Efficacy of 60-day percutaneous peripheral nerve stimulation in reducing persistent postoperative pain and improving function in patients over one-year post-total knee arthroplasty: a randomized controlled trial

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INTRODUCTION:

Total knee arthroplasty (TKA) is an effective surgical procedure, but regardless of the success of the implant, persistent postoperative pain can affect up to 20% of patients, impacting their function and quality of life. Persistent pain still present 1 year post TKA can be particularly challenging to treat. This study evaluated the efficacy of 60-day percutaneous peripheral nerve stimulation (PNS) in reducing persistent postoperative pain and improving function following TKA.

METHODS:

This prospective (NCT04341948), randomized, double-blind, placebo-controlled trial included individuals with persistent postoperative pain following TKA. Key exclusion criteria included high opioid use (≥90 mg/day MED) and pain caused by implant failure requiring revision. Subjects received an FDA-cleared PNS device (SPRINT PNS; SPR Therapeutics Inc., Cleveland, OH, USA) and were randomized to receive either active PNS or placebo (sham) stimulation for 8 weeks. The primary outcome was the percentage of subjects achieving ≥50% pain relief relative to baseline during weeks 5-8 of treatment on a 0-10 numerical rating scale (NRS). Primary and secondary endpoints demonstrated significant pain relief and have been reported elsewhere [1]. Pain scores were assessed with daily pain diaries, and functional outcomes included improvements relative to baseline on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC, 0-10 NRS) and the Six-Minute Walk Test (6MWT, distance walked over 6 minutes). WOMAC data are reported to 12 months after start of treatment in the PNS group. Data in the placebo group are included out to 3 months as subjects were unblinded and offered the opportunity to crossover (with data collection in progress). The present *post-hoc* analysis focused on subjects that enrolled at least one year after primary TKA surgery.

RESULTS:

Fifty-two subjects were randomized and received treatment for persistent pain following TKA. 35 of these 52 subjects were at least one-year post-TKA at the time of enrollment and reported data during the primary endpoint (weeks 5-8 of treatment). Among these subjects, baseline pain scores were approximately the same in both groups (7.2 out of 10 and 7.3 out of 10 in the PNS group and placebo group, respectively), and a significantly higher proportion of subjects in the PNS group (61%; 11/18) achieved ≥50% pain relief relative to baseline during the primary endpoint compared to the placebo group (23%; 4/17) (p=0.04). For the primary endpoint, the PNS subjects reported an average reduction of 3.9 points compared to 1.7 points in the placebo group (p=0.004).

Subjects in the PNS group showed improvements in walking ability compared to those in the placebo group. For subjects who completed the 6MWT, the PNS group increased their walking distance by 49% (n=16) at the end of treatment (EOT) and by 52% (n=12) at month 3. In contrast, the placebo group saw increases of only 8% (n=13) at EOT and 5% (n=13) at month 3.

Average WOMAC pain scores, reported on a 10-point scale, were similar at baseline (PNS=6.2 vs. placebo=6.8). Subjects were considered responders if they had ≥50% improvement in their WOMAC score relative to baseline. At EOT, subjects in the PNS group had an average improvement of 4.0 points (64%) compared to a 1.9-point improvement (25%) in the placebo group (p=0.03). In the PNS group, 78% (14/18) of subjects were classified as responders for the WOMAC pain subscale compared to 31% (5/16) of the placebo group (p=0.01). At the 12-month follow-up, 54% (7/13) of the PNS group continued to be responders demonstrating enduring improvements following treatment. For the WOMAC physical function subscale, 78% (14/18) of subjects in the PNS group were responders at EOT compared to 38% (6/16) of the placebo group (p=0.03). In the PNS group, 62% (8/13) continued to respond for the WOMAC physical function subscale at the 12-month follow-up.

DISCUSSION AND CONCLUSION:

The findings of this multicenter, randomized, double-blind, placebo-controlled trial provide strong evidence that 60-day percutaneous PNS is an effective non-opioid treatment in patients with persistent postoperative pain, including those with pain at least one year after their TKA. The enduring pain relief and functional improvements that were observed in the PNS group demonstrate that percutaneous PNS can play a crucial role in improving long-term outcomes in pain and function.

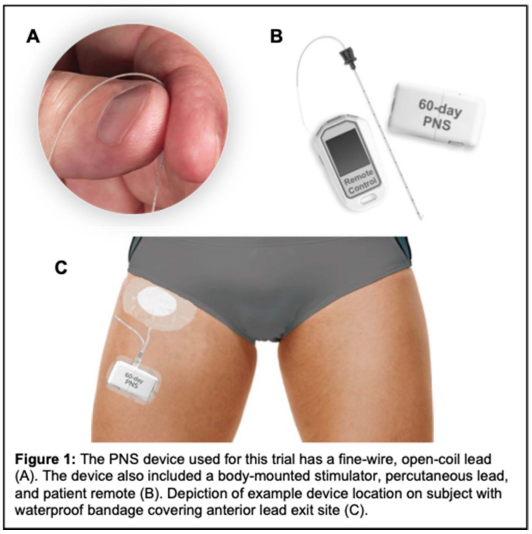

Figure 1: The PNS device used for this trial has a fine-wire, open-coil lead (A). The device also included a body-mounted stimulator, percutaneous lead, and patient remote (B). Depiction of example device location on subject with waterproof bandage covering anterior lead exit site (C).

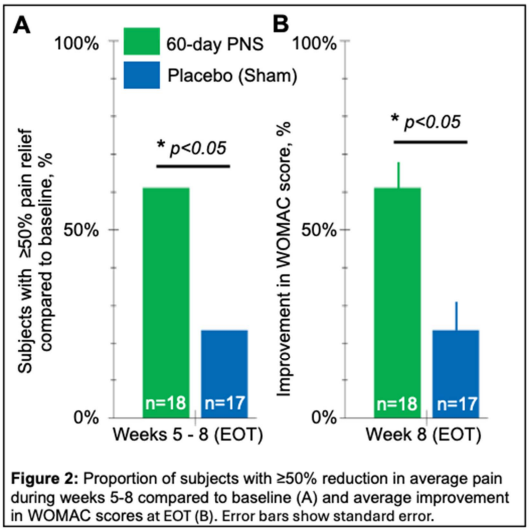

Figure 2: Proportion of subjects with ≥50% reduction in average pain during weeks 5-8 compared to baseline (A) and average improvement in WOMAC scores at EOT (B). Error bars show standard error.