

Shockwave Treatment in Acute Fractures of the Lower Extremity

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Background

High-energy long bone fractures are at risk of poor fracture healing and high rate of non-union ranging from 10% to 30%.

Many physical factors had been investigated to improve bone healing including electric stimulation, ultrasound, CPM and hormone therapy.

Most factors demonstrated limited effects in selected series, but none showed universal success.

Background

Extracorporeal shockwave is a new therapeutic modality with proven efficacy in bone healing.

The success rate in the treatment of nonunion of long bone fracture ranged from 65% to 85%.

Valchanou VD et al Int. Orthop 1991

Haupt G J Urology 1997

Vogel J et al Arch Orthop Trauma Surg 1997

Rompe JD et al CORR 2001

Schaden W et al CORR 2001

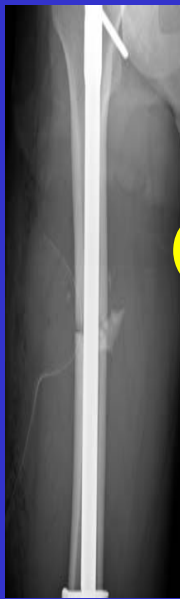
Wang CJ et al CORR 2001



However, the effects of shockwave in acute fracture is unknown.

Purpose of the Study

This prospective clinical study was aimed to investigate the effects of extracorporeal shockwave treatment in acute high-energy fractures of the femur and tibia in the lower extremity.



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Inclusion Criteria

Patients with acute displaced diaphyseal fractures of the femur and tibia from high-energy trauma that required open reduction and internal fixation were recruited in this study.

Exclusion Criteria

Patients with undisplaced fracture.

Patients with pathological fracture.

Patients with hematological coagulopathy.

Patients on immunosuppressant drugs.

Patients with active infection, local or remote.

Patients with cardiac arrhythmia or pacemaker.

Pregnancy.

Skeletal immaturity.

Patients with poor compliance.

Patient Recruitment

From January to October 2004, 56 patients with 59 acute high-energy fractures of the femur and tibia were enrolled in the study.

There were 40 men and 16 women with an average age of 34.2 ± 16.7 years (range 15 to 81).

There were 40 femur and 19 tibia fractures. Forty-two cases were closed fractures and 17 open fractures.

Three patients sustained ipsilateral fractures of the femur and tibia.

Patient Randomization

Patients were randomly divided into two groups with 28 patients (28 fractures) in the study group and 28 patients (31 fractures) in the control group.

In **the study group**, patients received open reduction and internal fixation for the respective fracture and shockwave treatment immediately after surgery under the same anesthesia on the odd numbered days of the week.

In **the control group**, patients received open reduction and internal fixation for the fractures without receiving shockwave treatment on the even numbered days of the week.

Patient Demographics

	Study group	Control group	Total
Patients / fractures	28/28	28/31	56/59
Average age (years)	35.5 ± 16.0	35.4 ± 19.2	34.2 ± 16.7
Sex: Male / Female	20 / 8	20 / 8	40 / 16
Side of fracture			
Right / Left	15/ 13	16/ 15	31/ 28
Location of fracture			
Femur	19	21	40
Tibia	9	10	19
Type of fracture			
Open Fracture	8	9	17
Closed Fracture	20	22	42
Type of internal fixation			
Nailing	21	28	49
Plate	7	3	10
Mechanism of injury			
Motorcycle	19	19	38
Falling accident	6	4	10
Motor vehicle	3	5	8
Average follow-up (months)	14.2 ± 3.1 (12 to 20)	14.1 ± 2.5 (12 to 20)	14.2 ± 2.8 (12 to 20)

Surgical Intervention

For closed fractures, open vs closed reduction with internal fixation with either intramedullary nailing or plate fixation were performed at the optimal time.

For open fractures, primary open reduction and internal fixation were performed for type I, II, III-A and III-B open fractures according to Gustilo's classification.

For type III-C open fractures, the initial treatments consisted of wound debridement and external fixator immobilization. Delayed open reduction and internal fixation were performed when the local condition optimized.

Case Demo



(Pre-Op.)



(Post-op.)



(Pre-Op.)



(Post-op.)

Shockwave Application

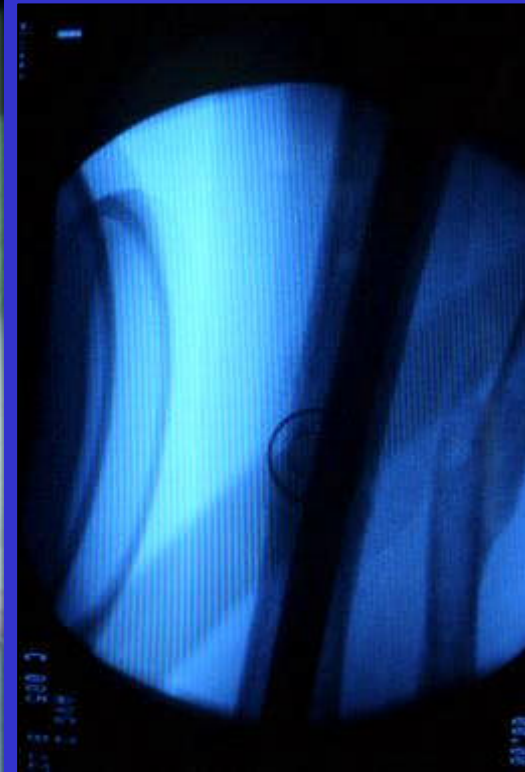
In the study group, shockwaves were applied immediately after open reduction and internal fixation under the same anesthesia.

The source of shockwave was from an OssaTron (High Medical Technology, Kreuzlingen, Switzerland)

A total of 6000 impulses of shockwaves at 28 Kv (= 0.62 mJ/mm²) were delivered to the fracture site in two different planes with equal dosage in each plane.

In the control group, no shockwave treatment was provided after open reduction and internal fixation for the respective fractures.

Application of Shockwaves



Postoperative Managements

Early ambulation with non-weight bearing on the operated leg until fracture healing on X-rays.

Range of motion and quadriceps and hamstrings muscle exercises to the affected leg as tolerated.

Partial weight bearing was permitted when there was partial fracture healing noted on radiographs.

Full weight bearing was permitted when complete fracture healing was confirmed with radiographs.

The same protocol of postoperative managements was applied to both groups.

The Evaluation Parameters

Follow-up examinations were scheduled at 1, 3, 6 and 12 months.

The evaluation parameters included clinical assessments of pain score and weight bearing status of the affected leg, and serial radiographic examinations to assess the healing status of the fracture.

Clinical Assessments

Pain score was based on the intensity of pain at the fracture site assessed subjectively with a visual analogue scale from 0 to 10 with 0 for no pain and 10 for severe pain.

The weight bearing status was defined as following;

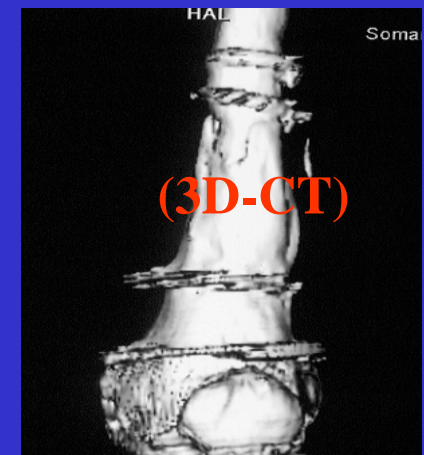
A **0%** weight bearing was assigned to patients ambulating on two crutches with non-weight bearing; a **25%** to patients ambulating on two crutches with partial weight bearing; a **50%** to patients ambulating with one crutch; a **75%** to patients walking with a cane and a **100%** to patients walking with no external support.

Radiographic Evaluation

Serial radiographs of the affected bone in A-P and lateral views were performed at 1, 3, 6 and 12 months.

The radiographs were used to assess the fracture alignment, callus formation and bony union with bridging bone tissues across the fracture site.

In case that complete fracture healing and bony union was in question on plain X-rays, a three dimensional computed tomography (3D-CT) was performed to confirm the healing status of the fracture.



Statistical Analysis

A power analysis revealed that a sample size of 25 would be required to establish the statistical significance under $\alpha = 0.05$ and power value = 0.8.

The rates of fracture healing at each of the time intervals at 3, 6 and 12 months within the same group were compared statistically using a paired t test. The data between the study and the control group were compared using a Mann-Whitney test with statistical significance at $P < 0.05$.

The **primary end-point** is the rate of established non-union at 12 months.

The **secondary end-point** is the rates of fracture healing at 3, 6 and 12 months.

The Results of Clinical Assessment

	Study(N=27)	Control (N=30)	P-vale ⁻⁴
At 1 week			
VAS (Range)	9.1±0.7 (8~10)	9.2±0.7 (8~10)	0.300
Weight bearing	0	0	
At 3 months			
VAS (Range)	3.3±0.9 (2~5)	4.1±0.7(3~6)	<0.001
Weight bearing	57.4±11.6(50~75)	49.2±16.7(25~75)	0.02
P-vale ⁻¹	<0.001	<0.001	
At 6 months			
VAS (Range)	1.2±0.7 (0~2)	2.5±0.6 (1~3)	<0.001
Weight bearing	87.0±12.7(75~100)	77.5±17.8(50~100)	0.01
P-vale ⁻²	<0.001	<0.001	
At 12 months			
VAS (Range)	0.2±0.5 (0~2)	0.8±0.9(0~2)	<0.001
Weight bearing	97.2±8.0 (75~100)	90.8±12.3(75~100)	0.01
P-vale ⁻³	<0.001	<0.001	

The Results of Radiographic Assessment

Time	Study group (N = 27)			Control group (N = 30)			
3 months	Femoral (N=18)	Tibia (N=9)	Total (N=27)	Femoral (N=20)	Tibia (N=10)	Total (N =30)	P-value- ³
Union	28% (5/18)	11% (1/9)	22% (6/27)	0	10% (1/10)	3% (1/30)	< 0.001
Non-union	72% (13/18)	89% (8/9)	78% (21/27)	100% (20/20)	90% (9/10)	97% (29/30)	
6 months							
Union	67% (12/18)	56% (5/9)	63% (17/27)	15% (3/20)	30% (3/10)	20% (6/30)	< 0.001
Non-union	34% (6/18)	44% (4/9)	37% (10/27)	85% (17/20)	70% (7/10)	80% (24/30)	
P-value ⁻¹			< 0.001			< 0.001	
12 months							
Union	83% (15/18)	100% (9/9)	89% (24/27)	70% (14/20)	100% (10/10)	80% (24/30)	< 0.001
Non-union	17% (3/18)	0 (0/9)	11% (3/27)	30% (6/20)	0% (0/10)	20% (6/30)	
P-values ⁻²			< 0.001			< 0.001	

Serial Radiographic Examinations

Preop.



Postop.



3 months



6 months



12 months



(Shockwave)



(Control)

Complications

Superficial wound infection occurred in 5 cases (2 in the study group and 3 in the control group).

Deep infection and subsequent osteomyelitis developed in two cases (1 in each group).

In the shockwave group, one case showed an over distraction with a 6.5 mm fracture gap noted on the postoperative x-rays and this case resulted in non-union at 12 months.

No DVT, fat embolism, pulmonary embolism or neurovascular complications.

No device-related problem, no systemic or location complications directly related to shockwave application.

Discussion

High-energy fractures in the lower extremity are at risk of poor fracture healing and high rate of non-union.

In this study, the rate of non-union after open reduction and internal fixation is 20% at 12 months which is comparable to other reported series.

Discussion

This study is the first to investigate the effects of physical shockwaves in acute high-energy long bone fractures of the lower extremity.

The results of this study showed the rate of non-union was 11% in the study group (shockwave plus surgery) versus 20% in the control group (surgery alone) at 12 months ($P < 0.001$).

Furthermore, significantly better and faster rate of fracture healing was observed in the study group at each of the different time intervals at 3, 6 and 12 months as compared with the control group.

Discussion

The exact mechanism of shockwaves in bone healing remains unknown.

The results of our studies demonstrated that the application of physical shockwaves induced the ingrowth of neovascularization and increased expressions of angiogenic growth factors including eNOS, VEGF, PCNA and BMP-2.

Neovascularization may play a role in the improvement in blood supply to the fracture site and promoting bone healing in acute long bone fractures of the lower extremity.

Conclusions

Currently, extracorporeal shockwave is only recommended in chronic non-unions of long bone fracture.

The results of this study showed that physical shockwaves accelerated bone healing and decreased the rate of non-union in acute high-energy fractures of the lower extremity.

Based on the results of this study, we recommend concomitant shockwave application and surgical stabilization may provide beneficial effects in the management of acute high-energy fractures of the lower extremity.

