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Shock Waves and Radial Pressure Waves: Time to Put a Clear Nomenclature into Practice

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Abstract

Extracorporeal focused shock wave therapy and radial pressure wave therapy are noninvasive approaches with high success rates that hold promise for treating a rapidly increasing number of clinical indications. However, reports, presentations at scientific meetings, and information published by manufacturers reflect confusion in the terminology used. This situation is worrisome because both desired and undesired biological effects depend on the pressure profile and the physical parameters used. Moreover, in many cases, the detailed biological mechanisms involved are yet not fully understood. Only a clear knowledge of the physical concepts can enable comparison among and improvement of treatment protocols and technology. Fortunately, specific definitions and recommendations have been agreed upon by scientific societies promoting international standardization. The main goal of this article is to raise awareness of the importance of having a clear nomenclature worldwide and explain some of the concepts based on the international consensus that has been accepted to date.

Keywords: Shock waves, Radial pressure waves, Physical parameters

Introduction

Advances in science and technology in the 19th and 20th centuries fostered the development of several overlapping systems of units of measurements [1]. The General Conference on Weights and Measures, which was established by the Meter Convention of 1875, brought many international organizations together to define standards to create a new system and normalize the rules for reporting measurements [2].

The use of a unified language in science improves communication among researchers, makes it possible to replicate experiments and, in the case of medicine, enables the creation of common treatment protocols. The therapeutic use of mechanical waves is not an exception.

Mechanical forces in nature have influenced living beings since time immemorial. The use of these forces for therapeutic purposes began at the end of the 20th century. New scientific fields emerged and novel concepts in basic science and clinical practice were developed. Extracorporeal shock wave lithotripsy (SWL), i.e., the noninvasive use of focused shock waves to break up urinary stones, revolutionized the treatment of urolithiasis in the early 1980s and motivated considerable research [3, 4, 5]. SWL is still considered the method of first choice for most patients with stones smaller than 20 mm in the upper or middle calices of the renal pelvis, stones smaller than 15 mm in the lower pole calices, and upper ureteric stones smaller than 10 mm [6].

Initially, shock waves were not expected to be used clinically to treat conditions other than lithotripsy; however, surprisingly and unexpected biological effects of shock waves were detected very soon after the emergence of SWL, opening doors to the use of shock waves in musculoskeletal pathology and generating accelerated and incessant developments spanning neurology to dentistry [7, 8, 9, 10, 11, 12, 13, 14, 15]. The novel applications were referred to as extracorporeal shock wave therapy (ESWT). In the 1990s, in addition to focused shock waves, so-called radial shock waves broke through into clinical use, increasing the range of indications for mechanotherapy [5, 12]. However, due to a lack of awareness, as well as for historical and commercial reasons, this technology has been referred to by many different terms, such as radial shock wave therapy, extracorporeal pulse activation therapy, radial pressure wave therapy and radial ESWT [5, 16]. Unfortunately, there has been no clear differentiation between shock waves and "nonshock" pressure waves. The aforementioned terms became commonly used in names and descriptions for equipment, treatment centers, courses, and clinical reports, leading to confusion that has persisted up to the present. The term ESWT is used in most publications, including this one, although several of the techniques referenced do not involve the use of shock waves, and a terminology, such as extracorporeal pressure wave therapy, would be more accurate.

During the early days of ESWT development, there was no consensus on how to evaluate radial pressure wave sources. The International Electrotechnical Commission (IEC) 61846 International Standard [17] was used as a reference by most authors and

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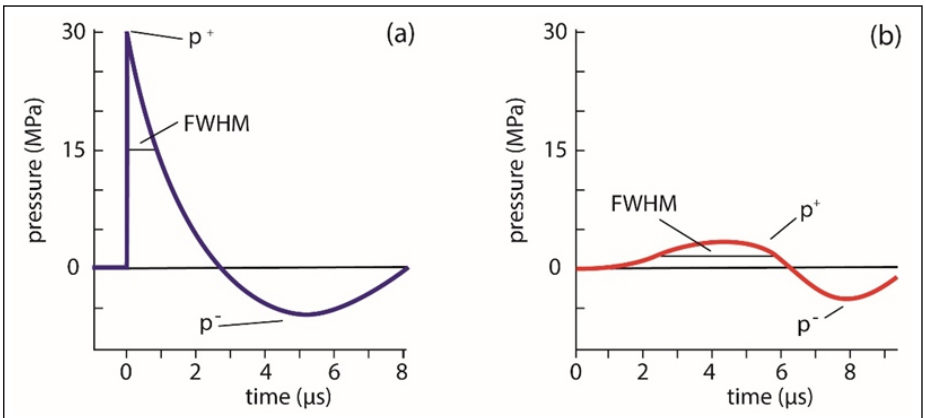

Figure 1: (a) The pressure profiles generated by most shock wave sources consist of 0.5–3 µs compression pulses with 2–500 ns rise times and peak-positive pressures between approximately 10 and 150 MPa, followed by 2–20 µs rarefaction pulses. (b) The pressure profiles generated by a radial pressure wave source consist of a positive pressure pulse with longer rise times (approximately 3 µs) and lower amplitudes. Adapted from (3).

manufacturers; however, this norm was developed for SWL, not for radial pressure pulse devices. Currently, the IEC 63045:2020 Standard (Ultrasonics Nonfocusing short pressure pulse sources including ballistic pressure pulse sources - Characteristics of fields) specifies the parameters that should be measured and reported when evaluating and comparing the acoustic output of extracorporeal equipment producing non-focused or weakly focused pressure pulses released as single events with a duration of up to 25 µs that have only one significant positive peak and one negative peak carrying more than 95% of the total energy. The IEC standard also describes the methods of measurement and characterization that should be used for these sources. The IEC has advised that this standard should not be applied to other physiotherapy equipment, shock wave generators, and ultrasound sources [17].

The main objective of this article is to raise awareness of the importance of developing a correct and unified nomenclature and clarify some of the concepts and definitions based on the international consensus that has been accepted to date. This text is not an exhaustive technical guide but may be useful as a complement to the information provided during certification courses.

Parameters and Units

A few of the physical concepts and the most important parameters mentioned here that might not be well-known to all readers will be briefly explained in this section.

As previously mentioned, two types of pressure waves are used in ESWT: shock waves and radial pressure waves, which are often referred to as radial shock waves, although strictly speaking radial or so-called ballistic devices generate radial pressure waves, not shock waves [5, 15]. The profiles of these two types of pressure waves are shown in Fig. 1. Shock waves can be distinguished from other mechanical waves in being able to produce an extremely fast pressure rise. Compared to focused shock wave generators, which produce shock waves at least at the focus of the device, radial "shock wave" generators emit pressure waves with a lower peak positive pressure and much longer rise times [5, 18, 19].

Most shock waves used in clinical applications are focused. Focused ESWT is a commonly used technology. However, in general, shock waves and pressure waves can be planar or defocused. Some radial pressure wave sources have applicators that can slightly focus the pressure field.

As shown in Fig. 1, the peak positive pressure, generally designated p+, is the maximum compressional pressure. Analogously, p– is defined as the peak negative pressure, i.e., the maximum pressure of the trough or tensile wave that follows the positive peak. The rise time of a pressure pulse is defined as the time taken for the positive pressure to increase from 10% to 90% its maximum value p+. The pulse duration or pulse width generally refers to the positive pressure pulse and is defined as the time from the moment when the pressure exceeds 50% of its maximum value to the instant when the pressure drops to this value again (Fig. 1). The pulse duration is sometimes designated as the full width at half maximum.

Therapeutic effects depend on whether energy is distributed over a relatively large treatment zone or focused on a small region. Thus, the energy flux density (EFD), that is, the energy transmitted per unit area per pulse, is an important concept in ESWT [5, 19]. The EFD is normally reported in mJ/mm2 and depends on how energy is focused. Thus, two devices producing the same energy may have different EFDs. Intuitively one might expect that doubling the electric energy, intensity setting or pneumatic pressure of a therapeutic device would result in twice as much EFD; however, this is not the case.

Unlike shock wave sources, the highest pressure and EFD of radial pressure wave therapy equipment occur at the surface of the applicator and decrease rapidly as the penetration depth increases because the energy is not focused on a treatment target zone. Consequently, it is difficult or impossible to treat deep tissues efficiently using radial pressure waves [5].

The -6 dB focal volume or half-maximum focal zone, which was originally described in reference to SWL, is defined as the volume within which the positive pressure is at least half of its peak value and has also been used to characterize equipment other than

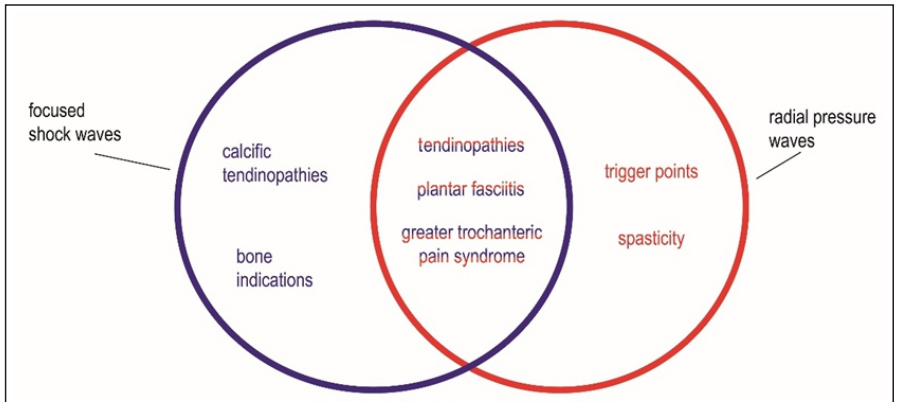

Figure 2: Musculoskeletal indications for focused shock waves and radial pressure waves.

lithotripters [5, 19]. This parameter provides information on how shock waves are focused but is not a measure of the energy in the focal volume. Another parameter that has been proposed is the 5-MPa zone or treatment zone, which is defined as the volume within which the pressure exceeds 5 MPa. This zone was defined assuming that the positive pressure limit above which shock waves generate "clinical effects" is 5 MPa; however, lower pressure therapy has been used successfully. Other measures, such as the impact or impulse at the skin (the integral of the force with respect to time) may also be useful to characterize ballistic devices [20].

As bioeffects are related to the pressure waveform, the therapeutic effects of radial pressure waves may differ from those of focused shock waves. The level of risk associated with focused generators is different from that associated with radial sources [21, 22]. Both desired and undesired biological effects may vary depending not only on the method of pressure pulse generation but also on the manufacturer and the specific model. The current international consensus is that shock waves should be used only by physicians certified in the respective technique. Both technologies are useful when starting from a precise diagnosis based on the use of adequate equipment and correct treatment protocols. As shown in Fig. 2, both techniques share indications; however, there are also indications specific to each method.

International Consensus and Definitions

The current consensus of the International Society for Medical Shockwave Treatment (ISMST) [23] and the Ibero-American Shock Wave and Tissue Engineering Federation (ONLAT) [24] is that clear terminology should be used to prevent confusion.

In a meeting in Naples in 2016, the ISMST reached a consensus on indications, terms and definitions of mechanical waves applied to medical treatment [25]. The related guidelines were approved during the ISMST Congress in San Sebastián, Spain, in 2017 [23]. This consensus establishes that focused or defocused extracorporeal shock waves, as generated by electrohydraulic, electromagnetic, and piezoelectric sources, should only be applied by experienced physicians. Radial pressure waves emitted by ballistic or electromagnetic devices may be used by trained physicians and, following diagnosis by a physician, also by certified physiotherapists and nurses. Good clinical results are only obtained when the characteristics of the pressure field used are known.

According to the Conjoint Physics Working Group of ISMST and DIGEST [26], the use of currently established shock wave parameters to describe the physical conditions used during in vitro or clinical studies is insufficient for the following reasons.

"We do not yet know the key effect of shock waves on tissue: the biological response is not clear, and the best "shape" of shock waves is not known."

"Depending on the measurement setup and the shock wave technology the meaning and significance of the parameters may vary a lot."

"It should be investigated which additional parameters could be helpful to improve the physical description of the equipment used to perform ESWT, given all the different devices and techniques (focal, radial, planar, and defocused ESWT) [26]."

In June 2020, ONLAT reached a consensus that was published in Spanish [24], which basically coincides with that of ISMST except for an additional definition of the following groups of waves used for therapeutic purposes.

1. "Focused shock waves are defined as abrupt pressure changes that propagate through a medium at a speed greater than that of sound. These waves are characterized as having a wide frequency range (from approximately 150 kHz-100 MHz) and a large pressure amplitude (up to 150 MPa) with a short rise time and a small pulse width, followed by a pressure trough (down to −25 MPa). Electrohydraulic, electromagnetic, and piezoelectric transducers can generate these waves"
2. "Flat and defocused waves are variants of previously defined waves (electrohydraulic, piezoelectric, electromagnetic and diamagnetic generators)"
3. "Radial pressure waves are acoustic waves with pressure peaks of up to 30 MPa and rise times of approximately 3 μs, that are considerably larger than those of focal shock waves. These waves can be produced by ballistic and electromagnetic generators."

Additional agreements reached by ONLAT [24] are given below:

"The voltage applied to the capacitors of shock wave generators should be reported in kilovolts, and the pressure generated by the compressor of radial devices should be reported in bars."

"The energy delivered to the patient by each pulse should be expressed in joules (J), where the total energy per treatment is the energy delivered by each pulse multiplied by the number of pulses. The total energy per treatment should also be reported in J."

"The energy generated by each equipment should not be directly extrapolated to determine the energy delivered to the patient, although these energies are proportional to each other."

"Pressure and EFD are different concepts. Thus, there is no direct conversion between pressure units (bar, MPa) and EFD units (mJ/mm2). The EFD is considered an important parameter, that should be reported in any treatment protocol and clinical report. This value should be provided by the manufacturer and accompanied by information on how the EFD was measured."

Depending on the interfaces and media for transmission, shock waves and radial pressure waves, are exposed to phenomena such as reflection, refraction, and absorption. Inadequate coupling of these waves with the patient's body and the presence of air bubbles between the applicator and the skin markedly decrease the energy transmitted to the region to be treated.

A high acoustic impedance (the resistance to the acoustic conductivity) mismatch, as occurs at soft tissue-bone interfaces causes several physical effects, such as tear forces, shear forces, and cavitation, that may trigger beneficial biological responses.

Focused shock waves are more likely to produce cavitation than radial pressure waves; however, radial pressure pulses can also generate cavitation, which may be partially responsible for therapeutic effects but may also produce undesired side effects.

ONLAT made the following statements regarding risk levels [24]:

"The potential risks of using shock waves or radial pressure waves vary significantly because of the physical differences between these types of waves. This result has been published worldwide by scientists without commercial bias and recognized by scientific societies and techno-vigilance agencies. The different levels of risk and the specific clinical

indications should be used to define the range of action for health care providers."

This year, the Spanish Society of Shock Wave Treatments (SETOC) published a perspective on the therapeutic use of radial pressure waves and shock waves, which coincide with those of the aforementioned institutions [27].

"So-called "focused shock waves" are extracorporeally generated shock waves with a wide frequency range (between 150 kHz and 100 MHz) that achieve a high-pressure peak (up to 100-150 MPa) in a very short period of time, even less than a nanosecond, which is followed by a tensile wave (with pressures down to –25 Mpa)."

"Defocused or nonfocused shock waves are considered useful for treating relatively large and superficial regions of tissue, as are found in certain skin conditions. These waves transfer energy to a relatively large area (approximately 30-50 mm2) of soft tissue."

SETOC released the following statement on radial pressure waves [27]:

"Radial pressure waves cannot be considered shock waves, because a sufficiently high-pressure amplitude is not reached and the rise time is too short; however, radial pressure waves may produce cavitation."

The Brazilian Medical Society for Shock Wave Treatment (SMBTOC), one of the largest societies of this kind in the world, published the following definition [28].

"Real shock waves applied to the musculoskeletal system are referred to as "focused." These waves can be used both for treating superficial and deep injuries. Radial waves, despite being physically different from real shock waves, may result in similar treatment outcomes in cases of superficial tendinopathies."

The German Society for ESWT (DIGEST), the pioneering national institution in this medical field, made the following statement [29].

"Shock and pressure waves differ not only in their physical characteristics and generation technology but also in the order of magnitude of commonly used parameters."

Discussion

The correct use and clear knowledge of respective parameters and definitions can improve communication between physicians, physiotherapists, and researchers and make it possible to reproduce, compare and improve treatment protocols. Confusion, lack of crucial information, and contradictions remain common in conference presentations, clinical reports, and commercial advertisements worldwide.

Fortunately, as reported here, most of the scientific societies that have investigated this matter have taken clear positions and made recommendations based on physical phenomena and clinical studies, promoting international standardization.

In principle, no one type of pressure field produced by a clinical device is better than another. The efficiency, mode of action, safety, dose, energy density, and penetration of a pressure wave depends on the specific therapeutic use; however, unlike SWL, in which direct physical destructive phenomena act on concrements, in ESWT, the influence of each pressure-field parameter is still not known precisely. One reason for this lack of knowledge is that the reaction to the effects of radial pressure waves or shock waves, such as mechanotransduction, tissue healing, gene expression, and enzymatic responses, is a combination of biological mechanisms. Another reason is that more data needs to be obtained using reliable, well-designed, and standardized measurements of the pressure fields generated by ESWT devices. Scientific collaboration with the rapidly increasing number of manufacturers is crucial to achieve this goal. Currently, ample research is being conducted to determine the parameters affecting specific cascades of molecular events and responses at the cellular level. Unfortunately, a large percentage of published studies have not helped to improve this situation because of the different parameters, pressure wave sources, scores, and follow-up times used. In many publications, authors report certain "intensity levels," without mentioning the type of device used. Grave errors have appeared in peer-reviewed journals, such as a figure of a pneumatic radial pressure-wave source being shown next to an image of the pressure variation of a shock wave emitted by other types of generators, along with an explanation that the shock wave was produced by a ballistic device [30].

Clinical reports should include all settings, as well as complete information about the equipment and the treatment protocols used. Furthermore, it is important to describe the methodology that was followed to obtain pressure or energy values. Otherwise, comparison between treatments is of limited or no utility, and improvements in research and clinical treatment will be slow. Mandatory equipment regulations and certified courses for all users will improve patient safety and clinical results and should not be substituted for by short courses.

Some manufacturers do not produce any reports at all, or only publish in-house pressure-field studies without describing the experimental setup used to obtain the results. The resulting conclusions may be unreliable because pressure and energy values should only be compared when the same methodology was used to obtain the results. It is also important to keep in mind that even if the same form of generation is used for pressure fields, it is unreasonable to compare the corresponding voltage, intensity, or pneumatic pressure settings because the emitted energy depends on the design (model) of the device.

Furthermore, before acquiring shock wave or radial pressure wave devices, verification of whether these devices meet the ISMST standards is recommended. Clinical protocols and reports should at least include the EFD, number of shock or radial pressure waves applied, information on the pressure profile (peak-positive and peak-negative pressures, rise time, and pulse duration), pressure pulse rate, model, and manufacturer of the device used, energy level, coupling method and medium, as well as the number of sessions and the interval between treatments.

Conclusions

Despite the current confusion in the terminology used for mechanical waves with therapeutic applications, clear and specific definitions, and parameters have been agreed upon by scientific societies based on well-known physical phenomena and concepts. These definitions and parameters should be applied unanimously to improve research coordination, adequately compare results obtained by different researchers and create reliable treatment protocols. Good clinical results can only be obtained when the characteristics of the pressure field used are known. Certification courses, such as offered by many recognized societies, involving in-depth theoretical and practical instruction should be made mandatory in all countries.

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.
Conflicts of Interest: Nil. **Source of Support:** None.

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