Quality Standards and Techniques for the Application of Focused Shockwaves and Radial Pressure Waves in Musculoskeletal Disorders

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Abstract

Focused shockwaves and radial pressure waves are safe and effective if used correctly. Nevertheless, poor results and complications have been described due to missdiagnosis and technical errors. The aim of this review is to introduce the basic principles of quality and technical recommendations for each method.

Keywords: Shock waves, Radial pressure waves, Quality standards.

Introduction

Since its inception in the late 1980s [1], the use of Extracorporeal Shock Wave Therapy (ESWT) in the treatment of musculoskeletal pathology has grown steadily. A great deal of scientific evidence and indications have been added [2]. Its use in combination with other regenerative techniques has been advocated. There is an availability of a wide range of equipment. Many medical and non-medical specialties have incorporated shock waves as a therapeutic tool, not always having in-depth knowledge of the pathology to be treated, not always respecting professional scopes. There is an educational offer that includes scientific societies, universities, industry, and even beginners, who simply by having access to social media become opinion makers. This panorama makes it essential to have quality standards including recommendations and guidelines to meet them. To complicate matters even more “shock wave” term includes two technologies used in the field of musculoskeletal pathology. Focused shockwaves (F-ESWT) and Radial pressure waves (RPW). They present clear related to the pressure waveform [2]. Nevertheless, RPW may induce acoustic cavitation [2]. The modes of action and the effects of RPW on living tissue may differ from those of focused shockwaves because bioeffects are related to the pressure waveform [2]. The level of risk associated with focused generators is different from that associated with radial sources [7]. For this reason and according to the consensus of most scientific societies [5, 6, 8], focused devices should be operated only by trained physicians. Non-physicians, as nurses, physiotherapists or technicians may perform RPW after previous diagnostic and prescription by trained physicians [5, 6].

Physical Principles and Generators

Two basic types of technical principles are included in ESWT: focused ESWT (F-ESWT) and RPW, which are often referred to in the literature as radial shockwaves. However, we must point out that shock waves and pressure waves can also be planar or defocused. Some radial pressure wave sources have applicators that can slightly focus the pressure field. Focused shock wave devices have classically three types of generators: electrohydraulic, electromagnetic, and piezoelectric. RPW devices have two types of generators: electropneumatic and electromagnetic. These devices do not emit shockwaves because the rise times of the pressure pulses are too long and the pressure outputs are too low [2, 3]. Nevertheless, RPW may induce acoustic cavitation [2]. The modes of action and the effects of RPW on living tissue may differ from those of focused shockwaves because bioeffects are related to the pressure waveform [2]. The level of risk associated with focused generators is different from that associated with radial sources [7]. For this reason and according to the consensus of most scientific societies [5, 6, 8], focused devices should be operated only by trained physicians. Non-physicians, as nurses, physiotherapists or technicians may perform RPW after previous diagnostic and prescription by trained physicians [5, 6].

Diagnosis

Diagnosis should be the initial step in the indication of any treatment. Unfortunately, this obvious concept presents many distortions in practice. Kibler [9] has stated that a great effort has been put into developing new therapeutic techniques but there is no proportional interest in improving our diagnostic ability. Most of the poor results of shock wave treatment are related to an improper diagnosis [10]. The International Society for Medical Shockwave Treatment has developed a list of approved clinical indications that are based on the strength of the supporting evidence (Table 1) [2, 11, 12]. The indications are divided into standard approved, empirically proven, exceptional or expert indications, and experimental indications [11, 13]. Whoever performs the treatment must not only be able to have an accurate diagnosis but also know the characteristics of the pathology to be treated and the possible complications related to it. The existence of pathology associated with the most obvious should
also be ruled out since other injuries and disorders may be associated. Only a specialist medical doctor is trained and qualified to perform a complete clinical diagnosis, rule out associated injuries, request all the necessary complementary studies and, if necessary, opt for an invasive treatment of the lesion.

When to Indicate Shockwaves?
The ideal indication is considered to be when conventional conservative treatment has failed and as an alternative to surgery or other conventional conservative treatment before moving on to shockwaves. Many of the musculoskeletal indications of shock waves have a good response with other methods that give faster results and are cheaper, therefore it is justified to treat only those cases that have not had an adequate result with them. The basic recommendations for the indication of treatment are:

1. Patient over 18 years of age
2. Pain due to chronic tendinopathy diagnosed clinically by a medical specialist
3. Symptoms greater than 6 months
4. Previous medical treatment with Non-steroidal anti-inflammatory drugs (NSAIDs), infiltrations and physiotherapy (more than two rehabilitation programs not continuous in a period not less than 3 months) without satisfactory clinical results
5. Patient scheduled for surgical treatment
6. Previous surgical treatment of tendinopathy without satisfactory clinical results.

Contraindications
Malignant tumor and fetus in the treatment area are absolute contraindications both for radial and focused waves. High energy-focused waves have been also contraindicated when lung tissue, epiphyseal plate, and brain or spine are underlying the treatment area [11]. The new indications in the brain and spinal cord are leading in both cases to go from being absolute to relative contraindications, but extreme care must be taken in application.

Large vessels and nerves should always be avoided when applying shockwaves [14].

What Technology Should be Used?
As we mentioned, there are shared indications and others specific to each method. To treat superficial soft tissue conditions, devices with or without focusing technology are useful; close attention must be paid to the depth of penetration of the shockwave source when treating deep tissue structures.

Comparison of the results of the use of focused and radial waves in pathologies such as lateral epicondylopathy, patellar tendinopathy, Achilles tendinopathy, and plantar fasciopathy have shown comparable results for both techniques [2]. In accordance with most scientific evidence, medical societies recommend the use of focused generators and high energy levels to treat bone non-unions and calcified tendinopathies [5, 6].

General Recommendations for the Use of RPW
Treatment must start from a specific diagnosis and a precise indication. The patient should be located in a comfortable position that allows exposure of the area to be treated. The use of this type of equipment implies the support of the applicator by the operator, so it is important to work in an ergonomic position.

Many patients come to treatment with a misconception about it. They think the application will be painful. It is important to take time to prove that this is not the case. It is advisable that in the first session the operator applies the waves on his own hand and then does it on the patient’s hand.

The use of local anesthesia is contraindicated, we will not delve into the subject as it will be discussed in another article in this volume. The location of the area to be treated can be done taking into account anatomical landmarks, patient feedback, and in some cases with the help of ultrasound images. The need for ultrasound is controversial, and there are studies that have not found significant differences with its use [15, 16].

Treatment should start with a low energy level. In radio wave equipment, the pressure generated by the compressor is measured in Bar. This may vary according to each device but is around 1.5 Bar. Initially, it is advisable not to do it at the point of greatest pain and to evaluate the patient’s tolerance. Progressively you can advance on the points of greatest pain and always avoid bony prominences.

It has been considered in general terms that the ideal is to reach a value of 2 Bar in the equipment to achieve a therapeutic action. The maximum dose varies according to the author, the pathology to be treated and the characteristics of the equipment. Not being able to indicate an exact dosage for each pathology is one of the weak points of this type of treatment. In any case, the appropriate dose will vary according to each device, the applicator’s experience and the patient’s circumstances.

Table 1: Indications according to diagnosis, technology and the degrees of recommendation according to scientific evidence [2,12].

| Pathology                          | Technology     | Grade of recommendation |
|------------------------------------|----------------|-------------------------|
| Calcifying tendinopathy of the shoulder | Focused       | A                       |
| Calcifying tendinopathy of the shoulder | Radial        | I                       |
| Non calcifying tendinopathy of the shoulder | Focused/Radial | C                       |
| Lateral epicondylopathy of the elbow | Focused/Radial | B                       |
| Greater trochanter pain syndrome   | Focused/Radial | B                       |
| Patellar tendinopathy              | Focused/Radial | B                       |
| Achilles tendinopathy              | Focused/Radial | B                       |
| Plantar fasciitis                  | Focused/Radial | A                       |
| Bone non-union                     | Focused       | B                       |
Frequency is measured in Hertz. Radial devices usually have a maximum frequency between 15 and 20 Hertz. The most frequently used frequency ranges from 4 to 8 Hz. The number of pulses varies between 2000 and 3000 per session. The number of sessions is in most cases 3, with a weekly interval.

Focused shockwaves and RPW had a fast development in the field of musculoskeletal disorders during the last decades. Although the procedures are safe and effective if used correctly, poor results and complications have been described due to misunderstandings and technical errors.

When treating bone healing delays and non-unions, the post-application protocol is immobilization or unloading according to the affected bone, similar to what would be done with the acute injury. The first radiographic examination is performed at 6 weeks and the final one at 12 weeks. If there is no conclusive evidence in the latter, a CT scan may be useful.

In rotator cuff calcifications we perform radiographic controls with the same time interval and we always incorporate a rehabilitation program.

**Overview**
Focused shockwaves and RPW had a fast development in the field of musculoskeletal disorders during the last decades. Although the procedures are safe and effective if used correctly, poor results and complications have been described due to misunderstandings and technical errors. With an accurate diagnosis, adequate indications approved therapeutic protocols and proper application technique, F-ESWT, and RPW are very good non-invasive options for treating musculoskeletal disorders.

### General Recommendations for the use of Focused Shock Waves
When applying focused waves, the type of generator to be used must be taken into account. Electrohydraulic generators typically have a wider focus and are less painful. Electromagnetic devices have a smaller focus and their application is usually more painful. The size of the focus of piezoelectric applicators that have multiple piezoelectric elements is usually the smallest of all.

For more specific indications of focused waves such as rotator cuff calcifications and bone pathology, patient feedback is not a reliable localization factor. Anatomical landmarks, ultrasonography [17], fluoroscopy (Fig. 1), and even computed tomography (CT) scans can be used [18]. The use of local anesthesia is also contraindicated, but general anesthetic sedation is useful when working with high energy levels, especially with electromagnetic generators.

The basic treatment protocols can be for the treatment of calcifications and non-unions can be seen in Tables 2 and 3.

### Table 2: Rotator Cuff Calcification Treatment Basic Protocols with Focused Waves

| Parameters   | Electrohydraulic | Electromagnetic |
|--------------|------------------|-----------------|
| Energy flux density | 0.2 – 0.32 mJ/mm² | 0.4 – 0.6 mJ/mm² |
| Frequency    | 1 to 5 Hz        | 1 to 5 Hz       |
| Pulses       | 2000             | 2000 to 3000    |
| Sessions     | 1 to 3           | 2 to 4          |

### Table 3: Nonunion Treatment Basic Protocols with Focused Waves

| Parameters   | Electrohydraulic | Electromagnetic |
|--------------|------------------|-----------------|
| Energy flux density | 0.3 – 0.55 mJ/mm² | 0.4 – 0.6 mJ/mm² |
| Frequency    | 1 to 5 Hz        | 1 to 5 Hz       |
| Pulses       | 2000 to 4000     | 3000 to 6000    |
| Sessions     | 1 to 3           | 3 to 4          |

tolerance. Coupling gel should be used to ensure the best transmission of the waves to the target tissue and to allow a more comfortable application.

There are a large number of application heads available that influence the physical characteristics of the waves. The most frequently used in musculoskeletal pathology is 15 mm.

Frequency is measured in Hertz. Radial devices usually have a maximum frequency between 15 and 20 Hertz. The most frequently used frequency ranges from 4 to 8 Hz. The number of pulses varies between 2000 and 3000 per session. The number of sessions is in most cases 3, with a weekly interval.

The post-application protocol includes sports rest to avoid overload, the use of analgesics avoiding NSAIDs and the excessive use of ice.

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### Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

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