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Percutaneous PNS Relieves Persistent Postoperative Pain and Improves Function after TKA: Results from a Placebo-Controlled RCT

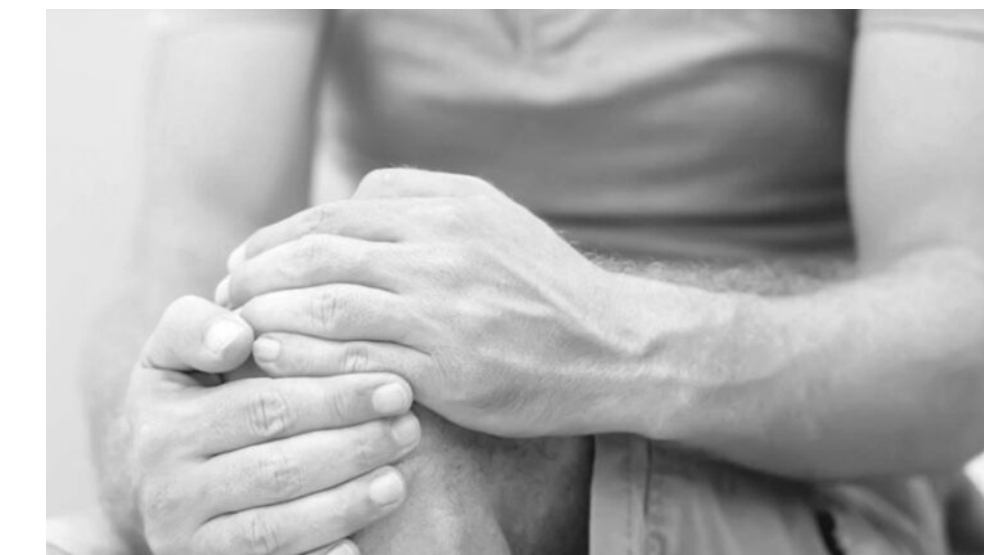
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OBJECTIVE

- Total knee arthroplasty (TKA) is an effective surgical procedure, and approximately 800,000 procedures are performed in the United States each year, but ~10-20% of patients continue to experience persistent postoperative pain (i.e., pain >3 months after surgery or past the time of normal tissue healing)
- Postoperative pain may lead to functional limitations and poor quality of life [1]

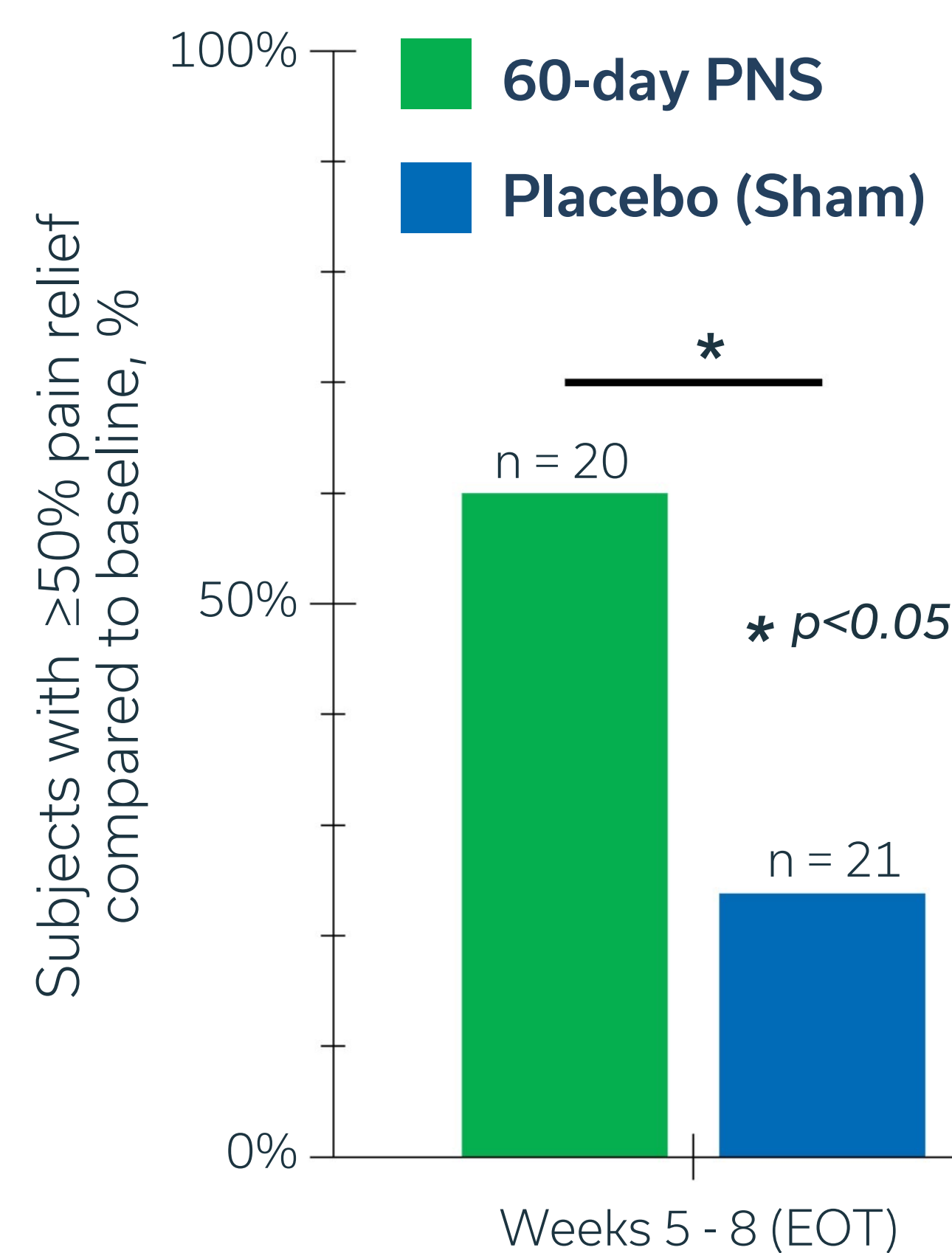


Study Goal: Characterize responses to 60-day percutaneous PNS in a post-market, institutional review board (IRB)-approved, prospectively registered (NCT04341948), multicenter, double-blind, placebo-controlled, randomized trial.

RESULTS

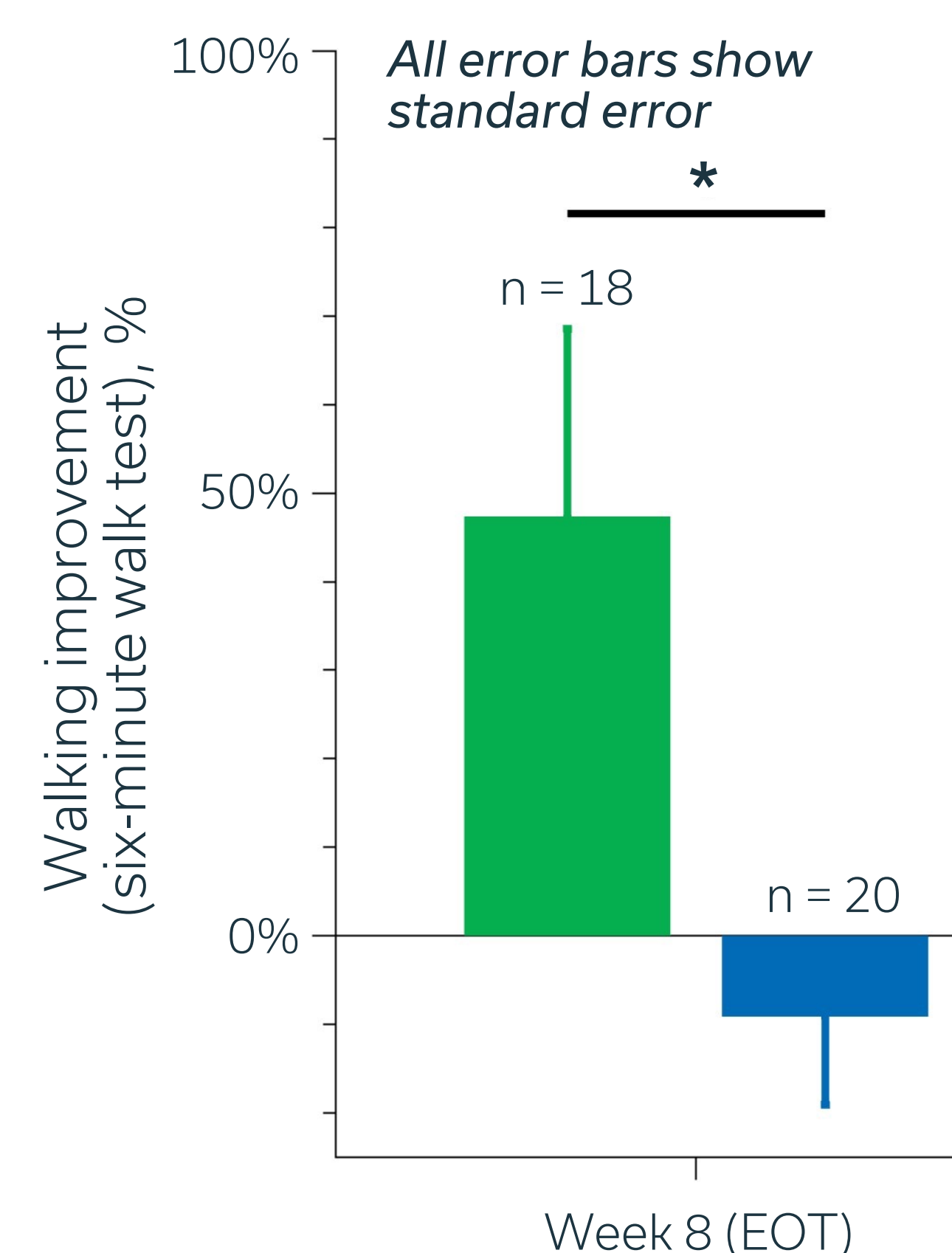
Successful Primary Endpoint

Majority of PNS group (60%) had $\geq 50\%$ pain relief compared to baseline



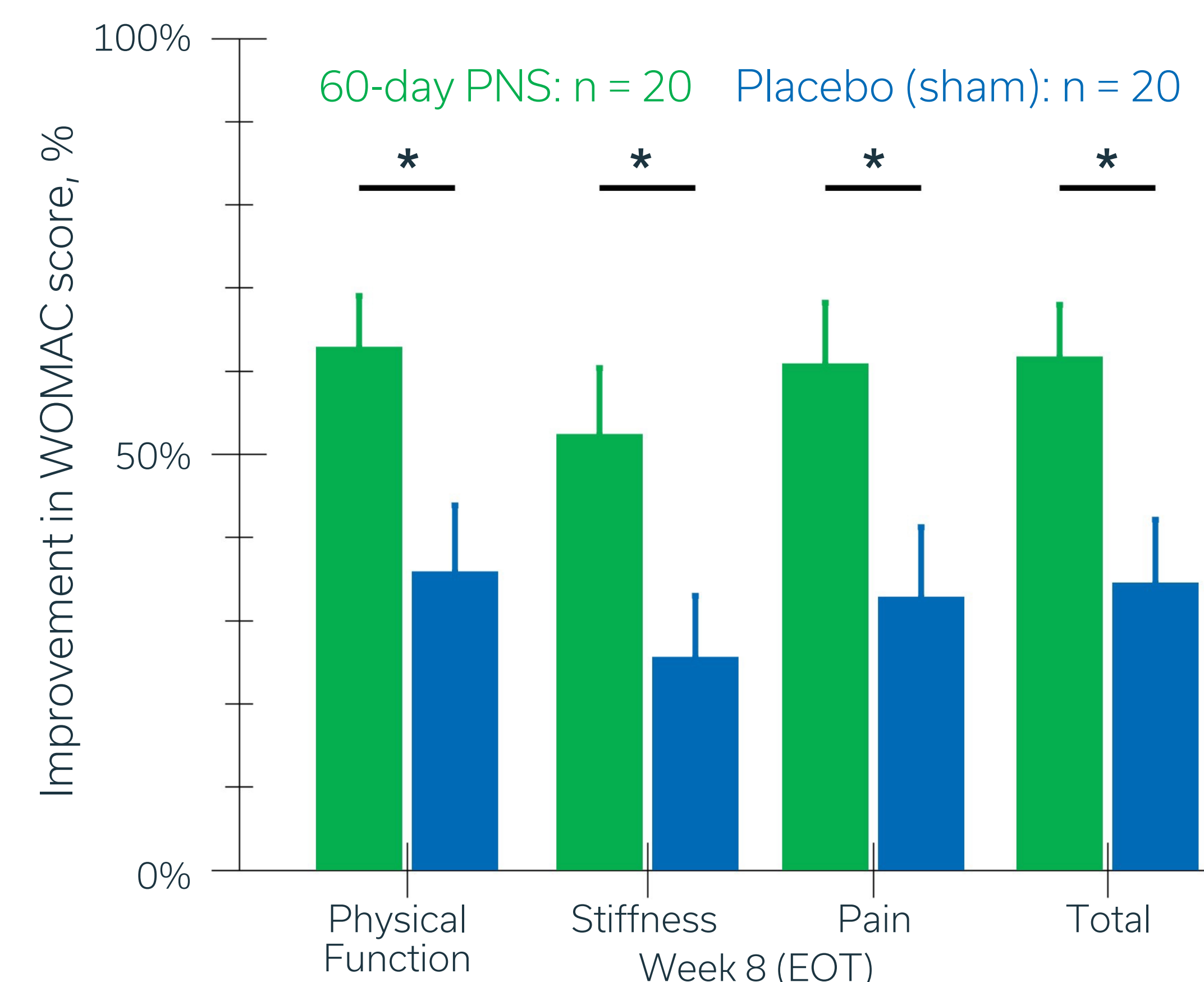
Objective Walking Test

47% improvement in walking ability in PNS group (6MWT)



Functional Improvement (WOMAC)

Greater improvement in PNS group than placebo (sham) group across all WOMAC subscales



Demographics: Standardized differences between groups for primary demographic variables (age, gender, time since surgery, baseline pain) were balanced and not clinically important.

Persistent Pain: Median time since surgery: 2.5 years (range: 0.6 to 18.7 years).

Pain Relief: 54% average pain relief for 60-day PNS group versus 28% pain relief for placebo (sham) group (weeks 5-8; $p < 0.05$).

- 74% pain relief among primary endpoint responders in PNS group.

Patient Global Impression of Change (Quality of Life): 90% of PNS group reported improved quality of life (PGIC ≥ 1) compared to 55% of placebo (sham) group ($p < 0.05$)

Adverse Events (AEs): No study-related serious or unanticipated AEs.

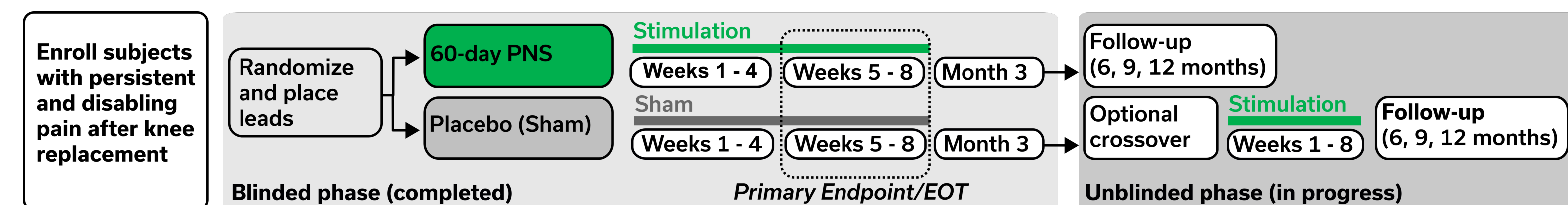
Statistical Tests: Continuous data: Wilcoxon Rank Sum test
Proportional data: Fisher's exact test

CONCLUSIONS

Non-opioid, non-destructive, non-surgical, minimally invasive, 60-day percutaneous PNS demonstrated:

- Significant pain relief** compared to placebo (sham) stimulation during weeks 5-8.
- Increased walking ability** compared to placebo (sham) stimulation, which may be beneficial for encouraging activity and improving functional recovery for TKA patients with decreased postoperative mobility.
- Improved function and quality of life in multiple outcomes** compared to placebo (sham) stimulation, including stiffness and physical function.

METHODS



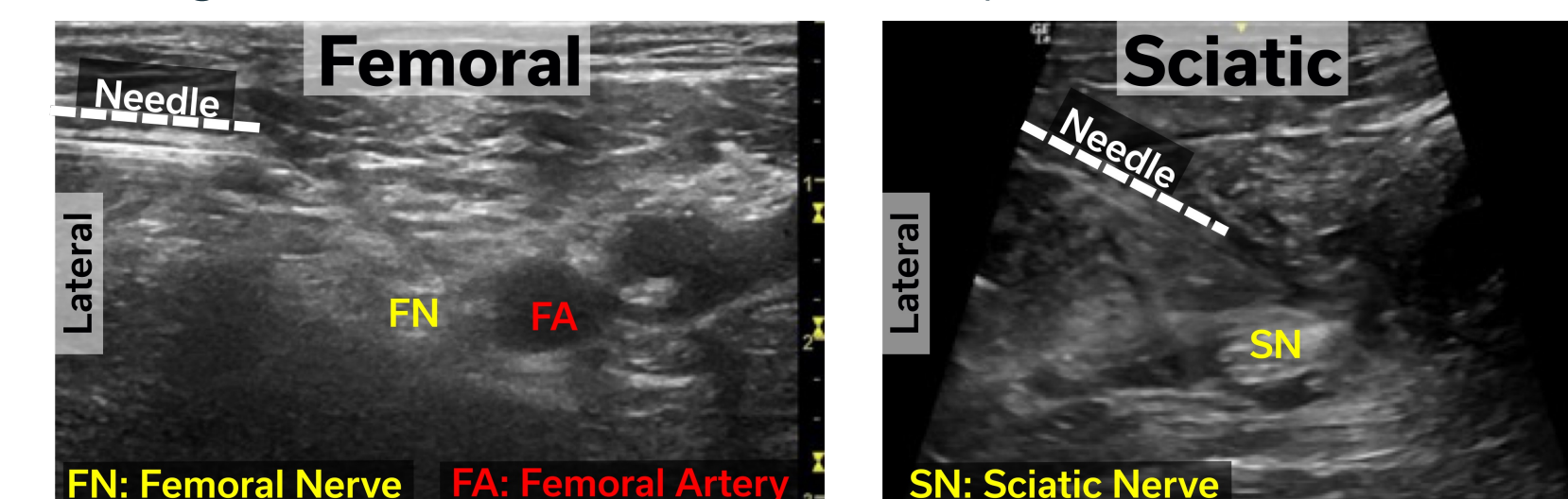
- IRB-approved study; informed consent obtained from each subject.
- Participants were randomized 1:1 to 60-day PNS or Placebo (Sham) with subjects and a designated evaluator blinded to group assignments.
- Present poster shows data through primary endpoint (End of Treatment; EOT). Long-term follow up/crossover phase is ongoing.

Key Eligibility Criteria:

- Subjects with persistent moderate to severe postoperative pain following knee replacement (BPI-SF Q#5 ≥ 5) and stable for 2 weeks.
- Stable medication usage for ≥ 4 -weeks prior to baseline visit and current opioid-use ≤ 90 mg morphine equivalent dose (MED).
- No conditions contraindicated by PNS system's instructions for use.
- 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 using a wearable stimulator and percutaneous coiled lead.



Lead Placement: Percutaneous PNS leads placed under ultrasound guidance remotely targeting the femoral and sciatic nerves proximal to the region of postoperative pain [2-4].



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