

Use of Noninvasive Interactive Neurostimulation to Improve Short-Term Recovery in Patients with Surgically Repaired Bimalleolar Ankle Fractures: A Prospective, Randomized Clinical Trial

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ABSTRACT

We undertook a trial with 60 patients who had undergone operative reduction and internal fixation of bimalleolar, AO type B2 ankle fractures with comminution. Patients were randomized into 2 groups, one of which received postoperative treatment using a noninvasive interactive neurostimulation device (InterX[®]) and the other with a sham device. The trial was designed to test the hypothesis that incorporation of noninvasive interactive neurostimulation into the rehabilitation protocol would result in reduced pain, increased range of motion, reduced edema, and reduced consumption of pain medication, in comparison with the sham therapy group. Outcome measurements included the patient's subjective assessment of level of pain, range of motion, and the extent of edema in the involved ankle, and the use of ketorolac for postoperative control of pain. The results showed significantly better results in the patients receiving treatment with active neurostimulation (repeated measures analysis of variance, $P < .001$).

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Ankle fractures derive from a diverse set of traumatic injuries, collectively comprising one of the most common categories of fracture seen by foot and ankle surgeons. Several epidemiological studies in North America and Europe describe incidence rates of 107 to 187 events per 100,000 person-years (1–3), suggesting more than 60,000 cases annually in a country the size of the United Kingdom, and more than 300,000 cases each year in the United States. These same reports document a growing incidence of ankle fractures over the past half-century, and researchers particularly note the frequent occurrence of these injuries among young adult men as well as middle-age and older women (1, 4, 5).

Most ankle fractures are isolated, affecting only the lateral malleolus (1, 6, 7). Most of these cases can be addressed without surgery,

and several clinical studies consistently show no advantage to operative treatment versus closed treatment with such fractures (4, 7, 8); however, bimalleolar and trimalleolar fractures involving both the tibia and fibula present a very different situation. A number of reports demonstrate that these injuries are best treated using operative reduction and internal fixation, whether considering functional or radiographic outcome measures (7–9). Furthermore, fractures of this type are almost always considered unstable, and there is broad consensus within the surgical community that operative correction is indicated in such a situation (6).

Less evidence exists, however, to determine the most appropriate postoperative care for surgically repaired ankle fractures. Many clinicians advocate early weight bearing within days of the operative intervention, combined with a regimen of ankle exercises to foster bone strength and promote restoration of mobility (9–11). Nonetheless, some practitioners maintain that the risk of postsurgical complications, including wound infection and fracture re-displacement, from more aggressive rehabilitation approaches outweigh the potential benefits (12). In fact, a review of clinical trials designed to evaluate different postoperative management strategies fails to reveal consistent, lasting advantages to any one particular method (7, 13). Practically, postsurgical therapy is largely based on the

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physician's personal preference, along with patient-specific considerations such as their willingness to adhere to various protocols, ability to use crutches, and the like (14–17). In cases for which early weight bearing and mobilization of the ankle are paramount, there is a need for therapeutic methods during the short-term recovery period that helps promote rehabilitation by enhancing range of motion in the affected joint, reducing pain and edema, and accelerating the restoration of normal function. Historically, a number of electrical stimulation modalities have been used to manage pain and facilitate recovery from various traumatic conditions (18). In particular, noninvasive interactive neurostimulation (NIN) recently has been shown to produce beneficial results in the postoperative care of patients suffering trochanteric fractures of the femur (19). NIN technology allows the therapist to scan an area of skin, without the need for conductive gel, and identify the optimal points to apply stimulation. The waveform of the NIN device is impedance sensitive (19), and is used to identify points or areas of low impedance. The low skin impedance corresponds with myofascial trigger points (20) and acupuncture points (21), which also have a high correlation with major nerve branches (22), and are treatment points that often respond well to electrical stimulation (23). It is believed that increases in blood flow and sweat secretion account for the changes in skin impedance (20). It is also hypothesized that the delivery of high-amplitude stimulation to multiple treatment points in this way enhances the pain relief achieved as compared with lower amplitude stimulation delivered only over the pain site. The mechanism of pain relief for this type of cutaneous stimulation is thought to include both segmental and descending neural inhibition (24), whereas the mechanism for reducing inflammation may be mediated by peripheral opiates (25).

The study described in this article was undertaken to determine whether NIN could be helpful in improving immediate postsurgical outcomes for patients undergoing operative restoration and internal fixation of unstable bimalleolar ankle fractures. The randomized controlled trial was designed to test the hypothesis that incorporation of NIN therapy into the rehabilitation protocol could result in (1) lower levels of reported pain, (2) accelerated restoration of the injured ankle's mobility, (3) more rapid alleviation of swelling and edema in the traumatized site, and (4) reduced patient consumption of pain medication.

Patients and Methods

The protocol for this investigation received formal approval from the institutional ethics committee and the study review board of the Department of Traumatology and Orthopedics - City Clinical Hospital No.71, Scientific Educational Medical Centre of Federal Government Institution of the President of the Russian Federation, Moscow, Russia.

Participants

Patients were recruited over the 8-month period from April to November 2006. Eligible patients were between the ages of 20 and 60 years and had undergone operative reduction and internal fixation of bimalleolar, AO type B2 ankle fractures with comminution and displacement of fragments (26). Surgery was performed an average of 7 (range 5 to 10) days following the injury. Additional requirements for participation in the study included the ability to begin the specified postsurgical therapy within 24 hours of the initial procedure, as well as compliance with the ongoing regimen of care. Exclusion criteria were any limitations that could interfere with delivery of electrical stimulation including the presence of an insulin pump, pacemaker, or neurostimulation implants, as well as a history of epilepsy or seizure, current pregnancy, active malignancies, or inability to consent to participation in clinical research.

Study Design

For this prospective, randomized, controlled study, sample size was determined by considering observed variation in pain scores from earlier studies of NIN (19, 27), as well as the investigators' judgment that a 3-point (30-mm) reduction in reported pain (on an analog scale ranging from 0 to 100 mm) represented a clinically meaningful

result. The study was designed to provide 95% power to detect a statistically significant difference at the 5% ($P \leq .05$) level, and based on previous experience (19) the estimate allowed for 15% loss to follow-up. Enrolled subjects were assigned to treatment groups using a fixed randomization scheme executed with sealed envelopes. Although health care personnel delivering postoperative therapy with the NIN device were necessarily aware of treatment status, all of the patients, evaluating physicians and nurses (including individuals responsible for collection of outcome measures), and the clinical coordinator were blinded to group assignment.

All patients were treated with a similar surgical protocol, consisting first of a direct lateral incision to access the fibular fracture, and use of a one-third tubular plate and screws to restore fibular length and achieve fixation. Next, the medial fracture site was opened and the fragment was adjusted, after which the fracture was stabilized with partially threaded lag screws.

Postoperative Rehabilitation and NIN Treatment Protocol

All individuals were provided with standard interdisciplinary postoperative care, including routine assessment and daily care by an orthopedic surgeon (authors A.I.G. and O.N.U.), supported by a physiotherapist and nurse. Rehabilitation goals were achieved by daily physiotherapy sessions focused on exercise to increase range of motion, and mobility to support ambulation. A non-narcotic analgesic (ketorolac) was given as needed up to 3 times per day.

Starting no more than 24 hours after surgery, patients assigned to the active treatment group underwent twice-daily NIN therapy sessions using a portable, hand-held device (InterX 5000, Neuro Resource Group, Plano, TX). The InterX 5000 device has been previously described (19, 28), and generates high-amplitude, pulsed, damped biphasic sinusoidal current that is delivered to the tissue via a pair of concentric electrodes placed in direct contact with the target area. The technology differs from traditional transcutaneous electrical nerve stimulators (TENS) because the interactive waveform adjusts in response to changes in skin impedance (Fig. 1). This facilitates the application of the electrodes directly to the skin (Fig. 2) without the need for a conductive medium, which allows the treatment protocol and, specifically, the NIN therapy to be aimed at optimizing electrode placement and the amplitude of stimulation. It is recognized in research that optimal treatment locations relate to points of low impedance (20, 21, 23) and may positively influence clinical outcomes (22). In fact, greater pain relief has been demonstrated with delivery of high-amplitude stimulation (24). It is suggested that combining these variables, namely optimal electrode placement and high amplitude, could further enhance clinical efficacy. It is also interesting to note that, since this trial was conducted, the InterX 5000 has been replaced by the InterX 5002 (Fig. 2), which delivers the same stimulation but uses a more advanced user interface.

Individuals assigned to the control arm of the trial also received twice-daily treatment sessions, which were initiated within 24 hours of surgery. However, for these patients a sham instrument was used which, although identical in appearance to the active NIN device (including the generation of similar audio/visual signals and tactile sensations of vibration), was disabled so as not to produce any electrical neurostimulation. The clinician (author O.N.U.) delivering the treatment was not blinded to the patients' group status because the active treatment involved interactive feedback from the device to determine optimal treatment point location. Any therapist trained to correctly apply NIN can immediately recognize a sham device, which does not offer the same feedback to the operator.

Treatments with either the active or sham device were conducted over 10 consecutive days, once each morning and once each evening. All therapy sessions required approximately 20 minutes and included delivery of NIN to the target sites identified in Fig. 3, covering both the injured and contralateral limbs. Each treatment was initiated by first scanning the target site using minimal stimulation intensity to identify the electrode position, which correlated with lowest tissue impedance (29, 30). The device was then held stationary at this location and the intensity was increased to

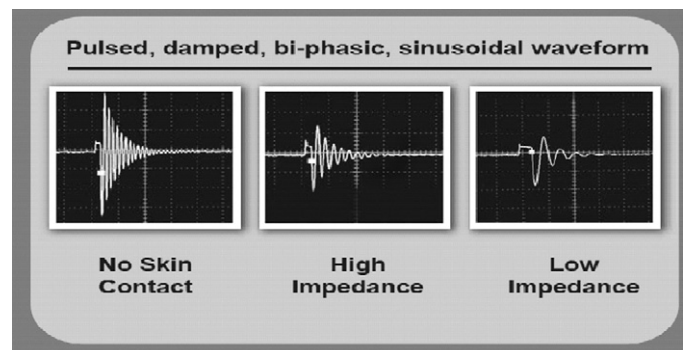


Fig. 1. The interactive waveform.



Fig. 2. The InterX 5002 in use with the small electrode on the ankle.

produce a comfortable sensation for the patient. It is of interest to note that the current recommended protocol indicates that the intensity should be increased prior to scanning for areas of low impedance. Stimulation at each site was terminated based on device feedback that indicated change in tissue impedance. This procedure was replicated for every target location on both limbs. Next, the entire ankle was palpated by the therapist to identify pressure-sensitive sites, and visually examined for signs of redness. Any such areas of sensitivity or redness were subsequently treated with NIN as described previously.

Outcome Measurements

All patients received baseline evaluations by the attending physician before their first NIN session. Outcome measurements included the patient's subjective assessment of level of pain, range of motion (ROM) in the injured ankle, and the extent of swelling (edema) in the affected limb. Each of these measurements was repeated within 30 minutes of the initiation and conclusion of all morning therapy appointments. Additionally, intake of prescribed non-narcotic medication was recorded on a daily basis. A standard visual analog scale (VAS) was used to determine pain levels. This tool has been well established as a reliable and sensitive measure of pain intensity in acute conditions (31). Range of motion was determined with the patient in a sitting position and the affected limb placed forward in a nonloaded condition. The subject was instructed to actively plantarflex and dorsiflex the ankle, and a goniometer was used to record the corresponding degree of maximal plantarflexion and dorsiflexion. These 2 figures were summed to produce a combined measure of total range of motion for the injured ankle (32).

The extent of edema or swelling was determined using a standardized measuring procedure to compare the circumference of the injured ankle with that on the

unaffected, contralateral side. Indelible lines were marked proximal to the lateral malleolus of both ankles, and a paper measuring tape was used to obtain consistent recordings of limb circumference from the same position each time. Based on similar measurements obtained by 2 different observers for a common subject, we found this approach to be sufficiently reliable and considerably more practical than alternative methods based on volumetric displacement.

Statistical Analysis

Longitudinal data were analyzed using repeated measures analysis of variance (with treatment as the between-group factor and time as the within-group factor) to determine significant differences between the 2 treatment groups across the entire time period, as well as treatment-time interactions. Comparisons between individual means for continuous variables were carried out with Student 2-sample *t* test, and comparisons between individual means for discrete variables were carried out using the Mann-Whitney test. Categorical data were analyzed with Fisher's exact test. Computations were performed with the SAS 9.1 for Windows statistical software package (SAS Institute Inc, Cary, NC).

Results

All patients gave informed consent to participate in the study. The completed trial included 60 patients, of which 30 were assigned to the active treatment arm receiving daily NIN therapy and 30 were assigned to the control arm receiving the sham treatment. A total of 69 consecutive patients with AO type B2 ankle fractures with comminution were admitted to the study institution during the trial's enrollment period (Fig. 4), although 9 of these did not meet the protocol criteria, all because their age fell outside of the specified inclusion range. All 60 enrolled patients completed the full protocol as described by the study design, and the results described as follows provide statistically and clinically significant evidence to affirm each of the hypothetical statements denoted in the last sentence of paragraph 4 of this report.

Baseline Characteristics

Baseline characteristics for the study population are summarized in Table 1. Demographic and clinical traits upon enrollment were very similar for the 2 treatment groups, and differences were randomly



Fig. 3. Diagram of the anatomic treatment sites, which included (1) medial surface of the first ray, (2) superior surface of the second ray, (3) superior surface of the first and second tarsal-metatarsal joints, (4) immediately superior to the medial malleolus, (5) the Achilles tendon, (6) approximately 10 cm superior to the lateral malleolus, and (7) superior surface of the fourth and fifth metatarsals (all sites indicated by areas of black shading).

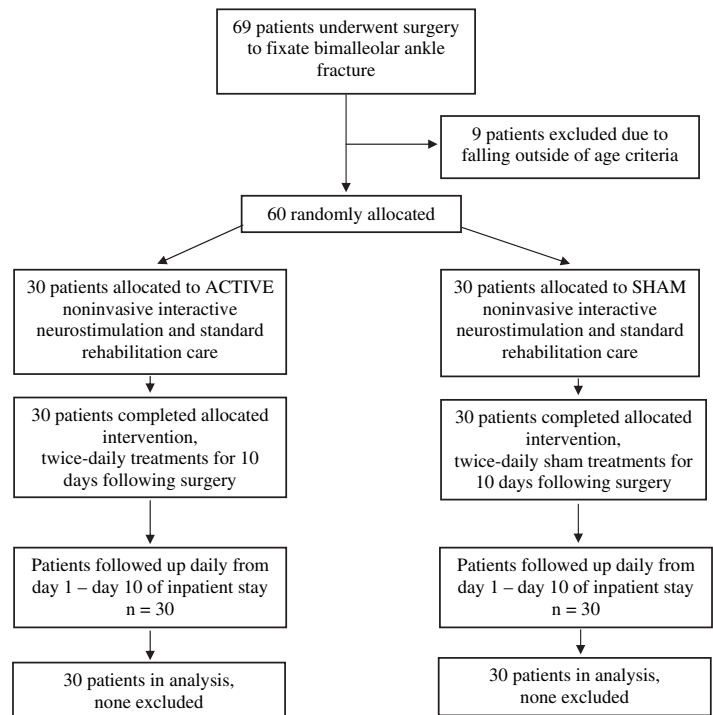


Fig. 4. CONSORT flow chart.

Table 1
Demographics of study patients (n = 60 patients)

Variable	Active NIN Therapy Group (n = 30)	Sham Therapy Group (n = 30)	P Value
Gender			
Male	16 (53%)	17 (57%)	1.0
Female	14 (47%)	13 (43%)	
Age, years, mean (min, max)	35.3 (21, 57)	38.4 (22, 58)	.24
White race	30 (100%)	30 (100%)	1.0
Diagnosis of diabetes	2 (7%)	3 (10%)	1.0
Side of injury			
Left	14(47%)	8 (27%)	.18
Right	16 (53%)	22 (73%)	

Abbreviations: NIN, noninvasive interactive neurostimulation.
P values derived from tests of independence (Fisher's exact test) for categorical variables, and from tests of equal means (2-tailed Student *t* test) for age.

distributed between the groups. All participants were white (race), and suffered closed ankle fracture with dislocation of the ankle.

Outcomes

Pain

Just before initiation of NIN therapy, both treatment groups experienced similarly high levels of pain, with an average VAS score of 8.20 ± 0.92 for controls and an average VAS score of 8.40 ± 1.02 for the NIN group ($P = .48$ for the 2-tailed *t* test of the means). However, immediately following the first therapy session and continuing throughout the duration of the 10-day trial, reported VAS scores declined more rapidly in the active treatment arm (Fig. 5). After one course of treatment, the mean VAS score for the NIN group dropped 28% to 6.00 ± 0.91 , whereas the mean VAS score for the control group fell 3% to 7.90 ± 0.98 . Likewise, following morning therapy sessions on day 5 and on day 10, average reported VAS scores for NIN subjects were 1.00 ± 0.55 and 0.00 ± 0.00 , respectively, whereas those for controls were 5.40 ± 0.86 and 2.10 ± 0.73 for the same time periods. Repeated measures analysis of variance showed a significant ($P < .001$) difference between treatment group means, as well as a significant ($P < .001$) interaction between treatment and time, indicating the gap between active and control VAS scores continued to evolve with additional therapy sessions (Table 2).

Medication Usage

Evaluation of medication usage by trial participants supported the findings described previously. In addition to reporting considerably lower pain levels, NIN subjects consumed less pain medication over the 10-day period than did the controls (Fig. 6). Mean total analgesic

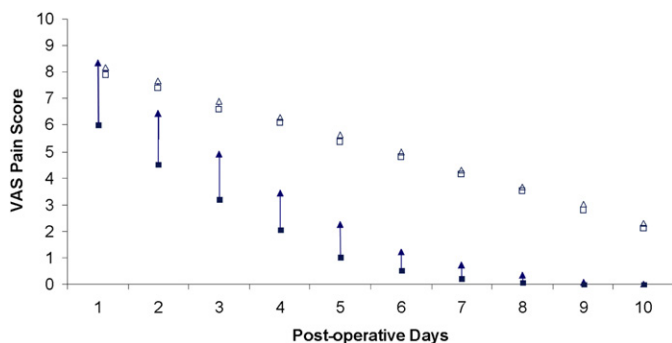


Fig. 5. The mean visual analog scale (VAS) pain score with noninvasive interactive neurostimulation (solid squares and triangles) and without noninvasive interactive neurostimulation (open squares and triangles). Bars represent the range of pain reduction, with mean VAS before treatment represented by a triangle, and mean VAS after treatment represented by a square. The difference between treatment groups and the time/treatment interaction were significant ($P < .001$).

use was 112.0 ± 33.4 mg per patient in the active treatment group, and 209.0 ± 32.9 mg per patient in the control arm, and the Mann-Whitney test showed this difference to be statistically significant ($P < .001$).

Mobility

Mobility of the surgically repaired ankle improved with NIN therapy (Fig. 7). Initial total ROM (comprising the sum of plantar and dorsal flexion) was limited and nearly identical for both groups, averaging only $14.0^\circ \pm 5.5^\circ$ in the active treatment arm and $13.8^\circ \pm 4.5^\circ$ in control subjects immediately before commencement of therapy ($P = .90$ for the 2-tailed *t* test of the means). After one neurostimulation session, total ROM for the NIN subjects improved more than 50% to a mean of $21.2^\circ \pm 6.7^\circ$, whereas total ROM for the sham-treated patients did not change ($14.0^\circ \pm 4.6^\circ$). The difference in mobility between the 2 treatment groups continued to escalate as the study proceeded. Following the 5th morning therapy session, mean ROM for NIN subjects was $33.8^\circ \pm 6.9^\circ$ versus $20.7^\circ \pm 3.7^\circ$ for controls, and after the 10th morning session, mean ROM for NIN subjects was $46.0^\circ \pm 9.3^\circ$ versus $28.0^\circ \pm 4.3^\circ$ for controls. Repeated measures analysis of variance showed a significant ($P < .001$) difference between treatment group means, as well as a significant interaction ($P < .001$) between treatment and time, consistent with the observation that the difference in ROM between the 2 groups increased over the course of the recovery program (Table 3).

Edema

Treatment with NIN also reduced the amount of edema present in the injured limb (Fig. 8). Immediately before the first therapy session, swelling was similar for both groups. The mean difference between affected and unaffected ankle circumferences in the NIN patients was 35.9 ± 3.5 mm, versus 35.1 ± 3.3 mm in the control subjects. A 2-tailed *t* test of the means provided no evidence that this difference was statistically significant ($P = .36$); however, over the next 10 days of therapy, the active treatment group experienced considerably more edema reduction. By the end of the fifth morning session, the mean circumferential difference between injured and noninjured ankles of the NIN group declined 38% to 22.3 ± 2.4 mm, whereas the mean circumferential difference for the sham-treated group decreased only 12% to 30.8 ± 2.7 mm. Following the morning treatment on day 10, this difference was further pronounced, with a mean of 16.3 ± 1.3 in the NIN subjects and a mean of 27.3 ± 2.1 mm in the controls. Repeated measures analysis of variance again showed a significant ($P < .001$) difference between treatment group means, as well as a significant interaction ($P < .001$) between treatment and time, indicating the effect of NIN treatment on edema became more evident as therapy progressed (Table 4).

Discussion

The hypothesis of this study was that NIN could help improve immediate postsurgical outcomes for individuals recovering from operative restoration and internal fixation of unstable bimalleolar ankle fractures. The results demonstrated a beneficial effect in regard to pain reduction, medication usage, joint mobility, and edema for

Table 2
Summary of analysis of variance for pain scores

Source	df	SS	MS	F statistic	P Value
Treatment	1	2537.2	2537.2	310.1	<.001
Error	58	474.5	8.18		
Time	19	5448.0	286.7	1945.6	<.001
Treatment × Time	19	351.8	18.5	125.6	<.001
Error	1102	162.4	0.15		

Abbreviations: df, degrees of freedom; SS, sum of squares; MS, mean square.

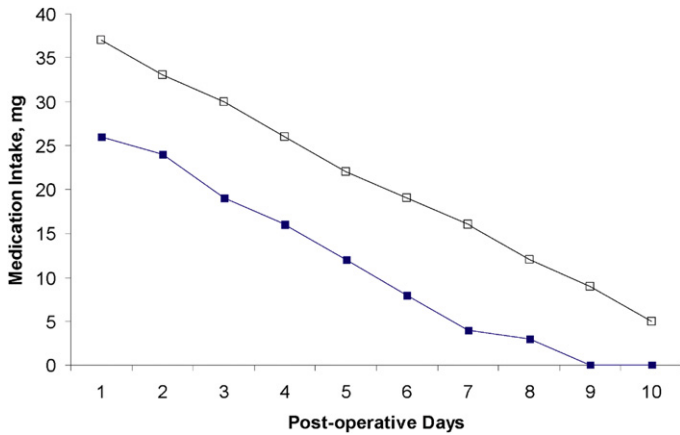


Fig. 6. Mean consumption of pain medication (ketorolac) with noninvasive interactive neurostimulation (solid squares) and without noninvasive interactive neurostimulation (open squares). The difference between treatment groups was significant ($P < .001$).

these types of cases during the near-term postoperative period. The impact of NIN was evident after a single session of stimulation, and became more apparent with subsequent therapy. By the completion of 5 days of the protocol, patients in the active treatment group on average experienced a reduction in VAS pain scores that was 2.6 times the magnitude observed in subjects from the sham group. Similarly after 5 days of NIN therapy, the improvement in ROM was 2.9 times that of controls, and the reduction in circumference of the injured ankle was 3.2 times that of controls.

It is commonly assumed that operative reduction and internal fixation of unstable ankle fractures generally produces good clinical outcomes, and several studies with intermediate-length follow-up periods support this view (33–35). However, a longer term report by Day et al (36) provided evidence of less favorable results over more extended time frames, as nearly half of individuals in the series experienced only fair or poor overall outcomes at 10 to 14 years of follow-up. The study’s authors recommend that a more guarded approach to giving a prognosis of a uniform good long-term outcome should be adopted for these surgical procedures. Their observations also might underscore the importance of identifying and implementing physiologically sound rehabilitation strategies that can lead to more rapid restoration of normal ankle function.

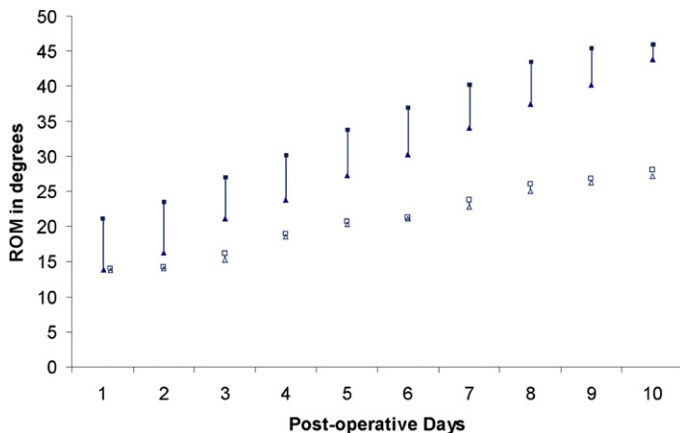


Fig. 7. Mean total range of motion (ROM) with noninvasive interactive neurostimulation (solid squares and triangles) and without noninvasive interactive neurostimulation (open squares and triangles). Bars represent the change in ROM, with mean ROM before treatment represented by a triangle, and mean ROM after treatment represented by a square. The difference between treatment groups and the time/treatment interaction were significant ($P < .001$).

Table 3
Analysis of variance summary for range of motion

Source	df	SS	MS	F statistic	P Value
Treatment	1	36908	36908	60.8	<.001
Error	58	35229	607.4		
Time	19	61124	3217.0	606.8	<.001
Treatment × Time	19	8110	426.9	80.5	<.001
Error	1102	5842	5.30		

Abbreviations: df, degrees of freedom; SS, sum of squares; MS, mean square.

Despite numerous clinical investigations, relatively little objective data has been produced to establish the lasting advantages of various postoperative care regimens for ankle fractures (7). Theoretical arguments and results from animal experiments suggest that intermittent loading of the joint promotes fluid exchange in the articular cartilage, and that continuous motion can aid healing cartilage injuries (37–39). These considerations lend support to advocates of early weight bearing and mobilization following the surgical repair of fractured ankles. Additionally, many patients and physicians recognize practical advantages in such a postoperative strategy, including facilitation of the rehabilitation process and a faster return to normal daily activity (15, 32, 40). In these cases, NIN offers a potential means of accelerating the recovery process.

The clinical trial described here had several limitations, arguably the most significant of which was its restricted duration of follow-up. Although the benefits of improved ROM and less pain and edema are widely accepted, longer-term studies will be needed to verify with other objective criteria the benefit of improvement in these parameters. Hopefully, communication of the near-term results that can be achieved with this emerging technology will lead to increased awareness and the initiation of more definitive research.

It also should be acknowledged that the postoperative NIN treatment protocol used for this analysis (twice-daily sessions for 10 consecutive days) could present logistical challenges for clinical settings in which patients are typically discharged from the hospital less than a week following operative reduction and internal fixation procedures. Further study will be needed to reveal whether the therapeutic benefits of NIN are sufficiently robust to allow more streamlined treatment regimens that may be more compatible with the time constraints of many surgical practices. Since this study began, it is interesting to note, the manufacturer of the InterX device has designed and marketed an unattended method of application of

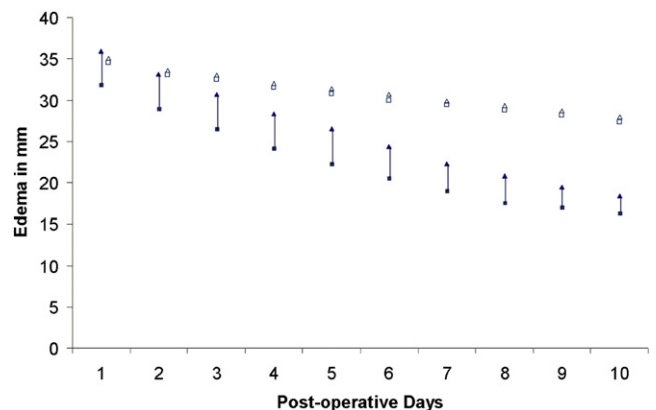


Fig. 8. Edema in the injured ankle with noninvasive interactive neurostimulation (solid squares and triangles) and without noninvasive interactive neurostimulation (open squares and triangles). Triangles represent mean difference in ankle circumference between affected and unaffected limbs before treatment, and squares represent mean difference after treatment. Bars indicate the average change in this measurement during a treatment session. The difference between treatment groups and the time/treatment interaction were significant ($P < .001$).

Table 4
Analysis of variance summary for edema

Source	df	SS	MS	F statistic	P Value
Treatment	1	13541	13541	126.6	<.001
Error	58	6206	107.0		
Time	19	18471	972.2	828.5	<.001
Treatment × Time	19	3714	195.5	166.6	<.001
Error	1102	1293	1.17		

Abbreviations: df, degrees of freedom; SS, sum of squares; MS, mean square.

NIN, which could also be taken home by the patient upon discharge. Further study of this newer and more efficient method of application is also warranted.

Additionally, the patients in this investigation were of the same race, and none of them was elderly (range 21 to 58 years). Evaluation of NIN on a larger and more demographically diverse set of subjects will be required in order to objectively assess the extent to which these results can be generalized to a broader population, including individuals with other injuries and surgical procedures. Moreover, the methodology used in this trial to measure and quantify edema is recognized as less reliable and precise than alternative volumetric techniques (41, 42). However, as acknowledged by other researchers working with displaced ankle fractures, it often is not possible to use volumetric means with these types of severe injuries because of inordinate patient discomfort from such an approach (43). Finally, the operator of the NIN was not blind to the intervention, although we do not feel that this substantially biased the results, as blind assessors or the subjects themselves performed all of the other assessments.

In conclusion, the results of this investigation provide clear evidence that NIN can improve short-term outcomes, namely pain and edema reduction, and increased ROM, for individuals recovering from operative restoration and internal fixation of displaced bimalleolar ankle fractures. We believe the results suggest that early introduction of NIN in these cases affords considerable patient benefit and warrants further investigation.

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