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Treatment of Chronic Plantar Fasciitis with Noninvasive Interactive Neurostimulation: A Prospective Randomized Controlled Study

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ABSTRACT

The initial treatment of plantar fasciitis should be conservative, with most cases responding to standard physiotherapy, nonsteroidal anti-inflammatory drugs (NSAIDs), heel pads, and stretching. In cases of chronic refractory symptoms, more invasive treatment could be necessary. Noninvasive interactive neurostimulation (NIN) is a form of electric therapy that works by locating areas of lower skin impedance. The objective of the present prospective randomized controlled study was to evaluate whether the use of NIN for chronic plantar fasciitis could result in greater improvement in a foot functional score, lower levels of reported pain, reduced patient consumption of NSAIDs, and greater patient satisfaction compared with electric shockwave therapy in patients without a response to standard conservative treatment. The patients were randomized using random blocks to the NIN program (group 1) or electric shockwave therapy (group 2). The outcome measurements were the pain subscale of the validated Foot Function Index (PS-FFI), patient-reported subjective assessment of the level of pain using a standard visual analog scale, and daily intake of NSAID tablets (etoricoxib 60 mg). The study group was evaluated at baseline (time 0), week 4 (time 1), and week 12 (final follow-up point). Group 1 (55 patients) experienced significantly better results compared with group 2 (49 patients) in term of the PS-FFI score, visual analog scale score, and daily intake of etoricoxib 60 mg. NIN was an effective treatment of chronic resistant plantar fasciitis, with full patient satisfaction in >90% of cases. The present prospective randomized controlled study showed superior results for noninvasive neurostimulation compared with electric shockwave therapy, in terms of the functional score, pain improvement, and use of NSAIDs.

Plantar fasciitis is one of the most common painful diseases of the heel of the foot, affecting >2 million people in the United States alone (1,2). It can affect ≤10% of people during their lifetime (3). This condition is often referred to as plantar heel pain, because the histologic findings show a degenerative fasciosis. Consequently, the term "plantar fasciosis" has also been used (4). The most frequent clinical presentation is severe pain when the patient takes the first steps in the morning or stands for long periods and physical activities in which lower limbs are used heavily, exacerbating the symptoms. The radiologic examination could show heel spurs, with ≤50% of patients experiencing plantar heel pain (5). The formation of plantar spurs seems to result from the fasciosis, and they are not directly related to plantar heel pain (6). Controversies exist regarding the etiopathology, with several factors considered to increase the risk, such as greater body mass index in nonathletes, older age, reduced ankle dorsiflexion, reduced first metatarsophalangeal joint extension, and prolonged standing (7).

Treatment of plantar fasciitis is usually conservative, with most patients responding to nonsteroidal anti-inflammatory drugs (NSAIDs), heel pads, splints, and physical therapy, and, as second-line treatment, corticosteroid injections (8). When treating plantar fasciitis, the physician should also consider the natural history of the disease, which is characterized by a self-limiting nature (6). Thus, according to the practical guidelines of the American College of Foot

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and Ankle Surgeons, a reasonable approach would be to start with the lowest risk and lowest cost treatment (standard physiotherapy, plantar orthoses, NSAIDs), and, if not successful, to switch to corticosteroid injections or second-level physical therapy, such as shockwave therapy.

Recently, the analgesic effects of a relatively new form of electrotherapy, the application of noninvasive interactive neurostimulation (NIN) has shown positive results in the treatment of myofascial syndrome and other musculoskeletal conditions (9) and for the postoperative care of femur fractures (10), knee replacement surgery (11), and ankle fractures (12). This device is usually trademarked InterX® (Neuro Resource Group, Plano, TX). The manufacturer has stated that the device works by locating areas of lower skin impedance, which generally "relate to major nerve branches, trigger points, acupuncture points and localized areas of sympathetic skin response" (13). The most interesting aspect of NIN is adaptation in relation to the body (area of lower electric impedance), with the beneficial effects arising from the selective stimulation of nerve fibers A, delta, and C. Similarly, selective stimulation can also occur at the level of the corresponding spinal cord vertebral body by action of the central nervous system (13). Compared with transcutaneous electrical nerve stimulation (TENS), the differences with NIN have been attributed to a distinctive electrode positioning and greater amplitude and density of the applied current (10,13). The published data regarding NIN suggest that it might exert an anti-inflammatory effect in areas of local inflammation (11,12). Its anti-inflammatory effects and interactive nature of the electric stimulation, with diagnostic feedback regarding skin impedance, which informs the therapist regarding which areas to treat and when treatment of a location is complete, means that it can be used for the treatment of chronic tissue degeneration and inflammation, such as plantar fasciitis.

Recently, electric shockwave therapy (ESWT) has been recommended as an appropriate and effective method for the treatment of plantar fasciitis (14). The exact therapeutic effects of ESWT and the timing for using this form of physical therapy are not completely understood. One high-quality controlled clinical trial evaluated ESWT versus a stretching technique and found that patients were not satisfied with ESWT when applied as a primary treatment protocol (15). Accordingly, its use should be recommended as second-line treatment.

The objective of the present prospective single-blind randomized controlled study was to evaluate whether the use of NIN for chronic plantar fasciitis could result in greater improvement in a foot functional score, lower levels of reported pain, reduced patient consumption of NSAIDs, and greater patient satisfaction compared with ESWT in a consecutive series of patients without a response to standard first-line conservative treatment. The null hypothesis of the present study was that NIN and ESWT would have identical clinical efficacy in patients with chronic plantar fasciitis at a short-term follow-up examination.

Patients and Methods

The Centro Medico Erre ethical committee and study review board approved the study protocol (approval no. 2016/15). Evaluation of NIN versus placebo was not permitted. Patients received oral and written information about the 2 treatments and gave informed consent to participate in the present study. Owing to the pain resulting secondary to ESWT applications, double-blind randomization was not possible. All rights of the enrolled subjects in the present study were protected. The study was performed in accordance with the Declaration of Helsinki (World Medical Association).

From May 1, 2014 to April 31, 2016, patients with a diagnosis of plantar fasciitis with or without plantar spurs not responding to conventional physical therapy (TENS, Tecar therapy, laser) in addition to NSAIDs and/or plantar heel pads were enrolled in the present randomized clinical trial.

The inclusion criteria were as follows:

- Chronic (>6 months) unilateral presence of tenderness at the proximal insertion of the plantar fascia into the heel bone, either plantar medially or plantarly
- The presence or absence of plantar heel spurs on standard radiographic examination
- A primary complaint of heel pain on weightbearing after a period of rest, with pain dissipating after a few minutes of walking but returning after prolonged periods of walking or standing
- A self-rating of >60 points using a 100-point visual analog scale (VAS) reported by the patient over a 2-day period, with the VAS score recorded immediately after taking the first steps in the morning or after a period of prolonged sedentary behavior (eg, sitting or driving for 6 hours)
- One or more previous treatments with standard physical therapy, NSAIDs, and/or plantar heel pads without satisfactory results, with ≥4 weeks of washout before enrollment in the present study (complete physical therapy is intended to be 10 sessions)
- Age >18 years

The exclusion criteria were as follows:

- Receipt of local steroid injections
- Standard radiographs showing calcaneus deformities, stress fracture, or bone tumor

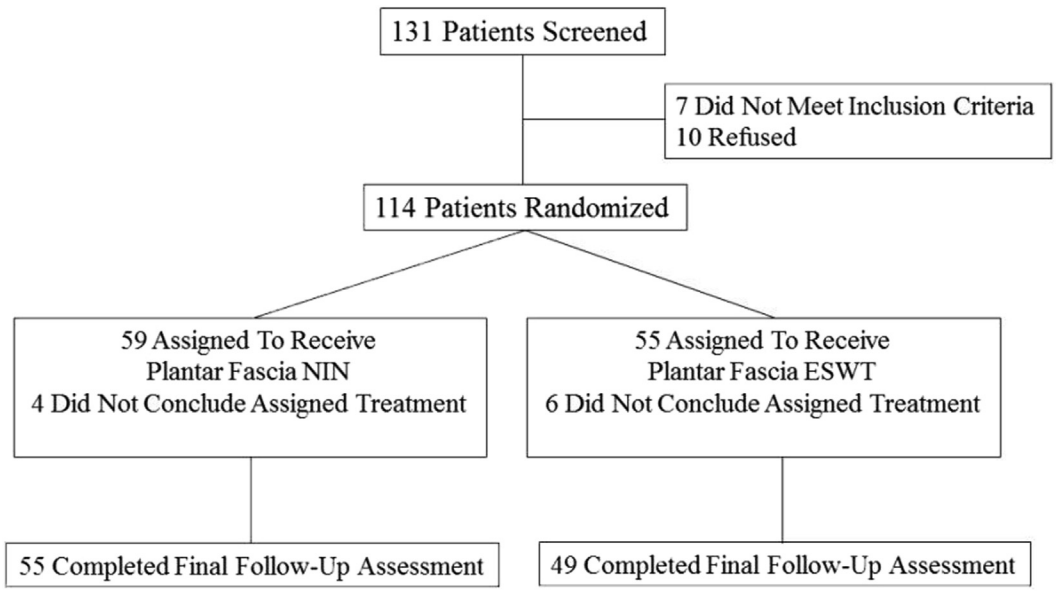

Fig. 1. Flowchart of the study. ESWT, electric shockwave therapy; NIN, noninvasive interactive neurostimulation.

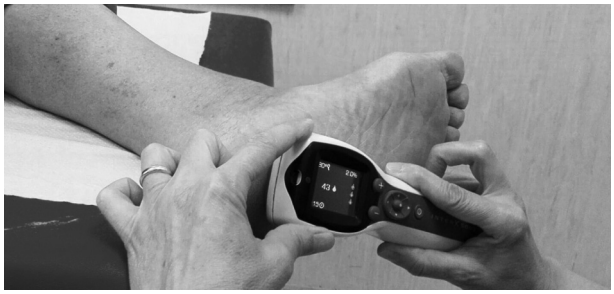

Fig. 2. The InterX® 5002 handheld device, with treatment starting by scanning the target site using a minimal stimulation intensity to identify the correct electrode position for the first 10 minutes. Shown with permission of InterX Technologies.

- Tendinopathy of the Achilles tendon with clinical and sonographic evaluation
- Neurologic heel pain due to nerve entrapment
- Contraindications to ESWT (e.g., pregnancy)
- Previous fractures of, or surgery to, the lower limb
- The presence of neurologic or vascular disease

The selection and exclusion of the patients was consistently executed by 1 of us (C.R.). The demographic (i.e., age, sex) and morphometric (i.e., body mass index [BMI]) characteristics of the patients were recorded.

Of the 131 patients with a diagnosis of plantar fasciitis, 7 did not fulfill the inclusion criteria and 10 were reluctant to participate. The remaining 114 eligible patients were randomized using random blocks to the NIN program (59 patients, group 1) or ESWT (55 patients, group 2; Fig. 1). To avoid any cost-related bias, the patients in the 2 groups paid the same fee.

Non-invasive Interactive Neurostimulation (NIN) 5002 Protocol

The treatment protocol consisted of 3 sessions weekly for 20 minutes at each session using a portable, handheld device (InterX® 5002; Neuro Resource Group) for a total of 10 sessions. The InterX® 5000 device has been previously described (10,13) and generates a high-amplitude, pulsed, damped biphasic sinusoidal current that is delivered to the tissue using a pair of concentric electrodes placed in direct contact with the target area. The InterX® 5002 differs, because it uses a more advanced user interface. With the handheld device, the treatment starts by scanning the target site using a minimal stimulation intensity to identify the electrode position, which will correlate with the lowest tissue impedance (Fig. 2). Next, the device is held stationary at this location, and the intensity is increased to produce a comfortable sensation to the patient (electrical paresthesia) for the first 10 minutes. Immediately thereafter, the InterX® multiflex array electrode is used for the next 10 minutes of treatment (Fig. 3). This protocol was repeated 10 times, 3 times each week. The patients who could not attend to this schedule were excluded from the present study. All the patients were treated by the same 1 of us (C.R.).

ESWT Protocol

Intermediate shockwave therapy with an electrohydraulic shockwave system able to apply a 0.15 mJ/mm^2 energy level (Duolith® SD1 extracorporeal shockwave therapy system; Storz Medical, Tägerwilen, Switzerland) was protocol used. Once each week for 3 consecutive weeks, 2000 shockwave impulses were applied. A total of 900 mJ/mm^2 was given to each patient (16,17). During the treatment, the patient was placed prone on a medical examination cot. The area where the patient reported the maximum tenderness was marked with a skin marker, and ultrasound gel was applied to this area. During ESWT, the use of anesthetics or narcotics was not allowed. All patients were treated by 1 of us (C.R.).

Outcome Measurements

An assessor (S.C.) not involved in the protocol and kept unaware of the treatment groups consistently collected the outcome measurements.

All the patients underwent the baseline evaluations before their first NIN or ESWT session (time 0; Table 1). The outcome measures included the use of the pain subscale of the validated Foot Function Index (PS-FFI) (18), self-reported subjective patient assessment of the level of pain using a standard VAS, and daily intake of NSAIDs (etoricoxib tablets 60 mg). Questions from the PS-FFI were used to produce the primary numerical outcome score. The scores for the PS-FFI range from 0 (no pain) to 10 (worst pain imaginable). We used only the first 7 items of the PS-FFI, because the remaining 2 items relate to orthotic use.

In the VAS, 0 represents "no pain" and 100 the "worst pain possible." The VAS has been previously validated for chronic conditions (19). The pain rating was calculated as the average VAS score reported by the patient over a 2-day period, with the VAS score immediately recorded after taking the first steps in the morning or after a period of prolonged sedentary behavior (e.g., sitting or driving for 6 hours).

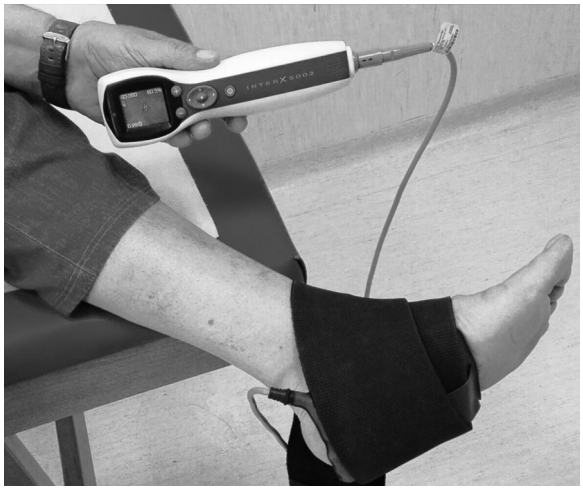

Fig. 3. The InterX® multiflex array electrode was used for the second 10 minutes of treatment. Shown with permission of InterX Technologies.

Patients who did not use the prescription of etoricoxib 60 mg oral tablets when needed and used other form of analgesics were excluded from the present study.

The complications that developed were assessed. The study groups were evaluated at baseline (time 0), week 4 (time 1), and week 12 (final follow-up point). At time 1, the patients were asked whether they were completely satisfied (would suggest the treatment to a friend), satisfied, or not satisfied.

Statistical Analysis

We supposed that α equaled 0.05 and 1 – β (power) equaled 0.80 for the power analyses. Thus, for an average 35-point decrease in the FFI score at 12 weeks after application of NIN or ESWT, a minimum of 44 subjects would be required for statistical analysis in each group. For the comparative study, 2-way analysis of variance, with the group as the between-patient factor and time as the within-patient factor, was used to assess the presence of significant differences between the groups and within each group before treatment and at the scheduled follow-up examinations. Potential correlation between the demographic (age, sex) and morphometric (BMI) data, with the final result (PS-FFI score) were calculated using a multivariate linear regression model. The patient characteristics are described using the average ± standard deviation for continuous variables. Statistical analysis was performed using SPSS software, version 16.0 (SPSS, Chicago, IL). Statistical significance was defined at the 5% ($p \leq .05$) level.

Results

Of the 114 eligible patients randomized in the 2 groups (59 in the NIN group and 55 in the ESWT group), 10 were excluded from the final follow-up examination (4 in the NIN group and 6 in the ESWT group). The reasons for exclusion were not reachable for the final examination for 3 patients and patient request for corticosteroid injections for 1 patient in the first group. In the second group, 2 were not reachable for the final examination and 4 were not compliant with ESWT (severe pain during the procedure). The groups (55 in group 1 and 49 in group 2) were comparable for the demographic and morphometric characteristics and the baseline functional score (PS-FFI), VAS score, and daily tablets of etoricoxib 60 mg ($p > .1$; Table 1).

For the change in the pain subscale scores of the PS-FFI, analysis of variance demonstrated a significant effect of treatment ($p < .031$) and a significant treatment–time interaction ($p < .01$) at 4 weeks after baseline in favor of NIN (group 1) compared with ESWT (group 2). The details are listed in Table 2. Similar significant differences persisted at the 12-week follow-up point. The results of the VAS and etoricoxib tablet intake analysis showed statistically significant differences at both 4 and 12 weeks of follow-up (Table 3) in favor of the NIN group.

At the end of the treatment period, when the last NIN or ESWT session had been given, 51 patients (92.7%) in group 1 and 18 patients

Table 1
Summary of baseline measures stratified by treatment group

Characteristic	Group 2, NIN (n = 55)	Group 2, ESWT (n = 49)
Age (y)		
Mean	53	50.6
Range	37 to 71	30 to 69
Male sex	30 (54.5)	23 (46)
Weight (kg)		
Mean	82.1	79
Range	47 to 136	50 to 110
BMI (kg/m^2)		
Mean	26.2	25.3
Range	19 to 36	22 to 34
Affected foot, right	20 (36.3)	21 (42.8)
PS-FFI*		
1. Pain at its worst	8.7 ± 0.6	8.9 ± 0.5
2. Pain during first steps of walking in morning	8.3 ± 0.8	8.5 ± 1.0
3. Pain at end of day	5.6 ± 1.2	5.8 ± 1.0
4. Pain while walking barefoot	7.2 ± 0.9	7.2 ± 1.0
5. Pain while standing barefoot	4.3 ± 1.2	4.6 ± 1.0
6. Pain walking wearing shoes	3.9 ± 0.8	3.6 ± 0.9
7. Pain standing wearing shoes	4.1 ± 1.1	4.1 ± 1.0
VAS score†		
Mean	78	75
Range	60 to 90	60 to 95
NSAID use (etoricoxib tablets)	2.3 ± 0.6	2.1 ± 0.5

Abbreviations: BMI, body mass index; ESWT, electric shockwave therapy; NIN, noninvasive interactive neurostimulation; NSAID, nonsteroidal anti-inflammatory drug; PS-FFI, pain subscale of the validated Foot Function Index; VAS, visual analog scale. None of the between group comparisons was statistically significant at baseline. Data presented as mean and range, n (%), or mean ± standard deviation.

* Subscale scores range from 0 to 10, with higher scores indicating greater impairment.

† Higher score indicates greater impairment.

(36.7%) in group 2 declared they were satisfied. In groups 1 and 2, 2 and 15 patients were partially satisfied (3.6% in group 1 and 30.6% in group 2). The number of patients who were not satisfied was 2 (3.6%) in group 1 and 16 (32.6%) in group 2.

A statistically significant negative correlation ($p = .005$) was found between the BMI and final result (PS-FFI score) in both groups. No statistically significant correlation was found between age and sex and the final result (PS-FFI score). The 2 patients who were not satisfied in group I had a BMI of 32 and 36 kg/m^2, respectively.

Side Effects

All 49 patients in the ESWT group (group 2) reported moderate to severe pain during treatment and transient reddening within the few hours after treatment. No device-related complications occurred in either group.

Discussion

In the present prospective randomized controlled study, a consecutive series of patients affected by chronic plantar fasciitis were evaluated to compare the short-term results of InterX® 5002 NIN compared with ESWT using the PS-FFI, VAS, and daily intake of the NSAID etoricoxib. Our findings showed that although both treatments are doubtless effective in the treatment of chronic plantar fasciitis, NIN resulted in improved patient satisfaction for control of the pain associated with chronic fasciosis compared with ESWT.

In the NIN group, the >90% of the patients were completely satisfied with the results at both 4 and 12 weeks of follow-up, without short-term recurrence of the fasciitis. The only 2 patients who were not satisfied were obese, confirming that obesity is a major risk factor for the occurrence of plantar fasciitis and its resistance to treatment.

To the best of our knowledge, the present study is the first to study a consistent consecutive number of patients affected by plantar fasciitis treated with InterX® neurostimulation. The exact mechanism of action in plantar fasciitis is unknown. The neurologic effect as a gate control mechanism of pain control might partially explain it; however, the short duration of the treatment sessions, the long-lasting effects, and the cumulative reduction in pain bring into question the possibility that gate control is the primary mechanism of pain reduction. Probably, similar to TENS stimulation (20), the mechanism of pain relief for this type of cutaneous stimulation will be found in both segmental and descending inhibition and in local regulation of inflammation. A unique characteristic of this device is that continuous interaction occurs between the InterX® device and skin impedance as it changes relative to the blood flow and degree of sweating. The InterX® device changes its stimulation in response to the skin impedance changes, resulting in a greater concentration of stimulation. This high amplitude of stimulation at multiple points of lower

Table 2
Change in pain subscale scores of Foot Function Index from baseline to 4- and 12-week follow-up points

PS-FFI Item	Time 1 (4 wk)	*p* Value (Baseline)	Final Follow-Up Point (12 wk)	*p* Value (Baseline)
1. Pain at its worst		.004		.0022
NIN (n = 55)	4.1 ± 1.9		3.5 ± 1.3	
ESWT (n = 49)	6.7 ± 1.3		6.0 ± 1.1	
2. Pain during first steps of walking in morning		<.001		<.001
NIN (n = 55)	3.9 ± 1.2		2.8 ± 0.8	
ESWT (n = 49)	7.1 ± 1.8		6.0 ± 1.2	
3. Pain at the end of day		.023		.01
NIN (n = 55)	3.6 ± 0.8		2.8 ± 1.0	
ESWT (n = 49)	5.1 ± 1.0		4.9 ± 0.8	
4. Pain while walking barefoot		.03		.02
NIN (n = 55)	4.8 ± 1.1		3.0 ± 0.5	
ESWT (n = 49)	5.6 ± 0.9		4.5 ± 0.7	
5. Pain while standing barefoot		.012		.008
NIN (n = 55)	2.9 ± 0.5		2.0 ± 0.8	
ESWT (n = 49)	4.0 ± 1.2		3.3 ± 1.0	
6. Pain while walking with shoes		.031		.029
NIN (n = 55)	2.3 ± 0.6		1.5 ± 0.5	
ESWT (n = 49)	3.2 ± 0.5		2.9 ± 0.5	
7. Pain while standing with shoes		.027		.015
NIN (n = 55)	1.9 ± 1.2		0.5 ± 1.0	
ESWT (n = 49)	3.1 ± 1.0		2.0 ± 1.2	

Abbreviations: ESWT, electric shockwave therapy; NIN, noninvasive interactive neurostimulation; PS-FFI, pain subscale of the validated Foot Function Index.
Data presented as mean ± standard deviation.

Table 3
Change between visual analog scale score and daily intake of etoricoxib 60 mg from baseline to 4- and 12-week follow-up points

Variable	Time 1 (4 wk)	*p* Value (Baseline)	Final Follow-Up Point (12 wk)	*p* Value (Baseline)
VAS score* (0 to 100)		.02		.032
NIN (n = 55)	28 ± 13		20 ± 12	
EWST (n = 49)	48 ± 15		35 ± 16	
Daily etoricoxib 60 mg		.007		.021
NIN (n = 55)	0.7 ± 0.4		2.8 ± 0.8	
EWST (n = 49)	1.2 ± 0.8		1 ± 0.8	

Abbreviations: ESWT, electric shockwave therapy; NIN, noninvasive interactive neurostimulation; VAS, visual analog scale.
Data presented as mean ± standard deviation.
* Higher scores indicate greater impairment.

impedance, not only at the pain site, might enhance the analgesic and anti-inflammatory effects, with satisfactory clinical results.

Recently, Macias et al (21) showed that low-level laser therapy is a promising treatment of plantar fasciitis compared with placebo. They found a significant improvement in VAS scores, with a high percentage of patient satisfaction. They also studied the fascial thickness before and after treatment using ultrasonography, and their patients completed the FFI (18). Both low-level laser and InterX® therapies seem effective; however, in contrast to their study, we selected patients with chronic plantar fasciitis, who had already undergone 6 months of physical therapy, heel pad use, and NSAID usage. Similar to our study, Costantino et al (22) recruited a cohort of patients affected by plantar fasciitis with heel spurs refractory to 6 months of standard physical therapy, NSAID use, and heel pad treatment. They treated patients using cryoultrasound therapy or cryotherapy alone. The results were significantly better in the cryoultrasound group, which also proved true longer follow-up (18 months). Nevertheless, they only considered the VAS, which records the purely psychologic outcome. Following the principle of pain treatment using areas with lower tissue impedance, Arslan et al (23) treated a particular feature of plantar heel pain with radiofrequency neural ablation and reported excellent results. Although our study and the study by Arslan et al (23) were basically different owing to the neurologic plantar heel pain and the invasive technique they proposed, both showed that working on areas with lower tissue impedance improves the efficacy of the treatment. A direct comparison of NIN with other forms of treatment options (e.g., orthobiologic agents, laser) is necessary to highlight any superior efficacy of this relatively new form of electric therapy.

The strengths of our study included the prospective, randomized design and the method of patient selection; to minimize confounding variables, we adopted strict inclusion criteria. A potential limitation was that follow-up duration was relatively short; however, because plantar fasciitis is a self-limiting condition, with a longer follow-up duration, it would be difficult to attribute the healing to the treatment only, which could jeopardize the results. We empirically assumed that 12 weeks of follow-up would be long enough to study the effects of InterX® applied to plantar fasciitis, because none of the patient had had a response to ≥6 months of conventional therapy. Another possible limitation was that we used the FFI pain subscore. Thus, one might argue that the FFI-PS is not a validated instrument. Nevertheless, this score has been used in some prospective randomized high-quality studies (15,24). In the wide scenario of physical therapy methods, we believe that patient satisfaction is the most important factor to consider, because it accounts not for only pain relief, but also the invasiveness, cost, and time needed to conclude the treatment, which, in general, results in better patient compliance.

In conclusion, NIN using the InterX® 5002 was shown to be an effective treatment of chronic plantar fasciitis resistant to treatment, with full patient satisfaction in >90% of cases. The present prospective randomized controlled study showed superior results with NIN compared with ESWT, in terms of the functional score, pain improvement, and daily intake of NSAIDs.

References

1. Thomas JL, Christensen JC, Kravitz SR, Mendicino RW, Vanore JV, Weil LS Jr, Zlotoff HJ, Bouché R, Baker J; American College of Foot and Ankle Surgeons Heel Pain Committee. The diagnosis and treatment of heel pain: a clinical practice guideline-revision 2010. J Foot Ankle Surg 49(3 suppl):S1–S19, 2010.
2. Rompe JD, Furia J, Weil L, Maffulli N. Shock wave therapy for chronic plantar fasciopathy. Br Med Bull 81-82:183–208, 2007.
3. Uden H, Boesch E, Kumar S. Plantar fasciitis—to jab or to support? A systematic review of the current best evidence. J Multidiscip Healthc 4:155–164, 2011.
4. Lemont H, Ammirati KM, Usen N. Plantar fasciitis: a degenerative process (fasciosis) without inflammation. J Am Podiatr Med Assoc 93:234–237, 2003.
5. Amis J, Jennings L, Graham D, Graham CE. Painful heel syndrome: radiographic and treatment assessment. Foot Ankle 9:91–95, 1998.
6. Buchbinder R. Clinical practice: plantar fasciitis. N Engl J Med 350:2159–2166, 2004.
7. Irving DB, Cook JL, Menz HB. Factors associated with chronic plantar heel pain: a systematic review. J Sci Med Sport 9:11–22, 2006.
8. Gill LH. Plantar fasciitis diagnosis and conservative management. J Am Acad Orthop Surg 5:109–117, 1997.
9. Schabrun SM, Cannan A, Mullens R, Dunphy M, Pearson T, Lau C, Chipchase LS. The effect of interactive neurostimulation therapy on myofascial trigger point associated with mechanical neck pain: a preliminary randomized, sham-controlled trial. J Altern Complement Med 18:946–952, 2012.
10. Gorodetskyi IG, Gorodnichenko AI, Tursin PS, Reshetnyak VK, Uskov ON. Use of noninvasive interactive neurostimulation in the post-operative recovery in patients with trochanteric fracture of the femur: a randomised controlled trial. J Bone Joint Surg Br 89:1488–1494, 2007.
11. Nigam AK, Taylor DM, Valayeva Z. Non-invasive interactive neurostimulation (InterX™) reduces acute pain in patients following total knee replacement surgery: a randomised, controlled trial. J Orthop Surg Res 6:45, 2011.
12. Gorodetskyi IG, Gorodnichenko AI, Tursin PS, Reshetnyak VK, Uskov ON. Use of non-invasive interactive neurostimulation to improve short term recovery in patients with surgically repaired bimalleolar ankle fracture: a prospective, randomized clinical trial. J Foot Ankle Surg 49:432–437, 2010.
13. Neuro Resource Group I. InterX Therapy. Available at: http:www.nrg-unlimited.com. Accessed January 2015.
14. Kapoor S. Pain management in patients with plantar fasciitis: the emerging role of radial extracorporeal shock-wave therapy. J Foot Ankle Surg 51:541, 2012.
15. Rompe JD, Cacchio A, Weil L Jr, Furia JP, Haist J, Reiners V, Schmitz C, Maffulli N. Plantar fascia-specific stretching versus radial shock-wave therapy as initial treatment of plantar fasciopathy. J Bone Joint Surg Am 92:2514–2522, 2010.
16. Buchbinder R, Ptasznik R, Gordon J, Buchanan J, Prabaharan V, Forbes A. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis: a randomized controlled trial. JAMA 288:1364–1372, 2002.
17. Gollwitzer H, Diehl P, von Korff A, Rahlfs VW, Gerdesmeyer L. Extracorporeal shock wave therapy for chronic painful heel syndrome: a prospective, double blind, randomized trial assessing the efficacy of a new electromagnetic shock wave device. J Foot Ankle Surg 46:348–357, 2007.
18. Budiman-Mak E, Conrad KJ, Roach KE. The Foot Function Index: a measure of foot pain and disability. J Clin Epidemiol 44:561–570, 1991.
19. Wessel J. The reliability and validity of pain threshold measurements in osteoarthritis of the knee. Scand J Rheumatol 24:238–242, 1995.
20. Sluka K, Walsh D. TENS: basic science mechanisms and clinical effectiveness. J Pain 4:109–121, 2003.
21. Macias DM, Coughlin MJ, Zang K, Stevens FR, Jastifer JR, Doty JF. Low-level laser therapy at 635 nm for treatment of chronic plantar fasciitis: a placebo-controlled, randomized study. J Foot Ankle Surg 54:768–772, 2015.
22. Costantino C, Vulpiani MC, Romiti D, Vetrano M, Saraceni VM. Cryoultrasound therapy in the treatment of chronic plantar fasciitis with heel spurs: a randomized controlled clinical study. Eur J Phys Rehabil Med 50:39–47, 2014.
23. Arslan A, Koca TT, Utkan A, Sevimli R, Akel İ. Treatment of chronic plantar heel pain with radiofrequency neural ablation of the first branch of the lateral plantar nerve and medial calcaneal nerve branches. J Foot Ankle Surg 55:767–771, 2016.
24. DiGiovanni BF, Nawoczenski DA, Lintal ME, Moore EA, Murray JC, Wilding GE, Baumhauer JF. Tissue-specific plantar fascia-stretching exercise enhances outcomes in patients with chronic heel pain: a prospective, randomized study. J Bone Joint Surg Am 85:1270–1277, 2003.