

Percutaneous Peripheral Nerve Stimulation (PNS) Relieves Persistent Postoperative Pain and Improves Function: Long-term Follow-up from a Double-Blind Randomized Controlled Trial

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OBJECTIVE

- Knee arthroplasty, including total knee arthroplasty (TKA), is an effective surgical procedure, and ~800,000 procedures are performed in the United States each year.
 - Despite successful surgeries, ~10-20% of patients continue to experience persistent postoperative pain (*i.e.*, pain more than 3 months after surgery or past the time of normal tissue healing).
 - Disabling pain may lead to delayed or reduced functional recovery and poor quality of life unless it is effectively treated [1].
- Study Goal:** Characterize responses to 60-day percutaneous PNS in a post-market, institutional review board (IRB)-approved, prospectively registered (NCT04341948), multicenter, double-blind, placebo-controlled, randomized trial [2].

Recently published results found that percutaneous PNS significantly reduced persistent postoperative pain at the end of treatment and improved function compared to sham (placebo) following TKA. The present work reports pain relief and functional improvement in the treatment group up to 12 months from the start of treatment.

METHODS

Minimally invasive procedure and a self-managed treatment:

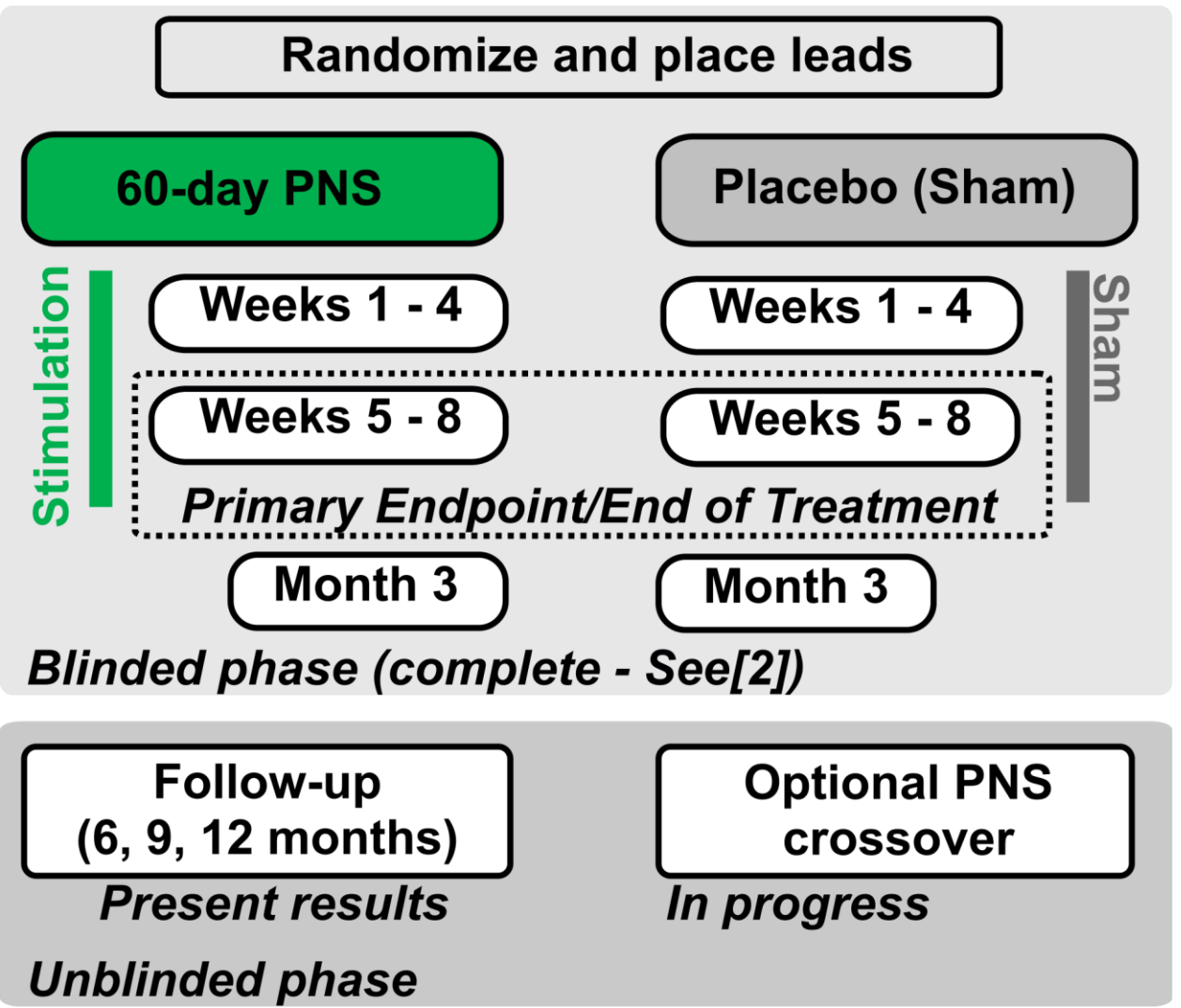
- Leads placed in a minimally-invasive ultrasound-guided procedure using a single needle insertion per lead.
- Leads targeted the femoral and sciatic nerves proximal to the region of pain [2].
- Patients self-managed treatment with a handheld remote.



Key Eligibility Criteria:

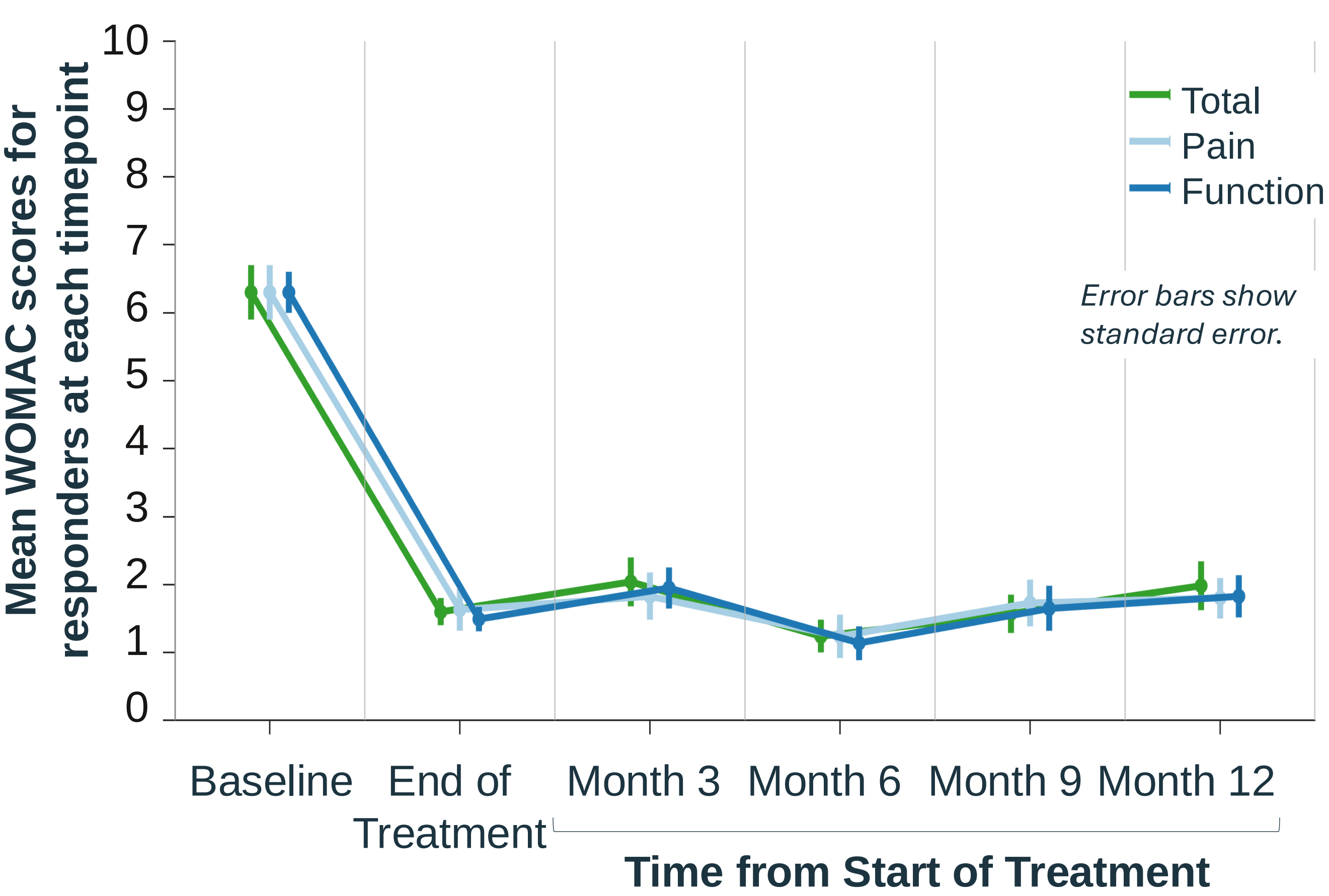
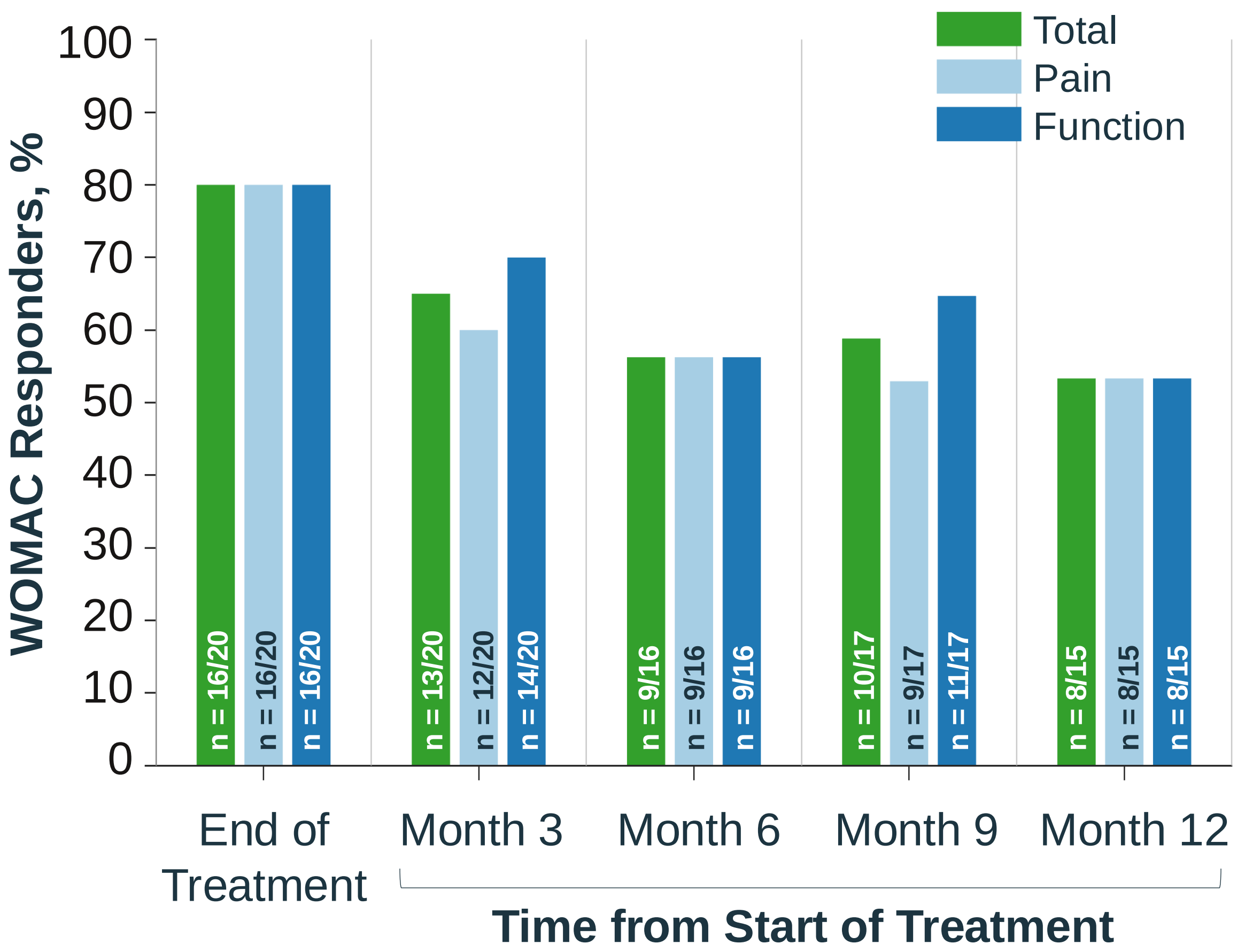
- Persistent and stable (≥ 2 weeks) moderate to severe pain after TKA; BPI-SF Q#5 ≥ 5).
- Stable medication usage for ≥ 4 -weeks prior to baseline visit
- Current opioid use ≤ 90 mg morphine equivalent dose (MED).
- No conditions contraindicated by PNS system's IFU
- Age ≥ 21 years
- BMI ≤ 40 kg/m²
- No diagnosis of diabetes.

Treatment: Active or placebo (sham) stimulation for 24 hours/day for up to 60 days



RESULTS

Most 60-day PNS subjects had improvements in pain and function during treatment and long-term at each timepoint out to 12 months



Western Ontario McMaster University Osteoarthritis Index (WOMAC): common assessment for pain and function in knee pain. Responses are reported for the total WOMAC scale as well as the pain and function subscales. 0-10 numerical rating scale. Responders: $\geq 33\%$ improvement relative to baseline.

Baseline information:

- No clinically important differences between groups regarding age, gender, time since surgery, and baseline pain or function.
- Median time since surgery: 2.5 years (range: 0.6 to 18.7 years).

Safety:

- No study-related serious or unanticipated Adverse Events. Skin irritation was the most common adverse event.

KEY TAKEAWAYS

60-day percutaneous PNS provided enduring pain relief and improved physical function at each timepoint out to 12 months from the start of treatment.

- Most subjects were responders at each timepoint for WOMAC pain and function subscales.
- Responders at each timepoint had substantial improvements in mean WOMAC pain and function subscales compared to baseline.

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References:

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