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Treatment of Nonunions of Long Bone Fractures With Shock Waves

Ching-Jen Wang, MD; Han-Shiang Chen, MD**; Chin-En Chen, MD*; and Kuender D. Yang, MD, PhD†*

A prospective clinical study investigated the effectiveness of shock waves in the treatment of 72 patients with 72 nonunions of long bone fractures (41 femurs, 19 tibias, seven humeri, one radius, three ulnas and one metatarsal). The doses of shock waves were 6000 impulses at 28 kV for the femur and tibia, 3000 impulses at 28 kV for the humerus, 2000 impulses at 24 kV for the radius and ulna, and 1000 impulses at 20 kV for the metatarsal. The results of treatment were assessed clinically, and fracture healing was assessed with plain radiographs and tomography. The rate of bony union was 40% at 3 months, 60.9% at 6 months, and 80% at 12 months followup. Shock wave treatment was most successful in hypertrophic nonunions and nonunions with a defect and was least effective in atrophic nonunions. There were no systemic complications or device-related problems. Local complications included petechiae and hematoma formation that resolved spontaneously. In the authors' experience, the results of shock wave treatment were similar to the results of surgical treatment for chronic nonunions with no surgical risks. Shock wave treatment is a safe and effective alternative method in the treatment of chronic nonunions of long bones.

Lithotripsy is widely accepted as the treatment of choice for a high proportion of urinary stones. It however, recently has been adapted to the treatment of orthopaedic disorders. Bone has an acoustic impedance of 4100 m/s, which is very similar to that of urinary stones, which vary between 4000 and 6000 m/s. Shock wave treatment theoretically can produce microfractures of bone, which, in turn, can stimulate neovascularization, osteoblast formation, and bone healing.[2–6,8,10] Haupt et al[7] in an experimental model in rats, confirmed a positive effect of shock waves on fracture healing. Johannes et al[8] showed the promotion of bony union with shock waves in hypertrophic nonunions in dogs. Forriol et al[3] reached an alternative conclusion, however, and thought that shock waves might delay bone healing and did not recommend its use in clinical orthopaedics. From experimental work in rabbits, Delius et al[2] showed that shock waves could produce radiographic lucencies in the bone marrow, intense formation of new cortical bone, and minor tra-

From the *Department of Orthopedic Surgery, the **Department of Surgery, and the †Department of Medical Research, Chang Gung Memorial Hospital, Kaohsiung Medical Center, Kaohsiung, Taiwan.

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Reprint requests to Ching-Jen Wang, MD, Department of Orthopedic Surgery, Chang Gung Memorial Hospital - Kaohsiung Medical Center, 123, Ta Pei Road, Niao Sung Hsiang, Kaohsiung, Taiwan.

becular remodeling but did not cause gross fractures. A review of the literature confirms inconsistencies in the potential effects of shock waves on bone healing, with a divergence of opinion on its value for chronic nonunion.[2,3,7,8]

The current study reviews the clinical results in the treatment of 72 patients with nonunited fractures of long bones treated with shock waves.

MATERIALS AND METHODS

A clinical study of the value of shock waves for chronic nonunions was approved by the ethical committee of the authors' hospital and the Department of Health of Taiwan in 1998. The patients first were recruited in August 1998.

Inclusion criteria were established nonunions of long bone fractures defined as a failure to show bony union 6 months after initial closed or open treatment. The fractures included in the study comprised diaphyseal fractures of the femur, tibia, humerus, radius, ulna, and metatarsal. All patients were skeletally mature and agreed to comply with the followup requirements for a period of at least 1 year.

Exclusion criteria included underlying neoplastic disease or other causes of pathologic fracture, fractures in the epiphyseal region of the bone, a fracture gap greater than 5 mm, active infection, and fractures in younger patients in whom the physes had not yet closed because of the potential for disrupting growth. Patients with fractures near major neurovascular structures that could be damaged by shock wave treatment such as those in the spine, chest, or skull also were excluded. In addition, patients who were pregnant, had cardiac pacemakers, or who were receiving immunosuppressive drugs or anticoagulants were excluded.

The preoperative evaluation included a complete medical history, the date of the original fracture, and prior methods of treatment. The presence of orthopaedic implants was not a contraindication to inclusion. The clinical examination included an assessment of pain, local tenderness, and motion at the fracture site. In addition, up-to-date radiographs, an electrocardiogram, a pregnancy test in women of childbearing age, and a full range of laboratory tests including a full blood count, biochemical screen, creatine phosphokinase, prothrombin time, partial thromboplastin time, and bleeding time were obtained.

All treatments were provided under general or spinal anesthesia. Those patients with nonunions of the lower extremity were treated on a fracture table, and those with fractures of the upper extremity were treated on a standard operating table. The fracture site was localized with a C-arm image intensifier and the control guide of the treatment device OssaTron (High Medical Technology, Kreuzlingen, Switzerland) that was used for all treatments. The technical parameters of treatment were 6000 impulses at 28 kV (0.62 mJ/mm^2 energy flux density) for the femur and tibia, 3000 impulses at 24 kV (0.56 mJ/mm^2 energy flux density) for the humerus, 2000 impulses at 24 kV (0.56 mJ/mm^2 energy flux density) for the radius and ulna, and 1000 impulses at 20 kV (0.47 mJ/mm^2 energy flux density) for the metatarsal fracture. The shock waves were applied in two planes and the region of any metallic internal fixation, such as a cortical plate, was avoided. The presence of an intramedullary rod, however, did not interfere with the application of shock waves.

Once the fracture had been localized in position and depth, surgical lubrication gel was applied to the area of skin in direct contact with the tube of the OssaTron. The shock wave impulses and generated kilovolts were adjusted with a control guide. Half of the impulses were applied in one plane and the other ½ were applied in a different plane. The vital signs were monitored by the anesthetist throughout the course of treatment. Local swelling, ecchymosis, hematoma formation, and the alignment and stability of the fracture were assessed.

Postoperative treatment included an ice pack, mobilization with crutches, partial weightbearing for patients with fractures of the lower extremity, and a sling to support fractures of the upper extremity. Patients with stable fractures, with or without internal fixation, received no additional external immobilization. The three unstable, nonunited humeral fractures were immobilized with a splint in addition to the sling.

Patients returned to the same weightbearing status after shock wave treatment as before this therapy. All but one patient were admitted overnight to the hospital and subsequently were discharged with nonnarcotic analgesics.

Followup assessments were done at 6 weeks and 3, 6, 9, and 12 months. The intensity of pain was assessed subjectively with a visual analog scale from 0 to 10 with 0 for no pain and 10 for severe pain. Local tenderness and motion at the fracture site, the percentage of weightbearing on the affected limb, and its alignment were evaluated. Radiographs were taken to assess alignment, callus formation, the maximal and minimal fracture gaps, and the presence of bony union across the fracture site. Tomography was done for patients in whom adequate information could not be obtained with plain radiographs. Patients were offered an additional session of shock wave treatment if nonunion persisted longer than 3 months after the initial treatment.

Seventy-two patients with established nonunions of long bone fractures were treated with shock waves. There were 53 males and 19 females with an average age of 39.4 years (range, 15–74 years). The types of nonunions were 38 (52.8%) hypertrophic, 13 (18%) atrophic, and 21 (29.2%) with a defect. Fifty-seven patients had varying amounts of callus formation with 25% to 50% union of the fracture site in eight patients and less than 25% in the remaining 49 patients.

The average maximum fracture gap was 4.8 mm (range, 2–15 mm) and the minimum fracture gap was 1.91 mm (range, 1–5 mm). The nonunion was confirmed by clinical examination and radiologic appearance. Eight patients were treated initially with a closed reduction and cast immobilization. The remaining 64 patients had undergone at least one open reduction and internal fixation. Of the 41 patients with femur fractures, 33 initially were treated with an intramedullary nail, seven were treated with plate fixaiton and one was treated with combined nail and plate. The average number of operations before shock wave therapy was 1.32 (range 1–6). Twenty-three patients also had received bone graft procedures on one to three occasions 6 months or longer before shock wave therapy. The intensity of pain at the fracture site was graded as 2.66 (range, 1–4). Those patients with lower limb fractures could take approximately 57% of their weight on the affected limb, but required crutches or a cane. The average maximum functional capacity of the affected limb was assessed as 48%, but less than 31% of the patients had returned to active employment.

RESULTS

Nine patients were lost to followup, two patients at 3 months, four patients at 6 months, and three patients at 12 months. In addition, eight patients chose surgical intervention during the course of treatment, five patients at 3 months and three patients at 6 months, respectively. Therefore, the followup data included 70 patients at 3 months, 61 patients at 6 months, and 55 patients at 12 months.

Seventy patients were followed up for 3 months, including 41 patients with femoral fractures, 18 patients with tibial fractures, seven patients with fractures of the humerus, two with fractures of the ulna, one with a fracture of the radius, and one with a metatarsal fracture. There were 38 hypertrophic, 13 atrophic, and 19 fractures with a defect. The intensity of pain was 2.65 before treatment and 1.11 after treatment, a decrease of pain that was highly significant ($p < 0.001$). Before treatment, the percentage of weightbearing on the affected limb was 60%, as opposed to 74% after treatment ($p < 0.001$). After treatment, the subjective improvement was a total resolution of pain in nine patients (12.9%), substantial improvement in 27 patients (38.6%), some improvement in 30 patients (42.9%), and no change in four patients (5.7%). The average minimal fracture gap was 1.87 mm before treatment as opposed to 1.23 mm after treatment ($p = 0.002$). The callus formation in the fracture gap is shown in Table 1. The assessment of fracture healing by plain radiographs showed consolidation in 28 patients (40%) and no apparent change in 42 patients (60%) (Fig 1). There was bony union in 19 of 38 patients (50%) with hypertrophic nonunion, in nine of 19 patients (47.4%) with nonunion with a de-

TABLE 1. Callus Formations at the Fracture Sites Before and 3 Months After Shock Wave Treatment

Callus Formations	Before Treatment	After Treatment
Number of patients	70	70
0	13 (18.6%)	6 (8.6%)
< 25%	49 (70%)	20 (28.6%)
25%–50%	8 (11.4%)	14 (20%)
50%–75%	0	5 (7.1%)
> 75%	0	25 (35.7%)

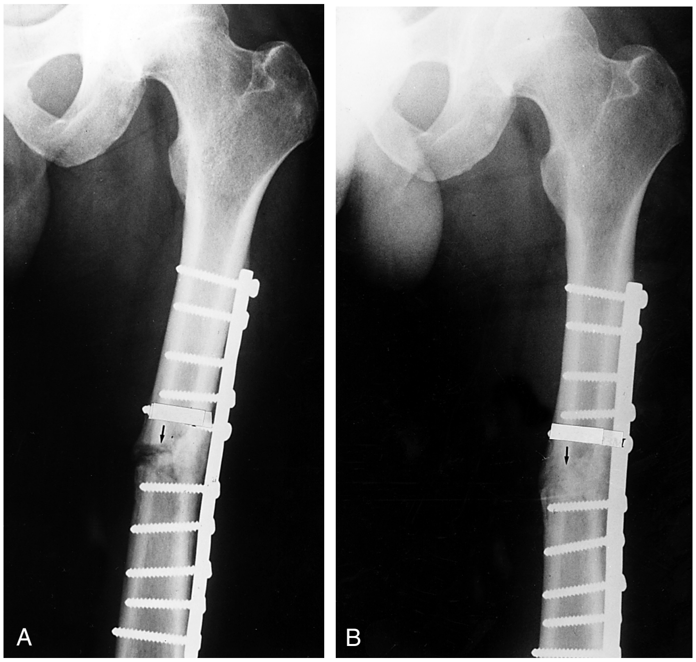

Fig 1A–B. (A) Radiograph of the right femur of a 32-year-old man showing nonunited fracture 9 months after the initial open reduction and internal fixation. (B) Radiograph of the same femur taken 3 months after treatment with 6000 shock wave impulses showing bony union.

fect, and in none of 13 patients with atrophic nonunions. Bony union was seen as early as 6 weeks in nine patients.

Sixty-one patients (38 femoral, 13 tibial, six humeral, two ulnar, and one each of radial and metatarsal fracture) have been followed up for 6 months. The intensity of pain was 2.5 before treatment as opposed to 0.4 after treatment ($p < 0.001$). The percentage of weightbearing before treatment on the affected limb was 60%, as opposed to 82% weightbearing at the 6-month followup ($p < 0.001$). The functional use in the affected limb improved from 50% to 74% ($p < 0.001$). Fifty-nine of 61 patients did not have pain at the site of the fracture. After treatment, the subjective improvement was total resolution of pain in 15 patients (24.6%), substantial improvement in 30 patients (49.2%), some improvement in 15 patients (24.6%), and unchanged in one patient (1.6%). The average minimal fracture gap was 1.8 mm before treatment as opposed to 0.6 mm after treatment ($p = 0.001$). The callus formation in the gap is shown in Table 2. Radiologic examination of the fracture showed consolidation in 37 patients (60.7%) and no apparent change in 24 patients (39.3%) (Fig 2). There was bony union in 23 of 34 patients (67.6%) with hypertrophic nonunion, in 11 of 16 patients (68.8%) with nonunion with a defect, and in three of 11 patients (27.3%) with atrophic nonunion.

Fifty-five patients (35 femoral fractures, 11 tibial, five humeral, two ulnar, and one each of radial and metatarsal fracture) have been followed up for 12 months. The intensity of pain was 2.6 before treatment as opposed to 0.1 af-

TABLE 2. Callus Formations at the Fracture Sites Before and 6 Months After Shock Wave Treatment

Callus Formations	Before Treatment	After Treatment
Number of patients	61	61
0	12 (19.7%)	1 (1.6%)
< 25%	42 (68.9%)	12 (19.7%)
25%–50%	7 (11.5%)	8 (13.1%)
50%–75%	0	13 (21.3%)
> 75%	0	27 (44.3%)

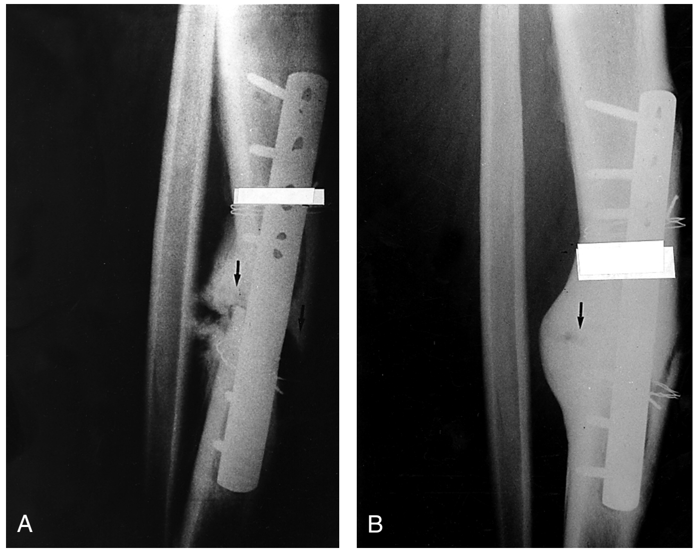

Fig 2A–B. (A) Radiograph of the right tibia of a 38-year-old man showing nonunited fracture 18 months after the initial open reduction and internal fixation. (B) Radiograph of the same tibia taken 6 months after treatment with 6000 shock wave impulses showing complete bony union.

ter treatment ($p < 0.001$). The percentage of weightbearing before treatment on the affected limb was 60% as opposed to 90.6% weightbearing at followup ($p < 0.001$). The functional use in the affected limb improved from 47% to 80% ($p < 0.001$). All 55 patients did not have pain at the site of the fracture. After treatment, the subjective improvement with total resolution of pain was seen in 24 patients (43.6%), substantial improvement was seen in 27 patients (49.1%), some improvement was seen in three patients (5.5%), and in one patient remained unchanged (1.8%). The average minimal fracture gap was 1.8 mm before treatment as opposed to 0.38 mm after treatment ($p < 0.001$). The callus formation in the gap is shown in Table 3. Radiographic examination of the fracture showed consolidation in 44 patients (80%) and no change in 11 patients (20%). The assessment of fracture healing by plain radiographs showed consolidation in 25 of 31 patients (80.6%) with hypertrophic nonunion, in 13 of 16 patients (81.3%) with nonunion with a defect, and in six of eight patients (75%) with atrophic nonunion.

Of those 55 patients who had followup of 1 year, the bony union rate was 50.9% (28 of 55) at 3 months, 67.3% (37 of 55) at 6 months, and 80% (44 of 55) at 12 months, respectively. It seemed that the effect of shock wave on bone healing continued for as many as 12 months.

Seven patients (three femoral, two tibial, and two humeral fractures) received a second treatment because of persistent nonunion 3 months after the initial treatment. Three patients with two femoral and one tibial fracture, respectively, had bony unions after the second treatment. There was significant improvement in pain, weightbearing status, and the function of the affected limb after the second treatment. The remaining four patients (one femoral, one tibial, and two humeral fractures) failed to

TABLE 3. Callus Formation at the Fracture Site Before and 12 Months After Shock Wave Treatment

Callus Formations	Before Treatment	After Treatment
Number of patients	55	55
0	10 (18.2%)	1 (1.8%)
< 25%	39 (70.9%)	1 (1.8%)
25%–50%	6 (10.9%)	7 (12.7)
50%–75%	0	4 (7.3%)
> 75%	0	42 (76.4%)

achieve bony union in 6 to 8 months after the second shock wave treatment.

There were no device-related problems or systemic complications. Local complications included petechiae ranging from 1 to 15 mm in 58 patients (80.6%) and hematoma formation ranging from 3 to 20 mm in 27 patients (37.5%). These problems resolved spontaneously within a few days with the use of an ice pack and conservative treatment. There were no neurovascular problems. None of the patients required narcotics after treatment. Mild nonnarcotic analgesics were given on the first day after treatment.

DISCUSSION

Open reduction with internal fixation using an intramedullary nail, bone grafting, and external fixation are choices in the treatment of patients with long bone fractures with chronic nonunion. Cattaneo et al[1] reported 86% successful union of humeral fractures treated with the Ilizarov external fixator. Wu and Shih[17] reported an 88% success rate in achieving bony union in 84 patients with nonunited femoral fractures treated with intramedullary nails. In chronic, nonunited tibial fractures, bone transplantation has led to a union rate of 85% to 93%[9,12] and success in 89% to 93% of patients treated with intramedullary nailing.[15,16]

Surgical treatment of chronic nonunions can, however, lead to serious complications. Warren and Brooker[15] reported an infection rate of 13% in 47 patients undergoing surgical treatment for chronic nonunion. Younger and Chapman[18] reported an 8.6% incidence of major complications, including deep infection, persistent wound drainage, hematoma formation, sensory loss, unsightly scars, and pain persisting more than 6 months. Minor complications included a 20.6% incidence of superficial infection or wound problems, temporary sensory loss, and mild pain at the donor site for bone graft. In addition, a proportion of patients required additional operative procedures. An alternative, minimally invasive technique for treatment of such poorly healing fractures seems desirable.

A review of the literature reveals contrasting reports on the value of shock wave treatment for chronic nonunions especially as assessed from animal experiments. Haupt et al[7] showed the potential value of shock waves for fracture healing in a rat model with accelerated fracture healing and improved mechanical stability. Johannes et al[8] confirmed accelerated healing of pseudarthroses in dogs. Clinical studies of shock waves for treating chronic nonunions have confirmed a success rate of 75% to 91%.[6,11,13] Schleberger and Senge[11] showed fracture healing in three of four pseudarthroses treated with 2000 shock waves. Valchanou and Michailov[13] reported bony unions in 70 of 82 patients with delayed or chronic nonunion of fractures at various locations. Rompe et al[10] reported a 50% success rate in the treatment of delayed bone union with shock waves in another clinical study, whereas Vogel et al[14] reported a 60.4% union rate in 48 patients with pseudarthroses treated with 3000 shock wave impulses. These authors concluded that such treatment was less likely to succeed with atrophic pseudarthroses and underlying bone abnormalities such as fibrous dysplasia or osteogenesis imperfecta.

The clinical results of the current study have shown that 6000 impulses of shock wave energy have resulted in a 60.7% success rate for achieving bony union for chronic nonunited fractures of long bones by 6 months. In some cases, bony union was observed in as early as 6 weeks after shock wave therapy. The success rate was 67.6% in patients with hypertrophic nonunion and 68.8% in patients with nonunions with a defect. The success rate was much lower (27.3%) in patients with atrophic nonunions. The success rate of bony union was 80% at 12 months followup. Patients with hypertrophic nonunions and nonunions with a defect consistently had a better rate of success than patients with atrophic nonunions. Assessment parameters including pain intensity, weightbearing, callus formation, and decrease in fracture gap showed significant improvement by 3 months after treatment ($p < 0.001$). Such improvement was observed to be time-dependent. In the current series, 44 of 55 patients (80%) with 12 months followup had complete or almost complete abolition of pain at the fracture site and were able to resume routine daily activities, including active employment.

The authors' results are comparable with those from other centers.[4–6,10,11,14] The results at 12 months confirm an 80% success rate. Local complications were mild and resolved spontaneously. The success rate seems comparable with that achieved with routine surgical treatment. Because of the potential complications and often extensive nature of surgery, the authors recommend shock wave treatment as a safe and effective alternative method of treatment for patients with chronic nonunited fractures. If such treatment is unsuccessful, there have been no changes that would preclude subsequent surgery.

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