Percutaneous PNS Relieves Persistent Postoperative Pain and Improves Function Following TKA: Initial RCT Results

David M Dickerson, MD,[1,2] JH Goree, MD,[3] Stuart A Grant, MD,[4] BM Ilfeld, MD,[5] Y Eshraghi, MD,[6] S Vaid, MD,[7] AK Valimahomed, MD,[8] JR Shah, MD,[3] GL Smith, MD[3] JJ Finneran, MD,[5] NN Shah, MD,[1,2] MN Guirguis, MD,[6] MS Eckmann, MD,[9] AB Antony, MD,[10] BJ Ohlendorf, MD,[11] M Gupta, MD,[12] JE Gilbert, PhD,[13] A Wongsarnpigoon, PhD,[13] JW Boggs, PhD[13]

[1]NorthShore University HealthSystem, [2]University of Chicago, [3]University of Arkansas for Medical Sciences, [4]University of North Carolina at Chapel Hill, [5]University of California San Diego, [6]Ochsner Medical Center
[7]Better Health Clinical Research, [8]Grammercy Pain Center, [9]University of Texas San Antonio, [10]The Orthopaedic Institute, [11]Duke University, [12]Neuroscience Research Center, [13]SPR Therapeutics, Inc.

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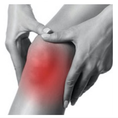
OBJECTIVE

- 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 three months after surgery or past the time of normal tissue healing).
- Postoperative pain may lead to functional limitations and poor quality of life [1].

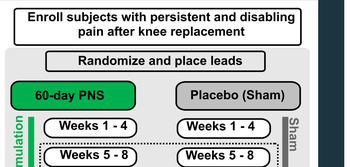
Study Goal: Characterize responses to 60-day percutaneous PNS in a post-market, institutional review board (IRB)-approved, prospectively registered (NCT04341948), multicenter, double-blind, placebo-controlled, randomized trial [2].

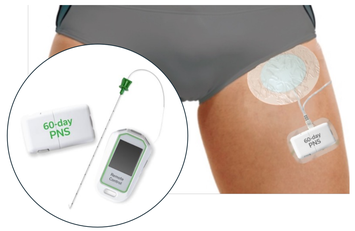


METHODS

- 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).

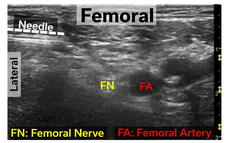
Key Eligibility Criteria:
- Subjects with persistent and stable (≥2 weeks) moderate to severe postoperative pain following knee replacement (BPI-SF Q#5 ≥5).
- Stable medication usage for ≥ 4-weeks prior to baseline visit and current opioid-use ≤90 mg morphine equivalent dose (MED).
- No conditions contraindicated by PNS system's instructions for use.
- Age ≥21 years
- BMI < 40 kg/m^2
- No diagnosis of diabetes.

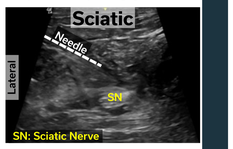




Treatment:
Active or placebo (sham) stimulation for 24 hours/day for up to 60 days using a wearable stimulator and percutaneous coiled lead.

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

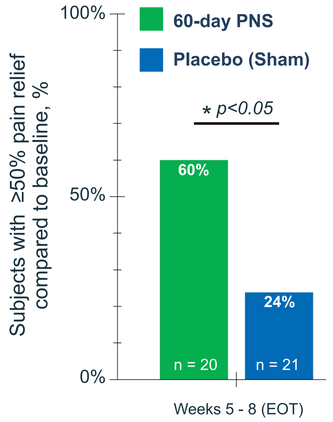




RESULTS

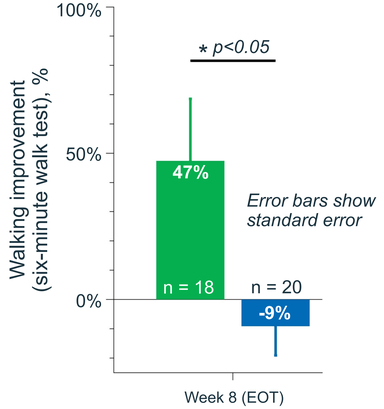
Successful Primary Endpoint

Proportion of responders (subjects with ≥50% pain relief) was twice as high in PNS group as the placebo group.



Improved Walking Ability

Subjects in the PNS group demonstrated a 47% improvement in walking ability (6MWT).



Demographics:

There were no clinically important differences between groups regarding age, gender, time since surgery, and baseline pain.

Persistent Pain:

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

Improved Function (WOMAC):

Subjects in PNS group reported substantially greater average improvements across WOMAC subcategories (63%, 52%, 61% for physical function, stiffness, and pain, respectively) compared to placebo group (36%, 26%, 33%; p<0.05).

Safety:

No study-related serious or unanticipated Adverse Events.

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
- **Improved function and quality of life in multiple outcomes** compared to placebo (sham) stimulation, including stiffness and physical function.

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[1] Wylde V, Beswick A, Bruce J, Blom A, Howells N, Gooberman-Hill R. Chronic pain after total knee arthroplasty. EFORT Open Rev. 2018 Aug 16;3(8):461-470. doi: 10.1302/2058-5241.3.180004. PMID: 30237904; PMCID: PMC6134884.
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