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Review

Shock wave therapy of fracture nonunion

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ABSTRACT

We have used the principles of extracorporeal shock wave therapy (ESWT) in the treatment of nonunion of fractures in 44 patients (49 bones).There were 35 males and 9 females with a mean age of 34 years(range14–70). Clinical and radiological assessment was performed at regular time intervals with a minimum follow up of 18 months. Most common sites involved were the femur and tibia. The average time from initial fracture treatment to intervention with ESWT was 11.9 months (6 months to 5 years). Thirty eight non-union sites had one session of treatment and the rest (11) had more than one session. Union was successful in 75.5% of cases at a mean time of 10.2 months (range 3–19). Failure in the remaining cases was due to more than 5 mm gap, instability, *compromised* vascularity (type of bone) and deep low grade infection; which was discovered at the time of surgical intervention when no signs of radiological healing occurred after 6 months from treatment. Failing sites were shaft of femur, scaphoid, neck of humerus and neck of femur. No local complications were observed.

Contents

Introduction

A shock wave can be defined as a sonic pulse with certain physical characteristics. It has high peak pressure and short life cycle of about 10ms.It has broad frequency spectrum in the range of 16–20MHz [1].

The shock waves could be one of three types, depending on the mechanism they are produced [1,2];

- Electrohydraulic shock wave (such as the HMT OssaTron machine).
- Electromagnetic shock wave (such as the Sonocur and Dornier Epos machine).
- Piezoelectric shock wave (such as the Piezoson by Wolf).

The energy generated by these methods may be: (a) low energy $<$0.27 mJ/mm^2; (b) medium energy 0.27–0.59 mJ/mm^2 or (c) high energy $>$0.60 mJ/mm^2.

Bone responds better to high energy, whereas soft tissues *respond* better to lower energy levels. Extracorporeal shock wave therapy (ESWT) is an intense, but very short energy wave which is faster than the speed of sound (1500 m/s), translated past the skin and superficial tissues, and is focused at the desired tissue depth.

Extracorporeal generated shock waves have been introduced in routine medical practice around 1982 to treat kidney stones [3].

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Since then their application has expanded in a number of medical disciplines [2–12].

In the trauma and orthopaedic discipline, extracorporeal shock wave therapy was used successfully in the 1980s for the treatment of pseudoarthrosis [2], and more recently in other applications, such as insertion tendonitis, avascular necrosis of the head of femur and other necrotic bone conditions [3].

The results of treatment of non and delayed union with extracorporeal shock wave therapy have not been consistent, *with success rates* ranging between 50% and 85% [9,10,13–17].

The aim of this study is to evaluate the effectiveness of ESWT in a series of patients presenting to our institution with nonunion.

Patients and methods

Between January 2006 to December 2009, patients who were treated with ESWT for non or delayed union of fractures were eligible to be included in the study. Inclusion criteria included type A1 and2 nonunion, according to Weber and Cech [2] and patients who had nonunion after surgical procedures; i.e., osteotomies, as well as those previously treated, either non-operatively or by *open reduction internal fixation* (*ORIF*).

Exclusion criteria, included active infection and types A3, B1,2 and 3,and sites were open physis was *still present*.

Treatment protocol

We *used* shock wave device OssaTron (HMT High Medical Technologies AG) with movable therapy head of about 350° degree (Fig. 1).

Fig. 1. Illustrates shock wave device.

After machine preparation and fixing the limb or site of nonunion, the nonunion was marked in 2–3 areas using X-ray machine (Fig. 2).

The number of pulses depended on the site. We used 3000–4000 pulses for Femur, Tibia, Fibula, Humerus and 2000–3000 to other smaller bones. The frequency was set to 4 s^{-1} with 26 kV.

The number sessions of ESWT were as follows:

1) One session—38 bones.
2) Two sessions—9 bones.
3) Three sessions—2 bones.

Fig. 2. (a–c) Limb positioning and marking prior to initiation of ESWT treatment.

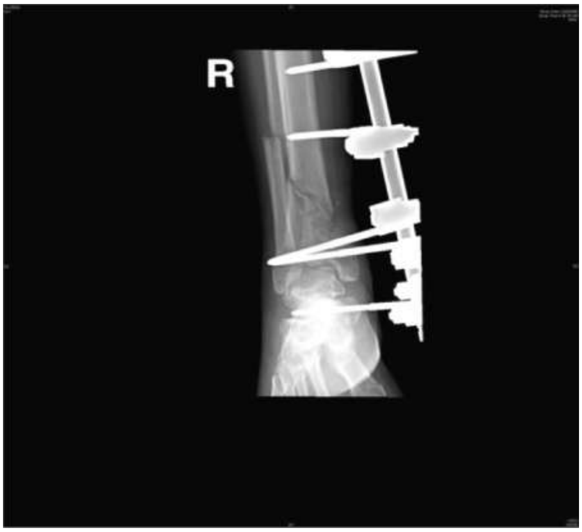

Fig. 3. Tibial nonunion.

Fig. 4. Clavicular nonunion.

Every session lasted for 15–20 min depending on number of pulses.

The follow-up at the outpatient clinic was every 6 weeks for the first 6 months, and every 3months thereafter with new X-rays taken every visit in at least anteroposterior and lateral planes. *Progress of healing was evaluated by assessment of the amount of crossing trabeculae and callus formation. Range of motion of the affected extremity was also recorded as well as the amount of pain using visual analogue scale (VAS) from 0 to 10, with 0 being no pain and 10 being the presence of extreme pain.*

Out of all patients treated, 4 were from other institutions. One patient had been managed with external fixation (tibial fracture, Fig. 3), while the other 3 had non-operative treatment (1 with mid shaft clavicular fracture; Fig. 4), 1 with fracture 5th metatarsal base and 1 with a missed scaphoid fracture.

Union was considered progressing if there *was* callus formation (secondary healing) or crossing trabeculae in rigidly fixed fractures (primary healing) [2]. If there was progressive healing, no more sessions *were* given, but if the radiological signs were halted, then another ESWT session was planned.

Interval time between sessions was a period of 12 weeks. Post operatively, patients with lower limb nonunion were kept non-weight bearing for 6 weeks or longer when healing signs have been delayed. In cases where there was no internal fixation, immobilisation by cast was used for at least 6 weeks or until healing.

Local complications such as formation of haematoma, petechial haemorrhage, swelling, deep vein thrombosis and superficial infection when developed were all recorded.

Patients were followed up for a minimum of 18 months from start of treatment, (range18–24 months).

Table 1
distribution of anatomical sites and No. of sessions.

Site	Number	Sessions		
		One	Two	Three
Shaft of femur	22	21	1	
Shaft of tibia	8	8		
Neck of femur	5	3	2	
Humerus	4	3	1	
Scaphoid	4		2	2
Clavicle	1	1		
Base of 5th.metatarsal	1	1		
Subtrochanteric osteotomy	1	1		
Intertrochanteric osteotomy	1		1	
High tibial osteotomy	2		2	
Total	49	38	9	2

Results

In total 44 patients with 49 nonunions who met the inclusion criteria, formed the basis of the study (Table 1).

Forty six out of 49 nonunions had previous treatments before ESWT application which included; ORIF (43), cast (2), and external fixation (1). Out of the 44 patients who had previous surgeries, 28 had one surgery, 9 had two, 4 had 3 and 3 had 5 surgeries.

Bony healing occurred in 37 out of 49 bones (75.5%), at a mean time of 10.2 months (range 3–19).

Analysis of causes of failure included the presence of mechanical instability (Fig. 5), nonunion gab larger than 5 mm (these cases were included as there was some calcification crossing the gap and there was narrower gap in one of the planes on X-ray, Fig. 6), type of bone (scaphoid), or because of the existence of low grade infection which was discovered when these patients were later operated and tissue cultures revealed staphylococcus epidermedis in 4 patients despite normal biochemical screening.

The 12 (24.5%) nonhealed cases are shown in Table 2.

The VAS preoperative mean was 3.4 (5–7), and postoperatively was 0.46 (0–2). For the lower limb cases, the mean knee ROM prior

Figure 5 and 6. Humeral instability and larger than 5 mm gap in a femur.

Fig. 6. (*Continued*).

to the intervention was 126° (range 109–140) and after the intervention was 146° (range 134–150).

The mean preoperatively elbow ROM was 112.5 (105–120) and 121.5 (113–130) postoperatively.

Discussion

Fracture healing is a complex process *facilitated* by the interaction of cellular elements activated by cytokines and *other molecular mediators*, resulting in formation of new bone which is structurally and mechanically similar to the pre-fracture state [18,19].

There is no universal definition of fracture nonunion. *Most* authorities would diagnose it if a fracture does not unite within the time *usually anticipated for the fracture to progress to healing. Usually delayed union is considered when the fracture fails to unite within 6 months and nonunion when union has failed within 9 months* [2,20].

The incidence of nonunion is very variable depending on site, type of fracture and whether it is closed or open, and ranges between 10% and 50% [22].

The causes of non or delayed union are variable, some are due to type of fracture and gap between ends, other causes related to *the compromised* vascularity of bone and soft tissue as well as host factors [3,20].

In this series of patients, we have included those who had no history of infection and were considered adequately fixed at *the* time of presentation. The non-invasive treatment options of nonunion includes ESWT, LIPUS, and electric stimulation [20,22]. The Low Intensity Pulsed Ultra Sound (LIPUS) is similar to the wave length used in diagnostic US, and is a kind of thermal treatment, whereas the ESW is a high *intensity*, short wave which is focused and can penetrate up to 10 cm [1,20,22]. In deciding *what* dose *to* be given, we have followed the recommendations *made* by previous *authors* [23–35].

With success rate of 86–94%, surgical treatment using either internal or external fixation with bone grafting is still considered the golden standard in treatment of nonunion [11,16]. The Diamond Concept, which *was recently introduced, provides an algorithm for promoting a successful fracture healing response* [21].

Nevertheless, surgical management of nonunion has been shown to be associated with several complications [20,22]. This has led to searching for alternative treatment modalities.

First animal studies on ESWT *carried out* in Germany *and subsequently the work* by Graff and Haist [2,3,23] *showed the positive effect of shock wave on bone healing.* Ekkernkamp has shown a dose-dependent osteogenesis and transformation from callus to mature bone effect of shock wave histologically and by fluorescence microscopy [18].

Krause has distinguished between a direct and indirect effect of the shock wave. The direct effect is due to the kinetic energy of the shock wave whereas the indirect effect is caused by cavitation [11]. According to different authors, ESWT influences the conduction ability of sensitive nerves through gate control mechanisms as well as influencing the metabolic activity of osteoblasts (phosphate turnover) [12,36–39].

Wang et al demonstrated the positive effect on bone healing and the positive effect of high energy shock wave; as compared to low energy; on callus size, BMD and bone strength in humans [36]. Wang have also shown that shock wave promotes bone marrow stromal cell growth and differentiation as well as mediating activation for osteogenesis in human bone marrow stromal cells [2].

In clinical studies, the success of shock wave therapy in treating non or delayed union varied (13,9,14,10–15,17), although the average was comparable to surgical intervention (76–79%), but without the hazards and complications of *operative procedures* [2,3].

Our results are comparable to others. We had a total bony healing average rate of 75.5% [2,10,14,15]. We had comparable results of failed union of humerus and scaphoid to those reported by other authors, and had excellent results in *the* treatment of tibia nonunion [10,14,15,40].

Our patients were *seen regularly for* follow up in the *appointment.* We had some difficulty with patients outside *the catchment area of the hospital*, but we phoned them and asked them to do X-rays in their city and to bring them on their next outpatient hospital visit. Fortunately, this only happened with a hand full of patients. Our failures were caused by four main causes, large gap between bone ends (as in the femoral shaft cases), instability (as in the humerus fixed with Nancy nails), compromised vascularity of the bone *as seen in specific fracture patterns* (scaphoid and neck of femur) and deep low grade infection. The infection cases could not be diagnosed by routine preoperative blood tests, and were only discovered on tissue cultures at *the* time of surgical intervention after failure of ESWT.

The limitations of this study include its retrospective nature, the relative small number of patients studied and the evaluation of healing of different anatomical sites.

Table 2
Site and cause of failure.

Site	Number	Percentage of total	Cause
Femoral shaft	8	36%	Low grade infection 4 More than 5 mm gap 4
Scaphoid	2	50%	Vascularity of bone
Humerus neck	1	25%	Instability
Neck of femur	1	20%	Vascularity

Conclusion

Based on the experience in this series of patients, the use of shock wave therapy can be considered as a non-invasive first line treatment for nonunion of fractures. Patient selection is very important. Fractures with gap of more than 5 mm should not be considered for this type of treatment, as well as those with suspected instability, either clinically or radiologically. Finally, in cases of atrophic fracture nonunion shock wave should be combined with bone grafting and stable fixation, because of the consistent low response of this type of nonunion to ESWT in literature [3,41].

Conflict of interest

None.

References

[1] Anna Toth-Kischkat A. Principles of shockwave therapy. In: Coombs R, Schaden W, Zhou S, editors. Musculoskeletal shockwave therapy. London: GMM; 2000. p. 3–10.
[2] Wang CJ. Extracorporeal shockwave therapy in musculoskeletal disorders. J Orthopaedic Surg Res 2012;7:11.
[3] Schaden W. Shockwave treatment for chronic non-union and pseudoarthroses. In: Coombs R, Schaden W, Zhou S, editors. Musculoskeletal shockwave therapy. London: GMM; 2000. p. 197–202.
[4] Alves EM, Angrisani AT, Santiage MB. The use of extracorporeal shock waves in the treatment of osteonecrosis of the femoral head: a systematic review. Clin Rheuma 2009;28(11):247–51. 1.
[5] Kong FR, Liang YJ, Oin SG, Li XL. Clinical application of extracorporeal shock wave to repair and reconstruct osseuos tissue framework in the treatment of a vascular necrosis of the femoral head (ANFH). Zhonggua Gushang 2010;23(1): 2–5. 1.
[6] Wang CJ, Wang FS, Yang KD, Weng LH, Huang HY. Treatment for osteonecrosis of the femoral head: comparison of extracorporeal shock waves with core decompression and bone grafting. J Bone Joint Surg-Am 2005;87(11):2380–7.
[7] Buchbinder R, Ptasznik R, Gordon J, Buchanan J, Prabaharan V, Forbes A. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis: a randomized controlled trial. JAMA 2002;288(11):1364–72.
[8] Speed CA, Nichols D, Wies J, Humphrys H, Richard CRurnet S, Hazioeman BL. Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomized controlled trial. J Orthop Res 2003;21(5):937–40.
[9] Haupt G. Use of extracorporeal shock wave in the treatment of pseudoarthrosis, tendinopathy and other orthopaedic diseases. J Urol 1997;158:4211.
[10] Valchanou VD, Michailow P. High energy shock waves in the treatment of delayed and non union of fractures. Int Orthop 1991;151:181–4.
[11] Birnbaum K, Wirtz DC, Siebert CH, Heller KD. Use of extracorporeal shockwave therapy (ESWT) in the treatment of non-union: a review of literature. Arch Orthop Trauma Surg 2002;122:324–30.
[12] Schelling J, Delius M, Gsehender M, Grafe P, Gambichler S. Extra-corporeal shockwaves stimulate frog sciatic nerves indirectly via a cavitation-mediated mechanism. Biophys J 1994;66:133–40.
[13] Wang CJ, Chen HS, Chen CE, Yang KD. Treatment of non unions of long bone fractures with shock waves. Clin Orthop Rel Res 2001;378:95–101.
[14] Schaden W, Fischer A, Sailer A. Extracorporeal shock wave therapy of non union or delayed osseous union. Clin Orthop 2001;387:90–4.
[15] Vogel J, Hoph C, Eysel P, Rompe JD. Application of extracorporeal shockwaves in the treatment of pseudoarthrosis of the lower extremity: preliminary results. Arch Orthop Trauma Surg 1997;116:480–3.
[16] Rompe JD, Rosendahl T, Schollner C, Theis C. High energy extracorporeal shockwave treatment of non unions. Clin Orthop 2001;387:102–11.
[17] Schleberger R, Senge T. Noninvasive treatment of long bone pseudoarthrosis by shock waves (ESWL). Acta Orthp Trauma Surg 1992;111:224–7.
[18] Giannoudis PV, Kanakaris NK, Einhorn TA. Interaction of bone morphogenetic proteins with cells of the osteoclast lineage: review of existing evidence. Osteoporos Int 2007;18(12):1565–81.
[19] Gerstenfeld LC, Cullinane DM, Barnes GL, Graves DT, Einhorn TA. Fracture healing as post-natal developmental process: molecular, spatial, and temporal aspects of its regulation. J Cell Biochem 2003;88(5):873–84.
[20] Lemaire R. Management of nonunion: an overview. In: Duparc J, editor. Surgical techniques in orthopaedics and traumatology. Paris: Elsevier; 2003. 55-030-F-10: 1–10.
[21] Giannoudis PV, Panteli M, Caroli GM. Bone healing: the diamond concept. In: George Bentley, editor. European instructional lectures, vol. 14. London: Springer; 2014. p. 3–16.
[22] Zimmermann G, Moghaddam A. Trauma: nonunion: new trends. In: George Bentley, editor. European instructional lectures, vol. 10. Madrid: Springer; 2010. p. 15–9.
[23] Wang CJ, Gau YL, Wang JW, Chin CY, Chen CE. The treatment of fracture nonunion by shockwaves. In: Coombs R, Schaden W, Zhou S, editors. Musculoskeletal shockwave therapy. London: GMM; 2000. p. 173–84.
[24] Lok V, Baloglu I, Aydinok H. Experience of shockwaves for non-union in Izmir. In: Coombs R, Schaden W, Zhou S, editors. Musculoskeletal shockwave therapy. London: GMM; 2000. p. 185–6.
[25] Schaden W, Fischer A, Sailler A. Single session shockwave treatment for 115 patients with delayed union or chronic non-union. In: Coombs R, Schaden W, Zhou S, editors. Musculoskeletal shockwave therapy. London: GMM; 2000. p. 203–18.
[26] Guimaraes A, Duarte JA, Fernandes ME, Vianna MB, Rocha Bonfim VF, Casado DC, et al. The effect of autologous concentrated bone-marrow grafting on the healing of femoral shaft non-unions after locked intramedullary nailing. Injury 2014;45(Suppl 5):S7–13.
[27] Santolini E, Goumenos SD, Giannoudi M, Sanguineti F, Stella M, Giannoudis PV. Femoral and tibial blood supply: a trigger for non-union? Injury 2014 ?Nov;45(11):1665–73.
[28] Pountos I, Panteli M, Panagiotopoulos E, Jones E, Giannoudis PV. Can we enhance fracture vascularity: what is the evidence? Injury 2014;45(Suppl 2):S49–57.
[29] Ollivier M, Gay AM, Cerlier A, Lunebourg A, Argenson JN, Parratte S. Can we achieve bone healing using the diamond concept without bone grafting for recalcitrant tibial nonunions? Injury 2015;46(7):1383–8.
[30] Rodrigues FL, de Abreu LC, Valenti VE, Valente AL, da Costa Pereira Cestari R, Pohl PH, et al. Bone tissue repair in patients with open diaphyseal tibial fracture treated with biplanar external fixation or reamed locked intramedullary nailing. Injury 2014;45(Suppl 5):S32–5.
[31] Calori GM, Colombo M, Mazza EL, Mazzola S, Malagoli E, Marelli N, et al. Validation of the non-union scoring system in 300 long bone non-unions. Injury 2014;45(Suppl 6):S93.
[32] Tay WH, de Steiger R, Richardson M, Gruen R, Balogh ZJ. Health outcomes of delayed union and nonunion of femoral and tibial shaft fractures. Injury 2014;45(10):1653–8.
[33] Ashman BD, Slobogean GP, Stone TB, Viskontas DG, Moola FO, Perey BH, et al. Reoperation following open reduction and plate fixation of displaced midshaft clavicle fractures. Injury 2014;45(10):1549–53.
[34] Hankenson KD, Zimmerman G, Marcucio R. Biological perspectives of delayed fracture healing. Injury 2014;45(Suppl 2):S8–15.
[35] Hak DJ, Fitzpatrick D, Bishop JA, Marsh JL, Tilp S, Schnettler R, et al. Delayed union and nonunions: epidemiology, clinical issues, and financial aspects. Injury 2014;45(Suppl 2):S3–7.
[36] Wang CJ, Yang KD, Wang FS, Hsu CC, Chen HH. Shock wave treatment shows dose-dependent enhancement of bone mass and bone strength after fracture of the femur. Bone 2004;34:225–30.
[37] Bruemmer F, Braeuner T, Huelser DF. Biological effects of shockwaves. World J Urol 1990;8:224–32.
[38] Melzack R. Prolonged relief of pain by brief, intense transcutaneous somatic stimulation. Pain 1975;1:357–9.
[39] Suhr D, Bruemmer F, Huelser DF. Cavitation generated free radicals during shockwave exposure: investigation cell-free solutions and suspended cells. Ultrasound Med 1991;17:761–8.
[40] Elster EA, Stojadinovic A, Forsberg J, Shawen S, Andersen RC, Schaden W. Extracorporeal shockwave therapy for nonunion of the tibia. J Orthop Trauma 2010;24:133–41.
[41] Ricardo Rodriguez de Olya J, Sanchez Benitez de Soto M, Munilla G. Shockwave treatment for chronic non-union. In: Coombs R, Schaden W, Zhou S, editors. Musculoskeletal shockwave therapy. London: GMM; 2000. p. 169–72.