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Case Series

Extracorporeal Shockwave Therapy in the Treatment of Bone Disorders: Fracture Nonunions, Delayed Unions, Chronic Stress Fractures and Bone Marrow Edema: A Case Report Series in a Private Practice Setting

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Abstract

Extracorporeal shockwave therapy (ESWT) is increasingly used as an adjuvant therapy in the management of nonunions, delayed unions, chronic stress fractures, bone marrow edema and more recently fresh fractures. This is in an effort to increase union rates and bone healing or obtain unions when fractures have proven recalcitrant to healing.

We describe 6 cases of fractures, bone marrow edema and stress fractures which were unable to be corrected by conventional conservative care but which we were finally able to heal using extracorporeal shockwave therapy.

BACKGROUND

In the management of fractures, nonunions, delayed unions and chronic stress fractures, there continues to be significant complications. They can result from a confluence of patient factors such as smoking, diabetes, vascular disease or other comorbidities or injury factors such as high-energy trauma or significant soft tissue loss [3-5]. Nonunions after bone fractures and chronic stress fractures are usually treated surgically with risk of infections and failure of osteosynthesis. The cost associated with these are not insignificant and they can include both personal and societal costs such as lost wages and productivity as well as direct health care costs [3-6]. Bone marrow lesions show similar complications [8-11]. A noninvasive alternative is extracorporeal shock wave treatment, which potentially stimulates bone regeneration. This case report series investigates whether ESWT is an effective and safe treatment for delayed unions, nonunions, bone marrow lesions and stress fractures non-responsive to conservative treatment in a private clinical setting.

INTRODUCTION

Initially used for treatment of urinary, kidney and salivary stones, extracorporeal shockwave therapy has been used more and more as a noninvasive treatment modality for chronic soft tissue lesions like tendinopathies and nonunions, delayed unions, bone marrow lesions and chronic stress fractures non-responsive to conservative care. Literature reviews have shown excellent results with union rates between 71-86 % for delayed unions and nonunions. A relative risk reduction of 46 % when it is used for acute high-energy fractures have been shown [3-5]. Treatment of stress fractures have shown similar success rates [6,7]. Fewer studies have been done on bone marrow lesions, but good quality studies have shown rapid pain relief and functional improvement [8-11]. No significant adverse events were reported in any of the trials [4].

The mechanism of action of ESWT on bone healing might be stimulated because of an increase in neovascularization and an upregulation of angiogenic and osteogenic growth factors [1,2].

Animal studies reported an increase in several growth factors after ESWT, which are important in bone regeneration (VEGF, TGF-beta1, and BMPs). Also, it has been shown that ESWT leads to an increased differentiation of bone marrow stem cells toward osteoprogenitor cells and thickening of the periosteum by proliferation of osteoprogenitor cells [1-5].

Protocols reported have used focused mid and high- energy shockwave devices. In addition to focused ESWT, the use of radial or pressure waves has proven successful in the treatment of superficial tendinopathies, but they do not have evidence in the current literature for the treatment of bone lesions. Applying shockwaves on a painful bone usually requires sedation or anesthesia depending on the generating technology applied, and the best results are obtained with high-energy shockwave generators.

Most authors have used the same devices and protocols approved for bone healing. The general consensus and the best results have been obtained using 1 to 4 sessions of minimum 2000 shockwaves of 0.1-0.5 mJ/mm^2 with a focused device over the lesion site, but most protocols have been poorly described in relation to bone lesion localization, positioning of the ESWT device and dose delivery for the specific fracture site [1-11].

Protocol

We treated the 6 cases with focused shockwaves generated with the PiezoWave2 device, ELvation Medical GmbH, generating focused shockwaves using the piezo-electric principle. We chose the FB10G6 therapy source due to its double piezo- ceramic layer design delivering a powerful and homogenous focal zone and deep penetration depth which does not require sedation or anesthesia due to its direct focusing technology (Figure 1). The -6dB zone, which corresponds to the center of the focal zone with the highest energy density, measures about 20 mm in length and 3 mm in diameter on this therapy source, depending on the energy level chosen. In addition, the so-called "effective zone", the 5 MPa zone is 56 mm in length and 9 mm in diameter. All included patients were chosen due to lack of conservative treatment after at least 3 months regarding nonunions and stress fractures and for bone marrow lesions after at least 12 months.

The bone lesion site, location and size were diagnosed and measured using a combination of x- rays, CT and MR-scans and high-end ultrasound evaluation before and after treatment. 3 treatments were delivered to each patient once a week. The bone lesion was skin marked and measured (Figure 2). The depth of the bone lesion was also measured and targeted by using interchangeable gel pads for exact treatment. For each 3 mm we delivered a dose of 1000 shockwaves of 0.2-0.5 mJ/mm^2 increasing the dose under the treatment to patient tolerance. We started the treatment with a low dose and a high frequency to desensitize the patient first so that we could increase the dose to the relevant level more quickly as the treatment progressed. Precision of the treatment was assured by placing the therapy source according to the skin marking and depth, confirmed by ultrasound and x- ray/MR-scanning examination, holding the device with 2 hands resting on the patient without taking up any skin slack (Figure 3). All patients were radiologically and symptomatically evaluated after 1, 3 and 6 months. All patients were advised not to employ in pain provoking activities for 4-8 weeks depending on the specific lesion and they were followed by the in-house physiotherapist with gradual strengthening and stretching exercises. No stabilizing orthotics, bandages or casting was used during the treatment.

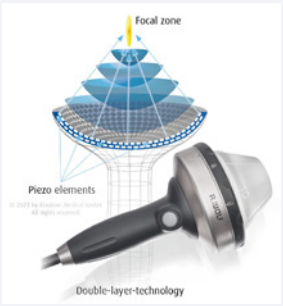

Figure 1 Direct focus with the double layer therapy source FB10G6 of the PiezoWave2 (ELvation Medical GmbH).

Figure 2 Skin marking of the bone lesion.

Figure 3 Treatment with the FG10G6 therapy source.

CASE PRESENTATIONS

Case 1

A 21-year-old female patient presented herself at the clinic with left sided groin pain. The pain was elicited under a half marathon run one year earlier and she had not been able to run or walk for long distances since then. 4 months after the debut she was diagnosed with x-ray with a nonunion/stress fracture localized to the inferior ramus of the pubic bone at a local

Figure 4 The arrow shows the cortical irregularity of the inferior ramus.

hospital and the orthopedic surgeon advised rest from running and long walking activities but the pain had not resolved (Figure 4). Treatment was initiated with a dose of 5000 shock waves per treatment according to the fracture line and 3 months after the first treatment the pain was decreased by 50 %. 6 months after treatment we found full bone healing radiologically and the patient was pain free in all daily activities and able to run without pain (Figure 5).

Case 2

A 44-year-old female patient presented herself to the clinic complaining of pain in her right forefoot. The pain was first noticed while running 6 months earlier where she was diagnosed with a stress fracture located at the 3. Metatarsal bone at the hospital (Figure 6). She was advised to stop running and wear stabilizing orthotics but had still pain upon standing, walking and was not able to run. Treatment was initiated with 3000 shock waves per treatment and after 4 weeks she was pain free. After 8 weeks she was able to resume running activities without pain and there was full bone healing radiologically after 3 months (Figure 7).

Case 3

A 56-year-old male patient presented himself at the clinic with pain located to the right midfoot. The pain presented itself suddenly without provocation 5 months earlier and 1 month after the debut the patient was diagnosed with a stress fracture/ nonunion at the hospital of the 4. Metatarsal (Figure 8). The patient was advised by the orthopedic surgeon to rest the foot and avoid running and jumping activities and to wear shoes with a stiff sole, but there was no relief. Treatment was initiated with 5000 shock waves per treatment and after 3 months the patient was pain free and able to walk and run without symptoms. The fracture was seen fully healed on x-ray after the same period (Figure 9).

Case 4

A 20-year-old male patient presented himself with chronic pain in the right midfoot which had been present for the past 18 months. The pain arose after a tackle during soccer and initial x-ray examination did not show any fracture. After 4 months and lack of pain relief the patient was examined with an MR-examination which showed a complex non-union localized to the lateral and intermediate cuneiform bone with joint widening and ligament rupture (Figure 10,11). Treatment was initiated consisting of 6000 shock waves per treatment. After 3 months the patient was pain free and able to resume soccer and follow-up MR-examination showed full bone healing with minimal cartilage injury and bone bruising (Figure 12).

Case 5

A 44-year-old male patient presented himself at the clinic with persisting pain localized to the lateral ankle. The pain

Figure 5 Follow up x-ray examination shows full cortical healing of the pubic bone after 6 months.

Figure 6 The 2 arrows show the cortical deficit with a cloudy appearance at the distal 3. Metatarsal bone typical of a stress fracture.

Figure 7 Follow up x-ray examination shows full bone healing with solid callus formation at the lesion site following 3 months of treatment.

Figure 8 The arrows point to the nonunion/stress fracture of the distal 4. Metatarsal bone.

Figure 9 The arrows point to full bone healing with callus formation on x-ray follow up after 3 months of the 4. Metatarsal.

was elicited after twisting the ankle stepping down the stairs 4 months earlier. The patient was diagnosed at the hospital with a distal fibula fracture on x-ray examination and the lower leg and ankle were immobilized using a cast for 7 weeks. Follow up x-ray examination showed nonunion of the fracture and the patient was referred to shock wave treatment before surgery would be considered (Figure 13). The patient received 4000 shock waves per treatment. Follow up examination at 3 months showed full fracture healing on x-ray examination and the patient was able to walk and cycle without pain and only complained of slight stiffness in the ankle in the mornings (Figure 14).

Case 6

A 54-year-old male presented himself at the clinic with a painful bone bruise localized to the medial femoral condyle with slow pain debut one year earlier (Figure 15). He had not responded to conservative care consisting of pain medication and offloading the leg and could only walk short distances due to pain. After 6 weeks he could only feel mild discomfort on walking and after 8 weeks he was pain free. Follow up MR-examination 3 months later showed full healing of the bone marrow lesion (Figure 16).

SUMMARY

Our case reports confirm the efficacy of ESWT and shows that it should be considered when choosing the best approach to the treatment of patients with nonunions, delayed fracture union, stress fractures and bone marrow lesions and that this treatment can be administered in a private practice setting.

Although shock wave therapy cannot replace surgery for the

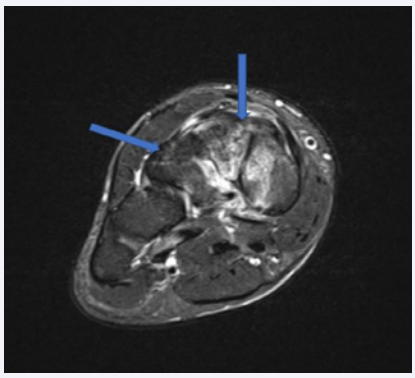

Figure 10 Initial coronal MR-examination shows fracture in the intermediate and lateral cuneiform bones according to the arrows.

Figure 11 Initial transverse view on MR-examination shows as the previous figure 10. fracture in the intermediate and lateral cuneiform bones with a free bone fragment and increased joint widening.

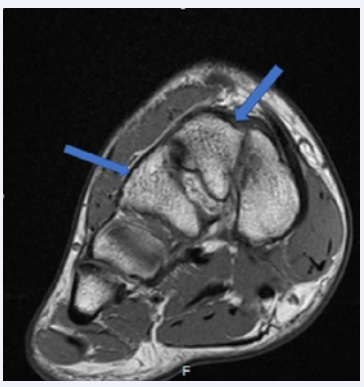

Figure 12 Follow up MR-examination shows full bone healing of the intermediate and lateral cuneiform fractures after 3 months of treatment.

Figure 13 Initial x-ray examination after casting for 7 weeks shows nonunion of the distal fibula.

Figure 14 Follow up x-ray shows full bone healing at the previous fracture site with good callus formation.

Figure 15 Initial MR-examination showed a large bone bruise located at the medial femoral condyle.

correction of malpositioning, stabilization of bone fragments or the filling of bone defects, it has a valuable place in the treatment of disturbed bone healing. Also considering the efficacy of ESWT in bone disorders and the fact that ESWT is easy to perform, inexpensive, safe, and related to good tolerance and high compliance, our results further validate ESWT as the treatment

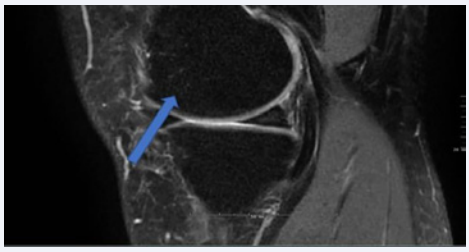

Figure 16 Follow up MR examination 3 months after treatment shows full bone healing of the bone marrow lesion in the medial femoral condyle.

of choice for fracture nonunions, delayed unions, chronic stress fractures and bone marrow edema.

CONSENT

Written informed consent was obtained from the patients for publication of this case report and accompanying images.

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