CASE REPORT

Extra-Corporeal Shock-Wave Therapy in the Treatment of Non-unions

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Summary

It has been at least a decade since the introduction of extra-corporeal shock-wave treatment (ESWT) for the treatment of non-unions. Despite conflicting opinions in the literature, it is recently experiencing a revival. This paper reports our experience with Ossa Tron, which produces shock-waves electro-hydraulically, on 5 patients. The two successful cases experienced remarkable results of union at an average of 22 weeks after ESWT. The remaining three had disappointing results. A description of the study and a note on the essential issues are presented.

Key Words: Non-union, Shock-wave, Fracture treatment, Non-invasive

Introduction

In an established non-union, there is no spontaneous healing within the expectant time frame. This implies an end-point in fracture healing, with some form of intervention becoming necessary. The current gold-standard for the treatment of non-unions usually involves some form of stabilization, frequently supplemented with the removal of any interpositional soft-tissue or necrotic bone, and bone-grafting. Initial surgical treatment of long bone fracture non-unions have reported success rates of up to 90%, with subsequent procedures producing much worse outcomes. Complications have remained relatively constant at approximately 5% for emergency or trauma, and about 1% to 2% for elective cases, while bone-graft donor site morbidity is between 6% to 20%. These factors have fueled the search for other viable non-surgical alternatives.

It has been just over a decade since a dedicated orthopaedic device producing shock-waves was introduced. These shock-waves theoretically produce micro-fractures which stimulate neovascularisation, osteoblast formation and bone healing. The literature reveals inconsistencies and conflicting opinions on its effects, despite reported success rates of between 50% - 85%. This paper reports our centre's experience in extra-corporeal shock-wave therapy (ESWT) for established non-unions.

Materials and Methods

The treatment device, Ossa Tron (High Medical Technology, Kreuzlingen, Switzerland) was available for the trial period from October 2002 to February 2003.

This was a prospective cohort study of five patients, with prior approval obtained from the Internal Review Board. Established non-union was defined as the failure of fracture union after a minimum of 6 months from initial injury, with no progression of radiographic healing for a minimum of 3 months before shock-wave

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treatment. The exclusion criteria included any underlying neoplasia or other causes of pathological fractures, epiphyseal fractures, fracture gap exceeding 5mm, active infection, open physes, pregnancy, presence of cardiac pacemakers, immunosuppression, coagulopathy, and lesions in the vicinity of major neurovascular structures (spine, chest, skull). A single session of 4000 impulses at 25kV, was administered under general or spinal anesthesia, in the Day Care Service. The non-union site was localised with image intensifier. The delivery arm of the unit's direct contact with skin is enhanced by surgical lubrication gel. Patients were allowed the same weight-bearing status after ESWT as before treatment. At regular follow-up intervals, clinical and radiographical union was confirmed with radiographs showing all 4 cortices healed, i.e. 2 on each anterior-posterior and lateral views. Figures 1 - 5 show the radiographs of the patients before and after ESWT.

Results

Table I is a summary of the results. There was a minimum period of 6 months before ESWT to exclude the possibility of spontaneous union. Patients were followed up for a mean of 31 (17 – 38) weeks. At an average of 22 weeks, 2 of 5 the non-unions were judged bridged, with full weight-bearing tolerated. The other persistent non-unions had average callus formations of approximately 50%, at a mean of 37 weeks after ESWT. We reviewed the three failures of treatment, and found that they underwent multiple operations and instrumentations. For patient ES, there was documented stitch abscess after the initial procedure. Patients ES and NFY also had concomitant ipsilateral posterior cruciate ligament injury with gross symptoms of instability of the knee. Finally, patient NFY admitted to smoking at least 10 cigarettes a day for the last 5 years. None of the patients complained of any increase in pain after the procedure. Beside transient local hematoma, there was no adverse effects noted. The shock waves had no observed effects on the implanted hardware. There was no device related problems nor systemic complications.

Table I : Results

	ES	IAH	NFY	AF	MS
Age (years)	24	48	19	27	40
Gender	Male	Male	Male	Male	Female
# site	Femur Mid Shaft	Femur Mid Shaft	Femur Mid Shaft	Femur Mid Shaft	Tibia Mid Shaft
# (closed / open)	closed	closed	closed	closed	closed
# type	oblique	Transverse	Transverse	Transverse	Comminuted
Period of nonunion (months)	6	84	29	8	6
Type of nonunion	hypertrophic	hypertrophic	hypertrophic	hypertrophic	hypertrophic
Number of operations	3	2	3	1	0
Miscl	-	-	smoker	-	-
Post-ESWT					
Period since ESWT (wks)	38	36	36	17.5	27
Callus (%)	50 - 75%	25 – 50%	50 – 75%	>75%	>75%
Clinical union	No	No	No	Yes	Yes
Radiographic union	1 cortex	1 cortex	1 cortex	4 cortices	4 cortices

success criterion : bridging of all 4 cortices in AP, Lat, oblique views

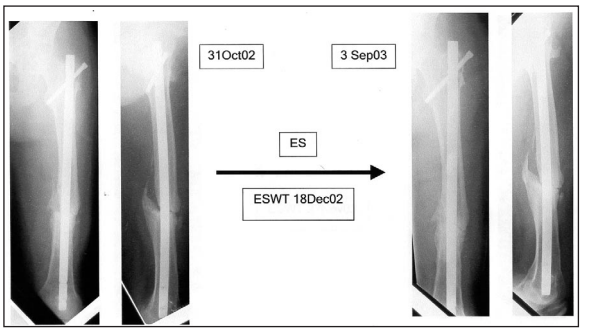

Fig. 1: Radiographs before and after ESWT for patient ES

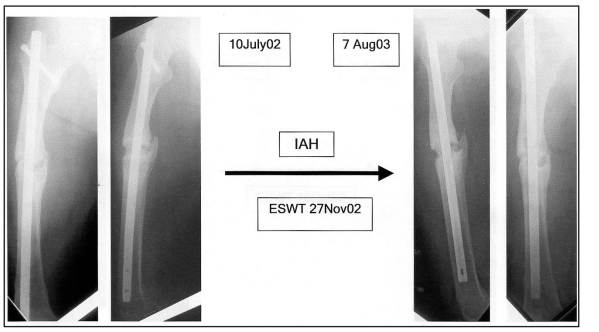

Fig. 2: Radiographs before and after ESWT for patient IAH

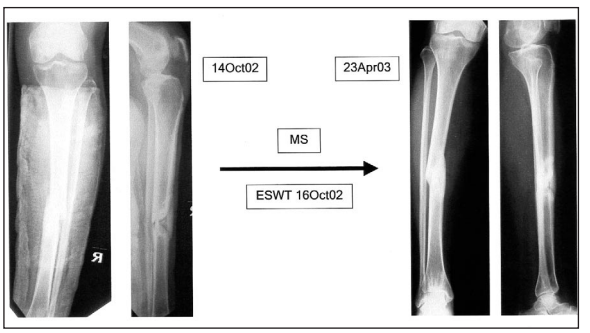

Fig. 3: Radiographs before and after ESWT for patient MS

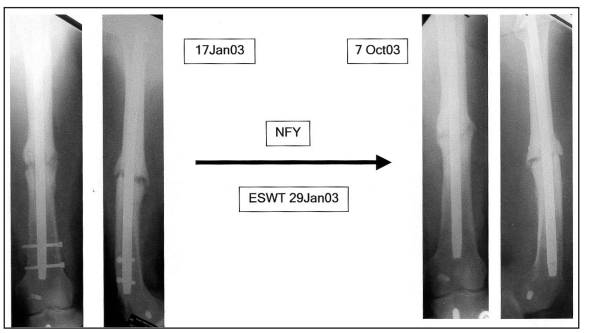

Fig. 4: Radiographs before and after ESWT for patient NFY

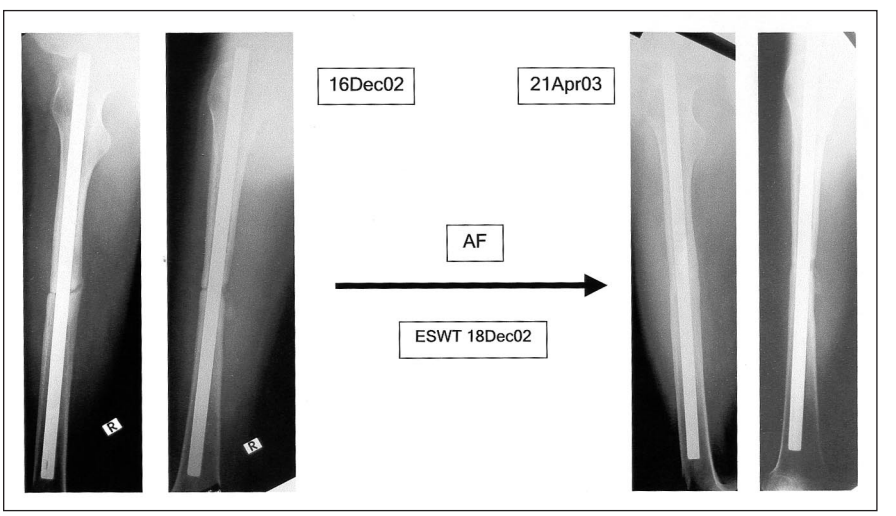

Fig. 5: Radiographs before and after ESWT for patient AF

Discussion

The results of this observational cohort study mirror the current literature's contrasting reports on the value of shock wave treatment for chronic non-unions, despite success rates of clinical studies ranging from 50% to 91%. Generally, there are three main weaknesses in the analysis of ESWT for chronic non-unions. Firstly, the definition of a nonunion has a wide range of inter-observer variability. Currently, there is no consensus on the duration after which cortical consolidation is regarded as improbable, even in hypertrophic or hypervascular non-unions. Secondly, it is difficult to interpretate the heterogeneity between the subjects in the study group, and relating how these differences influence the final outcome. Attempts at identifying a homogenous group may lead to smaller numbers and weaker statistical significance. Lastly, most trials have no control. An alternative would be to compare ESWT against a standard operative or conservative procedure. The unresolved variables concerning ESWT for chronic non-unions include the type of applied energy (low VS high energy), the number of treatment sessions (one VS multiple), the total number of applied shocks during each session, and the choice of anesthesia or sedation. The parameters which cause acute or chronic body tissue or organ damage are also not clearly delineated.

Conclusion

Currently, ESWT is only recommended in chronic nonunions of long bone fractures. The inconsistent outcomes and wide range of success rates in the literature require careful interpretation. The answer may lie in the standardisation of treatment parameters, better understanding of the tissue response, and the careful selection of suitable candidates most likely to benefit from ESWT. Still, it is a useful consideration in the armament for treatment of persistent chronic nonunions, especially of the hypertrophic variety.

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