

Principles of Shock Wave Therapy

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A shock wave is a transient pressure disturbance that propagates rapidly in three-dimensional space. It is associated with a sudden rise from ambient pressure to its maximum pressure. A significant tissue effect is cavitation consequent to the negative phase of the wave propagation. The current authors summarize the basic physics of shock waves and the physical parameters involved in assessing the amount of energy delivered to the target tissue and in comparing the various high- and low-energy devices being evaluated clinically for musculoskeletal applications.

Shock waves originally were applied clinically as lithotripsy to break up and disrupt calcific deposits within the body, specifically stones within the renal, biliary, and salivary gland tracts. Extracorporeal shock wave therapy now has become established as the procedure of choice for most renal calculi. It represents a noninvasive and very effective technique for treating as many as 98% of renal calculi.^{2,23,26}

For the past 10 years this technology has

been increasingly applied to a broad range of musculoskeletal conditions.^{7,19} These applications include calcific tendinitis of the shoulder, nonunion, and delayed union of fractures.^{19,20} These applications initially stemmed from the concept of disintegrating calcifications in the shoulder that were similar to lithotriptic renal stone disintegration.²⁵ The fracture application was chosen based on observations obtained during animal lithotripsy studies of the biologic tissue effects of shock waves, namely that shock waves striking the pelvis elicited a significant osteogenic response.^{9,11,12} Because this technology is relatively new to orthopaedics, the authors think that potential users should have an overview of the physical principles involved when shock waves are directed toward musculoskeletal tissues.

Basic Physics

The steepening of a sound wave is caused by the pressure dependency of the wave propagation. The velocity of the sound wave increases with increasing pressure. Therefore, wavelets at high pressure move faster than the wavelets at lower pressure, which leads to a deformation of the wave. For very high sound intensities, the wave crest assumes a sawtooth appearance. With increasing amplitude, it subsequently becomes a shock wave.

A clinically applicable shock wave represents nothing more than a controlled explosion producing a sonic pulse in much the same way as a fast flying aircraft may produce a sonic

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boom. When the shock wave enters the tissue it may be dissipated and reflected so that the kinetic energy is absorbed according to the integral structure of the tissues or structures that are exposed to the shock waves. The transmitted force depends on the physical properties of the material in question; for example, the forces are different for air as compared with a liquid such as water. The shock wave is a transient pressure disturbance that propagates in three-dimensional space with a sudden rise from ambient pressure to its maximum pressure at the wave front. Medically useful shock waves usually are generated through a fluid medium (water) and a coupling gel to facilitate transmission into biologic tissues.

The basic physical properties of a shock wave cause expansion and concentration within a medium, and thereby change the local density.^{14,21} Wave propagation may be described as an alternating compression and relaxation of the medium along the direction of propagation. There are monofrequential sound waves similar to ultrasonic waves, and there are sound bursts (shock waves) that contain a wide frequency spectrum. The shock waves change their physical properties through attenuation and steepening when traveling through a medium and through reflection and refraction at the boundaries when subsequently moving into another medium. At the boundary layer between two media one part of an approaching shock wave will be reflected

and the other part will be transmitted. Losses through attenuation depend on the medium through which they are transmitted. In air, the attenuation is very high. The sound of a banging hammer is not going to hurt; traveling through air the sound wave generated by impact with a nail will have lost most of its energy by the time it reaches the body. In water, however, losses through attenuation are approximately 1000 times lower than in air.

A shock wave is a sonic pulse that has certain physical characteristics. There is a high peak pressure, sometimes more than 100 MPa (500 bar), but more often approximately 50 to 80 MPa, a fast initial rise in pressure during a period of less than 10 ns, a low tensile amplitude (up to 10 MPa), a short life cycle of approximately 10 μ s, and a broad frequency spectrum, typically in the range of 16 Hz to 20 MHz.¹⁹ The measured shock wave rise time is in the 30 ns range when determined by limited time resolution of the pressure recording hydrophone. The positive pressure amplitude is followed by a diffraction-induced tensile wave of a few microseconds duration. Figure 1 shows the form of a typical shock wave and highlights the various physical parameters associated with such sonic pulses.

For shock waves to be effective in the clinical situation, the maximally beneficial pulse energy must be focused (concentrated) at the point at which treatment is to be provided. There are two basic effects: the direct genera-

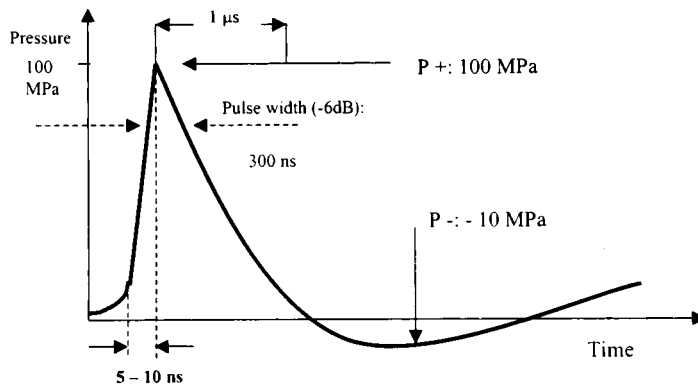


Fig 1. The typical form of a therapeutic shock wave is shown. There is a very rapid positive rise in pressure over nanoseconds to approximately 10 MPa, which eventually is followed by a variable negative pressure, which may affect cavitation. The extra wave lasts several microseconds.

tion of mechanical forces (primary effect), and the indirect generation of mechanical forces by cavitation (secondary effect).

During the tensile phase of the acoustical shock wave, the tensile forces of the wave exceed the dynamic tensile strength of water (interstitial fluid), generating cavitation bubbles. The bubble diameters oscillate, increasing and decreasing in volume. Some will resist a certain number of shock wave pulses, whereas others will collapse after the first cycle. The bubble oscillation is nonlinear because the variation in bubble size is not correlated with pressure amplitude. During the growth phase of the bubble, a huge amount of energy is delivered to the bubble. This energy is released from the bubble during its collapse (implosion) in the form of high-energy water jets and high temperature.^{1,5,6} The jets and elevated temperature are present within focal microscopic tissue volumes. In highly viscous liquids the cavitation phenomenon is suppressed dramatically.^{7,8}

In the vicinity of boundary areas (between materials of differing density) the symmetry of that implosion is perturbed. The liquid of the surrounding medium enters the bubble as a microjet, which is directed toward the boundary area with a large destructive potential. It is along the boundaries between different media such as muscle and bone or lung tissue that the

sound field experiences the biggest changes and emits the highest energies. This is where most of the biologic effects are expected.

Methods of Shock Wave Generation

There are three main techniques through which shock waves may be generated (Fig 2). These are the electrohydraulic, electromagnetic, and piezoelectric principles, each of which represents a different technique of generating the shock wave. All of these techniques of shock wave production depend on the conversion of electrical energy to mechanical energy.

The basic concept of each device is similar, and is based on the principle that the acoustic impedances within the human body are very similar to those of water. Accordingly, the shock waves are generated within water and subsequently transferred to the human body by means of an appropriate contact medium. This ensures small losses attributable to attenuation and reflection by any boundary areas. The energy of the shock wave will be concentrated in the treatment focus (F_2).

Electrohydraulic Principle

Shock wave generation through the electrohydraulic principle represents the first generation of orthopaedic shock wave machines (Fig 2A). The device acts in a similar way to the spark plug of a car. A high voltage from a charged ca-

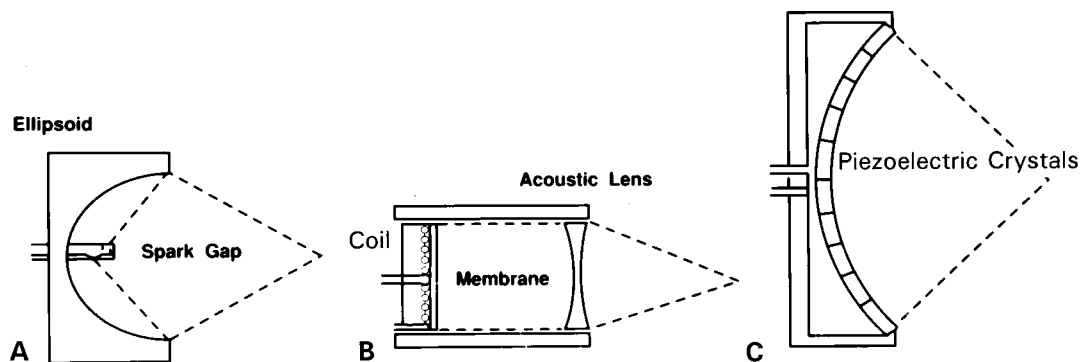


Fig 2A–C. The variations in the devices used to generate shock waves for clinical application are shown: (A) electrohydraulic, (B) electromagnetic, and (C) piezoelectric.

pacitor is applied across electrode tips (spark plug), which discharge rapidly across the spark-gap as the first focal (F_1) point within a water-filled ellipsoid reflector. The resultant spark heats and vaporizes the surrounding water, thereby generating a gas bubble filled with water vapor (gas) and plasma. The expansion of this bubble produces a sonic pulse, and the subsequent implosion a reverse pulse, manifesting as a shock wave. The concentrically (spherically) expanding shock wave is reflected by the surface of the ellipsoid and is then refocused into the second focal point (F_2) of the system (Fig 3). Geometry and the exact positioning of the device ensure that the second focal point is within the desired therapeutic anatomic region. Electrohydraulic shock wave devices usually are characterized by fairly large axial diameters of the focal volume and high total energy within that volume (Fig 4).

Electromagnetic Principle

The second device uses an electromagnetic coil and an opposing metal membrane (Fig 2B). This technique of producing shock waves first was described by Eisenmenger.⁸ An electric current is passed through a coil to produce a strong magnetic field. A high current pulse is released through the coil, generating a strong, variable magnetic field, which, in turn, induces a high current in the opposed metal membrane. This strong magnetic field then causes an adjacent, highly conductive membrane to be forced rapidly away, thus compressing the surrounding fluid medium to produce a shock wave. A lens is used to focus the

wave, with the focal therapeutic point being defined by the focal length of the lens. The amplitude of the focused wave increases by nonlinearities when the acoustical wave propagates toward the focal point.

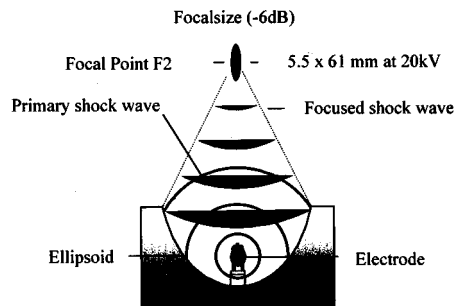
Piezoelectric Principle

A large number (usually > 1000) of piezocrystals is mounted on the inside of a sphere and receives a rapid electrical discharge (Fig 2C). This causes deformation (contraction and expansion) of the crystals (piezoelectric effect), which induces a pressure pulse in the surrounding water steepening to a shock wave. The geometric arrangement of the crystals along the inside of the sphere causes self-focusing of the wave toward the center. This leads to an extremely precise focusing and a high energy density within a well-confined focal volume.

Definition of Physical Parameters

When studying the effects of shock waves on soft tissues or bone the focal volume of the target tissue exposed to the shock waves becomes critical. In theory, the waves are focused on one focal point (F_2), but in fact they have effects over a far more substantial focal volume (Fig 4). In urology, the focal volume may be matched to the size of the renal stone. If there is too small a focal volume, the stone is not disintegrated fully and complications may ensue. A larger focal volume, which can be attained by manipulating a heel or elbow while the shocks are applied, ensures a greater area of involved tissue will be affected.

Fig 3. Schematic of electrohydraulic generation of a shock wave. The focal volume (F_2) represents the therapeutic portion of the focused shock wave.



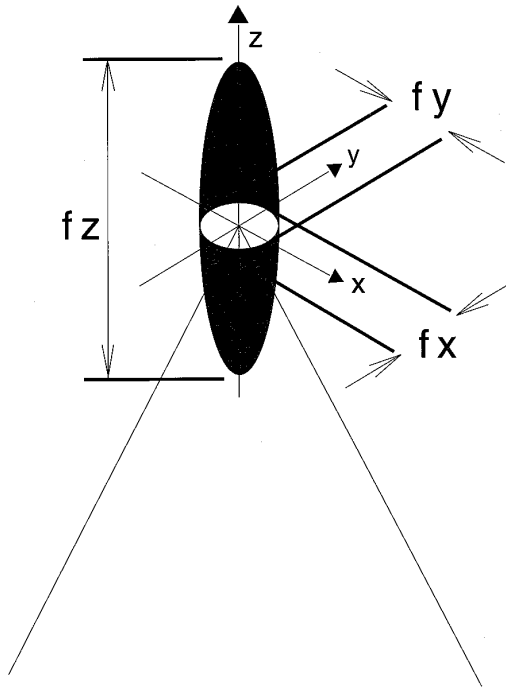


Fig 4. The typical ellipsoid (focal volume) for a zone of focused shock wave energy is shown. The x, y, and z dimensions of F_2 (respectively f_x , f_y , and f_z) are dependent on the generation mechanism (Fig 2) and the total energy applied to the tissues. The intersection of the f_x , f_y , and f_z axes is the true second focal point (F_2). The shape and overall volume of the treatment ellipsoid is influenced additionally by the focusing mechanism of the individual device. There are substantial differences between the zones and volumes of tissue effect generated by the different devices.

As mentioned previously, the processes induced in biologic tissues are not yet fully understood, especially as they relate to the induction of bone healing. It is particularly important to be able to correlate medical results to reproducible physical parameters.²⁸ Therefore, the parameters involved must be quantified. These parameters include the following:

Pressure Field

The pressure (measured in MegaPascals) generated by a shock wave as a function of time and space, is the parameter that is most amenable to

direct measurement. However, such measurements are challenging technically. They commonly were done with needle hydrophones on a polyvinylidene fluoride basis. The hydrophones use the piezoelectric effect, encounter problems measuring the tensile parts of the wave, and have a very limited life expectancy. Recently, a fiberoptic hydrophone has become available that also can measure the tensile forces. It has become the method of choice in shock wave measurements.

The pressure field is maximal at the focal center but in addition, significant effects may be produced over neighboring regions of tissue and the dimensions of such zones will vary according to the precise shock wave treatment provided. The zone around the focal region may be defined in three different axes to create the focal volume (Fig 4).

Energy Flux Density

The energy flux density is a measure of the energy per square area that is being released by the sonic pulse at a specific (finite) point. Energy flux density may be derived from pressure and can be computed as the area below the squared pressure time curve. Energy flux density must not be confused with energy. It is important when considering threshold values in generating certain biologic effects.

Energy

The energy flux (as much as 1.5 mJ/mm^2) and the peak pulse energy (as many as 100 MPa) are determined by the temporal and spatial distribution of the pressure profile. The energy flux density describes the maximum amount of acoustical energy that is transmitted through an area of 1 mm^2 per pulse. The total pulse energy is the sum of all energy densities across the beam profile. It describes the total acoustical energy per released shock wave.

Although energy flux density relates to the energy released at a certain point, the energy of a shock wave is the total amount of energy released within a defined region. The energy is the energy flux density as integrated over the entire region.

The total energy applied to the tissue is represented by the number of pulses multiplied by the energy per pulse. When considering the disintegration of renal stones, the total energy may be compared with the volume of the calculus that has been disintegrated, whereas the energy flux density will correspond to the depths of any crater produced on the surface of the stone. To assess the different shock wave devices, it is not sufficient to compare only single parameters such as maximum energy density. Comparable investigations in lithotripsy showed that pressure distribution, energy density and the total energy at the second focal point all are important parameters in assessing and comparing different shock wave devices.^{3,11,13}

In theory, pressure and energy are concentrated within a point, the focus. In this case, it is necessary to distinguish between energy and energy flux density. The treatment focus has finite dimensions. The pressure is highest in the focal center and decreases with increasing distance from the focus. According to ultrasound physics, the focal regions of the shock wave may be defined by three different conditions: the 5 mm area is simply a sphere of radius 5 mm surrounding the treatment focal point (F_2). The 6 dB area may be defined as the volume of tissue in millimeters within which the pressure is at least $\frac{1}{2}$ its peak value (Fig 5). The 5 MPa area may be defined in a similar fashion as the volume of tissue defined in millimeters along the x, y, and z axes within which the pressure exceeds 5 MPa.

The volume within these defined boundaries should be assessed for the maximum, minimum, and intermediate energy settings of any relevant shock wave device. The different focal areas are compared in Figure 6 for high- and low-energy settings for an identical device. The physical parameters of positive peak pressure (P_+ in MPa) and the various (x, y, z) zones in the clinically sensitive -6 dB focal area for high-, medium-, and low-energy devices may be found at the website of the International Society for Musculoskeletal Shock Wave Therapy.¹⁵ Measurements now have been completed using unified standards (Ta-

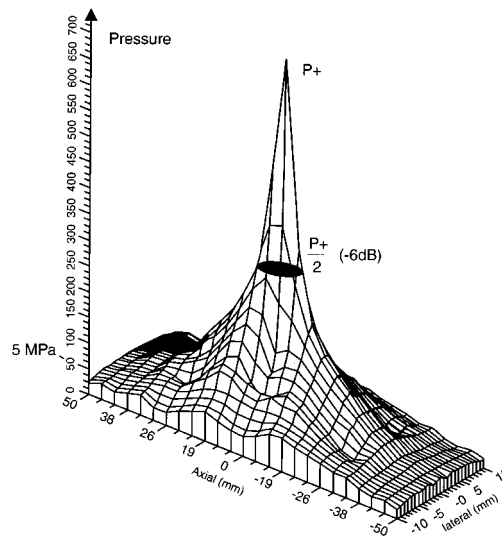


Fig 5. Computer-generated illustration of the three-dimensional effects of shock wave propagation into biologic tissues, and the mathematic definition of the 6 dB area, which, by definition, is 50% of the maximum pressure.

bles 1, 2). The individual values of the various devices on the market (especially in Europe) or being tested (in the United States) now are published by the German and International Society for Extracorporeal Shock Wave Therapy.¹⁰ Correlations between pressure, energy flux density, and the energy during shock wave treatment now can be analyzed accurately. It is hoped that the treatment of musculoskeletal conditions may be put on a more factual and rational basis.

Quantification of the sound field and measurements of its parameters will enable medical researchers to use the technical data to correlate them with biologic events. The influence of pressure, energy flux density, and energy of the shock wave on the medical applications can be analyzed. Hopefully, this will lead to better understanding of biologic processes such as bone healing induced by this method. Additional advances of the scientific understanding will determine whether there are specific orthopaedic requirements calling for technical refinements of the devices,

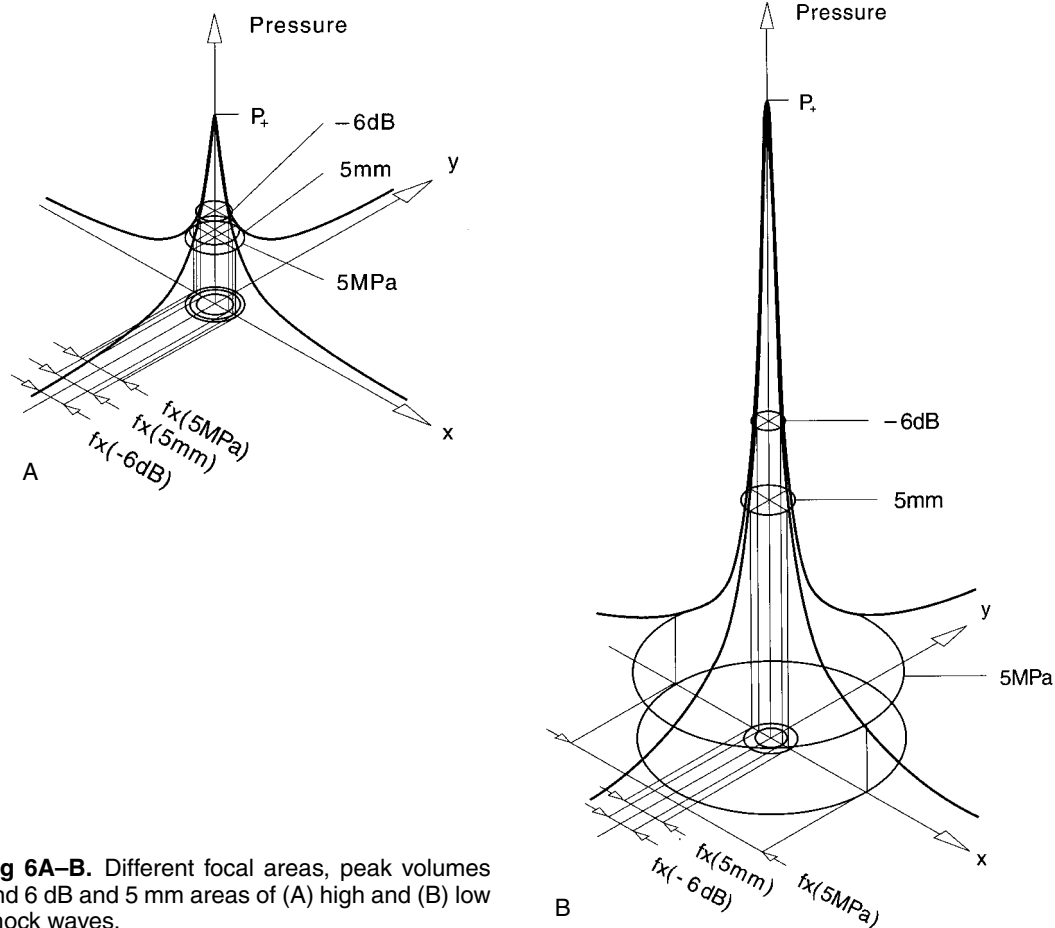


Fig 6A–B. Different focal areas, peak volumes and 6 dB and 5 mm areas of (A) high and (B) low shock waves.

whether it is possible to give well quantified dosage recommendations for specific medical indications, or whether additional technical and physical information on the sound field is required.

Biologic Effects

Understanding the basic effects of shock waves on various musculoskeletal tissues may be assessed by several concepts.

The pressure distribution, energy density, and the total acoustic energy are the most important physical parameters for the treatment of orthopaedic disorders. The exact impact that shock waves impart to different musculoskeletal tissues is not understood completely. Rela-

tive to stone disintegration, the shock waves presumably cause high stress forces on the stone surface by the high pressure amplitude and the short rise time, thus exceeding the elastic strength of the stone and disintegrating its surface.^{1,2,13}

Shock waves generate high stresses that act on boundary interfaces and, in addition, generate tensile forces that cause cavitation. In vitro studies by those concerned with urologic problems have defined the forces required to disintegrate artificial stones.¹³ The volume of stone material that will be disintegrated (V) is related to the number of shock wave pulses applied (n) and the total energy of each pulse (E) by a constant (e), which is the specific disinte-

TABLE 1. Pressure Fields of a High-Energy Device: the OssaTron®

Parameter	OssaTron		
Energy level	14kV	20 kV	28 kV
Maximum pressure (MPa)	40.6	45.6	71.9
Positive energy flux density (mJ/mm ²)	0.09	0.24	0.34
Total energy flux density (mJ/mm ²)	0.12	0.27	0.40
E _{-6dB} (mJ), positive	4.3	4.7	26.7
E _{-6dB} (mJ), total	4.9	5.1	28.0
E _{5mm} (mJ), positive	2.5	5.4	10.0
E _{5mm} (mJ), total	2.9	5.8	10.4
E _{5MPa} (mJ), positive	18.1	29.9	96.5
E _{5MPa} (mJ), total	22.2	34.2	110.2
6dB - Diameter lateral (mm)	6.8	6.4	8.7
6dB - Diameter axial (mm)	44.1	59.0	67.6
5 MPa - Diameter lateral (mm)	19.3	20	32

The OssaTron (High Medical Technologies, Lengwil, Switzerland) is currently the only device approved by the Food and Drug Administration, and only for the specific indication of proximal plantar fasciitis.

gration capacity for the material in question. These are related by the equation:

$$V = \epsilon E n$$

This equation has proved extremely helpful in analyzing the stresses that will produce disintegration of a renal stone with shock wave therapy, but has proved less helpful for analyzing the effects of shock waves on musculoskeletal tissues. In this latter situation, the shock waves usually are not being used to disintegrate tissue, but rather to microscopically cause interstitial and extracellular disruption. Currently, the therapeutic mechanisms of shock waves in musculoskeletal problems or their specific biologic effects on the various musculoskeletal tissues (bone, cartilage, tendon, ligament) are not fully understood.

Every medium has its own acoustic impedance, Z, which is a function of the sound ve-

locity, c, in that particular medium and its density, ρ .³

$$Z = \rho c$$

The reflected portion of the sound wave is growing with an increase of the differences of their impedance according to $I_R = I_0 (Z_2 - Z_1) / (Z_2 + Z_1)$ with I_R being the amplitude (intensity) of the reflected and I_0 the amplitude (intensity) of the initial sound wave. The higher the acoustic impedance mismatch, the higher the portion of reflected energy. If the impedance of medium 1 (Z_1) is larger than that of medium 2 (Z_2), this leads to a negative intensity of the reflected wave, which causes tensile forces.

When the shock wave is propagating through one medium and hits an interface of a second, different medium, part of the wave is transmitted and part of the wave is reflected. The ratio of the transmitted intensity (I_T) and the reflected in-

TABLE 2. Comparison of Devices in MegaPascals

Energy Level	Electrohydraulic	Electromagnetic	Piezoelectric
Positive peak pressure	40-87	25-91	15-40
-6 dB focal area	6-26	2-6	1-7
5 MPa focal area	13-45	16-32	15-17

tensity (I_R) are correlated to the incident intensity (I) by the following equations:

$$I_R = I_2 (Z_2 - Z_1 / Z_2 + Z_1)^2$$

$$I_T = I_2 4 Z_2 Z_1 / (Z_2 + Z_1)^2$$

$$I = Z^{-1} \int p^2 dt$$

I_2 is the intensity in medium 2 and $Z = \rho c$ is the acoustic impedance (ρ is the density of the medium and c is the velocity of sound in this medium). The pressure amplitude (measured in MegaPascals) is described by p and I corresponds to the acoustic energy density (measured in mJ/mm^2).

Examples of reflected and transmitted intensity within different musculoskeletal tissues are shown in Table 3. The intensity of a shock wave transmitted into cortical bone is approximately 65% of the incident intensity, whereas approximately 35% is reflected. This causes a strong direct effect on the interaction of shock waves with the cortical bone at the periosteal interface, which is responsible for the subperiosteal hematoma after treatment of a pseudarthrosis. Pressure measurements in animal bones confirm an abrupt reduction of energy (80% to 90%) after a depth of 1 to 2 cm of cortical bone.^{13,14} Other animal experiments have shown maximum stimulation of osteogenesis at the interface of cortical and cancellous bone.^{4-6,9} This could be attributable to indirect cavitation effects, which cause partial osteocyte death, followed by migration of osteoblasts in the focally treated region to cause local new bone formation.^{8,24}

Direct shock wave effects and indirect cav-

itation effects cause hematoma formation and focal cell death, which then stimulate new bone or tissue formation.

The microdisruption process and the side effects are a function of the total amount of energy absorbed in a finite volume, independent of cavitation or direct shock wave effects. The shock waves seem to cause trabecular microfractures or interstitial gaps, probably caused by cavitation.

The resorption of calcific deposits (in the shoulder) may be correlated with the total amount of applied acoustic energy.^{16,17} Pain relief also seems to be a function of the total applied energy.

A certain threshold value of energy density has to be exceeded to stimulate any healing process, and to lead to any significant side effects. Such a threshold dosage of energy is not different from concepts such as tidal and static effects of an antibiotic. Although the energy density (mJ/mm^2) of a shock wave is important, the more clinically relevant physical parameter may be the total amount of acoustic energy administered in one shock wave pulse.

The current overview is intended to give an introduction to the basic physics of extracorporeal shock wave therapy. The objective is to clarify the role of defined parameters necessary in quantitative research. Extracorporeal shock wave therapy has its roots in extracorporeal shock wave lithotripsy, a method firmly established in urology as a nonsurgical method to disintegrate concretions in the renal and urinary tracts. The method is noninvasive, very effective, and has few side effects. Currently, approximately 98% of renal concretions are being treated by extracorporeal shock wave lithotripsy.²⁰ However, the biologic effects of this method are not restricted to the fragmentation of concretions. Stimulation of bone formation in cases of retarded healing of bone fractures and nonunions and the promotion of healing of tendinopathies have been shown.^{8,27} Although the biologic mechanisms are not known in detail, the positive results of the treatments have been shown in an increasing number of studies.^{7,16,18-20,22}

TABLE 3. Acoustical Tissue Data

Material	Density (g/cm^3)	Sound Velocity (m/s)	Acoustic Impedance ($\text{g}/\text{cm}^2\text{s}$) 10^{-5}
Water	1.0	1492	1.49
Muscle	1.06	1630	1.72
Fat	0.9	1476	1.37
Cortical bone	1.8	4100	7.38
Cancellous bone	1.0	1450	1.45

(Reprinted with permission from Schultheiß R: Basic physical principles of shock waves. *J Mineralstoffwechsel* 5:22-27, 1996.)

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