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In the Garden of Extracorporeal Shock Wave Therapy, Not Everything is Roses

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Abstract

The popularity of extracorporeal shock wave therapy to treat a large variety of medical conditions is indisputable. Despite this, sometimes poor results are obtained, and mild to severe complications have been reported. In most cases, wrong information and lack of training are responsible for this. The objective of this article is to explain the potential danger of using shock waves and radial pressure waves, as well as the reasons why, from the point of view of physics, sometimes the outcome is not as expected.

Keywords: Extracorporeal shock wave therapy, Shock waves, Radial pressure waves, Interaction with matter, Acoustic cavitation

Introduction

Many manufacturers of equipment for extracorporeal shock wave therapy (ESWT) use the term "shock wave" as a descriptor, relating it to "efficiency," "treatment potential," or "success," when, in reality, their devices only generate radial pressure waves. The word "only" does not mean that shock waves are better than radial pressure waves. They are different. The efficiency depends on the specific application. Nevertheless, there are a few medical conditions that can be treated with both shock waves and radial pressure waves; however, it should be borne in mind that shock waves are potentially more dangerous than radial pressure waves.

In addition to the incorrect use of the term "shock wave," errors are frequently published in the definitions of concepts such as energy, dose, power, or focal zone. This prevents the reproduction of treatment protocols, which is one of the reasons why, in several cases, the selection of parameters for certain therapies has been rather empirical. An optimization can only have continuity if the set of reported values is complete and scientifically correct.

In both shock wave and radial pressure wave generators, the pressure field produced by two similar systems can vary significantly, causing different biological effects. The characterization of the pressure field, in accordance with international standards, is the responsibility of the manufacturers.

In several articles, only values of intensity, voltage, or air driving pressure, are reported. These data are insufficient to compare clinical studies. Furthermore, in general, the term "intensity" is not defined.

In ESWT, multifactorial physical and biological interactions occur involving complex phenomena such as mechanotransduction. It is crucial to have equipment whose scope and specifications are known in detail. Otherwise, the sale of unreliable systems, with supposedly outstanding functions for the treatment of an overly wide spectrum of medical indications, may be encouraged.

The objective of this article is to explain the potential danger of using shock waves and radial pressure waves, as well as the reasons why, in some cases, the results are not as expected.

In the scientific community, there is a consensus that the most relevant phenomena during ESWT are the biological effects induced by compression and rarefaction of the tissue, acoustic cavitation, and spalling. Other phenomena, such as circumferential compression, fatigue, superfocusing, and resonance, will not be discussed here, as they are less relevant.

Shock Waves and Radial Pressure Waves

A mechanical wave is a disturbance of a medium that carries energy from one place to another, making its molecules vibrate. In the case of ESWT, these are compressions and rarefactions in the direction of the movement of the wave, which is why they are called longitudinal waves.

In the focal region, the pressure profile, that is, the variation of pressure with time, of a shock wave typically used in medicine consists of a positive pulse of up to 150 MPa, with a duration, measured at half its maximum amplitude, of between 0.5 and 3 μs, followed by a decompression or negative pressure pulse with an amplitude of up to −25 MPa and a duration of between 2 and 20 μs. In ESWT, the maximum positive pressure (p+) generally does not exceed 50 MPa [1].

A characteristic of shock waves is that the rise time, that is, the time required for the pressure to increase from 10 to 90% of p+, is extremely short (between 2 and 500 ns). This is a fundamental difference with respect to radial pressure waves, where this time is much longer (approximately 3 μs). Furthermore, the duration of the positive pulse of a radial pressure wave (approximately 3 μs) is also much higher, and p+ is significantly lower [1]. These differences are crucial since both

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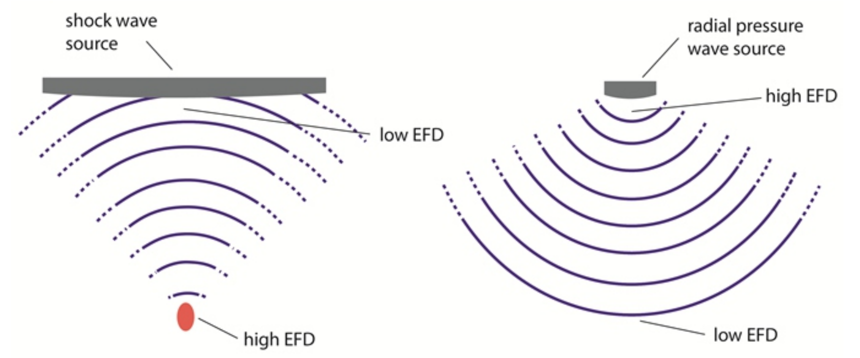

Figure 1: Sketch showing the energy flux density (EFD) near the treatment region of a shock wave source and a radial pressure wave source. Adopted from: Loske AM. Medical and Biomedical Application of Shock Waves. Cham, Switzerland: Springer International; 2017.

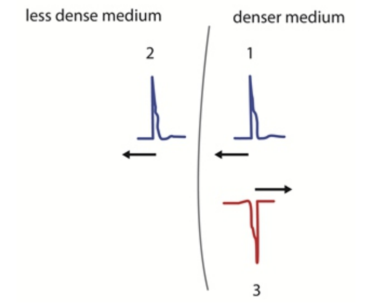

Figure 2: Sketch of a shock wave (1) propagating from a denser medium to a less dense medium. The wave is partially transmitted (2) and partially reflected (3). When reflected at the interface, the shock wave undergoes a phase change (Variations in the shape of the pressure profiles were not taken into account).

desired and unwanted biological effects depend on them.

Compared to ultrasound used in imaging, the amplitude of a shock wave is hundreds of times greater. Furthermore, ultrasound is a harmonic wave, whereas shock waves are pulses, also called shock fronts.

Focal Zone and Energy Flux Density (EFD)

Both tissue damage and therapeutic effects of shock waves depend on energy concentration, that is, whether the energy is focused on a small region or distributed over a large volume (Fig. 1). Two shock wave sources that emit the same energy can produce different biological effects. By decreasing the size of the focal region and increasing the energy density, the probability of generating damage increases.

The EFD is a measure of the energy concentration. It is defined as the energy transmitted per unit area per pulse (generally reported in mJ/mm^2). To determine the EFD, pressure profiles recorded at various distances around the focus are needed. Depending on the specific application, in ESWT, an EFD up to approximately 1.0 mJ/mm^2 is used. In equipment for extracorporeal shock wave lithotripsy (ESWL), the EFD can more than double.

It is important to keep in mind that most shock wave sources focus energy on a relatively small region a few inches from the patient's skin. Due to this, the term "focal shock waves" is often used.

The focal zone generally has a shape like that of a cigar or an ellipsoid of revolution, although some devices, such as those designed specifically for the treatment of erectile dysfunction, have elongated focal zones.

For purposes of comparison and the design of therapy protocols, it is important to specify what is referred to as the "focal zone." Although there are other definitions, most authors define the focal zone as the volume within which the positive pressure is equal to or >50% of p+. This focal region, adopted from ESWL, is called the -6 dB focal zone.

In principle, the focal zone can also be defined based on the negative phase of the shock wave, that is, on the minimum pressure (p-). A little discussed fact in the medical literature is that the point at which the pressure equals p-, is closer to the shock wave source than the point at which the pressure is p+. Furthermore, a focal zone defined based on negative pressure is larger than that corresponding to positive pressure. This spatial shift between focal zones can have consequences on biological effects; however, it is difficult to take advantage of it.

It is well known that radial pressure wave generators do not focus waves. Therefore, the EFD is maximum at the skin (Fig. 1). There are manufacturers that offer transmitters that are slightly concave; however, even with the use of these applicators, the EFD is highest in the vicinity of the patient's skin.

In addition to the EFD, the impact or impulse (J) on the skin of the patient has been proposed to compare radial pressure wave generators [2]; however, as with the EFD, there is no unique relationship between J and the biological effects.

Compression and Rarefaction

The interaction of a mechanical wave with matter depends to a large extent on its pressure profile. Compression and rarefaction cause stresses on tissue. The effects may or may not be desirable and can increase when the wave passes from one medium to another.

At an interface, both shock waves and radial pressure waves undergo reflection, refraction, and diffraction. The transmitted wave can change its direction of propagation or spread out. The damage to tissue depends on several

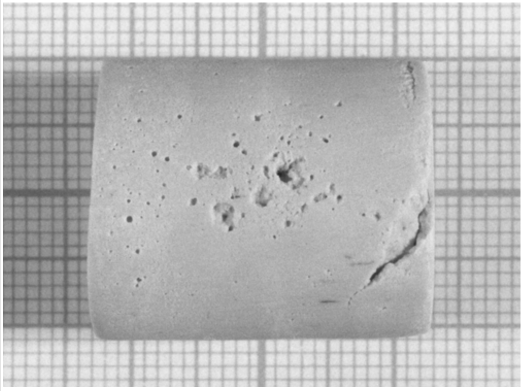

Figure 3: Photograph of the damage produced to a cylinder made of Vel-mix Stone dental plaster (Kerr Division of Syborn Corp., Romulus, MI, USA), after exposure to 500 shock waves (p+ 35 MPa) in water using an electrohydraulic shock wave generator. Small pits and craters were formed by cavitation-induced microjets.

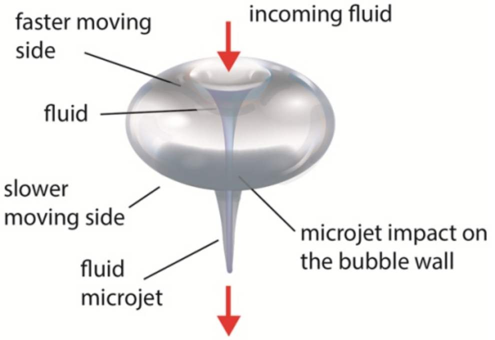

Figure 4: Diagram of an air bubble collapsing within a fluid due to the passage, from top to bottom, of a shock wave. The upper part of the bubble regresses faster than the lower part, sucking fluid into it. Due to this, the bubble acquires a toroidal shape, producing a microjet that impacts the opposite wall of the bubble. This impact is so violent that a secondary shock wave is produced. The microjet passes through the toroid at high speed before bubble fragmentation.

factors, such as the type of equipment used, the energy density, the coupling, the type of tissue, the amount and sizes of previously existing microbubbles, the number of pulses, and the application rate.

When tissue is exposed to pressure variations, forces arise that oppose deformation. Although mechanical waves only carry energy, their passage generates movement in the medium. At the tissue interfaces, cell layer deformations can occur that promote mechanotransduction.

Compared to soft tissue, which absorbs energy through plastic deformation, that is, without breaking, bone structures absorb relatively little energy before cracking. Furthermore, under certain conditions, shock waves can produce shear stresses. These stresses arise, for example, when parallel forces are transmitted to bone structures.

Spalling

When a shock wave propagates from a medium with a higher acoustic impedance (resistance of the medium to the passage of a wave) to one whose impedance is lower, a large amount of energy is reflected. In addition, the reflected pulse goes from being positive to negative, generating significant stresses in the vicinity of the interface (Fig. 2). This phenomenon, called spalling, plays an important role in urinary stone fracture during ESWL. It can cause damage at bone-soft tissue or soft tissue-air interfaces.

By adjusting the parameters properly, microcracks can be generated in bone, which are desirable for the treatment of certain medical conditions. The same physical phenomenon is dangerous when a shock wave goes from soft tissue to air, as might be the case in the lungs.

Acoustic Cavitation

One of the most important consequences of the passage of shock waves through soft tissue and fluids is the formation and collapse of microbubbles, called acoustic cavitation. This indirect effect is largely responsible for the fragmenting of urinary stones during ESWL, but it also plays a crucial role in ESWT. Cavitation generally arises when the medium is exposed to fast pressure variations. It can occur due to cavitation nuclei, that is, sites in which the cohesion between the fluid and some particle is relatively low, or from previously existing microbubbles. In the first scenario, the rarefaction phase of the shock wave creates microbubbles that increase in size until the pressure difference between the inside and the outside causes them to collapse. In the second case, the positive pulse of the wave compresses the microbubble, increasing the pressure inside it. This forced collapse is followed by sudden growth until, hundreds of microseconds later, the bubbles collapse violently. Because the pressure around the bubbles is not homogeneous, they collapse asymmetrically, generating fluid microjets of up to 700 m/s [3]. These microjets pass through the bubbles and can cause damage even to very hard materials (Fig. 3). The collapse occurs so fast that the impact of the microjet with the opposite face of the bubble, that is, the one through which the microjet exits, generates a secondary shock wave (Fig. 4). Secondary shock waves can also be emitted at the instant when the bubble acquires its maximum volume, as well as at the final stage of the collapse. These secondary shock waves produce additional physical and biological changes. The remaining bubble fragments, generated by the previous shock wave, are again subject to the passage of shock waves.

Regardless of the effects mentioned, the growth of microbubbles can cause the rupture of small blood vessels. On the other hand, by collapsing, they can cause the invagination of vessels.

Depending on the energy of the shock wave, the collapse of microbubbles will be more or less violent. Consequently, the biological effects can vary, from favoring tissue regeneration to the destruction of it. Because their negative phase has a relatively large amplitude, radial pressure waves can also cause cavitation [1].

An important fact is that the density of cavitation nuclei and microbubbles in a vascular system is relatively low [4]. For this reason, it is not expected that the effects of cavitation will be noticeable at the beginning of a treatment. By increasing the number of shock waves applied, more bubble fragments appear, and cavitation increases. This phenomenon could be used to improve therapeutic protocols. Given a fixed total number of shock waves, several sessions (or interruptions during the same session) could reduce the effects caused by cavitation. Conversely, non-stop treatments promote cavitation. The most suitable scheme will depend on the specific case and the role played by microbubble growth and collapse in inducing certain effects. Regardless, cavitation occurs more easily in liquids than in tissue.

Discussion and Conclusion

The success of ESWT in treating a growing variety of medical conditions is indisputable; however, not everything is idyllic, and it must be recognized that poor results and complications have occurred due to incorrect or incomplete information, lack of training, or improper use of equipment.

There are numerous parameters involved in ESWT. In addition to the name of the manufacturer and the model of the equipment used, a clinical report should include information on the pressure profile (p+, rise time, and duration of the positive pressure pulse), the distance between the skin and the treated area, the EFD, the dimensions of the focal zone, the number of waves applied, the application rate, the number of sessions, and the time between each session. The manufacturer must provide the values of the pressure field emitted by its equipment, including the variations that occur when changing parameters such as the air driving pressure or the application rate [5].

From the point of view of physics, some errors that limit the success of a treatment or generate injuries, which can be serious, are as follows:

- Poor coupling of the waves into the patient's body due to the presence of air between the applicator and the skin
- An inappropriate angle between the handpiece and the patient's skin
- Exerting inappropriate pressure with the handpiece on the patient's skin
- Assuming that the pressure fields emitted by two systems that have the same energy are equal
- Assuming that the pressure fields emitted by two similar pneumatic systems, adjusted with equal driving pressure, are the same
- Locating the region to be treated in an area of very low or very high EFD
- Using inappropriate equipment or confusing radial pressure waves with shock waves
- Using an inappropriate application rate
- Interpreting the EFD or the impulse as

unique values of "efficiency"

- Using unproven therapy parameters.

Due to possible cavitation effects and stress generated at interfaces between soft tissues, bone, and/or fluids, radial pressure waves, and shock waves should not be applied when infected tissue, a tumor, or a fetus are near the passage of the waves. Generating pressure variations of the type discussed in this article, near organs with cavities or large blood vessels, is risky.

Any therapy involving shock waves or radial pressure waves should only be applied by specialist physicians, certified by a recognized association. Depending on the regulations of each country, radial pressure waves may be used for some medical conditions by properly trained and certified physiotherapists. Instruction in the use of the equipment by the manufacturer is not a substitute for a certification course.

Due to the dizzying rate of technological advances, as well as the speed at which ESWT is used to treat new medical conditions, it is important to keep up to date with the latest innovations.

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