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PILOT STUDY
Peripheral Nerve

Pilot Study: A Multicenter, Prospective Study Demonstrating Safety, Usability, and Feasibility of Perioperative 1-hour Electrical Stimulation Therapy for Enhancing Peripheral Nerve Regeneration

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Background: Electrical stimulation (ES) applied for 1 hour following surgical intervention enhances axonal regeneration and functional outcomes. Clinical implementation, however, has been hindered due to the lack of appropriately designed stimulators.

Methods: This multicenter, prospective, open-label study aimed to demonstrate the safety and device feasibility of a novel, single-use stimulator for implementing perioperative ES therapy in a variety of upper extremity surgical procedures. Patients undergoing surgical intervention for upper extremity nerve injury, neuropathy, or lesions were included. An investigational version of a novel therapeutic peripheral nerve stimulator was used to deliver 1-hour ES therapy perioperatively. Safety was assessed by the cumulation of adverse events. Patient tolerance to ES therapy was obtained during the treatment, and pain was also assessed at the first postoperative visit. Device usability questionnaires were completed by the study surgeons.

Results: A total of 25 patients were enrolled. There were no related adverse events or adverse device effects. Implementation of the device took less than 5 minutes in the operating room in most cases. Bipolar stimulation was preferred, with a mean ± SD stimulus level of 2.2 ± 0.7 mA, and therapy was well tolerated. The mean first postoperative pain score was 1.2 out of 10. Surgeons indicated that perioperative implementation of the therapeutic peripheral nerve stimulator was easy and did not cause major disruptions to the clinical workflow.

Conclusions: Perioperative application of 1-hour ES therapy is a feasible, safe, and promising approach to enhancing peripheral nerve regeneration as an adjunct to surgical intervention. *(Plast Reconstr Surg Glob Open 2025;13:e6729; doi: 10.1097/GOX.0000000000006729; Published online 6 May 2025.)*

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INTRODUCTION

Peripheral nerve injuries account for a high cost burden to the healthcare system, and outcomes are often poor and suboptimal.[1,2] Over the last 30 years, many experimental therapies have been investigated to accelerate nerve regeneration with almost all being limited to small animal models. The vast majority of these therapies are pharmacological or biomaterial-based.[3–6] One therapy that has generated considerable interest is the application of brief, 1-hour direct electrical stimulation (ES) to injured nerves following nerve repair.

Limitations regarding long-term follow-up inherently exist in this article type.

Disclosure statements are at the end of this article, following the correspondence information.

This therapy has been widely investigated in small animal models and has further been translated clinically using large neuroscience electrical stimulators (Grass SD9).[7–18] With overwhelmingly positive results in both animal and human studies,[18–22] wide clinical adoption of this therapy has not occurred. Although rodent studies utilized intraoperative stimulation to deliver this therapy, direct human translation was not always possible, as many surgical nerve repair procedures may not have an additional hour of operating room (OR) time available. The early clinical studies used a perioperative approach to deliver this therapy with electrodes implanted at the time of the nerve repair and stimulation applied in the recovery room.[19–22] More importantly, the equipment used in these early clinical studies was a large research electrical stimulator (Grass SD9), which was difficult to procure for many and not approved for human use outside of a research setting. With these obstacles in place, other research groups have attempted to reduce the duration of stimulation to maintain intraoperative utility by using a handheld stimulator and manual timer set to 10 minutes.[18,23,24] This shorter duration of stimulation has limited evidence in rodent models but still presents a problem for surgeons, as no appropriately designed device exists to deliver this ES therapy in a reliable and repeatable manner.

In this study, we have evaluated the safety and usability of a purpose-designed disposable peripheral nerve stimulator with a simple-to-use stimulating electrode and attachable stimulator, designed to deliver 1 hour of stimulation. We present the clinical safety of a novel nerve stimulator (measured by the cumulative analysis of adverse events and patient-reported postoperative pain on a visual analog scale [VAS]) and device feasibility (measured by surgeon usability questionnaires and patient tolerance to ES therapy) in upper extremity injuries. The device was specifically designed to deliver the 1-hour ES in a perioperative setting, allowing intraoperative electrode placement and delivery of intraoperative or postoperative therapeutic stimulation.

Takeaways

Question: Can 1 hour of electrical stimulation (ES) therapy be applied perioperatively in a safe and feasible manner to enhance peripheral nerve regeneration?

Findings: Patients with upper extremity nerve injury, neuropathy, or lesions received surgery and 1-hour perioperative ES therapy via a novel peripheral nerve stimulator. Patients tolerated the stimulation therapy, and there were no related adverse events. Device implementation was easy, added less than 5 minutes of operating room time, and did not cause major disruptions to the clinical workflow.

Meaning: Perioperative 1-hour ES therapy as an adjunct to peripheral nerve surgery is a feasible, safe, and promising approach to better recovery and functional outcomes.

METHODS

This study was designed as an open-label, interventional clinical trial. Furthermore, it was a multicenter, prospective, first-in-human device feasibility trial. The study was conducted according to good clinical practice and in compliance with the Declaration of Helsinki. The study was approved by the Hamilton Integrated Research Ethics Board (approval ID 11031). The trial is registered with ClinicalTrials.gov (NCT04732936).

Study Participants and Design

Patients presenting with an upper extremity nerve injury, neuropathy, or lesions were recruited from plastic surgery clinics or the emergency department at Hamilton Health Sciences (Ontario, Canada) and St. Joseph's Healthcare Hamilton (Ontario, Canada). Inclusion criteria were (1) healthy adults between 18 and 65 years of age, (2) presenting with a suspected nerve lesion, neuropathy, or nerve injury of the upper extremity, and (3) receiving surgical care within 14 days. Exclusion criteria were (1) nerve plexus injuries, (2) polyneuropathies, (3) cognitive impairment and inability of the participant to consent for themselves, (4) uncontrolled diabetes, (5) surgical care past 14 days, (6) co-enrollment in another interventional clinical trial, and (7) pregnant women. Verbal and written informed consent were obtained before enrollment into the study.

Anesthesia

Patients were anesthetized under general anesthesia or short-acting local anesthesia (Xylocaine 1% without epinephrine). Nerve blocks and long-acting, local anesthesia were not applied, as any blockade or prevention of the retrograde propagation of action potentials would negate the effect of ES therapy.[25,26]

Surgical Procedure and Investigational PeriPulse Implementation

Standard of care procedures were conducted by qualified plastic and reconstructive surgeons (C.J.C., C.L., and J.R.B.). Good Clinical Practice guidelines were implemented and followed to reduce bias and patient influence. Following surgical repair, reconstruction, or decompression of the affected nerve, an investigational version of the PeriPulse device, a single-use temporary peripheral nerve stimulation system manufactured by Epineuron Technologies, Inc., was implemented as follows. The system consists of a battery-powered signal generator, a multicontact shapeable electrode lead, an adhesive surface return electrode, and an over-the-needle catheter introducer tool. The multi-contact electrode lead and surface return electrode allowed for either monopolar or bipolar stimulation settings to be applied. Surgeons selected monopolar or bipolar stimulation on a case-by-case basis, taking into account (1) whether adequate motor capture and/or sensory confirmation to stimulation was achieved with either setting and (2) whether there was sufficient room on the arm to place the monopolar surface return electrode. This study evaluated surgeon preference and

patient comfort corresponding to monopolar or bipolar stimulation.

The over-the-needle catheter introducer tool was used to create a para-incisional access point proximal to the surgical incision site. The needle was removed, leaving the catheter sheath in the surgical site, akin to the Seldinger technique used for vascular access. The electrode lead was inserted through the catheter sheath and placed proximal to the nerve repair/decompression/reconstruction site. In some cases, the electrode lead was shaped in situ for better contact of the electrode lead with the nerve. This was used most commonly for cubital tunnel release procedures, where there is a high degree of curvature, and shaping of the electrode lead was beneficial for precise placement. For example, Figure 1 demonstrates the shaping of the electrode lead tip in a "J-curve" and tucked underneath the ulnar nerve after decompression and anterior transposition. The "J-curve" formation allowed for the electrode lead contacts to remain in contact with the ulnar nerve for the remainder of the procedure and during ES therapy.

Steri-Strips were applied to adhere the electrode lead on the skin of the arm to maintain the lead in place and prevent migration. To further secure the electrode lead, a small tension relief coil was created proximal to the skin entry point and secured using Steri-Strips. The signal generator was connected to the electrode lead and adhered to the arm via a hydrogel-based adhesive surface electrode, above the planned placement of the dressing. Figure 2 demonstrates complete PeriPulse device implementation in a cubital tunnel release procedure. In cases where intraoperative confirmation of ES could be ascertained, this was done while the surgical incision site was still open. Otherwise, postoperative confirmation of ES was conducted in the recovery room. Skin closure, hand immobilization, and wound dressing procedures were conducted as per the standard of care.

Intraoperative Confirmation of ES

ES was confirmed intraoperatively for procedures under general anesthesia for motor nerves. After electrode lead placement and before the surgical incision was closed, the signal generator was connected to the electrode lead and powered on. Test stimuli at 1 Hz were applied in increasing increments of 0.1 mA until an expected muscle contraction was observed. Once ES was confirmed, ES therapy was initiated and continued during skin closure, dressing, and patient transport to the recovery room.

Postoperative Confirmation of ES

For procedures in which intraoperative confirmation of ES is not possible (eg, application of short-acting local anesthesia or procedures for a sensory nerve), confirmation was instead completed postoperatively in the recovery room. If general anesthesia was applied, ES was confirmed as soon as the patient regained consciousness. If short-acting local anesthesia was applied, a minimum of 90 minutes after the last applied bolus was allowed to elapse, to be in line with the elimination half-life of lidocaine.[27] Test stimuli were applied (ie, 1 Hz in increasing increments of 0.1 mA), and patients were asked to verbalize their perception of the test stimuli. If a patient could not perceive the stimuli, the test was paused and repeated after 15 minutes. Once ES was confirmed, ES therapy was initiated.

ES Therapy and Device Removal in the Recovery Room

The established effective dose of ES therapy was used (ie, 20 Hz continuously for 1 h),[19–22] and the treating physician set the initial stimulation parameters. Stimulus levels (mA) were adjusted such that effective stimulation could be confirmed, as described earlier, and were also within the patient's comfortable range. Standard postoperative activities occurred concurrently with ES therapy. After completion of 1 hour of ES therapy, the investigational PeriPulse device was removed by disconnecting the signal generator from the electrode lead and withdrawing it from

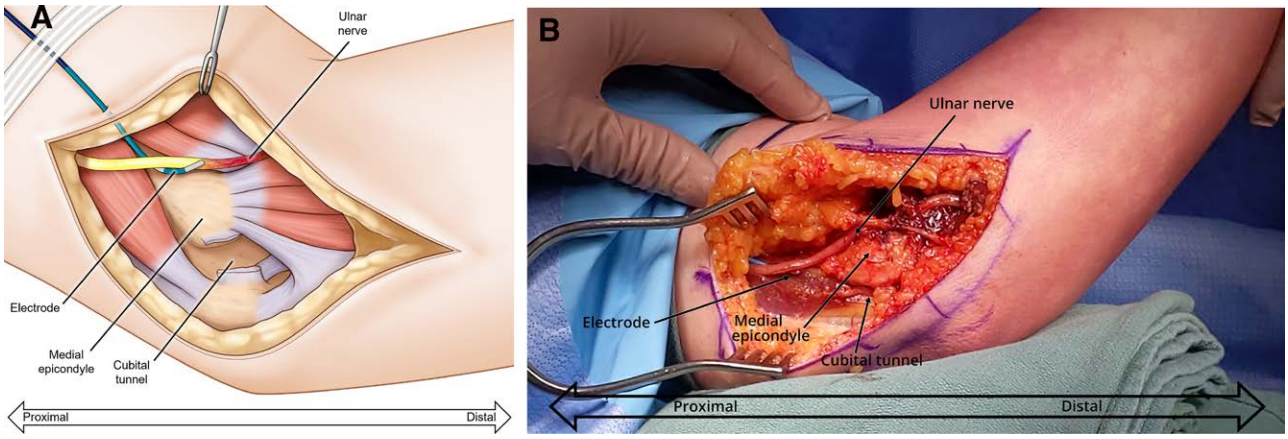

Fig. 1. Example of PeriPulse device electrode lead implementation in an ulnar nerve decompression and anterior transposition model. A, Illustration showing how the electrode lead is placed proximal to the decompression zone of the ulnar nerve and how the distal end of the electrode lead is shaped in a soft "J-curve" and tucked underneath the nerve. Shaping and placing the electrode lead this way allows for better security of the electrode lead to stay in contact with the nerve during perioperative ES therapy. B, Photograph of a case in which the described electrode lead placement and shaping method was implemented.

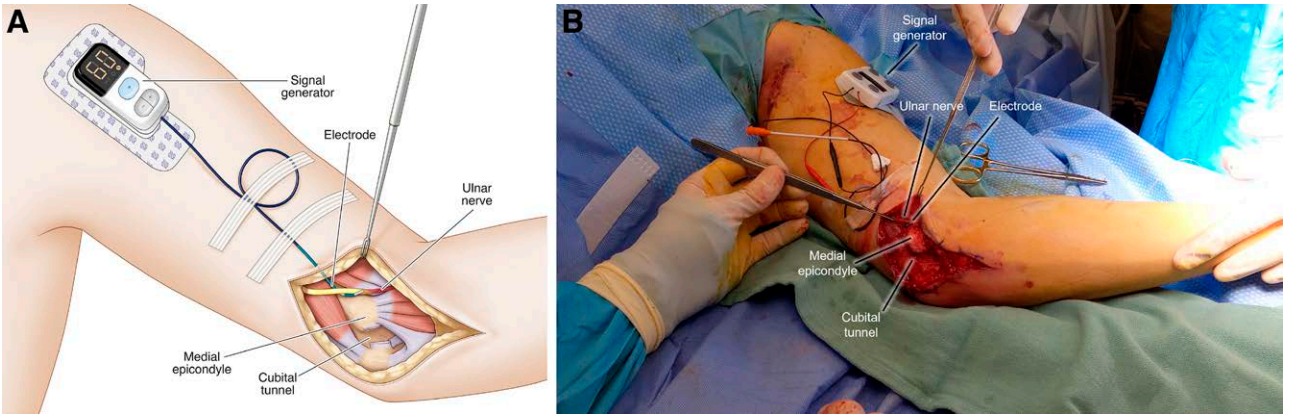

Fig. 2. Example of complete PeriPulse temporary peripheral nerve stimulation system implementation and perioperative 1-hour ES therapy in an ulnar nerve decompression and anterior transposition model. A, Illustration showing placement of the electrode lead near the ulnar nerve, securing the electrode lead on the arm via the application of a tension relief coil and Steri-Strips, and adhesion of the signal generator on the upper arm. The 1-hour ES therapy is initiated in the OR immediately after motor capture from the electric stimulus is confirmed intraoperatively. The 1-hour ES therapy continues during wound closure, dressing, and transport of the patient into the recovery room. B, Photograph of a case demonstrating complete implementation using an investigational version of the PeriPulse device.

the dressing. There were no significant disruptions of the surgical wound or dressing. The device was disposed of in the recovery room.

Patient-reported Tolerance Questionnaire

Patients were asked about their pain and sensation to ES in the recovery room periodically during the ES therapy. These responses were reported to both the surgeon-investigators and a study clinical engineer, who was independent of the surgical team (K.J.W.S.). A standardized procedure was implemented for the patient-reported tolerance questionnaire to reduce potential bias and patient influence. The information was captured in a patient tolerance questionnaire and provided continuous confirmation of ES therapy.

Surgeon-reported Device Usability Questionnaire

Following each procedure, study surgeons completed a device usability questionnaire to capture the time for device implementation, application of the shapeable electrode lead, stimulation setup chosen (ie, monopolar or bipolar stimulation), stimulation parameters applied, and overall satisfaction with the use of the stimulator. The questionnaire was designed specifically for the purpose of this clinical trial and has not yet been validated.

Postoperative Follow-up

We monitored all participants for the presentation of adverse events and adverse device effects, including wound infection and delayed wound healing. To reduce the potential for bias and influence from study team members, participants were asked to self-report any potential adverse events and adverse device effects to the surgeon-investigators and research coordinator (who was also independent of the surgical team) during their participation in the study, including at standard-of-care follow-up visits. At the first postoperative visit (2–4 wk), VAS pain scores were obtained. Participants were asked to report their pain on a VAS out of 10, where 0 represents "no pain" and 10 represents "greatest pain ever experienced."

Statistical Analysis

Descriptive statistics were performed using GraphPad Prism 10. Data are reported as mean ± SD, unless otherwise specified.

RESULTS

Between April 2021 and June 2023, 25 participants presenting with upper extremity nerve injury, neuropathy, or lesions were enrolled at 2 sites in Hamilton, Ontario, Canada. Of these, 7 participants presented with ulnar neuropathy at the elbow, 5 participants presented with median neuropathy or median nerve lesion, 1 participant presented with a radial nerve lesion, 1 participant presented with an axillary nerve lesion, and 11 participants presented with complete digital nerve transection. Two participants were excluded from the study before receiving ES therapy, corresponding to a participant presenting with symptoms of an axillary nerve lesion and a participant with a suspected digital nerve transection. Upon surgical exploration, it was determined that the nerve was not affected in both cases. Therefore, these patients did not meet the study criteria and were excluded from the study. Thus, a total of 23 participants received surgery and were treated with ES therapy. All 23 participants returned for the first postoperative visit (Fig. 3).

Participant demographics are summarized in Table 1. The mean age of participants was 43 years old, ranging from 21 to 73 years. One participant was included outside of the study age criteria (18–65 y old), and it was determined that this exception did not pose any additional safety concerns or impact the study data. Of the enrolled participants, 44% (n = 11) were women and 56% were men (n = 14). There were 6 participants (24%) reported to be smokers, and 11 participants (55%) indicated that they took time off work for their injury.

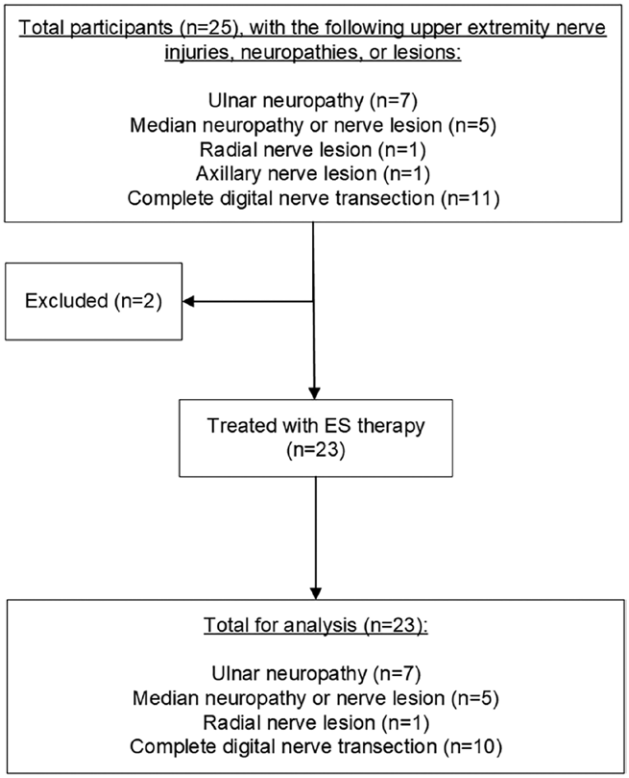

Fig. 3. Clinical trial flow chart depicting the recruitment and follow-up of all study participants. Of the 25 recruited participants presenting with upper extremity injury, neuropathy, or lesions, 7 presented with ulnar neuropathy, 5 with median neuropathy or median nerve lesions, 1 with a radial nerve lesion, 1 with an axillary nerve lesion, and 11 with complete digital nerve transections. During surgical exploration, it was found that 2 participants did not meet the eligibility criteria; thus, these participants were withdrawn from the study and did not receive ES therapy. Twenty-three participants received 1-hour ES therapy from an investigational version of the PeriPulse device. All 23 participants returned for their first postoperative follow-up visit, and the collected data were used for analysis.

Table 1. Summary of Participant Demographics

Variable	Value
Mean age, y	43 (range 21–73*)
Female, %	44
Male, %	56
No. participants who smoke	6 (24%)
No. respondents who took time off work for their injury	11 (55%)

*One 73-year-old participant with carpal tunnel syndrome was included in the study outside of the study age criteria. There were no determined impacts on the safety of this patient or on the study data.

In 65% of cases (n = 13 responses), surgeons reported less than 5 minutes for device implementation in the OR, and less than 10 minutes in 95% of cases (n = 19 responses). The electrode lead was shaped in 50% of cases (n = 10 responses), and there were no reported incidents of electrode lead migration. The mean stimulus level ± SD was 2.2 ± 0.7 mA (range 1–3.5 mA). In 76% of cases (n = 16 responses), bipolar rather than monopolar ES therapy was used (surgeon preference due to ease of implementation and not having to connect a return electrode). All participants reported tolerable levels of stimulation, and no ES therapy was discontinued early (100% tolerance to ES therapy). Patients reported the ES therapy to feel like "tingling" or "vibration," with 1 patient even reporting it to be "soothing." At the first postoperative visit, the mean VAS pain score was 1.2 out of 10. There were no patient-reported adverse events or adverse device effects during the surgical procedure and ES therapy (100% safety). None of the study patients presented with wound infections, delayed wound healing, or any other adverse device effects during participation in the study. An adverse event was reported from 1 participant 6 months postoperatively and was due to an accidental minor secondary injury, which was not deemed to be related to the investigational device or to the study. Surgeons were generally satisfied with the perioperative ES therapy approach, commenting that the process was "very smooth," and the device was "easy to use."

DISCUSSION

In this study, we aimed to further validate the established 1-hour ES therapy paradigm[19–22] and introduce a novel device and perioperative method that will better enable clinical adoption of this treatment. The PeriPulse temporary peripheral nerve stimulation system is optimal for the clinical translation of ES therapy, as it minimizes the disturbances to the clinical workflow, is user-friendly, and can be implemented by a single user (ie, does not require an electrophysiology technician). We measured that it takes approximately 5 minutes or less to implement the device in the OR once trained and fully familiar with the procedure. However, even during the training period (eg, the first 1 or 2 cases using the PeriPulse device), it took surgeons less than 10 minutes to implement the device.

Due to the complexity of applying ES therapy with existing devices and strategies intraoperatively for 1 hour, OR efficiency can be compromised. Some investigators have studied short durations of therapy, such as 10 minutes of intraoperative ES, in rodent models.[23,24] Alternatively, the perioperative method in our study added less than 5 minutes of operative time and still allows for delivery of the established 1-hour effective dose of ES therapy in humans.[19–22]

In some cases, therapy was initiated in the OR while other surgical activities were performed (eg, nerve transfer following decompression and stimulation proximal to the decompression site, skin closure, and dressing). In these cases, treatment was continuous while the patient was transported to the recovery room. The remaining duration of the 1-hour ES therapy was completed in the recovery room, and afterward, the device was removed and discarded. Device removal was simple, fast, and did not require disruption of the dressing. Patients did not complain of major pain during the device removal procedure.

Usability was further enhanced by the ability to shape the electrode lead in the surgical site to position the electrode lead contacts optimally. This was further confirmed as patients consistently reported perception of ES during

the therapy and did not complain of discomfort caused by the electrode lead or its removal. There were no incidents reported of lead migration or loss of effective stimulation; however, this is possible if major traction forces are applied to the electrode during use, and caution must be taken to avoid this. Creating a tension-relief coil on the electrode lead and applying Steri-Strips to secure the electrode lead on the arm are helpful strategies to avoid inadvertent migration or dislodgement of the electrode lead.

Bipolar stimulation was preferred over monopolar stimulation and presents numerous advantages. Application of monopolar stimulation requires a return electrode to be placed on the patient some distance away from the target nerve. These return electrodes are commonly needle electrodes and present additional risk of iatrogenic puncture injury, secondary site pain, and infection.[28,29]

Stimulus levels were adjusted such that motor and/or sensory capture was confirmed, in a similar manner to previous studies,[20,22] and were within the limits of patient tolerance. Patients did not report significant pain during stimulation, and no one requested termination of stimulation. Perioperative ES therapy allows for personalized stimulus adjustment, whereas limitations to intraoperative use would not. This is especially true for the repair or reconstruction of sensory nerves, where both sensory capture confirmation and determining the patient's tolerance limit occur in the postoperative environment, once the patient has regained consciousness from general anesthesia or after the local anesthesia has dissipated and the patient is able to confirm sensation to test stimuli.

The lack of reported adverse events supports the safety of this technique and technology in common procedures such as decompression of the carpal and cubital tunnel. Patients also reported very low pain scores at the first postoperative visit; however, the relationship between ES therapy and postoperative pain should be further studied.

Some limitations of this study include the lack of a control group, blinding measures, and collection of clinically relevant outcome measures. Despite these limitations, the results of this study demonstrate the safety, usability, and feasibility of this technology to be applied in other controlled studies. Future work may include evaluating meaningful clinical outcomes and device effectiveness in larger datasets from adequately powered, randomized controlled trials.

CONCLUSIONS

This study demonstrated the safety and usability of a temporary peripheral nerve stimulation system, and the feasibility of perioperative 1-hour ES therapy for a variety of upper extremity peripheral nerve procedures. We present a novel technology and perioperative methodology for surgeons to easily implement 1-hour ES therapy perioperatively into existing clinical workflows in a safe and simple manner.

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DISCLOSURES

Dr. Willand is a shareholder and employee of Epineuron Technologies, Inc. and is an inventor on patents related to the product described in this article. Katelyn So owns stock options and is an employee of Epineuron Technologies, Inc. She is also an inventor on patents related to the product described in this article. The other authors have no financial interest to declare in relation to the content of this article. This study was funded by Epineuron Technologies, Inc.

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