http://dx.doi.org/10.2106/JBJS.M.01331

TABLE E-1 Inclusion Criteria

Age of at least eighteen years
Ability to give written informed consent after being told of the potential benefits and risks of participating in the study
Signed informed consent
Diagnosis of painful heel proven by clinical examination
Six months of unsuccessful conservative treatment (i.e., must have undergone at least two unsuccessful nonpharmacological treatments and at least two unsuccessful pharmacological treatments; see examples below); the prior conservative treatments may have been completed as single, combined, or consecutive treatments
Nonpharmacological treatments
Physical therapy (e.g., ice, heat, ultrasound, iontophoresis, and electromyostimulation)
Physiotherapy (e.g., massage and stretching)
Over-the-counter devices (e.g., orthosis, tape, and heel pads)
Prescribed orthosis
Shoe modification (e.g., higher heels)
Cast or immobilization
Night splints
Pharmacological treatments
External (topical) application of analgesic and/or anti-inflammatory gels
Therapy with prescription analgesics and/or nonsteroidal anti-inflammatory drugs
Local anesthetic injections
Local corticosteroid injections
Time gap of at least six weeks since the last corticosteroid injection; four weeks since the last anesthetic injection, iontophoresis, ultrasound, and electromyostimulation; one week since the last nonsteroidal anti-inflammatory drugs; and two days since the last prescription or nonprescription analgesics, heat, ice, massage, stretching, modification of night splinting, and orthosis
Scores of ≥5 points on all three VAS pain scales
Roles and Maudsley score of fair or poor
Willingness to refrain from the painful-heel-related, concomitant therapies of iontophoresis, electromyostimulation, ultrasound, nonsteroidal anti-inflammatory drugs, corticosteroid injections, or surgery until the end of follow-up 1
Willingness to keep a diary on heel pain, medication, and other heel pain therapy until twelve months after the last treatment
A negative urine pregnancy test provided by female patients of childbearing potential immediately before the first extracorporeal shock wave therapy treatment
Willingness of female patients of childbearing potential to use contraceptive measures for two months after enrollment into the study

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TABLE E-2 Exclusion Criteria

Presence of tendon rupture or neurological or vascular insufficiencies of the painful heel
Presence of inflammation of the lower or upper ankle
History of rheumatic diseases, collagenosis, or metabolic disorders
History of hyperthyroidism
Presence of malignant disease with or without metastases
Presence of Paget disease or calcaneal fat pad atrophy
Presence of osteomyelitis (acute, subacute, or chronic)
History of fracture of the calcaneus
Use of an immunosuppressive therapy
Long-term treatment with corticosteroids
Presence of diabetes mellitus or severe cardiac or respiratory disease
Presence of coagulation disturbance and/or therapy with phenprocoumon, acetylsalicylic acid, or warfarin
Bilateral painful heel (i.e., if both feet need medical treatment)
Subjects who, at entry, are known to have treatment (e.g., surgery) planned within the next eight weeks, which may abruptly alter the degree or nature of pain experienced on the painful heel and render the shock wave therapy no longer necessary
Time gap of less than six weeks since the last corticosteroid injection; four weeks since the last anesthetic injection, iontophoresis, ultrasound, and electromyostimulation; one week since the last nonsteroidal anti-inflammatory drugs; and two days since the last prescription or nonprescription analgesics, heat, ice, massage, stretching, modification of night splinting, and orthosis
Previous surgery of the painful heel
Previous unsuccessful treatment of the painful heel with a similar shock wave device
History of allergy or hypersensitivity to bupivacaine or local anesthetic sprays
Clinically relevant abnormalities in hepatic function
Poor physical condition
Pregnancy in female patients
Recent or prior infection in the treatment area
History or documented evidence of peripheral neuropathy such as nerve entrapment and tarsal tunnel syndrome
History or documented evidence of systemic inflammatory disease such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, aseptic bone necrosis, or Reiter syndrome
History or documented evidence of Workers' Compensation claim or litigation
Participation in a clinical study within thirty days prior to selection or current inclusion in any other clinical study or research project
In the opinion of the investigator, subject is inappropriate for inclusion into this clinical study or would not comply with the study requirements

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TABLE E-3 Time Gaps and Correction Methods for Interfering Concomitant Analgesic Therapy

Insufficient time gap*
Less than six weeks since the last corticosteroid injection
Less than four weeks since the last anesthetic injection, iontophoresis, ultrasound, and electromyostimulation
Less than one week since the last nonsteroidal anti-inflammatory drugs
Less than two days since the last prescription or nonprescription analgesics, heat, ice, massage, stretching, night splinting, and orthosis
Correction methods†
Confirmatory analyses: if interfering concomitant therapy occurred within the critical time frame of a certain follow-up visit, the VAS scores were adjusted at this follow-up visit for interfering concomitant analgesic therapy, adding 2 points in the 10-cm VAS score (with a maximum score of 10 points) and 1 point in the 4-point Roles and Maudsley score (with a maximum score of 4 points)
Sensitivity analyses: supportive sensitivity analyses were defined with use of the worst-rank score technique (setting the VAS scores to the highest possible value of 10 points and the Roles and Maudsley scores to the highest possible value of 4 points), treating patients with interfering analgesic therapy as treatment failures, and performing data analysis without any correction for concomitant analgesic therapy; the results of the sensitivity analyses were compared with the results of the confirmatory analyses

*Concomitant analgesic therapies were recorded every day in a patient's diary. For every entry in the patient's diary, it was decided if interfering concomitant analgesic therapy occurred within a critical time frame for baseline and follow-up visits. The time frames were defined in the blinded review report according to the predefined exclusion criteria. †The methods of adjustment of efficacy criteria for interfering concomitant therapy were defined in the blinded review report.

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TABLE E-4 Results of the Sensitivity Analyses Regarding the A Priori-Ordered Primary Efficacy Criteria

Corrections and Primary Efficacy Criteria	Mann-Whitney Effect Size*	P Value†	Valid No. of Patients		Data Set
			Extracorporeal Shock Wave Therapy Group	Placebo Group	
No correction for interfering analgesic medication					
Composite score of heel pain (VAS) percent change from baseline to follow-up 1‡	0.5996 (0.5276)	0.0035	125	121	Intention to treat
Roles and Maudsley score at follow-up 1	0.6063 (0.5389)	0.0012	125	121	Intention to treat
Correction for interfering analgesic medication by means of the worst-rank score technique§ instead of predefined score correction for interfering analgesic therapy					
Composite score of heel pain (VAS) percent change from baseline to follow-up 1‡	0.6002 (0.5282)	0.0033	125	121	Intention to treat
Roles and Maudsley score at follow-up 1	0.6135 (0.5466)	0.0006	125	121	Intention to treat
Data as available instead of the last value carried forward to replace missing values (with predefined score correction for interfering analgesic therapy)					
Composite score of heel pain (VAS) percent change from baseline to follow-up 1‡	0.6041 (0.5302)	0.0031	119	113	Intention to treat
Roles and Maudsley score at follow-up 1	0.6050 (0.5362)	0.0017	119	114	Intention to treat
Data as available instead of the last value carried forward to replace missing values (without predefined score correction for interfering analgesic therapy)					
Composite score of heel pain (VAS) percent change from baseline to follow-up 1‡	0.6011 (0.5272)	0.0039	119	113	Intention to treat
Roles and Maudsley score at follow-up 1	0.5972 (0.5279)	0.0034	119	114	Intention to treat
Worst-rank replacement for all subjects lost to follow-up					
Composite score of heel pain (VAS) percent change from baseline to follow-up 1‡	0.5998 (0.5278)	0.0034	125	121	Intention to treat
Roles and Maudsley score at follow-up 1	0.6032 (0.5357)	0.0016	125	121	Intention to treat
Per-protocol data set with specifications for the confirmatory analysis					
Composite score of heel pain (VAS) percent change from baseline to follow-up 1‡	0.6020 (0.5290)	0.0032	122	117	Per protocol
Roles and Maudsley score at follow-up 1	0.6113 (0.5435)	0.0008	122	117	Per protocol

*The values are given as the Mann-Whitney effect size, with the lower bound of the one-sided 97.5% confidence interval in parentheses. †The p values of the one-sided test for superiority were determined with use of the Wilcoxon-Mann-Whitney test. ‡This value was the sum of scores of heel pain (VAS) while taking the first steps of the day, heel pain (VAS) while doing daily activities, and heel pain (VAS) after application of the F-Meter. §This technique corrected for the interfering analgesic therapy.