

Percutaneous 60-Day PNS relieves postoperative pain and pain interference after total knee arthroplasty 12 months after treatment

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More Clinical Evidence
for 60-Day PNS

Objective

- Total knee arthroplasty (TKA) is an effective procedure for treating end-stage knee osteoarthritis, and more than 1.2M TKAs per year are expected in the U.S. by 2040 [1].
- Up to 10-20% of patients continue to experience persistent intractable postoperative pain despite a technically successful surgery and no obvious surgical issues [2].
- If not effectively treated, persistent intractable postoperative pain can impair function and interfere with daily activities.
- Percutaneous 60-Day Peripheral Nerve Stimulation (PNS) is a minimally invasive treatment (no permanent implant) designed to produce durable long-term pain relief that has been shown to last more than 4 years in several indications [3,4].

Study Goal: Evaluate the efficacy of Percutaneous 60-day PNS in relieving persistent intractable postoperative pain and improving function compared to sham (placebo) stimulation [5].

RCT Design and Methods

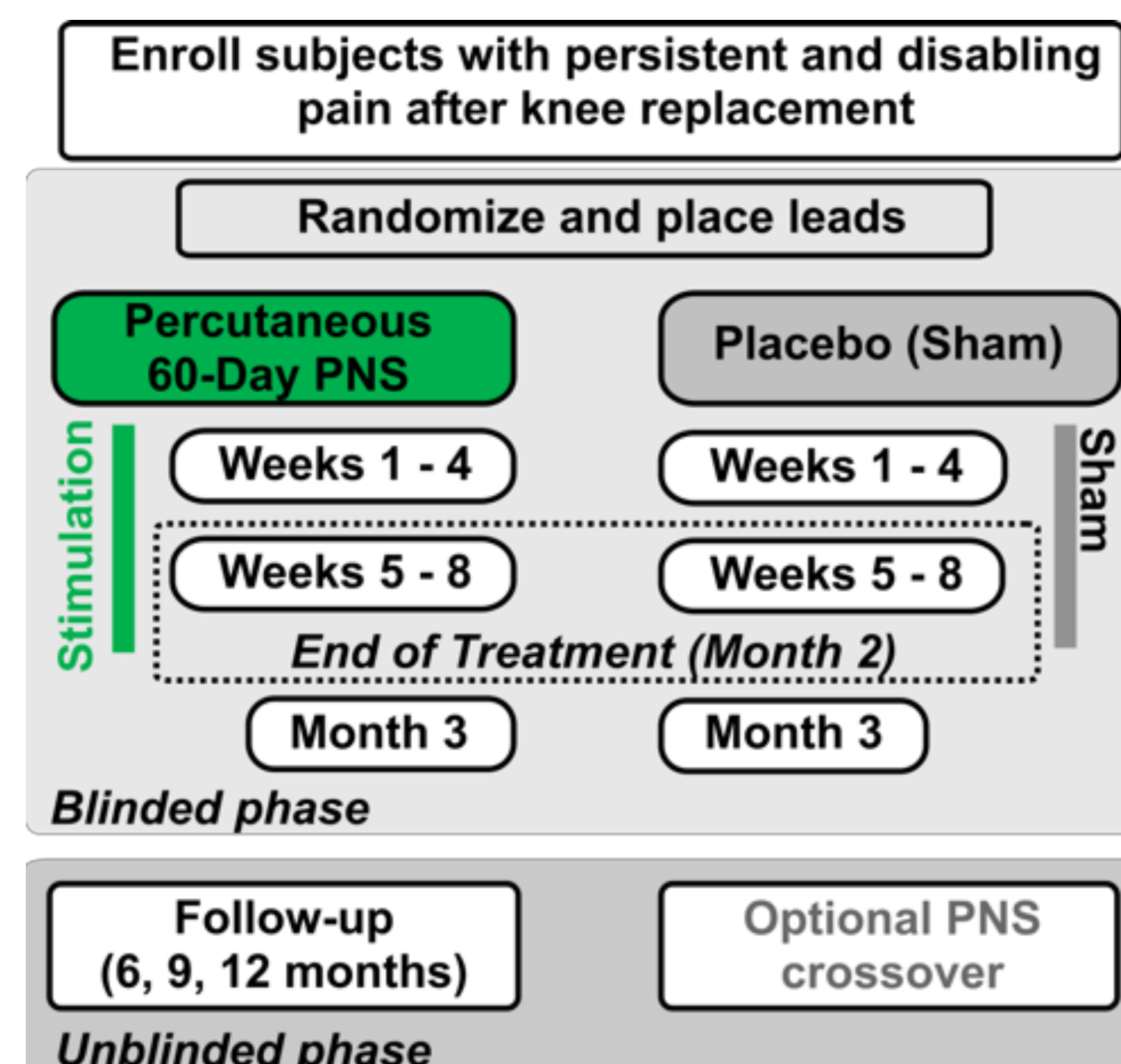
- Post-market, multicenter, double-blind, randomized placebo-controlled trial.
- Institutional review board (IRB)-approved and prospectively registered (NCT04341948) [5].
- Leads placed in a minimally-invasive ultrasound-guided procedure with single needle insertion per lead.
- Leads targeted the femoral and sciatic nerves in the upper thigh [5].
- Participants received active or placebo (sham) stimulation for 24 hours/day for up to 60 days.

Key Eligibility Criteria:

- Persistent and stable moderate to severe pain after TKA (BPI-5 ≥ 5).
- Stable medication usage for ≥ 4 weeks prior to baseline visit.
- Opioids ≤ 90 mg morphine equivalent dose.
- No contra indicated conditions.
- Age ≥ 21 years.
- BMI ≤ 40 kg/m².
- No diagnosis of diabetes.

Outcomes:

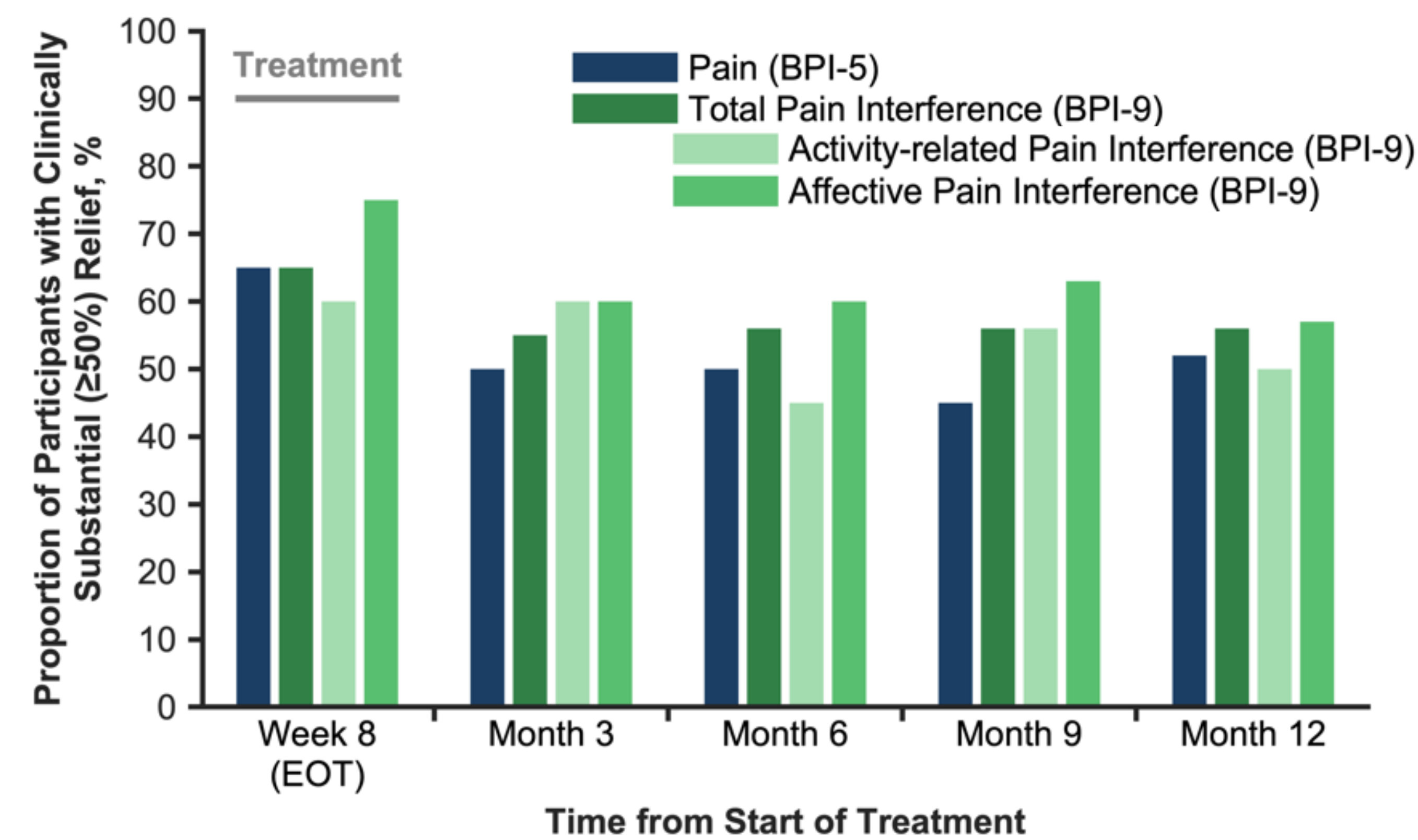
- Brief Pain Inventory Short Form: pain (BPI-5) and pain interference (BPI-9). Scores assessed on 0-10 numerical rating scale (NRS).



Results

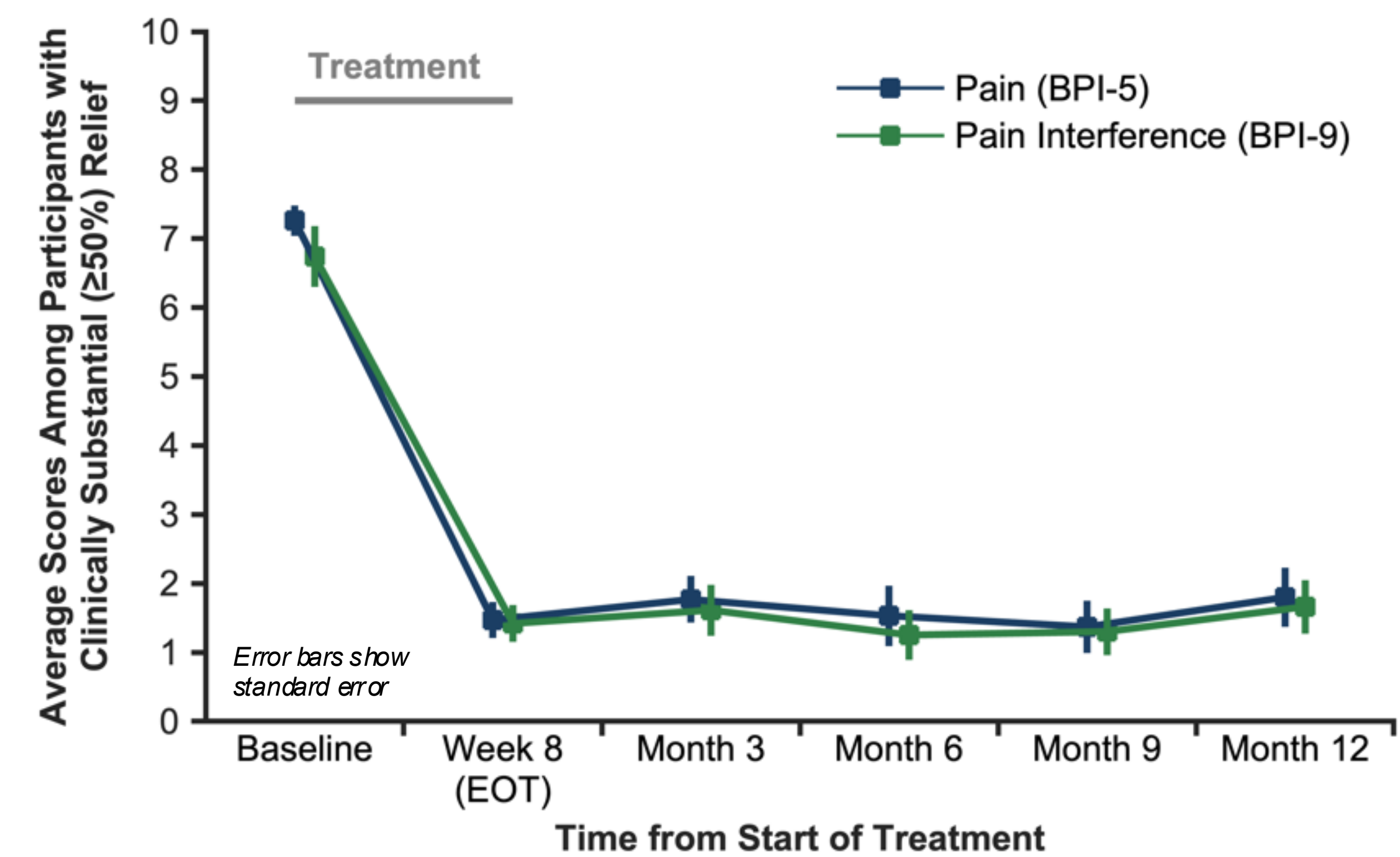
Successful primary endpoint: The PNS group had significantly more responders ($\geq 50\%$ pain relief during weeks 5-8 of treatment) than the placebo group (PNS=60% vs. Placebo=24%; $p=0.03$).

Sustained pain relief and relief of pain interference with daily activities: The majority of participants in the Percutaneous 60-Day PNS group had pain relief and relief of pain interference with daily activities during treatment and long-term at 12 months.



Responders reported consistent and substantial reductions in pain scores and pain interference scores. At Month 12:

- Average pain relief: **75%**
- Average relief of pain interference with daily activities: **76%**



Baseline information: No clinically important differences between groups regarding age, gender, time since surgery, and baseline pain or function. Median 2.5 years since surgery.

Outcomes: All changes are reported relative to baseline. $N=20$ participants treated with Percutaneous 60-Day PNS. Missing data were imputed using a mixed-effects model. Month 6, 9, and 12 outcomes were derived from the combined observed and imputed data.

Pain interference activity-related domains: general activity, walking ability, work

Pain interference affective domains: mood, relations with other people, sleep, enjoyment of life

Safety: No study-related serious or unanticipated adverse events. Skin irritation was the most common adverse event.

Key Takeaways

Percutaneous 60-Day PNS is a minimally invasive treatment option used for persistent intractable postoperative knee pain with:

- A strong safety profile
- Sustained relief of pain and pain interference, including both activity-related and affective domains

Acknowledgments

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References: [1] Shichman et al. JBJS Open Access 2023 [2] Wylde et al. EFORT Open Rev. 2018. [3] Vorenkamp et al. Pain and Therapy 2025. [4] Gilmore et al. Pain and Therapy 2025. [5] Goree et al., Neuromodulation, 2024.