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Application of extracorporeal shock-waves in the treatment of pseudarthrosis of the lower extremity

Preliminary results

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Abstract Between January 1991 and January 1996, pseudarthroses of the legs were treated prospectively in 48 patients by application of high-energy extracorporeal shock waves with an experimental device. The mean duration of pseudarthrosis was 12 months. On average, 2.4 surgical interventions had previously been performed. A total of 3000 impulses with an energy density of 0.6 mJ/mm^2 was applied to the pseudarthrosis. Bony union was achieved in 60.4% of our patients after an average of 3.4 months. Failures were found especially in the atrophic types of pseudarthrosis as well as in congenital bone disorders like fibrous dysplasia or osteogenesis imperfecta. No serious complications were observed. Even after numerous surgical interventions high-energy extracorporeal shock-wave therapy showed a fair success rate. A higher success rate of this non-invasive method for the treatment of bony non-unions may be expected by applying strict selection criteria.

Introduction

Even with advanced concepts of conservative treatment and sophisticated implant designs, the rate of disturbances in bone and fracture healing has remained at a constant level of approximately 5% [2]. In addition, elective surgery as for correction of axial deformities leads to non-union in 1%–2%.

With a success rate of between 86% and 94%, surgery using internal and external fixation devices as well as bone grafting is still the golden standard in the treatment of pseudarthroses.

While searching for alternative treatment modalities, Valchanou and Michailov [28] and Schleberger and Senge [25] introduced high-energy extracorporeal shock-wave therapy (ESWT) as a minimally invasive method for the treatment of delayed bone healing and pseudarthrosis. The purpose of the present study was to evaluate the success rate of this method critically and to establish selection criteria.

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Patients and methods

Between January 1991 and January 1996 48 patients with a pseudarthrosis of the legs were treated. Only non-unions with a history of more than 6 months were included [30]. Exclusion criteria were: acute osteomyelitis, defects close to growth plates, pathological fractures as well as coagulation disorders, pregnancy and malignancy. ESWT was applied using an experimental device, the Siemens Osteostar (Siemens AG, 91052 Erlangen, Germany), which integrates an electromagnetic shock-wave generator in a mobile fluoroscopy unit. The shock-waves are generated by passing a strong electric current through a flat coil. This induces a magnetic field, which itself induces another magnetic field in a metal membrane overlying the flat coil. Just as similar poles repel each other, so do the generated magnetic fields of the membrane and the coil. By means of an acoustic lens, the focus of the shock-wave source is identical to the center of the C-arch. The focal area of the shock-waves is defined as the area in which 50% of the maximum energy is achieved. It has a length of 50 mm in the direction of the shock-wave axis and a radius of 3.5 mm in the direction perpendicular to the shock-wave axis.

With the exception of one child, in all patients the application of shock-waves was done under regional anaesthesia (3-in-1 block, plexus or epidural anaesthesia) during a short hospital stay. Three patients needed additional pain medication. Once the pseudarthrosis was situated in the center of the C-arch, the shock-wave unit was docked to the skin by means of a water-filled cylinder. Common ultrasound gel (University Hospital, Mainz, Germany) was used as a contact medium between cylinder and skin.

Subsequently, all patients were treated by a single application of 3000 impulses with an energy density of 0.6 mJ/mm^2. The positioning of the focus was changed 3–5 times in each case in order to minimalize local complications and to confirm that the position was correct. The target area consisted of the pseudarthrotic gap and the adjacent cortical structures. The duration of treatment varied between 35 and 65 min. Aftertreatment predominantly involved applying a cast. Follow-ups were done 3, 6, 12, 18, 24 and 52 weeks after ESWT.

Results

The mean age of the 23 women and 25 men was 38 years (range 12–81 years). The mean duration of non-union was

Table 1 Results of surgical treatment of pseudarthrosis

Reference	Localization	Surgical method	Success rate
Cattaneo [4]	Humerus	Ilizarov external fixator	86%
Warren [29]	Tibia	Intramedullary nail	93%
Wiss [31]	Tibia	Intramedullary nail	89%
Simon [27]	Tibia	Posterolateral bone grafting	92%
Bhan [3]	Tibia	Percutaneous bone grafting	86%
Rijnberg [18]	Tibia	Iliac bone graft	94%

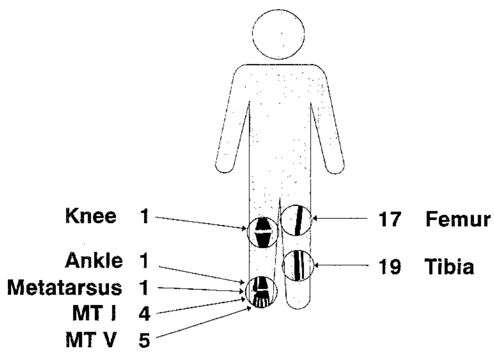

Fig. 1 Localizations of pseudarthroses treated

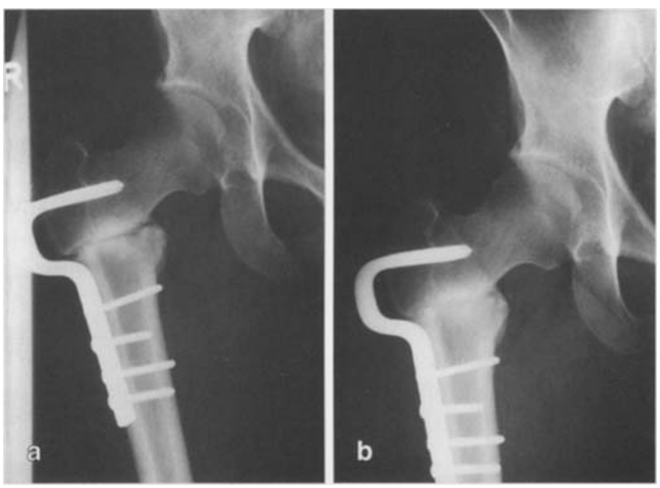

Fig. 2 a Pseudarthrosis of right femur in a 22-year-old man 10 months after varus osteotomy. **b** Bony consolidation 4 months after high-energy extracorporeal shock-wave therapy

12 months (range 6–48 months). On average, 2.4 operations had previously been performed. Eight patients initially suffered from an infected pseudarthrosis. Non-unions of the tibia and femur predominated with 73% (Table 1), with 24 lesions located on each side (Fig. 1).

After a mean of 3.4 months (range 2–9 months), in 29 patients (60.4%) complete healing of the pseudarthrosis was documented radiologically. Two cases are demonstrated in Figs. 2 and 3. No serious complications were seen in the group. Side effects consisted of a few petechia, dermal erosions and local oedema requiring no further treatment. All patients were mobilized the day after ESWT.

Fig. 3 a Pseudarthrosis of right base of first metatarsal in a 43-year-old woman 8 months after two failed closing wedge osteotomies. **b** Bony consolidation 3 months after high-energy extracorporeal shock-wave therapy

Treatment failures especially involved the atrophic type of pseudarthrosis and congenital bone disorders like fibrous dysplasia and osteogenesis imperfecta.

Discussion

In the treatment of pseudarthroses, surgery using sophisticated fixation devices like intramedullary nails, Ilizarov external fixator and unilateral fixator still represents the golden standard. Cattaneo et al. [4] reported bony consolidation of humerus pseudarthroses in 86% using the Ilizarov external fixator. The treatment of femoral non-unions with intramedullary nails by Wu and Shih [32] was successful in 88%. In tibial non-unions, bone transplantation alone was successful in 85%–93%, while the use of intramedullary nails showed success rates of between 89% and 93% [3, 22, 29, 31].

Nevertheless, the problems of operative treatment like the risk of anaesthesia, general risks of operation and failure of fixation devices must not be forgotten. In addition, local complications (e.g. soft-tissue infection, haematoma, nerve and vascular damage) in the often necessary autogenous bone transplantation occur, this so-called donor-site morbidity ranging from 6% to 20% [34].

In search of less invasive alternative or supplementary methods in the sense of non-operative osteoinduction for a faster bony consolidation, two methods have been recently recommended: electric and electromagnetic stimulation [7] and high-energy ESWT led to bony consolidation even in single cases of non-union after numerous failures with previous surgery.

At the beginning of the 1990s, the first reports were published on the use of ESWT for more than the already established disintegration of kidney and gall stones. Valchanou and Michailov [28], Schleberger and Senge [25], Haist et al. [11] and Kaulesar Sukul et al. [15] introduced the high-energy form of ESWT for the treatment of delayed and non-union of fractures, describing phenomena of local decortication and fragmentation with stimulation

Table 2 Experimental basis of extracorporeal shock-wave therapy: pro

Reference	Species	Effect
Graff [8]	Rabbit	Neogenesis of additional bone, induction of ossification in pseudarthrotic soft tissue
Ekkernkamp [5]	Sheep	Acceleration of fracture healing
Haupt [13]	Rat	Acceleration of fracture healing, increase of mechanical stability
Johannes [14]	Dog	Acceleration of healing in pseudarthrosis

Table 3 Experimental basis of extracorporeal shock-wave therapy: contra

Reference	Species	Effect
Graff [9]	Rabbit	Damage of osteocytes, bone marrow necrosis
Yeaman [33]	Rat	Epiphyseal dysplasia
Seemann [26]	Rat	Delay of bone healing
Augat [1]	Sheep	Reduction of mechanical stability
Perren [17]	Sheep	No proven bone neogenesis
Forriol [6]	Sheep	Delay of fracture healing

Table 4 Clinical studies involving high-energy extracorporeal shock-wave therapy

Reference	*n*	Localization	Previous surgical interventions	Success rate
Valchanou [28]	82	Various		85%
Schleberger [25]	4	Various	2	75%
Schleberger [24]	45	Various	9	91%
Haist [10]	40	Various		75%
Haupt [12]	30	Various		73%
This study	48	Lower extremities	2.5	60%

of osteogenesis. In the meantime ESWT has heen used successfully in the therapy of diseases like calcifying tendinits of the shoulder, epicondylitis of the elbow as well as for calcaneal spurs [16, 19–21].

Although the exact mechanism of shock-waves in bony defects is not yet completely understood, their net effect is the induction of calcifications in pseudarthrotic tissue and neogenesis of additional bone [8, 25]. Several authors, mainly in rat fracture models, independently demonstrated that therapy with low- and high-energy shock-waves leads to a stimulation of bone growth and acceleration of fracture healing [13]. Johannes et al. [14] described an accelerated healing of non-unions in dogs. A higher mechanical stability of the treated bone was shown in rats by Haupt et al. [13] (Table 2).

In contrast to the positive effects of shock-waves on bone healing, some authors found a delay after shock-wave treatment of experimentally produced defects [6, 34]. A reduction of mechanical stability after shock-wave therapy was described by Augat [1] (Table 3).

Although contradictory results with an acceleration of bone healing on the one hand as well as a delay of bone healing on the other were found in experimental animal models, all clinical studies published so far have reported high success rates of 75%–91% [19, 12, 24, 25, 28] (Table 4), which do not match our first experiences with this method. These success rates could not be confirmed in our study. We assume that one reason for this might be the fact that only non-unions according to the definition given by Wirth [30] with a duration of at least 6 months were included. All other authors except Schleberger and Senge [25] also included patients with a history of less than 6 months. Thus, one can presume that at least in a few cases only a delay in bone healing and not a real non-union was treated.

In addition, all authors reported repeated application of shock-waves in at least some patients. A positive effect in these cases can be assumed. In contrast, our patients received only a single treatment.

Moreover, the success rate in our study was negatively influenced by the inclusion of a case with a primarily poor prognosis: a patient with an indication for surgery (fracture of the neck of the femur and femoral head necrosis) was treated with ESWT because surgery was contraindicated. He suffered from a severe deterioration of lung function and was on continuous steroid medication for sarcoidosis.

Patients with congenital bone disorders like fibrous dysplasia, neurofibromatosis or osteogenesis imperfecta were included at the beginning of our study. In these special cases, ESWT failed without exception. By excluding them, the success rate of the single high-energy ESWT would have been 67%.

Moreover, the shock-wave generators used in the different studies vary in terms of the energy source and their transformation into acoustic waves. Therefore, a direct comparison of the energies applied is impossible. All authors treated non-unions at different localizations. For subgroups a reliable prediction of treatment success cannot be given with the exception of scaphoid non-unions, where Russo et al. [23] reported a successful therapy in 24 of 46 cases.

A tendency for a worse outcome in our own study was seen in cases, where tensile forces were put on the pseudarthrotic gap by muscle traction (e.g. fractures of the basis of the fifth metatarsal bone).

In summary, in the treatment of pseudarthroses, surgical therapy still represents the golden standard. At present, high energy ESWT still has to be regarded as experimental. Nevertheless, the clinical results published to date justify its use, especially considering its well-documented non-invasiveness and low complication rate. A higher success rate may be anticipated by strict exclusion of special cases and localizations with a primary negative prognosis. In controlled multi-centre studies, treatment parameters like the number of applied impulses and energy densities should be established for optimization of this therapy.

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