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ORIGINAL PAPER

Extracorporeal shock wave treatment in nonunions of long bone fractures

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Abstract We reviewed the clinical results of the past 7 years in order to investigate the effect of extracorporeal shock wave therapy (ESWT) in nonunions of long bone fracture. Sixty-nine patients with 69 nonunions (22 femora, 28 tibiae, 13 humeri, 5 radii, and 1 ulna) were treated with extracorporeal shock waves. The technical parameters were 6,000 to 10,000 impulses at 28 kV (0.62 mJ/mm^2 energy flux density) for the femur and tibia, 4,000 impulses at 24 kV for the humerus (0.56 mJ/mm^2 energy flux density), and 3,000 impulses at 24 kV (0.56 mJ/mm^2 energy flux density) for the radius and ulna. Sixty-six patients were followed up. The total successful rate of bony union was 75.4%. ESWT was successful in hypertrophic nonunions and seemed to have no evident effect in atrophic nonunions. We believe that extracorporeal shock wave therapy may be a good choice for nonunions of long bone fracture especially in hypertrophic nonunions.

Résumé L'objectif de cette étude a été d'évaluer cliniquement les résultats observés sur les 7 dernières années lde a technique extracorporelle "schock wave" (ESWT) sur le traitement des pseudarthroses des os longs. Matériel et méthode : 69 patients présentant 69 pseudarthroses (22 fémurs, 28 tibias, 13 humérus, 5 radius et 1 cubitus) ont été traités selon cette méthode. Les paramètres techniques étaient de 6000 et de 10000 impulsions à 28 kV (062 mJ/mm2) pour le fémur et le tibia, 4000 impulsions à 24 kV pour l'humérus (0.56 mJ/mm2), 3000 impulsions à 24 kV (0.56 mJ/mm2) pour le radius et le cubitus. Résultats : 66 patients ont été suivis pendant au moins 12 mois. Le taux de consolidation a été de 75,4%. La ESWT est une technique qui permet de traiter une pseudarthrose hypertrophique alors qu'elle a peu d'effet sur les pseudarthroses atrophique. Conclusion : nous pensons que cette technique est une technique de choix pour les pseudarthroses des os longs spécialement lorsque ces pseudarthroses sont hypertrophiques.

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Introduction

Bone nonunion remains one of the major complications of fracture despite advanced operative techniques and osteosynthesis material. Very often, revision surgery is needed, sometimes even requiring autogenous bone grafts. Some useful alternative treatments for nonunions such as pulsed electromagnetic fields, electrically pulsed current stimulation, and extracorporeal shock wave therapy (ESWT) are considered to have promising results as reported over the past 20 years [6, 15, 22].

The use of ESWT for medical purposes has been documented since the early 1970s and has been shown to be a well tolerated and effective method of treating most kidney and urinary calculi. Since the 1990s ESWT has been successfully used in bone nonunion, although the mechanism is still not very clear. The benefit of shock wave therapy for nonunions has already been reported in various experimental [2–4, 10] and clinical studies [1, 12, 13, 17]. More recently, shock wave has been introduced as therapy for other orthopaedic pathologies such as tendinopathies and bone necrosis [8, 9, 16, 18]. This study reviews the results of 69 nonunions of long bone fractures treated with shock wave.

Materials and methods

Between July 2001 and January 2007, 69 patients, 44 men and 25 women, with 69 nonunions of long bone fractures (22 femora, 28 tibiae, 13 humeri, 5 radii, and 1 ulna), were treated with extracorporeal shock waves (ESW). The age at the time of ESWT ranged between 22 and 72 years (38.1± 12.3). The time between fracture and ESWT ranged from 6 to 84 months (12.5±10.3). The diagnosis of nonunion was made by at least two post-op X-rays 3 months after the fracture or the previous operation. Pseudarthrosis and delayed union were excluded. Hypertrophic nonunion was diagnosed as obvious callus formation without sclerosis at the end of the fracture. Otherwise it was considered as atrophic nonunion. Fifty-eight (84.1%) nonunions were hypertrophic and another 11 (15.9%) nonunions were atrophic. Table 1 shows the baseline demographics and clinical characteristics of these patients.

Regarding the primary treatment of the fracture, 61 patients were subjected to open operations including 25 intramedullary pins and 36 plates, and the other eight patients were treated with external fixations.

With regard to secondary treatment, seven patients (four tibiae, two femora, one humerus) were revised with other internal fixation together with bone autograft. Two patients (two femora) were treated by dynamisation of the intramedullary nail. Two patients (two tibiae) had the previous internal fixation removed within 3 months because of infection and external fixation was applied.

As for the reasons for nonunions, 21 patients were subjected to inappropriate internal fixation, in 25 patients too much bone and soft tissue had been removed, nine patients were not firmly fixed, seven patients had inappropriate weightbearing, two patients were infected, and the other five patients had no obvious cause.

Table 1 Classification information of the 69 patients

Description	Hypertrophic nonunion	Atrophic nonunion	Total
Male/female	37/21	7/4	44/25
Femur	18	4	22
Tibia	23	5	28
Humerus	12	1	13
Radius	4	1	5
Ulna	1	0	1

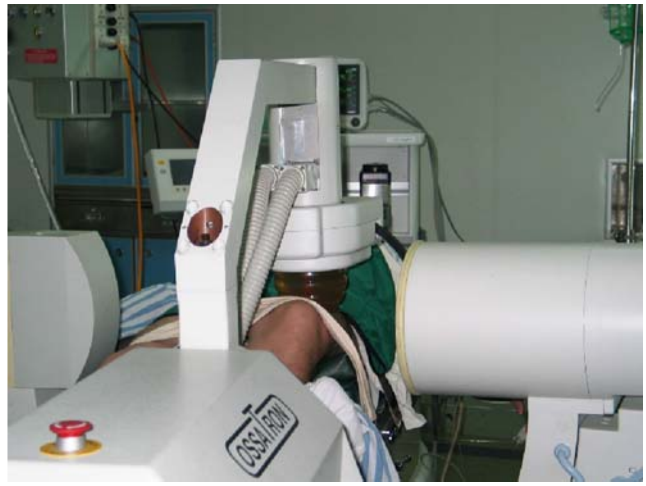

Fig. 1 Femur nonunion was treated with the Ossatron shock wave system and C-arm instrument

The preoperative evaluation included the date of original fracture and previous methods of treatment. The existence of local pain but no movement at the fracture site were found. Patients had up-to-date radiography, electrocardiography, and laboratory tests including a full blood count, prothrombin time, partial thromboplastin time, and bleeding time.

All treatments were performed with the Ossatron (HMT Co., Switzerland) under spinal or local anesthesia. The C-arm instrument and the control guide of Ossatron confirmed the treatment location as shown in Fig. 1. Technical parameters of the treatments were 6,000 to 10,000 impulses at 28 kV (0.62 mJ/mm^2 energy flux density) for the femur and tibia, 4,000 impulses at 24 kV for the humerus (0.56 mJ/mm^2 energy flux density), and 3,000 impulses at 24 kV (0.56 mJ/mm^2 energy flux density) for the radius and ulna. All patients received ESWT only once apart from one patient who received another ESWT during the dynamisation operation of the femoral intramedullary nail 3 months after the first osteosynthesis.

Postoperative treatment included an ice pack within the first 24 hours and avoidance of general activity for 1 week. Five patients received an additional external plaster. Patients returned to the same weightbearing status 7 days after the treatment. All patients left the hospital on the next day. Postoperative radiographs were obtained 2, 3, 4, and 6 months after original treatment, and some patients for much longer as necessary. Radiographs were taken to assess the alignment and callus formation and the presence of bony union across the fracture line.

Table 2 Bony union number and success rate at different follow-up times treated by ESW

Location of bony union (BU)	2 months	3 months	4 months	6 months	End
Femur	2	5	10	12	14
Tibia	0	7	15	18	21
Humerus	1	3	5	8	10
Radius	1	3	4	4	4
Ulna	0	0	1	1	1
Total success rate	6.1%	27.3%	53.0%	65.2%	75.8%

Success rate = BU number/all the patients followed

Statistics Mean and standard deviation were calculated for continuous variables.

Results

No systemic complications were observed. Local complications included petechiae and haematoma formation smaller than 3 cm. These complications disappeared in a few days with only ice pack treatment. No neurovascular problems were observed. No narcotics or analgesics were required after treatment.

Sixty-six patients (41 males and 25 females) were followed for 6–90 months. Three patients, including two hypertrophic nonunions of tibiae and one hypertrophic nonunion of humerus, were lost to follow-up 2 months after ESWT and were excluded from our analysis. Fifty of the 66 patients achieved bony union and the total success rate was 75.8%. All atrophic nonunions failed while 90.9% (50/55) of the hypertrophic nonunions achieved bony union. All of the 16 patients which failed had reoperations 3–8 months after ESWT and 13 achieved bony union but three patients still had poor results. Table 2 shows the detailed results of the bony union number and success rate at different follow-up times treated by ESW.

Most of the successful patients achieved bony union at 3 and 4 months after ESWT as shown in Table 2. In Figs. 2 and 3 we can see obvious callus formation and bony union at 3 months after ESWT.

Discussion

In this study, nonunion was defined as a failed bone healing of more than 6 months after fracture or previous operation, with obvious bone loss seen in the subsequent photographs. Pseudarthrosis, delayed union, and nonunion of acute infection were excluded. When analysing the literature, it becomes evident that the appreciation of nonunion and pseudarthrosis varies. According to the AO–Principles of Fracture Management, delayed union describes the situation where there are distinct clinical and radiological signs of prolonged fracture healing time. Pseudarthrosis is defined as formation of a false joint where a fibrocartilaginous cavity is lined with synovium producing synovial fluid [11]. Of course sometimes it is hard to distinguish nonunion from delayed union and pseudarthrosis, so at least two subsequent radiographs are necessary and useful.

The mechanism of shock wave in bone nonunion is still not clear. ESWT may produce microfractures of bone [5, 7], which, in turn, can stimulate neovascularisation, osteoblast formation, and bone healing. Scheberger and Senge thought ESW had a biological effect on bone derivation, which led to the bone creeping substitution of the scar between bone fracture terminals and finally led to bony healing [14]. The irritation of the fracture produces inflammatory medium and bone growth factor, which recruit bone blast cells and fibroblasts in the medullary cavity or around the parenchyma. And the aggregation and proliferation of the bone blast cells and fibroblasts can promote bone healing. Wang et al. reported that shock waves can promote osteogenic differentiation of mesenchymal stem cells through superoxide-mediated signal transduction [20]. Bone morphogenic proteins (BMP) play an important role in signalling ESW-activated cell proliferation and bone regeneration of segmental defects [21]. A further

Fig. 2 **a** Radiograph of the left tibia of a 55-year-old woman showing nonunited fracture 9 months after the initial open reduction and internal fixation. **b** Radiograph of the same tibia taken 2 months after treatment with 6,000 shock wave impulses showing visible callus formation

Fig. 3 **a** Radiograph of the right radius of a 29-year-old woman showing nonunited fracture 10 months after the initial open reduction and internal fixation. **b** Radiograph of the same radius taken 3 months after treatment with 3,000 shock wave impulses showing bony union

study suggested that TGF-beta 1 and VEGF-A play a chemotactic and mitogenic role in recruitment and differentiation of mesenchymal stem cells [19]. Extracellular signal-regulated kinase (ERK) and p38 may play important roles in communicating physical ESW stimulation into intracellular mitogenic responses [3].

The effectiveness of ESWT on nonunions varied from 50% to 90%. Some of the researchers recommended it as a first treatment choice of nonunion and delayed bone healing or pseudarthrosis [13, 17]. We believe that the different indications for selection and different machines contributed to the different results. Wang et al. treated a total of 72 patients with nonunion of long bone fractures with Ossatron [17]. They found 40% of the fractures healed after 3 months, 61% after 6 months, and 80% after 12 months. Furthermore, shock wave treatment was most successful in hypertrophic nonunion and bone defect, and was the least effective in atrophic ones. The success rate is close to that of traditional treatment. Schaden et al. also reported a 76% success rate with ESWT in 115 patients with nonunion in fractures that were treated nonoperatively [13]. Both of the two studies suggested that ESWT was a better method for treating nonunion with a defect smaller than 5 mm. In our opinion a defect of more than 5 mm with partial bony union may also be treated by shock wave. As shown in Fig. 4, a large bone defect finally closed 4 months after the ESWT. During ESWT the treatment point was located at the edge of the defect. But in some patients with evident fracture line we did not get satisfactory results. We think that ESW may be used in bone defects while partial bony connection can still be observed. In this study, only 14 patients failed and the total success rate was 75.8%. The success rate of hypertrophic nonunions was 90.9%, which is close to the traditional treatments.

Although ESWT, according to some reports, can be used as the first choice in nonunions of long bone, we still think it should be restricted to specific indications. First, the diagnosis of hypertrophic or atrophic nonunion is essential. We do not recommend ESWT as a single treatment of atrophic nonunion. Of course, sometimes there is dispute.

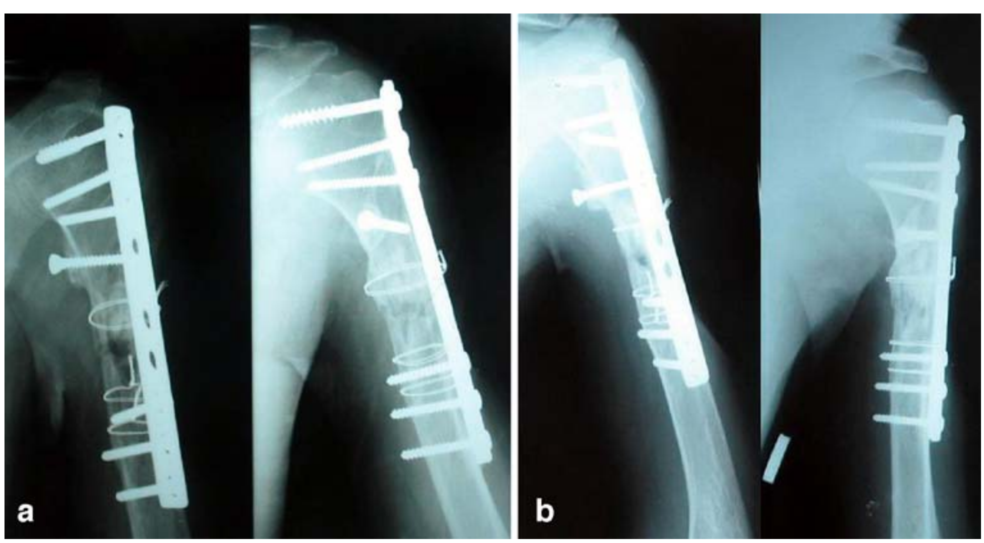

Fig. 4 **a** Radiograph of the left humerus of a 27-year-old man showing nonunited fracture 12 months after the initial open reduction and internal fixation. **b** Radiograph of the same humerus taken 4 months after treatment with 4,000 shock wave impulses showing the defect decreased

The second contraindication is when we decide that bone grafting is required. An inappropriate selection of treatment may mean the delay of recovery and the loss of function. Three months postoperatively almost all of the patients who achieved bony union had obvious changes such as new callus formation, decreased fracture gap, or pain alleviation at the fracture location. All of the failed patients had no change in radiographs after 3 months, so we always recommended bone grafting operations to them. Though some of the failed patients still waited for 8 months after ESWT, there were no obvious changes. Computed radiography may be useful to evaluate the callus formation and the sclerosis of the fracture site. Standard anteroposterior and lateral radiographs are important because they are the only objective evidence. A second ESWT is not necessary if there is no evidence of improvement in radiographs unless there are contraindications to an open operation.

In summary, ESWT has many advantages including avoidance of surgery and safety. It is especially effective for hypertrophic nonunions of long bone, while the atrophic nonunions may be not suitable for ESWT. A further study should be directed towards documentation of the standard indications for ESWT.

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