International Journal of Surgery 24 (2015) 131–134

Contents lists available at ScienceDirect

International Journal of Surgery

journal homepage: www.journal-surgery.net

Extracorporeal shockwave therapy (ESWT) in the treatment of atrophic non-unions of femoral shaft fractures

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HIGHLIGHTS

- ESWT can be utilized for atrophic non-unions of femoral shaft fractures.
- The success rate of ESWT can be as high as 100%, if applied within 12 months after the initial treatment.
- ESWT will not jeopardize subsequent bone grafting surgeries, if ESWT fails.

ARTICLE INFO

Article history:
Received 26 March 2015
Received in revised form
16 June 2015
Accepted 30 June 2015
Available online 9 July 2015

Keywords:
Atrophic non-union
Augmentative plating
ESWT
Femoral shaft fracture

ABSTRACT

Introduction: As of now, the role of extracorporeal shockwave therapy (ESWT) in the treatment of atrophic non-unions is inconclusive. The purpose of the study was to investigate the effectiveness of ESWT and the role of this technology in the treatment of atrophic non-union of femurs.
Methods: We retrospectively analyzed 22 patients treated between July 1999 and September 2007 in our hospital with ESWT for atrophic non-unions of isthmic femoral shaft fractures that were initially treated surgically using closed reamed nailing procedure. Patients with open fractures, skeletal immaturity, on anti-osteoporotic medications, with infections, pathological fractures, smokers, with systemic disease compromising bone healing, and excessive deformity were excluded from this study. Due to incomplete follow-up one (1) patient who moved abroad after ESTW treatment was not included in this study and as part of the 22-patients cohort. Radiographs were obtained before treatment and once a month after treatment for 12 months.
Results: Using ESWT we showed that 14 fractures out of 22 (63.6%) achieved bony union with an average union time of 9.2 months (range 6–13 months). The union rate was 100% (8 of 8 cases) when ESWT was performed within 12 months from closed reamed nailing surgery versus 42.9% (6 of 14 cases) when ESWT was performed after 12 months from initial surgery. The eight (8) patients out of the total 22 patients cohort, who did not achieve bony union after ESWT, received subsequent treatment with bone grafting with augmentative plating surgery and all achieved bony union within 5 months after intervention.
Conclusion: For patients with atrophic non-unions of femoral shaft fractures, ESWT can be used as an alternative and effective non-invasive method of treatment. ESWT treatment does not negatively influence/compromise previous surgeries and if needed it can be followed by additional surgeries without any complications.

1. Introduction

The union rate following closed reamed intramedullary nailing surgery for severe femoral shaft fractures was reported as high as 99% in some studies [1]. Atrophic non-unions are less frequent

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http://dx.doi.org/10.1016/j.ijsu.2015.06.075
1743-9191/

than hypertrophic non-unions after femur shaft fractures. However, the treatments of atrophic non-unions can be challenging to most orthopedic surgeons, when compared to hypertrophic non-unions. The preferred surgical treatment options for non-unions of femoral shaft fractures include nail dynamization, exchange of nail, and augmentative plating [2]. Despite of the high success rate, the invasiveness inherent to these surgeries is a major concern [3] Therefore, the search for a non-invasive alternative to achieve bony union and avoid surgical morbidities associated with existing treatment options appears to be attractive. Extracorporeal shockwave therapy (ESWT) represents a non-conventional medical technology that has been used in treating with success various musculoskeletal disorders, including long bone fracture non-unions, without major complications and morbidities [4–8]. Previous studies have reported that the effect of ESWT is comparable to surgery for femoral hypertrophic non-unions [8]. In the case of femoral atrophic non-unions, as reported in several small clinical studies, the success rate of ESWT was not as good as for hypertrophic non-unions, and the use of ESWT for atrophic non-unions was considered controversial [7,9,10]. Furthermore, little is known on the outcomes of subsequent surgeries needed after ESWT did not achieve bony union and whether the ESWT produces any negative impacts on these surgeries. The purpose of this study was to analyze the clinical outcomes of 22 patients who developed atrophic non-unions of femoral shaft fractures after initial nailing surgery, patients that were afterwards treated with ESWT for their atrophic non-unions. We hypothesize that ESWT is a viable non-invasive modality for the treatment of atrophic non-unions of the femur shaft fractures, and if ESWT does not heal the non-union it also does not pose any new risks to necessary subsequent surgeries for fixing the atrophic non-unions.

2. Methods

2.1. Patient population

The Institutional Review Board (IRB number: 99-2794B) of our hospital approved this study. Individual informed consent was not required due to retrospective nature of the study. After the IRB approval was granted, we retrospectively reviewed and analyzed 22 patients treated in between July 1999 and September 2007 in our hospital with ESWT for atrophic non-unions of isthmic femoral shaft fractures, patients who initially had a closed reamed nailing procedure in order to close their femoral fracture.

We adopted the definitions presented by Elster et al. to define a non-union as: 1) a fracture that failed to achieve cortical continuity on three of four cortices after initial nailing for 6 months or more; or 2) a fracture that showed no radiographic progress towards union for 3 consecutive months and was associated with inability to bear weight on the affected extremity, pain on palpation, or motion at the fracture site 6 months after the initial trauma [11].

Furthermore, using the Weber-Cech classification (Fig. 1A and B) we defined an atrophic non-union as the absence of viable callus across the fracture gap. On the other hand a bony union was defined as the union where the callus is bridging the fracture site in more than three-fourths of the circumference on both anteroposterior and lateral views of the plain radiograph (Fig. 1C and D) [3,12]. Patients with open fractures, skeletal immaturities, on anti-osteoporotic medications, with infections, pathological fractures, smokers, with systemic disease compromising bony healing and excessive deformity (angular deformity exceeding 5° in AP or lateral view radiographs) were all excluded. We also excluded from this study the patients with incomplete follow-ups.

2.2. Treatment of atrophic non-unions

For all patients ESWT procedures were performed using an OssaTron device (SANUWAVE Health, Inc., Alpharetta, Georgia, USA) with a single treatment session. For each of these patients shockwaves were applied in two (2) planes at 45° and 60° angles relatively to longitudinal axis of the femur, where each plane received 3000 impulses at 28 kV energy setting that produces a maximum energy output in the treatment zone of 0.58 mJ/mm^2 energy flux density. For all these patients crutch-supported partial weight-bearing was suggested for 4–6 weeks. More details about the treatment of non-unions of long bone fractures with shockwaves have been previously reported [7] and the particulars of plate augmentation were reported by Choi et al. [12].

Radiographs of the femoral shafts were obtained before treatment and once a month after treatment, for a total of 12 months. The time interval between ESWT application and the first radiographic confirmation of the union was defined as the union time.

Patients who did not achieve bony union in 12 months after ESWT application were subsequently treated with plate augmentation and bone grafting surgeries. (Fig. 2A and B) For these patients the radiographic assessments of union time followed the same rule described for union confirmation after the ESWT application (Fig. 2C and D).

The results of radiographic assessments were based on the consensus of 2 independent orthopedic surgeons blinded to patient profiles.

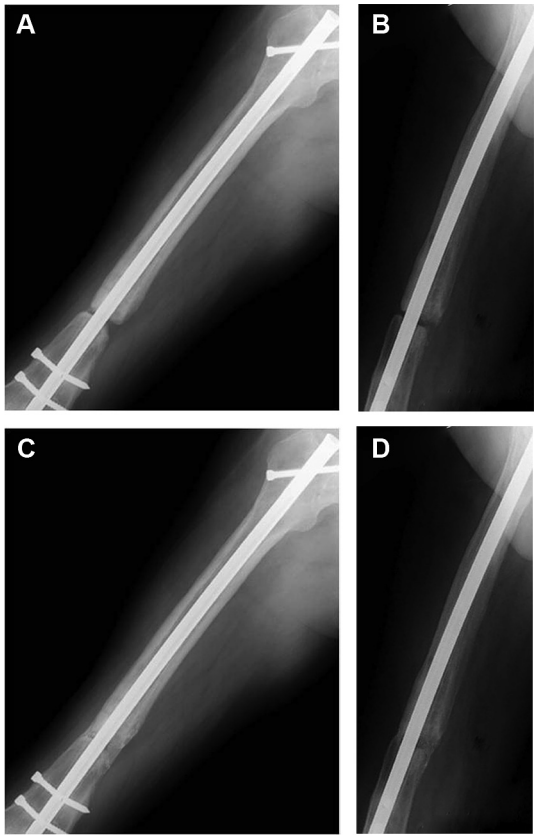

Fig. 1. The AP (1A) and lateral (1B) views of the femur demonstrate atrophic non-union of the femoral shaft fracture of a 29-year-old male. Ten months after ESWT treatment, AP (1C) and lateral (1D) views of the femur showed successful fracture union.

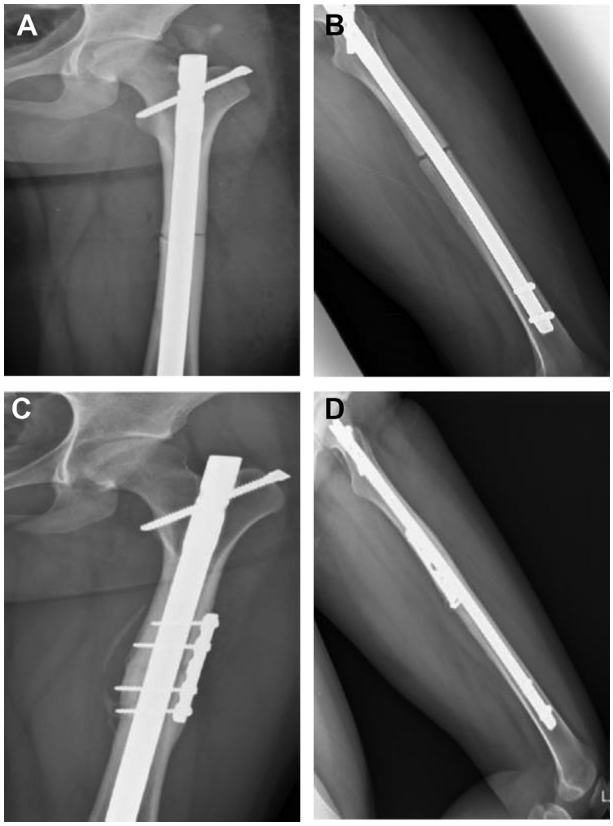

Fig. 2. The AP (2A) and lateral (2B) views of the femur demonstrate atrophic non-union of the femoral shaft fracture of a 25-year-old male 13 months after ESWT treatment. As a result, the patient underwent bone grafting surgery with augmentative plating. Five months after surgery, successful fracture union was noted (2C and 2D).

3. Results

Only one (1) male patient, who moved abroad after ESTW treatment, was lost to follow-up and was not included in this study and as part of the 22-patients cohort. Thus the follow-up rate was 95.7% (22/23). The remaining cohort of 22 patients consisted of 9 females and 13 males. Twelve (12) cases involved the left side and ten (10) the right side. The average age of the patients was 30 years (range 18–45 years). The average angular deformity on radiographs was 0.3° (range 0°–3°) on frontal plane and 0.4° (range 0°–3°) on sagittal plane. The average interval between the initial closed nailing surgery and ESWT application was 10.5 months (range 6–16 months).

At final analysis performed 12 months after ESWT application, 14 patients (14/22 = 63.6%) achieved primary union. There were no systemic or local complications. The union rate was 100% (8 of 8 cases), if ESWT was performed in less than 12 months after the initial nailing surgery, and 42.6% (6 of 14 cases) when ESWT was performed after 12 months from initial surgery of the fracture. The eight (8) patients out of the total 22 patients cohort, who did not achieve bony union after ESWT, received iliac crest autogenous bone grafting with augmentative plating at an interval of 12.9 months (range 12–14 months). These eight (8) patients all achieved bony unions after 3 months for one (1) patient, 4 months for one (1) patient, and 5 months for six (6) patients.

4. Discussion

Autogenous bone grafting with augmentative plating surgery used for treating femur non-union have been reported to have a high rate of success [3,12]. However, the related morbidities and invasiveness of this surgery prompted the need of a noninvasive and effective alternative. The alternative method should achieve comparable results and pose no harm to subsequent possible surgeries, if the treatment did not achieve the desired results. In our study, there was no patient suffering from local or systemic complications after ESWT application. Fourteen (14) patients (14/22 = 63.6%) achieved bony union after ESWT and the remaining eight (8) patients underwent bone grafting with augmentative plating surgery. All these eight (8) patients achieved bony union within 5 months after the bone grafting with augmentative plating surgery.

Treatment outcome of ESWT application for non-unions of long bone fractures is dependent on non-union type, with a success rate of 76% for hypertrophic non-unions and 29% for atrophic non-unions, as reported by one meta-analysis [13]. In contrast for our study, the overall union rate for the treatment of atrophic non-unions was 63.6%. Furthermore, the union rate was 100% when ESWT application was done in less than 12 months from the initial treatment of the fracture and declined to 42.6% when ESWT was used after 12 months from the initial surgery. The higher success rate of ESWT in our study (63.6%) compared to the previous reports (29%) can be attributed to our stringent selection criteria. We demonstrated that ESWT could produce good results for primary atrophic non-unions for a carefully selected patient population. If the non-union was treated with ESWT in less than 12 months from the initial fracture, the success rate can reach 100% (8/8).

The success of the ESWT treatment of the atrophic non-unions can be attributed to stimulation of neovascularization and reduction of inflammatory response of local tissues produced by shockwaves, in accordance with results reported in previous studies [14,15]. While hypertrophic non-union is related to mechanical instability, atrophic non-union is associated with compromised vascularity [16]. Based on our results, we believe that ESWT may rescue the compromised vascularity of atrophic non-unions via the neovascularization effect generated by shockwaves that produces enhanced local blood circulation, thus facilitating the bony union.

Previous authors reported about 100% success rate of autogenous bone grafting with augmentative plating for the treatment of atrophic non-unions. We utilized this effective method for our patients that did not heal after the ESWT. These patients achieved a similar 100% union rate, even if they were treated before with ESWT. According to Choi et al., the radiographic union time was 7.2 months (range: 5–11 months) [12]. Lin et al. reported the union time to be 24.9 ± 3.8 weeks (range, 12–40 weeks) for atrophic non-unions. In our study, we adopted the same three cortices criteria to define bony union. The patients who did not achieve the healing of their atrophic non-union with ESWT were treated afterwards with bone grafting with augmentative plating surgery. These eight (8) patients required 3 months to heal for one (1) patient, 4 months for one (1) patient, and 5 months for remaining six (6) patients, which was at least comparable or even better than the previous reports. We can hypothesize that ESWT may facilitate the healing of atrophic non-unions, although a larger population and a randomized prospective design are needed to prove this hypothesis. However, we can at least state that ESWT exerted no detrimental effects on later bone grafting surgeries, in cases where the ESWT application did not produced the complete healing of the atrophic non-union.

We also noticed the different success rates based on non-union age. If the age of non-union was 12 months or less, the union rate was 100% (8/8). If the age of non-union exceeded 12 months, the success rate declined to 42.9% (6/14). The same phenomenon was also observed when the non-unions or delayed unions were treated with low-intensity pulsed ultrasound [17,18]. For the treatment of delayed union, ultrasound was suggested to be started within 6

months of the most recent operation/surgery. The success rate apparently declined if the time delay for ultrasound treatment was more than 12 months [19]. According to our results, we also suggested that ESWT should be administered within 12 months after the primary nailing surgery used to treat the initial femoral fracture.

The retrospective design and no comparative control group were our main limitations. Also, the sample size was too small for having a valid statistical analysis. However, the study was conducted in a single medical institution, in which ESWT was performed with the same device and with the same shockwave dosage and the follow-up rate was high (95.7%). The fractures were uniformly located in the isthmus of the femur and stringent patient selection criteria were applied. The results of our study cannot be universalized or extrapolated to the patients beyond our selection criteria, since poor results have been reported by other authors when the patient selection criteria was not so stringent. Whilst age of the patients was not a selection criteria in our study, the patients in our cohort were relatively young. As a result, we cannot exclude the possibility that the good results of our study were due to young age of the patients.

In this study, we evaluated the efficacy of ESWT for treating atrophic non-unions of the femoral shaft fractures and our results showed a good success rate (63.6%) under appropriate selection criteria, success rate that can be as high as 100%, if the ESWT is applied within 12 months after the initial nailing surgery used to repair the severe fracture of the femur. Based on our observations, ESWT seemed to mildly facilitate bone growth when bone grafting surgeries are performed after the ESWT, for cases where the non-union closure was not achieved by the shockwave treatment. In conclusion, for the patients with atrophic non-unions of the femoral shaft fractures, ESWT may serve as an alternative and viable treatment that does not jeopardize the efficacy of subsequent surgeries, in case that ESWT did not produce the successful healing of the atrophic non-union.

Conflicts of interest

Non-declared.

Funding for research

No, retrospective chart and radiograph review only.

Ethical approval

IRB number: 99-2794B by the IRB committee of Chang Gung Memodial Hospital.

Author contribution

Shu-Jui Kuo: writing and data collection.
I-Chang Su: data analysis.
Ching-Jen Wang: study design.
Jih-Yang Ko: study design.

Guarantor

The Guarantor is the one or more people who accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

Ching-Jen Wang.

Acknowledgments

The authors would like to thank Iulian Cioanta, PhD and Mr. Barry Jenkin for editing this article, and Dr. Che Chen Shiu and Chen Da Wu for their efforts in radiographic interpretation..

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