Percutaneous auricular neuromodulation (nerve stimulation) for the treatment of pain following total knee arthroplasty: a randomized, double-masked, sham-controlled pilot study

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ABSTRACT
Background. Percutaneous auricular nerve stimulation (neuromodulation) is an analgesic technique involving the percutaneous implantation of multiple leads at various points around the ear followed by the delivery of electric current using an external pulse generator. A device is currently available within the USA cleared to treat symptoms from opioid withdrawal, and multiple reports suggest a possible postoperative analgesic effect. The current randomized, controlled pilot study was undertaken to (1) determine the feasibility and optimize the protocol for a subsequent definitive clinical trial and (2) estimate the treatment effect of auricular neuromodulation on postoperative pain and opioid consumption following total knee arthroplasty.

Methods. Within the recovery room following primary, unilateral, total knee arthroplasty, an auricular neuromodulation device (NSS-2 Bridge, Masimo, Irvine, California, USA) was applied using three percutaneous leads and one ground electrode. Participants were randomized to 5 days of either electrical stimulation or sham stimulation in a double-masked fashion. Participants were discharged with the stimulator in situ and removed the disposable devices at home. The dual primary treatment effect outcome measures were the cumulative opioid use (oral oxycodone) and the mean of the “average” daily pain measured with the Numeric Rating Scale for the first 5 postoperative days.

Results. During the first five postoperative days, oxycodone consumption in participants given active stimulation (n=15) was a median (IQR) of 4 mg (2–12) vs 13 mg (5–23) in patients given sham (n=15) treatment (p=0.039). During this same period, the average pain intensity in patients given active stimulation was a median (IQR) of 2.5 (1.5–3.3) vs 4.0 (3.6–4.8) in those given sham (p=0.014). Awakenings due to pain over all eight postoperative nights in participants given active stimulation (n=15) was a median (IQR) of 5 (3–8) vs 11 (4–14) in those given sham (p<0.001). No device-related localized cutaneous irritation, systemic side effects, or other adverse events were identified.

Conclusions. Percutaneous auricular neuromodulation reduced pain scores and opioid requirements during the initial week after total knee arthroplasty. Given the ease of application as well as the lack of systemic side effects and reported complications, a definitive clinical trial appears warranted.

WHAT IS ALREADY KNOWN ON THIS TOPIC
⇒ Percutaneous auricular nerve stimulation (neuromodulation) involves the percutaneous implantation of multiple leads at various points around the ear followed by the delivery of electric current using an external pulse generator and has been used to treat symptoms from opioid withdrawal, but multiple reports suggest a possible postoperative analgesic effect as well.

WHAT THIS STUDY ADDS
⇒ During the first five postoperative days, opioid consumption and average pain intensity were lower in participants who received active stimulation (n=15) vs those given sham (n=15) treatment.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY
⇒ Given the ease of application as well as the lack of systemic side effects and reported complications, a definitive clinical trial investigating the use of auricular neuromodulation to decrease postoperative pain following painful orthopedic surgery appears warranted.

Trial registration number NCT05521516.

INTRODUCTION
Pain following major joint replacement is frequently difficult to control given the surgical procedure invasiveness and joint innervation complexity. While local anesthetic-based peripheral nerve blocks provide potent analgesia, they have their disadvantages such as requiring specialized training and time for administration, inhibiting ambulation and—for continuous blocks—increasing the risk of falling.1 Opioid analgesics are associated with undesirable side effects and the risk of misuse, dependence, and diversion. An alternative analgesic with no systemic side effects and few reported complications is...
auriculotherapy, which may be applied using a laser, fingers, probes, or Vaccaria seeds (acupressure), needles (acupuncture), and neuromodulation (transcutaneous electrical nerve stimulation). For knee arthroplasty, neuromodulation has been used for the femoral and sciatic nerves using ultrasound-guided percutaneously inserted insulated leads and an external pulse generator. However, this technique requires advanced equipment, physician-level skills, and more time than a perineural catheter for insertion. Furthermore, each percutaneous lead can treat only a single nerve; and since the knee joint is innervated by three major nerves, this modality is—at least at the time of this writing—time- and cost-prohibitive for the majority of patients.

A possible alternative is percutaneous auricular neuromodulation which involves the stimulation of the peripheral and cranial nerves of the ear using trans-dermal electrodes. The mechanism of action is multifactorial, complex, and remains under investigation, but probably involves modulation of serotonergic, noradrenergic, and endorphinergic pathways with associated release of serotonin, norepinephrine, and endogenous opioids such as beta-endorphins. Auricular vagal nerve stimulation further chemically modulates nociceptive (pain) processing, anxiety, and depression.

A percutaneous auricular neuromodulation device is currently cleared by the US Food and Drug Administration to reduce symptoms associated with opioid withdrawal for up to 5 days (NSS-2 Bridge, Masimo, Irvine, California, USA; figure 1). Unlike peripheral nerve blocks and percutaneous single-lead neuromodulation systems, the device is relatively simple to apply—it necessitates neither advanced training nor physician application—requires no additional equipment, has few contraindications, and is not associated with serious complications. And in contrast with opioids, auricular neuromodulation is medication-free, lacks systemic side effects, and has no potential for misuse, dependence, or diversion. Furthermore, it theoretically treats pain originating from any number and/or combination of peripheral nerves, is disposable, and is a fraction of the cost relative to ultrasound-guided percutaneous neuromodulation devices.

We, therefore, conducted a randomized, double-masked, sham-controlled pilot study to assess feasibility of a future larger trial and estimate the potential benefits and risks of percutaneous PNS for analgesia after major joint replacement. Specifically, we sought to evaluate percutaneous PNS in both hospitalized and ambulatory patients following tricompartment knee arthroplasty to (1) determine the feasibility of and optimize a study protocol and (2) estimate analgesia and opioid sparing within the initial eight postoperative days.

METHODS

This study followed Good Clinical Practice and was conducted within the ethical guidelines outlined in the Declaration of Helsinki. The study was prospectively registered at clinicaltrials.gov (NCT05521516, PI: Brian Ilfeld, first registered 08/26/2022). The protocol was approved by the Institutional Review Board (University of California San Diego, San Diego, California, USA). The Institutional Board determined that the auricular stimulator is a non-significant risk device per the criteria outlined in 21 CFR 812.3(m), and therefore approved the off-label use of this device to investigate its potential to provide postoperative analgesia. Written, informed consent was obtained from all participants.

Participants

Enrollment was offered to adult patients at least 18 years of age scheduled for primary, unilateral, total knee arthroplasty and including a single-injection adductor canal peripheral nerve block for postoperative analgesia. Patients were excluded for (1) chronic opioid use inclusive of tramadol (daily use within the 2 weeks prior to surgery and duration of use >4 weeks); (2) neuromuscular deficit of the ipsilateral lower extremity; (3) history of opioid misuse or dependence; (4) concurrent use of another electric stimulator (eg, cardiac pacemaker); (5) history of bleeding disorder; (6) anticoagulation condition and/or therapy; (7) skin abnormality at the treatment site; (8) psoriasis vulgaris; (9) incarceration; (10) pregnancy, or (11) inability to contact the investigators during the treatment period, and vice versa (eg, lack of telephone access).

Intervention

Preoperatively, participants had an ultrasound-guided single-injection peripheral nerve block administered using ropivacaine 0.5% with epinephrine. Participants with a successful regional block and who underwent the anticipated surgical procedure were randomized within the recovery room and continued within the study. An investigational pharmacist (University of California San Diego, San Diego, California, USA) created the randomization list in blocks of 2 and a 1:1 allocation into active and sham treatment groups. Active and sham devices appear identical and were provided directly to the investigational pharmacist from the manufacturer (Masimo, Irvine, California, USA), differentiated only by serial number. The investigational pharmacist labeled each device with the appropriate randomization number, and no investigator, clinical staff, or participant was aware of the treatment group assignment until study completion.

The study device was affixed to the ear and activated prior to discharge from the recovery room. There is currently no consensus regarding the placement on the ipsilateral or contralateral ear relative to the surgical procedure. Therefore, the device was placed on the side that the participant sleeps on least. Removable clips were used to hold any protruding hair away from the treatment sites. The external pulse generator was placed posterior or inferior to the ear using benzoin, the included adhesive pad, and an occlusive dressing. The wire harness was inserted into the external pulse generator which initiated the passage of electrical current (for participants allocated to the active treatment group). The four electrode locations were cleaned with an alcohol pad and then a skin protectant wipe was applied (Sureprep, Medline, Northfield, Illinois, USA). A medical light was used to transilluminate the antihelix and the two electrodes on the cephalad half of the ear were placed 1–3 mm from a neurovascular bundle and never immediately opposite each other.

The first lead was placed at the most cephalad portion of the antihelix by simply pressing the electrode directly into the skin similar to a thumbtack (figure 1). The second electrode was inserted immediately cephalo-anterior to the incisura and either anterior or posterior to the superficial temporal arterial pulse. The third electrode was inserted on the posterior ear opposite the antihelix at the level of the incisura. The ground electrode with four 2 mm long integrated needles was inserted on the anterior side of the lobule. No local anesthetic was administered. Benzoin and small round bandages were used to secure the electrodes. If there was discomfort from any of the electrodes, that specific electrode was repositioned.

Postoperatively, patients received acetaminophen 975 mg three times daily, celecoxib 200 mg two times per day, and, if
Figure 1  A percutaneous auricular nerve stimulation system (NSS-2 BridgeTM, Masimo, Irvine, California, USA). Each of the three electrodes has a 2 mm long integrated needle/lead (inset) and the ground electrode has four 2 mm long integrated needles/leads (inset). Used with permission from BMI.
needed, the synthetic oral opioid oxycodone (5 mg tablets). Patients were instructed to keep the pulse generators and electrodes dry with the use of a shower cap when bathing. Prior to discharge, participants and their caretakers were provided with verbal and written instructions and the telephone and pager numbers of an investigator available at all times while the device was in use. Participants were discharged home with their electrodes in situ and with a prescription for immediate release oral opioid tablets (oxycodone 5 mg).

The pulse generators automatically ceased functioning after 120 hours (5 days) and patients or their caretakers then detached the device by first removing the round bandage of the grounding electrode, which extracted the electrode from the patient along with the bandage. The remaining three electrodes were subsequently removed in the same manner followed by the pulse generator, after which the single-use, disposable device was discarded. Following study completion, the results were provided to all participants using non-technical language.

Outcome measurements (endpoints)
Participants were contacted by telephone for endpoint collection daily for the first eight postoperative days. We selected outcome measures that have established reliability and validity, with minimal inter-rater discordance, and are recommended for pain-related clinical trials by the WHO and the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) consensus statement.12

Primary outcome measures
The dual primary outcome measures were the (1) cumulative oral opioid consumption (in oxycodone equivalents) and (2) mean value of the “average” daily pain scores measured on the 0–10 Numeric Rating Scale (NRS) within the initial five postoperative days. The NRS is a highly sensitive measure of pain intensity with numbers ranging from 0 to 10, zero equivalent to no pain and 10 equivalent to the worst imaginable pain; it is a valid and reliable measure for evaluating analgesic interventions.13 Additionally, NRS scores correlate well with other measures of pain intensity14 and demonstrate high test–retest reliability.15 These NRS characteristics led to WHO and the IMMPACT consensus recommendations for the use of the 10-point NRS of pain intensity for pain trials.12

Secondary outcome measures
The primary instrument was the Brief Pain Inventory (short form) which assesses pain and its interference with physical and emotional functioning.16 The instrument includes three domains: (1) pain, with four questions using an NRS to evaluate four pain levels: “current”, “least”, “worst”, and “average” (collected postoperative days 1–8); (2) a percentage of relief provided by pain treatments with one question (not used for this study); and (3) interference with physical and emotional functioning using a 0–10 scale (0=no interference; 10=complete interference) (collected postoperative days 2, 4, 6, and 8). The seven interference questions involve general activity, mood, walking ability, normal work activities (both inside and outside of the home), relationships, sleep, and enjoyment of life.16 These seven functioning questions can be combined to produce an interference subscale (0–70). The use of both single items (eg, mood) and the composite scores is supported by the IMMPACT consensus recommendations for assessing pain in clinical trials.12 17 Opioid consumption and awakenings due to pain were also recorded during each phone contact.

Statistical analysis
This investigation was designated a priori as a pilot study to assist in planning a subsequent definitive trial and we, therefore, used a convenience sample of 30 participants undergoing total knee arthroplasty. While there were two primary outcomes specified prior to enrolment, there was no specific data analysis plan defined prospectively. All analyses were intention to treat. Continuous, normally distributed data are reported as mean±SD. Categorical data or continuous data not normally distributed are reported as median (10–90th percentiles) or percent, as appropriate. Comparisons of independent samples were performed using a two-tailed Mann-Whitney U test. The χ² test and Fisher’s exact test was used for differences in proportions, as appropriate. A p<0.05 was considered statistically significant for the primary outcomes. Adjustments were not made for multiple comparisons. Results of comparisons in secondary outcomes must be interpreted as suggestive, requiring confirmation in a future trial before considering them as definitive. Prism V10.0.2 (GraphPad, Boston, Massachusetts, USA) was used for all analyses.

RESULTS
Between October 12, 2022 and July 3, 2023, a total of 30 participants were enrolled (table 1), randomized to either active stimulation (n=15) or sham (n=15), and had a neuromodulation device applied successfully (figure 2).

Primary outcomes
During the first five postoperative days, oxycodone consumption in participants given active stimulation was a median (IQR) of 4 mg (2–12) vs 13 mg (5–23) in patients given sham treatment (p=0.039). During this same period of time, the average pain intensity in patients given active stimulation was a median (IQR) of 2.5 (1.5–3.3) vs 4.0 (3.6–4.8) in those given sham (p=0.014).

Secondary outcomes
Daily average pain between days 2 and 7 was lower in the active treatment than sham group (figure 3). Worst and least pain scores (figure 3) as well as opioid consumption (figure 4) were generally lower in the active treatment group, though only occasionally to a statistically significant degree. Two (13%) participants who

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Values are reported as mean (SD) or percentage (number of subjects).
*Totals not equal to 100% due to rounding error.
received active stimulation avoided opioids for the entire study period, vs none (0%) in those given sham (p=0.483). Regarding the highest “average” daily pain level over the first eight postoperative days, no participants who received active stimulation experienced severe pain, vs 27% in those given sham (p<0.001, figure 5). Participants who received active treatment had less physical and emotional interference due to pain during both the treatment (postoperative days 2 and 4) and post-treatment (days 6 and 8) phases, although the differences did not reach statistical significance (figure 3). Awakenings due to pain over all eight postoperative nights in participants given active stimulation was a median (IQR) of 5 (3–8) vs 11 (4–14) in those given sham (p<0.001).

Adverse events and protocol deviations
No device-related localized irritation, systemic side effects, or other adverse events were identified. Three participants receiving active stimulation removed their devices early (postoperative days 0, 2, and 3) due to discomfort at one or more of the electrode sites. All three were included in the active treatment group for all analyses per the intention-to-treat protocol. Two participants receiving sham treatment had one electrode dislodge during the treatment period and both pushed their lead back into the skin after cleansing the area with alcohol.

DISCUSSION
This randomized, double-masked, sham-controlled pilot study provides evidence that percutaneous auricular neuromodulation reduces pain scores, opioid requirements, and sleep disturbances during the initial week after total knee arthroplasty. This would be a welcome development considering the limitations with current analgesic modalities including the limited duration of single-injection peripheral nerve blocks; increased falling risk with perineural local anesthetic infusion; time, expertize and expense of ultrasound-guided percutaneous peripheral nerve stimulation; and side effects of opioids as well as their potential
for misuse, dependence, and diversion. However, while the pilot study results appear promising, definitive conclusions require a subsequent, adequately powered clinical trial.

It is notable that the “average” daily pain scores collected on day 1 covering the period from recovery room discharge until the first data collection time point were similar between the treatment groups (figure 3). This is most likely due to the single-injection bupivacaine hydrochloride and epinephrine adductor canal block administered to all participants regardless of treatment group assignment. Interestingly, during this same period of time, auricular neuromodulation reduced opioid consumption. Following the first 24-hour period, pain scores were reduced to a statistically significant degree (figure 3), although statistical correction for multiple comparisons was not used due to the nature and power of this pilot study. Importantly, this improvement was found during the 2 days following the removal of the auricular stimulator on postoperative day 5. This was anticipated based on previously published reports, which was the reason we continued to collect data for 3 days following device removal.

Auricular neuromodulation also decreased pain’s interference with physical and emotional functioning as measured with the Brief Pain Inventory’s interference scale both during and following active treatment (figure 3), although the between-group differences did not reach statistical significance. This is unsurprising given the limited power of the current pilot study. However, if a subsequent adequately powered trial found the observed improvements reached statistical significance, it would be notable since they are in the range of what the IMMPACT

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Figure 3  Effects of 5 days of percutaneous auricular nerve stimulation on daily average, worst, and least pain as well as the Brief Pain Inventory (interference domain). Pain severity was measured using a Numeric Rating Scale with 0 equal to no pain and 10 being the worst imaginable pain. Regarding the Brief Pain Inventory, pain interference indicated using a Numeric Rating Scale of 0–70, with 0 and 70 equal to no and maximal interference, respectively. Data expressed as median (dark horizontal bars) with 25–75th (box), 10–90th (whiskers), mean (diamonds), and outliers (circles). Asterisks denote p<0.05.
concluded “would be a reasonable benchmark for future studies designed to identify to minimally clinically important changes.”

Various electrical percutaneous auricular neuromodulation devices have been employed in the management of both acute and chronic pain, exhibiting varying degrees of effectiveness. Their outcomes range from pain reduction to having no discernible impact, and in some cases, an exacerbation of discomfort has even been observed. These devices exhibit substantial variability in key parameters, including pulse duration, frequency, amplitude, duty cycle, electrode number, and electrode placement, which collectively determine the characteristics of the electric field produced. Consequently, different devices can induce significantly different physiological responses. This inherent variability significantly limits the generalizability of findings from individual clinical trials to other similar devices and may account for the widely varying results among investigations.

The pulse generator used in this study is equipped with an integrated 3-volt battery and can accommodate load impedances ranging from 1k to 10k Ω, with a maximum output of 3.2 volts. It operates on a symmetrical, biphasic stimulation cycle at a frequency of 0.125 Hz, interspersed with periodic rest intervals. This device is currently cleared by the US Food and Drug Administration to reduce symptoms associated with opioid withdrawal, including anxiety, insomnia, muscle aches, nausea, and vomiting: all also common following surgery. In addition, various small series and case–control studies have suggested its potential in providing postoperative analgesia for ambulatory orthopedic and breast surgery, joint arthroplasty, laparoscopic Roux-en-Y gastric bypass, kidney donor, and cesarean delivery. However, the only two published randomized, controlled studies—including colorectal and cesarean surgeries—were negative for their primary endpoints and most secondary outcomes. The differing results relative to the current study

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**Figure 4** Effects of 5 days of percutaneous auricular nerve stimulation on opioid consumption, measured in oxycodone equivalents. Data expressed as median (dark horizontal bars) with 25–75th (box), 10–90th (whiskers), mean (diamonds), and outliers (circles). Asterisks denote p<0.05.
may be due to the different types of surgery (soft tissue vs orthopedic), anatomic surgical sites (abdominal/pelvic vs knee joint), or the study protocols themselves.

The auricular neuromodulation device described in this report may be used for most patients, as there are a few contraindications listed on its label: (1) psoriasis vulgaris, (2) hemophilia, and (3) a cardiac pacemaker. After completing this pilot study we would add as relative contraindications: (1) infection at the electrode placement sites, (2) over-the-ear hearing aid use, and (3) a continuous positive airway pressure mask for sleep apnea, since the latter two are difficult to use with the periauricular neuromodulation device location. The only reported complications have been minor skin bleeding (0.91%) and dermatitis from the adhesive bandages (0.91%). For the pivotal studies of the device to reduce the symptoms of opioid withdrawal (n=1207), no analgesic was administered for electrode placement and only two participants had “significant” pain (0.17%). While we did not formally evaluate discomfort during placement in the recovery room, none of our patients complained of pain. This may have been due to opioid administration within the operating room. Offering further evidence of the relative lack of discomfort during application, two of our patients had an electrode dislodge during the treatment period and both simply pushed their lead back into the skin after cleansing the area with alcohol.

In contrast, the three participants receiving active treatment (20% of this group) who removed their devices prematurely due to discomfort at one or more of the electrode sites—versus none in the sham group—suggest that pain following electrode application is either due solely to the electric current, or a combination of current and mechanical factors. This problem might be averted if patients could adjust the pulse generator parameters—such as pulse duration, frequency, amplitude, and duty cycle—which are all currently fixed. Experience with ultrasound-guided percutaneous peripheral nerve stimulation has demonstrated the importance of enabling patients to titrate the degree of stimulation to their constantly changing analgesic requirements and toleration of electrical current. An additional concern arises when using the rigid, angular device positioned behind the ear, as it renders sleeping on that side quite uncomfortable, if not entirely impracticable. Consequently, we positioned the device on the side that participants indicated as their less preferred sleeping position. Nevertheless, patients expressed a desire to have the option to sleep on both sides. This issue has not been reported for a different auricular neuromodulation device with a considerably slimmer and more rounded design.

Figure 5  Effects of percutaneous auricular nerve stimulation on the highest “average” pain level experienced following knee arthroplasty. Pain severity was measured using a Numeric Rating Scale with 0 equivalent to no pain and 10 being the worst imaginable pain. Data expressed as median (dark horizontal bars) with 25–75th (box), 10–90th (whiskers), mean (diamonds), and outliers (circles). The difference between groups was statistically significant (p<0.001).
The most important weaknesses of this pilot study were the limited sample size and lack of a prospectively defined analysis plan. However, the positive findings for the two primary outcome measures along with a majority of “average” daily pain scores provide strong evidence against a false positive (type 1 error). Nevertheless, our findings certainly require confirmation with a subsequent adequately powered definitive clinical trial. In addition, we were unable to confirm that the electrodes remained adequately percutaneous and the devices continued to function throughout the entire 3-day treatment period because there is no light or other indication of proper functioning in the current version of the neuromodulation apparatus to confirm an active electrical circuit. A simple light-emitting diode in a future version would enable real-time confirmation of operation. An additional weakness is that we did not evaluate overall ambulation: it is possible that improving analgesia enabled greater (undetected) mobility. A future definitive trial should monitor patient activity, possibly with the use of wearable motion sensors.40

In conclusion, this randomized, controlled pilot study provides strong evidence that percutaneous auricular neuromodulation is feasible for knee arthroplasty and may be an effective analgesic enabling decreased opioid consumption both during hospitalization and following discharge. Further study with a larger, definitive trial appears warranted considering the ease of application, few contraindications, applicability to any anatomic surgical location, low patient and provider burden, lack of systemic side effects and serious adverse events as well as no misuse, dependence, or diversion potential.

Contributors
BMI: This author helped conceive the study, write the protocol, acquire the required study devices, implement the investigation, oversee data collection, interpret the results, and write the initial draft of the manuscript. BMI is the guarantor who accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish. JIF, BSA, WBA, JFS, and ETS: These authors contributed to protocol development, trial implementation, intervention management, participant care and safety oversight, data interpretation, and manuscript revision. STB and FRG: These authors contributed to protocol development, data interpretation, and manuscript revision. BM: This author contributed to protocol implementation, data collection and management, and manuscript revision. BJ: This author contributed to data management, manuscript preparation, and manuscript revision.

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Disclaimer
The contents of this article are solely the responsibility of the authors and do not necessarily represent the official views of the funding entities.

Competing interests
None declared.

Patient consent for publication
Consent obtained directly from patient(s).

Ethics approval
This study followed Good Clinical Practice and was conducted within the ethical guidelines outlined in the Declaration of Helsinki.

Provenance and peer review
Not commissioned; externally peer reviewed.

Data availability statement
Data are available on reasonable request. Deidentified patient-level data will be shared for collaborative analyses on request to BMI (email: billfield@health.ucsd.edu) shortly after publication. A data-sharing contract will be required.

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Original research


