

Efficacy of Percutaneous 60-Day Peripheral Nerve Stimulation in patients with serious persistent postoperative pain and impaired function after total knee arthroplasty: 12-month follow-up from a randomized controlled trial

Ravi Kant Bashyal, David Michael Dickerson, Johnathan Goree, Stuart Alan Grant, Yashar Eshraghi, Sandeep Vaid, Ali Valimahomed, Jarna R Shah, Gregory Lawson Smith, John J. Finneran, Nirav Shah, Jeffrey Benjamin Stambough, Maged Guirguis, Maxim Eckmann, John Gilbert, Amorn Wongsarnpigoon, Joseph Boggs

INTRODUCTION:

While total knee arthroplasty (TKA) is successful for many patients, up to 20% experience persistent postoperative pain and impaired function despite no obvious surgical issues¹. These symptoms may have a neurological basis and may not be amenable to further surgical intervention. Percutaneous 60-Day Peripheral Nerve Stimulation (PNS) has shown promise as a non-opioid treatment for persistent serious postoperative pain. A recent randomized controlled trial reported improved function and pain relief with PNS compared to placebo during the treatment period². This follow-up analysis evaluated outcomes through 12 months among participants who received active PNS treatment with moderate to severe impairments in both function and pain at baseline.

METHODS:

Patients with persistent postoperative pain following knee replacement were enrolled in this multicenter, post-market, IRB-approved, prospectively registered (NCT04341948) randomized controlled trial. Participants were treated using an FDA-cleared PNS system consisting of percutaneous fine-wire coiled leads connected to an external pulse generator. Two leads were placed away from the knee implant on the upper thigh of the affected leg under ultrasound guidance, remained indwelling for 8 weeks, and were removed at the end of treatment. One lead was placed approximately 3–5 cm distal to the femoral crease to target the femoral nerve, and the other lead was inserted lateral to the gluteal crease to target the sciatic nerve. Patients were screened at baseline to confirm moderate to severe persistent pain (≥ 5 out of 10 on Question 5 of the Brief Pain Inventory Short Form). The present analysis focused on participants who also had moderate to severe baseline impairment in function as measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC; 0-10 NRS, with higher scores indicating worse function; WOMAC Physical Function subscale ≥ 5). Outcomes for function and pain were assessed using the WOMAC questionnaire through 12 months after the start of treatment. Knee injury and Osteoarthritis Outcome Score, Joint Replacement (KOOS, JR) scores were derived from total WOMAC scores using a validated conversion method³. Substantial clinical benefit was defined for each outcome as an improvement of $\geq 50\%$ for WOMAC Pain and Function or an improvement of ≥ 20 points for KOOS, JR^{4, 5}. Additionally, a composite outcome captured the proportion of participants with a substantial clinical benefit in WOMAC Function and/or Pain⁶. Missing data were imputed using a mixed-effects model, and results were pooled across 50 imputed datasets to capture the variability and enhance the reliability of the imputed output. Month 12 outcomes were derived from and reported on the combined observed and imputed data.

RESULTS:

Twenty participants with moderate-to-severe baseline pain were randomized to receive PNS and reported outcomes at the end of treatment, as described previously². Sixteen of these PNS participants also had moderate-to-severe impaired function at baseline and were included in the present analysis. The majority of this subset with both moderate-to-severe baseline pain and impaired function improved by the end of treatment, with 81% ($n=13/16$) reporting a substantial clinical benefit for functional improvement, 69% ($n=11/16$) reporting a substantial clinical benefit for pain relief, and 81% ($n=13/16$) reporting a substantial clinical benefit for functional improvement and/or pain relief for the composite outcome. At Month 12, the benefits from Percutaneous 60-Day PNS persisted, with 67% achieving substantial clinical benefit for functional improvement, 65% achieving substantial clinical benefit for pain relief, and 77% achieving substantial clinical benefit for the composite outcome of functional improvement and/or pain relief (Figure 1). For calculated KOOS, JR scores, 81% ($n=13/16$) achieved substantial clinical benefit at the end of treatment and 66% had sustained substantial clinical benefit at Month 12.

DISCUSSION AND CONCLUSION:

This 12-month follow-up analysis from a multicenter, double-blind, randomized controlled trial demonstrates that Percutaneous 60-Day PNS provides substantial and sustained improvements in both function and pain for patients with persistent serious impaired function and postoperative pain following TKA. The majority of participants reported substantial improvements at the end of treatment, and these substantial improvements were sustained through one year. The magnitude and durability of improvement is notable given that these participants enrolled an average of nearly four years after their TKA and were experiencing serious persistent postoperative pain and impaired function.

These findings are particularly relevant in the context of recent policies from the Centers for Medicare and Medicaid Services (CMS) mandating the collection and reporting of patient reported outcome measures, including KOOS, JR, to evaluate outcomes approximately one year after TKA. In this analysis, a majority of participants achieved a substantial

benefit (≥ 20 -point improvement) in the calculated KOOS, JR scores at 12 months. These results highlight the opportunity to integrate Percutaneous 60-Day PNS into postoperative care to improve outcomes for patients that continue to experience functional impairments and postoperative pain after TKA, despite a technically sound surgery.

1. Cheng, H.Y., et al., *BMJ Open*, 2025
2. Goree, J.H., et al., *Neuromodulation*, 2024
3. Fleisher, I.T., et al., *J Arthroplasty*, 2022
4. Lyman, S., et al., *Clin Orthop Relat Res*, 2018.
5. Dworkin, R.H., et al., *Pain*, 2005
6. Pilitsis, J.G., et al., *Neuromodulation*, 2021

