

# ISMST (International Society for Medical Shockwave Treatment)

## ISMST Recommendations

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## Physics recommendations

### Basic physical principles

There are three different types of shock waves generators used today.

The first is the electrohydraulic generator, which uses the tips of an electrode as a point source. This electrode is placed in the first focal point F1 of a semiellipsoid and high voltage is switched to the tips of the electrode. Between this tips an electrical spark is generated and a shock wave is released right from the beginning by the vaporization of the water between the tips. The spherical shock waves are reflected by a metal ellipsoid and focused into the second focal point F2 which for the therapy is adjusted to the therapeutically volume inside the patients body. This principle is shown in Fig. 1a.

The second generator is the electromagnetic one, which uses an electromagnetic coil and a metal membrane opposite to it. A high current pulse is released through the coil generating a strong varying magnetic field, which induces a high current in the opposite membrane. The electromagnetic forces accelerate the metal membrane away from the coil creating a slow and low-pressure acoustical pulse. To focus the wave an acoustical lens is used. The focal point is defined by the focal length of the lens. The amplitude of the focused acoustical wave is increasing by nonlinearities when the acoustical wave propagates towards the focal point. The rise times of electromagnetic generated shock waves are in the range of a few hundred nano seconds ( $10^{-9}$  s). Another construction using a cylindrical source. The high current pulse forms an cylinder shaped pressure wave which is reflected by a hyperbole shaped metal reflector to achieve focusing. Again the rise time shortens to a few hundred nano seconds while the amplitude is increasing on the way to the focal point. The principle of a flat coil generator is shown in Fig. 1b.

The third generator forms acoustical waves by the piezoelectric effect. A few hundred to some thousand piezoelectric crystals are mounted to a spherical surface. When switching a high voltage pulse to the crystals they immediately contract and expand generating a low pressure pulse in the surrounding water. The system is self focusing by the geometrical shape of the sphere. Again the shock wave is created by nonlinearities and increasing amplitudes during the propagation of the wave to the focal point. The principle is shown in Fig. 1c.

A typical pressure profile of a shock wave in the focus F2 of an electrohydraulic system is shown in Fig. 2. Generally a shock wave can be described as a single pulse with a wide frequency range (up to 20 MHz), high-pressure amplitude (up to 120 MPa), low tensile wave (up to 10 MPa), small pulse width at  $-6$ dB and a short rise time. Basic physics could show rise times of the positive pressure amplitude  $<10$  ns. For shock wave devices the measured rise times are in the range of 30 ns as a result of the limited time resolution of the pressure recording hydrophones [2, 3, 4]. An optical

hydrophone has a considerably higher time resolution compared to a piezoelectric hydrophone. The rise time of an electrohydraulic generated shock wave measured with an optical hydrophone is below 10 ns.

The positive pressure amplitude is followed by a diffraction-induced tensile wave with a few  $\mu\text{s}$  duration. The energy density (up to  $1.5 \text{ mJ/mm}^2$ ) and the pulse energy (up to 100 mJ) are determined from the temporal and spatial distribution of the pressure profile. The energy density describes the maximum amount of acoustical energy, which is transmitted through an area of  $1 \text{ mm}^2$  per pulse. The total pulse energy is the sum of all energy densities across the beam profile multiplied by the area of the beam profile. It describes the total acoustical energy per released shock wave.

## **Mechanism of action of shockwaves**

Shock waves are able to disintegrate kidney stones and to cure non-unions as well as soft tissue diseases. The effect of the shock wave in urology and orthopedics seems to be different. At present two different mechanism of the shock wave are noted. Shock waves are characterized by high positive pressure, a rise time lower than 10 ns and a tensile wave. The positive pressure and the short rise time are responsible for the direct shock wave effect and the tensile wave for the cavitation, which is called the indirect shock wave effect. Interfaces between two different materials with different acoustic impedance influence the shock wave, which is travelling through the interface. Reflection, refraction at the interface and damping inside the material leads to energy loss of the shock wave. The very fast pressure transition of shock waves (high-pressure, short rise time) cause very high tension at the interfaces so that the structure of the material cracks. This effect depends on the plasticity of the material. The energy of the shock wave, which is sufficient to disintegrate a kidney stone cause on an intact bone no considerably alteration.

The tensile part of a shock wave corresponds to a local lowering of the pressure so that cavitation bubbles will be created, these bubbles are growing under the influence of the tensile wave. After a certain time the bubbles collapse uncontrolled. The collapse leads to further generation of shock waves. The interaction between shock waves and gas bubbles attached to a surface generates water jets. The positive part of the shock wave compresses a gas bubble with 1 mm radius within a few  $\mu\text{s}$  to  $0.5 \mu\text{m}$ . The pressure and the energy inside the bubble increase strongly. If the water jet comes across a surface a hole will be created on the surface. The disintegration of a kidney stone is a combination between direct and indirect shock wave effect. The mechanism of the shock wave for orthopedic diseases is under investigation, it's not clear at the moment, which effect is dominant, or whether it is a combination of direct and indirect shock wave effect.

As pointed out already histological investigations have shown the osteogenic potential of shock waves and the stimulation of fracture healing. Wang et al. reported on the 3rd ISMST congress (International Society for Musculoskeletal Shock Wave Therapy), 2000 about his animal experiments with shock waves on soft tissue. The result was that shock waves enhance neovascularization on the tendon-bone junction. Further experiments with high energy levels have shown the damage potential of shock waves on large vessels and nerves. Right from the beginning of shock wave therapy in medicine focusing of shock waves on large vessels and nerves have been contra indicated.

Manufactures of orthopedic shock wave devices agreed to measure and publish physical parameters, which describe their shock wave devices. The parameters are described in section Basic physical principles. The idea was to compare medical with physical parameters to find possibly a strong correlation between medical indications and a significant physical parameter to explain the differences in success rates, number of shock waves per treatment and re-treatment rate of the used various shock wave devices. The physical parameters are available and it looks quite clear that an easy correlation to only one parameter investigated up to now is not possible. Energy, energy flux density, pressure or other parameters alone are not sufficient to explain clinical success rates. Examination of medical literature shows that electrohydraulic shock wave devices are more

efficient compared to other generating systems. This is valid in all medical fields shock waves were used. (Efficiency means less expense per patient achieving medical success with minor side effects.)

Comparable success rates of ESWT for soft tissue indications were achieved with different expenses per patient. Therefore differences between electrohydraulic and other generating systems could be responsible for the differences in efficiency. In 1992 Folberth et. al. compared the pressure distribution in the focal region of two different shock wave generating systems, an electrohydraulic system (Dornier HM3) and an electromagnetic system (Siemens Lithostar Plus). Shock waves generated by an electrohydraulic system shows a shock wave represented in Fig. 2 in the center of the focus, in the vicinity of the center and far from the focus center. The essential characteristics like short rise time, small pulse width at -6 dB, high positive pressure amplitude followed by a small tensile part are fulfilled. This is different for an electromagnetic generated shock wave. Only in the center and 1 mm in lateral direction and 10 mm in axial direction the essential characteristics are fulfilled. This means electrohydraulic shock wave devices generated shock waves in a large focus volume whereas electromagnetic shock wave devices have a real shock wave only in the focus center and in a small area around the center.

Orthopedic shock wave devices show the same behavior. In the focus center both systems generated shock waves which fulfill the essential characteristics. Already 1 mm in lateral direction the shock wave of the electromagnetic system shows another behavior. The pulse width at -6 dB is much larger and the pressure of the tensile part is increased compared to the shock wave in the focus center.

Another difference between the shock wave generating systems is the ratio of positive to negative pressure amplitudes and therefore also the ratio of positive to negative energy. The so-called positive energy means the energy calculated out of the positive pressure amplitude and the negative energy means the energy out of the tensile wave. As it was discussed in the section "Effects of shock waves" the positive pressure amplitude is responsible for the direct and the tensile wave is responsible for the indirect shock wave effect. Electrohydraulic shock wave systems generates energy per shock wave considerably out of the positive pressure amplitude while other systems out of the tensile part. A real shock wave in a large focal volume and the higher positive energy of electrohydraulic shock waves could be a possible explanation why electrohydraulic shock waves show the highest efficiency in shock wave application in medicine.