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Extracorporeal Shock Wave Therapy of Nonunion or Delayed Osseous Union

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One hundred fifteen patients with nonunions or delayed fracture healing were treated with high-energy shock waves. After shock wave treatment, immobilization of the fracture also was done. The followup was at least 3 months and as long as 4 years. In 87 patients (75.7%), one treatment with shock waves resulted in bony consolidation with a simultaneous decrease in symptoms. Besides negligible local reactions (swelling, hematomas, petechial hemorrhages), no complications were observed. The treatment was noninvasive, and personnel and technical requirements were not problematic. The authors concluded that the application of extracorporeal shock wave therapy should be the first choice of treatment for patients with nonunions and delayed bone fracture healing.

In the treatment of urolithiasis, higher shock wave intensities and shock wave frequency were necessary for disintegration of concrements that were covered by bone.[10] The question arose as to what effect the absorption of the shock wave energy would have on the bony structure. Numerous investigators approached this problem.

The first group of investigators examined the effect of shock waves on the intact bone structures of rabbits and beagles.[4,5] Physical pressure measurements of the shock waves in the bone were taken and histologic sections of the pelvis (rabbit) exposed to the shock waves showed the influence on bone at the microscopic level. The shock waves were dampened and absorbed in the cortical bone, and even more strongly in the cancellous osseous tissues. The mechanical energy released at the interface of media with acoustically different densities showed its effect mainly in the cancellous part of the bone. Selective destruction of osteocytes, microfractures of trabeculae, and minor bleeding in the medullary space were observed. Approximately 3 weeks after exposure to the shock waves, thickening of the cortex, increase in the number of bony trabeculae, and a significant increase in the number of osteoblasts and their activity were observed. From these observations, it was hypothesized that shock waves could be used for stimulation of bone growth in patients with pseudarthrosis.

Another group investigated the effect of shock waves on artificially produced humeral fractures in rats.[7] Additional groups investigated the effect of shock waves on growth plates in animals[20] and bone development in infant rats[16] and on metallic implants.[8,9,19]

Subsequently, the first human trials were done, although no proof of the shock wave effect on a standardized fracture model was available. Dose-dependent osteogenesis with a significant transformation into lamellar, stable bone was confirmed by fluorescent mi-

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croscopy and histologic evaluation [3] These initial human applications were done using urologic lithotripters—an unsatisfactory and laborious procedure. Early clinical results were reported from 1991 to 1992.[1,2,6,15,18] Encouraged by these results, the development of special shock wave devices for orthopaedic and traumatologic use and their clinical applications began in 1991 and 1992.[1,11-14]

The current authors describe the early results in the application of high-energy shock waves using a device specifically designed for orthopaedic use. In particular, the treatment of delayed union and nonunion of fractures with such shock waves was assessed.

MATERIALS AND METHODS

Since January 1995, 115 patients with nonunions or delayed fracture healing were treated. There were 41 females between 15 and 85 years (mean, 47.1 years), and 74 males between 10 and 86 years (mean, 40.6 years). In 35 patients, the delay from the initial injury or the last operation was 3 to 6 months (delayed healing), and in 80 patients, it was more than 6 months with a range of as many as 25 years (nonunion). There were 72 shaft fractures in long bones and 43 fractures in cancellous bones. In 23 patients, initial fracture treatment was conservative, whereas 92 patients had operative treatment. Of these, 28 patients were operated on twice, and 25 patients were operated on three times or more. Twenty-two patients had deep wound infection before shock wave therapy, although none had evidence of active infection at the time of shock wave treatment. Numerous kinds of osteosynthetic devices were used for open reduction and internal fixation. In 60 patients, the devices still were present at the time of shock wave exposure.

Contraindications

If one of the seven exclusion criteria given below were present, shock wave treatment was contraindicated: (1) epiphyseal plate within the shock wave field; (2) coagulopathy; (3) acute infection; (4) alveolar tissue or (5) brain or spine within the shock wave field; (6) pregnancy; and (7) malignant tumor within the shock wave field. During shock wave application focusing the shock wave over large vessels or nerves was avoided.

Hospitalization

All patients were given precise information on the shock wave therapy before the application. On the day of admission, preoperative preparations were done. Twenty-five patients were treated on the day of admission, and the others were treated the following day. The patients' hospital stay was 2 to 3 days. In retrospect, with suitable preparation, almost all patients could have been treated as outpatients, or with an overnight hospital stay.

Anesthesia

Because of the pain associated with extracorporeal shock wave therapy, anesthesia was necessary for fracture treatment. Sixty patients were given general anesthesia (52.2%), and 51 patients were given a regional anesthetic (44.3%). Of these, 29 patients had plexus anesthesia, and 22 patients were given a spinal anesthetic. Four patients were treated with local anesthesia.

Treatment Procedure

All patients received one shock wave treatment. After therapy, the fractures were immobilized with a cast or splints. In most cases, the patients already had osteosynthetic devices implanted previously. If the implanted devices showed no signs of loosening and it could be assumed that the fracture was stable, external fixation was not used.

The shock wave intensity and the number of shock waves applied were selected according to the area of the fracture gap and the cross section of the bone to be treated. Scaphoid bone was treated with a considerable lower impulse strength of 0.25 to 0.35 mJ/mm^2 (20–24 kV) and a smaller number of shock waves (1000–2500 shock waves). Tibias and fermurs were treated with the highest energy flux density of 0.4 mJ/mm^2 (28 kV) and the maximum number of shock waves (12,000 shock waves); applied with a frequency of four pulses per minute.

The shock wave energy was selected according to the volume of bone per fracture area. To achieve stimulation of the fracture area as uniform as possible, the shock wave energy was positioned in the plane of the fracture, and the total energy from different directions was divided into approximately equal parts from two to 24 directions. In the case of hand and foot bones, adjustment in different directions frequently was not possible because of anatomic reasons, so the shock waves were directed along the fracture line by moving the focus at the field.

All treatment was done in an operating theater. The patient was placed on an operating table. The extremity to be treated was placed in such a way that the shock wave head could be positioned correctly with the simultaneous use of an image intensifier (BV 25, Philips, Endhoven, The Netherlands). The fracture was localized with the image converter, and the coupling of the water cushion was done using commercial ultrasound gel.

After each 500 to 1000 shock waves, a new direction was selected or the positioning was checked. If osteosynthesis (soundproof) material such as a plate was present at the fracture point, the shock wave direction was selected in such a way that the metal parts did not shield the energy from the fracture.

Fractures were treated with a maximum of 12,000 shock waves. Treatment lasted approximately 20 to 60 minutes.

To ensure healing of the fracture, adequate immobilization was necessary. In 81 patients (70.4%), the fracture was fixed by a cast or splint after treatment. In patients with implants still in position, a cast also was used if there were signs of the material becoming loose. The immobilization time was selected individually, depending on the type and localization of the fracture. The followup was 18 months (range, 3–48 months).

RESULTS

The case histories of all patients and the relevant radiographs were available on the day of admission. After treatment, radiographs were obtained at intervals of 4, 8, and 12 weeks. The total followup was 3 months to 4 years.

The results of shock wave treatment of all 115 patients are summarized in Table 1. There was no significant difference among the success rates of the group of patients with delayed fracture healing (26 patients; 74.3%), patients with nonunions (61 patients; 76.3%), and patients with previously infected nonunions (17 patients; 77.3%).

Nonresponsive Fractures

Those fractures that were not consolidated through shock wave treatment (28 patients; 24.3%) were checked for possible reasons for absence of osseous response (Table 2). Retrospectively, of the 28 fractures, nine fractures (7.9%) were classified as unsuitable for the shock wave treatment. A fracture can be described as unsuitable if the fracture gap has a width greater than 5 mm, or there is a defective zone greater than 5 mm in diameter. Additionally, fractures that could not be immobilized adequately also were deemed unsuitable. Two patients (1.7%) were in the category of no or inadequate immobilization. In two patients, reoperation was done as early as 4 and 6 weeks after shock wave treatment. Those two last groups included four patients whose after-treatment was not done by the authors.

TABLE 1. Types of Fractures and Treatment Outcome After Shock Wave Therapy

Region	Number	Osseous Union	Persistent Nonunion
Tibia	34	26	8
Ulna	9	7	2
Humerus	5	1	4
Scaphoid	21	14	7
Femur	12	11	1
Radius	5	4	1
Talus	2	2	
Knee	2		2
Ankle	9	9	
Elbow	4	3	1
Finger	7	6	1
Midfoot	3	2	1
Femural neck	1	1	
Pelvic osteotomy	1	1	
Total	115	87	28
Percent	100%	75.7%	24.3%

TABLE 2. Possible Reasons for Lack of Shock Wave Response

Reason	Number	Percent
Unsuitable	9	7.9%
No or inadequate immobilization	2	1.7%
Reoperation too early	2	1.7%
New trauma	1	0.8%
Unclear	14	12.2%
Total	28	24.3%

One patient suffered an additional trauma in the consolidation phase of a fracture of the shaft of the humerus 8 weeks after treatment. In 14 patients (12.2%), the reasons for absence of consolidation could not be determined.

The failures could be reduced to 13% or less if a strict selection of patients and a correct after-treatment was done. This was partly taken into account with the last 32 patients, of whom 28 (87.5%) achieved osseous healing.

No general correlation of the applied shock wave energy to healing success can be determined because of the extremely heterogeneous fracture cases and the small number of patients.

In correlating the positive results and the therapy failures, neither a connection with the age of the patient nor with the age of the fracture was observed. Individual conditions such as fracture gap width, adequate stabilization, and the energy introduced seemed to have a decisive effect on bone growth stimulation with shock waves.

Side Effects

The shock wave treatment had no negative effects on anesthesia. The following direct side effects from the shock wave energy were observed: local hematomas, petechial hemorrhages, and local swelling.

The hematomas occurred mainly when high shock wave energies and impulse numbers were used. No hematomas were found below 0.25 mJ/mm^2 (20 kV) and approximately 1500 shock waves. Even petechial hemorrhages were very rare; below 0.25 mJ/mm^2 (20 kV) and 1000 shock waves. Apart from the irradiated energy, bubble-free coupling with ultrasound gel is necessary for reducing the provocation of petechias and hematomas, particularly because these bubbles absorb a large amount of the applied shock wave energy. Patients with a lot of hair at the shock wave entry position were shaved locally, to facilitate air bubble-free coupling. The largest hematomas had a diameter of approximately 5 cm, and the petechial hemorrhages were 1 to 3 mm. The hematomas and the petechias healed without treatment and without complications within 5 to 7 days. The local swelling also subsided within a few days.

In none of the patients nerve or vascular lesions were found after treatment.

Pain Observation

Most patients had no complaints (or fewer complaints than before the treatment) immediately after treatment and on the day of discharge. In rare cases, the complaints were described as unchanged. No patient complained of increased pain. Typically, the pain complaints increased again after 3 to 4 weeks, and then subsided once more after consolidation of the fracture. Generally, the pain level did not reach the initial level again. Some patients remained symptom-free from the onset of shock wave treatment.

DISCUSSION

One hundred fifteen patients with nonunions or fractures with delayed healing had one treatment with shock waves done under general, regional, or local anesthesia. In 87 patients (75.7%), this resulted in bony consolidation with a simultaneous decrease in symptoms. Besides the negligible local reactions (swelling, hematomas, petechial hemorrhages), no complications were observed. In particular, the treatment resulted in no provocation of infection or nerve or vascular lesions. The treatment was noninvasive, and personnel and technical requirements were not problematic.

Therefore, it is concluded that the application of extracorporeal shock wave therapy should be considered as the first choice in the treatment of nonunions and delayed bone fracture healing.

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