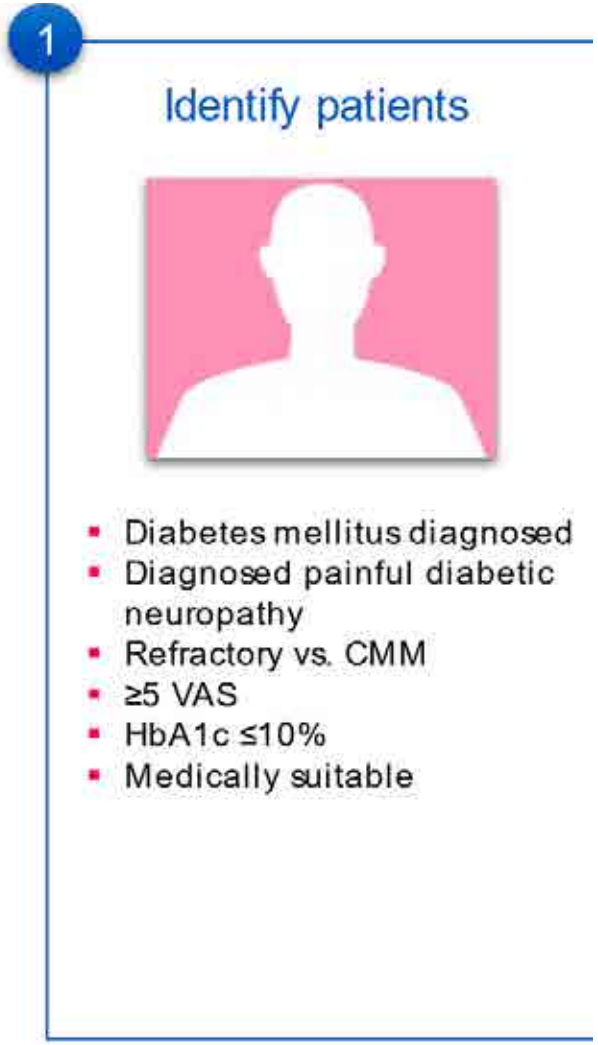
Table 2
Proposed Patient Eligibility Criteria for Spinal Cord Stimulation in Painful Diabetic Neuropathy

Eligibility Criteria
1. Clinically diagnosed diabetes with PDN of the lower limbs, and a) are symptomatic despite conservative therapy for a minimum of 12 months; b) have tried pregabalin OR gabapentin administered at an adequate dose and for an appropriate duration; c) have tried at least one other class of second-step medication; d) have been on a stable dosage of analgesic medications for at least 30 days.
2. Persistently high pain levels over time (average pain intensity of at least 5 out of 10 cm on the VAS), based on regular, documented assessments.
3. Assessed as by a psychologist as fit for SCS intervention.
Ineligibility Criteria
1. Hemoglobin A1c (HbA1c) >10%
2. Body mass index >45 kg/m^2
3. Life expectancy <1 year
4. Prescribed use of anticoagulation or antiplatelet medication (due to increased risk of epidural bleeding or bleeding from surgical site)
5. Progressive neurological disease such as multiple sclerosis, chronic inflammatory demyelinating polyneuropathy, rapidly progressive arachnoiditis, brain or spinal cord tumor, central deafferentation syndrome, complex regional pain syndrome, acute herniating disc, severe spinal stenosis, and brachial plexus injury
6. Conditions presenting excess risk, including a coagulation disorder, bleeding diathesis, platelet dysfunction, low platelet count, severely diminished functional capacity due to underlying cardiac/pulmonary disease, symptomatic uncontrolled hypertension, progressive peripheral vascular disease, or uncontrolled diabetes
7. Presence of a metastatic malignant neoplasm or untreated local malignant neoplasm
8. Significant spinal stenosis, objective evidence of epidural scarring, and/or any signs or symptoms of myelopathy based on MRI conducted within the past 12 months
9. History of surgery on the posterior elements (laminectomy, posterior fusion), resulting in a compromised epidural space
10. Local infection at anticipated surgical entry site or active systemic infection

MRI, magnetic resonance imaging; PDN, peripheral diabetic neuropathy; SCS, spinal cord stimulation.

QUESTIONS A RÉPONDRE

- **Comment gérer les douleurs des MS ?**
  - où mettre l'électrode ? dorsale (MI) ou cervicale (MI + MS)
  - 1 ou 2 temps ?
- **Les risques sont ils majorés chez les diabétiques ?**
  - deVos 2014: 1 infection / 40 implantés (2,5%)
  - Petersen 2021: 3 infections / 90 implantés (3%)
  - van Beek 2018: 2 infections / 48 (4%) mais 1 mort (HSD sur effraction durale)
  - mais qu'en est il hors étude ?
- **Quel stade de gravité ?**
  - quel est le seuil de gravité et comment l'évaluer ?
  - mal perforant ?
  - artériopathie associée ?
- **Comment proposer la stimulation médullaire pour ces patients ?**



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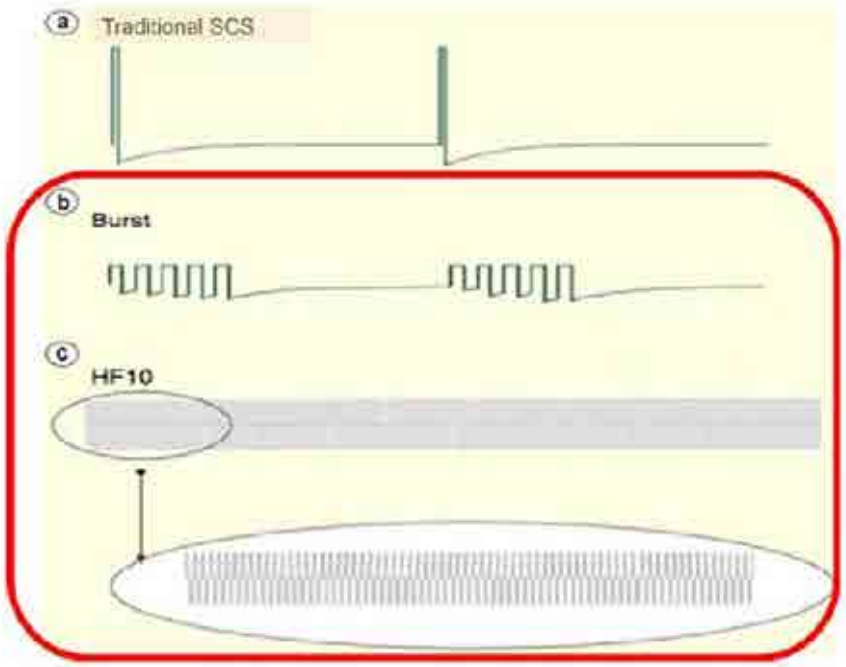

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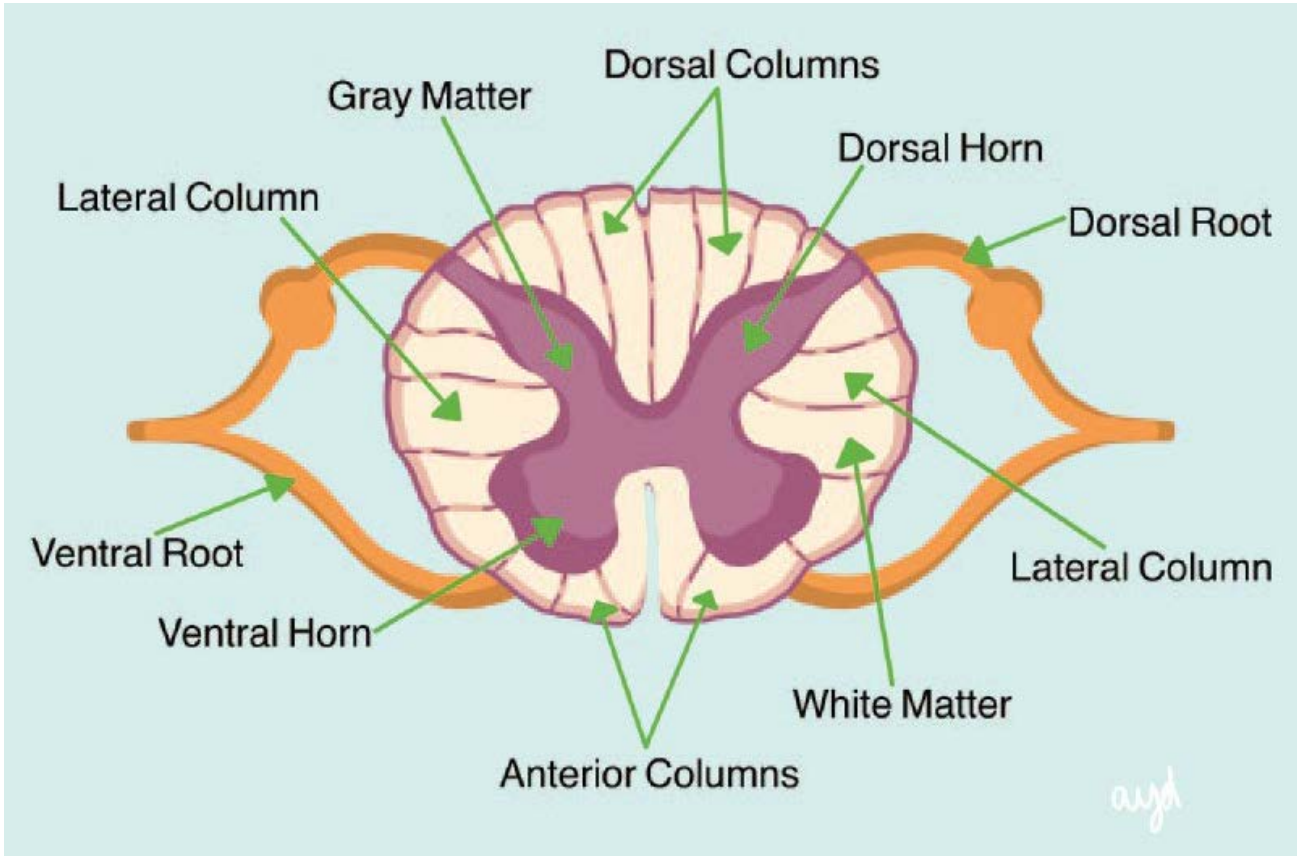

Journal of Pain Research

Dovepress

REVIEW

Painful Peripheral Neuropathies of the Lower Limbs and/or Lower Extremities Treated with Spinal Cord Stimulation: A Systematic Review with Narrative Synthesis

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Introduction: Painful peripheral neuropathy (PPN) is a debilitating condition with varied etiologies. Spinal cord stimulation (SCS) is increasingly used when conservative treatments fail to provide adequate pain relief. Few published reviews have examined SCS outcomes in all forms of PPN.

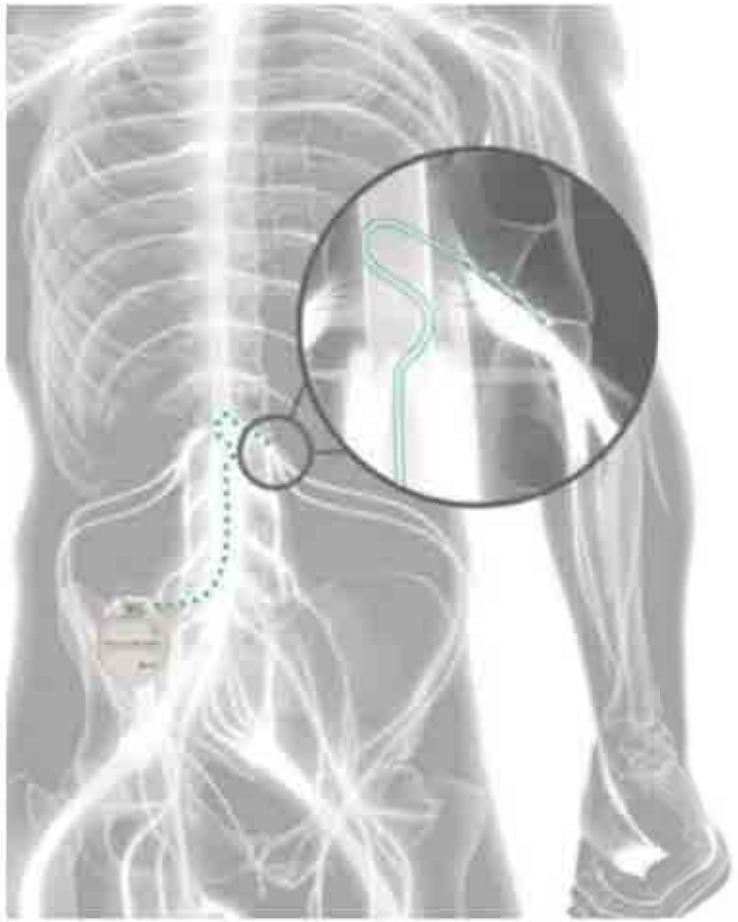
Methods: We conducted a systematic review of SCS in PPN. The PubMed database was searched up to February 7th, 2022, for peer-reviewed studies of SCS that enrolled PPN patients with pain symptoms in their lower limbs and/or lower extremities. We assessed the quality of randomized controlled trial (RCT) evidence using the Cochrane risk of bias tool. Data were tabulated and presented narratively.

Results: Twenty eligible studies documented SCS treatment in PPN patients, including 10 kHz SCS, traditional low-frequency SCS (t-SCS), dorsal root ganglion stimulation (DRGS), and burst SCS. In total, 451 patients received a permanent implant (10 kHz SCS, n=267; t-SCS, n=147; DRGS, n=25; burst SCS, n=12). Approximately 88% of implanted patients had painful diabetic neuropathy (PDN). Overall, we found clinically meaningful pain relief (≥30%) with all SCS modalities. Among the studies, RCTs supported the use of 10 kHz SCS and t-SCS to treat PDN, with 10 kHz SCS providing a higher reduction in pain (76%) than t-SCS (38–55%). Pain relief with 10 kHz SCS and DRGS in other PPN etiologies ranged from 42–81%. In addition, 66–71% of PDN patients and 38% of nondiabetic PPN patients experienced neurological improvement with 10 kHz SCS.

Conclusion: Our review found clinically meaningful pain relief in PPN patients after SCS treatment. RCT evidence supported the use of 10 kHz SCS and t-SCS in the diabetic neuropathy subpopulation, with more robust pain relief evident with 10 kHz SCS. Outcomes in other PPN etiologies were also promising for 10 kHz SCS. In addition, a majority of PDN patients experienced neurological improvement with 10 kHz SCS, as did a notable subset of nondiabetic PPN patients.

Keywords: painful diabetic neuropathy, peripheral neuropathy, spinal cord stimulation, 10 kHz SCS, diabetes, neuropathic pain, systematic review

PLACE DU DRG



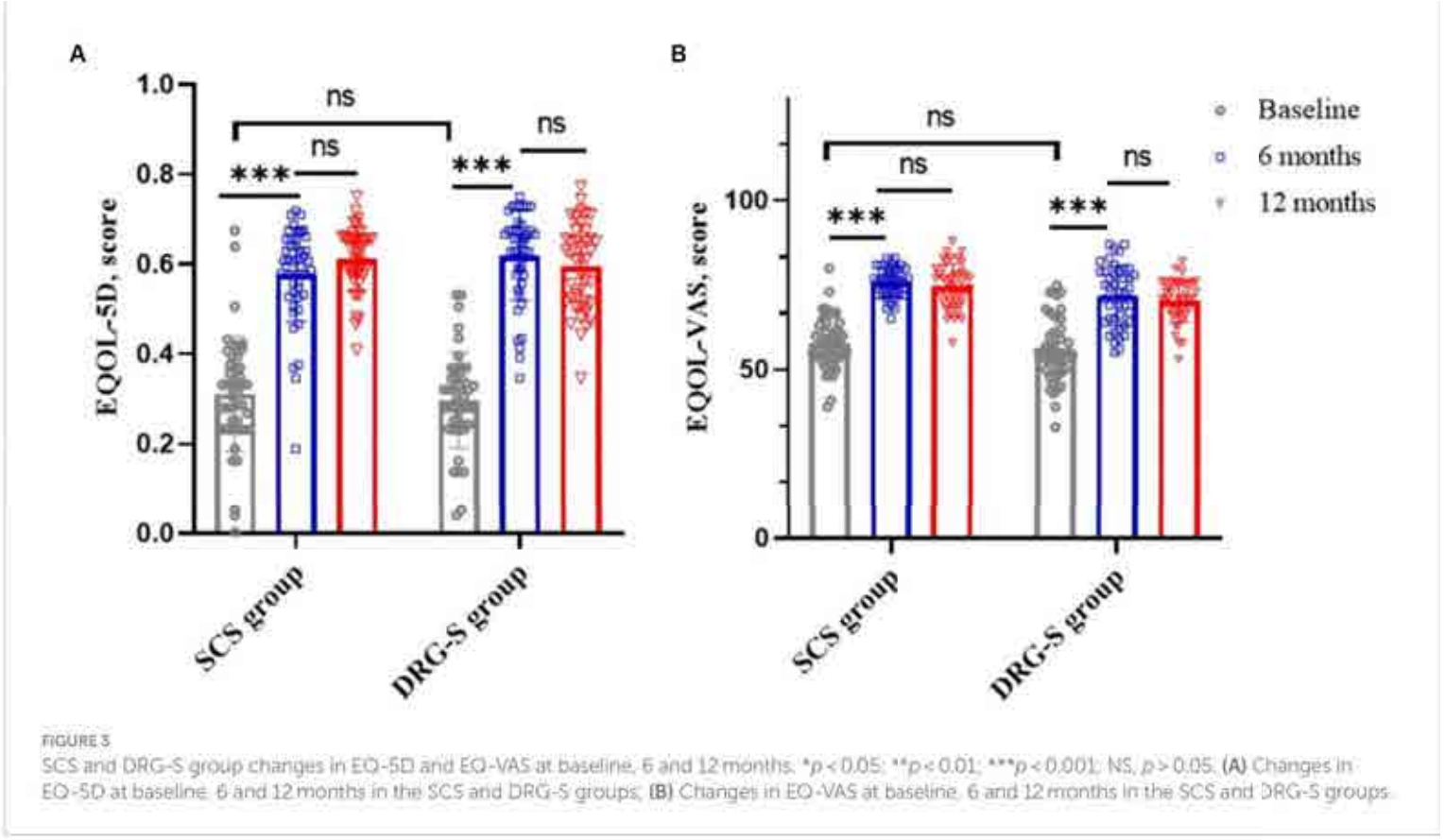


FIGURE 3
SCS and DRG-S group changes in EQ-5D and EQ-VAS at baseline, 6 and 12 months. *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$; NS, $p > 0.05$. **(A)** Changes in EQ-5D at baseline, 6 and 12 months in the SCS and DRG-S groups; **(B)** Changes in EQ-VAS at baseline, 6 and 12 months in the SCS and DRG-S groups.

CONCLUSION

- Stimulation médullaire = traitement symptomatique des douleurs neuropathiques sévères
  - PDN = indication couverte par l'HAS 2014, validée et remboursée
- PDDN – efficace + persistance de l'effet au long cours
- Peu de risques
- Trop peu de patients traités
- Barrière au développement de l'indication
  - (1) absence de diffusion de information
  - (2) absence de filière de soins
  - (3) absence de recommandation sociétés savantes
- Nécessité de créer des filières de soins (ces patients ne fréquentent pas forcement les structures douleur chronique) avec les
  - diabétologues,
  - neurologues,
  - algologues
  - MG
  - et association de patients

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