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History

Shock wave application in medicine, a tool of modern operating theatre

An overview of basic physical principles, history and basic research

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Abstract

Extracorporeal generated shock waves have been introduced for medical therapy approximately 20 years ago to disintegrate kidney stones. Since this time shock waves have changed the treatment of urolithiasis substantially. Today shock waves are the first choice to treat kidney and ureteral stones. A new indication in Urology is the shock wave treatment of IPP where first clinical investigations show promising results. Urology is not the only medical field for shock waves in medicine. Meanwhile shock waves have been used in Orthopedics and Traumatology to treat insertion tendinitis, non- or delayed unions, avascular necrosis of the head of femur and other necrotic bone alteration. Another field of shock wave application is the treatment of tendons, ligaments and bones on horses in veterinary medicine. The idea of the shock wave therapy for orthopedic diseases is the stimulation of healing processes in tendons, surrounding tissue and bones. This is a completely different approach compared to urology where shock waves were used for disintegration. This paper gives an overview of basic physical principles of shock waves, history and basic research of shock wave application in medicine.

Introduction

Extracorporeal shock wave therapy (ESWT) in orthopedics and traumatology is still a young therapy method. In the last few years the development of shock wave therapy was very fast and successful. Meanwhile ESWT has gained acceptance within the orthopedic community. Today physicians have an overview of several ten thousand treated patients worldwide. Nevertheless the healing mechanism of ESWT for treatment of the established indications like epicondylitis or heel spur is not completely understood. Shock waves have changed medical therapy substantially. Advantages of ESWT are avoidance of surgeries, safety and effectiveness. Compared to open surgery the costs of the ESWT are very reasonable. But nevertheless it's necessary to improve the basic understanding of the biological and medical effects of shock waves in cooperation between institutes, hospitals, physicians, societies and manufacturer of ESWT devices.

Shock waves are acoustic waves, which accompany our daily life without being noticed. The sound of thunderstorms, bangs of an explosion or of an applauding crowd are typical examples in which shock waves play an important role. An earthquake and the collapse of gas bubbles in a liquid generate shock waves. By means of shock waves energy can be broadcast over long distances. An airplane, which breaks the sound barrier, generates a very loud bang, which can lead to the jingle of glasses in a cupboard. The shock wave has transmitted energy from the airplane to the glasses.

The opportunity to transmit mechanical energy with shock waves leads to different applications, which can be classified in two groups [1].

Destruction of material structure:

Examples of this group are purification of nozzles, crushing of hard material like concrete, glass in a recycling process and removal of deposits in pipes. The extracorporeal shock wave therapy belongs to this group.

The other group is the application of shock waves as a source of signal.

In deep sea shock waves were used to measure distances because of the low energy loss over large distances.

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 μ s duration. The energy density (up to 1.5 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 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.

Historical overview

From the first investigation of the application of shock waves in medicine until today is a very short time. During the Second World War it was observed that the lung of castaways was cracked because of the explosion of waterbombs although no outer symptoms of violence existed. This was the first time that the influence of shock waves, created by the exploding bombs, on tissue was observed.

In the 50'ies the first systematic investigations for the use of shock waves in medicine have been performed. For example it was published that electrohydraulic generated shock waves were able to crush ceramic plates in water. In the USA the first patent of an electrohydraulic shock wave generator was accepted (Frank Rieber, New York, Patent No. 2.559.277). End of the 50'ies the physical properties of electromagnetic generated shock waves have been described.

In 1966 the interest in shock waves on human was stimulated accidentally at Dornier company [5]. During experiments with high velocity projectiles an employee touched the plate in the very moment where the projectile hit the plate. He felt something in his body like an electrical shock. Measurements show that no electricity was present. The generated shock wave traveled from the plate over the hand in the body. From 1968 until 1971 the interaction between shock waves and biological tissue in animals was investigated in Germany. The Department of Defense of Germany financed this program. The result was that high-energy shock waves cause effects in the organism over long distances. Particularly the effects of interfaces in the organism were investigated together with the difference and damping of the shock wave on its way through living tissue. Another field of interest was the transition of the shock wave into the body. It was observed that shock waves create low side effects on the way through muscles, fat- and connective tissue. Intact bone tissue remains unharmed under shock wave burden. The danger for the lung, brain, abdomen and other organs was part of the investigation in this program. The best transition media for the shock wave was water and gelatin because of the similarity in the acoustic impedance to the tissue.

These investigations and cooperation with physicians lead to the idea to disintegrate kidney stones with extracorporeal generated shock waves. In the beginning the technical and medical realization of the idea was not very clear but the idea was born. 1971 Haeusler and Kiefer reported about the first in-vitro disintegration of a kidney stone with shock waves without direct contact to the stone [5]. Further in-vitro experiments of contact-free stone disintegration followed. In 1974 the Department of Research and Science of Germany financed the research program "Application of the ESWL". Participants on this program were for example Eisenberger, Chaussy, Brendel, Forßmann and Hepp. 1980 the first patient with a kidney stone was treated in Munich with a prototype machine called Dornier Lithotripter HM1. In 1983 the first commercial lithotripter (HM3, Dornier, Fig.3) was installed in Stuttgart/Germany. In the next years in-vivo and in-vitro experiments with extracorporeal generated shock waves with the goal to disintegrate gallstones were carried out.

In 1985 the first clinical treatment of a gallbladder stone with ESWL was performed in Munich/Germany. One year later a prototype of a lithotripter without a bathtub was tested in

Mainz. Today the treatment of kidney and ureteral stones with extracorporeal shock waves is the treatment of the first choice. Modern lithotripters work without a bathtub and without anesthesia (Fig. 4). For localization of stones lithotripters are equipped with x-ray and/or ultrasound localization systems. In the last 16 years more than 3 Million patients have been treated. The shock wave therapy is safe and effective but nevertheless careless applied shock wave therapy has the potential to cause severe damage.

Urology is not the only field in medicine where shock waves were used successfully. In 1985 the first experiments were carried out to investigate the influence of shock waves on bones. The reason for this research was the apprehension that shock waves could damage the hip as a result of shock wave therapy on lower ureteral stones. The result of these experiments was that on an intact bone no considerable alteration was observed. Further animal experiments showed that shock waves have osteogenetic potential and stimulate fracture healing. Histological investigations confirmed the influence of shock waves on the activation of osteoblasts [6].

In 1988 the first shock wave treatment of non-union in human was successfully performed in Bochum/Germany. At the same time Valchanow et. al. [7] reported about shock wave therapy on non-unions and delayed unions. His success rate was 85% but the requirements of his clinical study were not exactly specified. In the next years different clinical studies reported about success rates between 60% and 90%. Two essential circumstances exert influence on the success of the shock wave therapy on non-unions or delayed unions. The influence of shock waves on hypertrophic non-unions seems to be more effective as on atrophic non-unions. The stabilization of the fracture after shock wave therapy seems to be an essential condition for the success of the therapy. As side effects local haematomas, petechial hemorrhage and local swelling were found. These side effects disappeared within a few days without any complications.

The first investigations and treatments on humans were performed with lithotripters, which are designed for the requirements of shock wave application in urology. Because of the anatomical decentralization of the therapy areas (shoulder to foot) it was necessary to develop a special orthopedic shock wave device. In 1993 a special orthopaedic shock wave device, OssaTron (HMT AG) with a free moveable therapy head became available (Fig. 5).

At the beginning of the 90'ies the first reports about shock wave therapy on tendinitis calcarea were published. Further investigations lead to successful treatment of epicondylitis and heel spur with reported success rates between 70% and 80%. Because of the increasing significance of shock wave therapy on soft tissue diseases, HMT developed a special shock wave device, the ReflecTron (Fig.6). The new concept of its electrode (ReflecTrode) is an increased durability of 50000 shock waves. For the scientific evaluation of the ESWT for orthopedic diseases many clinical studies and publications are available. Design, protocol and contents of the published studies are different but all publications agree that ESWT show high efficiency but very low complications and side effects.

Effects of shock waves

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 (Fig. 2). 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 μs to 0.5 μm . 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 [1,2]. The disintegration of a kidney stone is a combination between direct and indirect shock wave effect. Fig. 7 shows the different mechanism of a shock wave that disintegrates a kidney stone. 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 [6] have shown the osteogenic potential of shock waves and the stimulation of fracture healing. Wang et al. [8,9,10] 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 [11]. 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. [12] 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 [13].

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.

Prospect

The shock wave therapy on non-unions and delayed unions, tendinitis calcarea, epicondylitis and heel spur can be looked at as scientifically proved. Besides these indications further orthopedic diseases are under clinical studies already. In particular the preliminary results of the shock wave therapy on the avascular necrosis of the head of femur [14,15] are very promising. Osteochondritis dissecans [16], patellar tendinitis and achilles tendinitis are also orthopedic indications with very promising preliminary results.

Because of the results of the orthopedic shock wave therapy on tendons veterinarian physicians have started to treat several tendon problems on horses. The major problem is lameness of the horses. As a preliminary result lameness could be significantly improved.

Meanwhile ESWT is well known in many European countries. In the USA, Japan, Taiwan and in other countries of Asia ESWT will get the approval within the next months. Important impulses for the progress of the shock wave therapy can be expected from these countries. The biological influence of shock waves on tissue and bones is not very well understood so that basic research is necessary but the routine application of the therapy in hospitals and private practices must be possible because of the demonstrated safety and effectiveness of the shock wave therapy in orthopedics.

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Figures

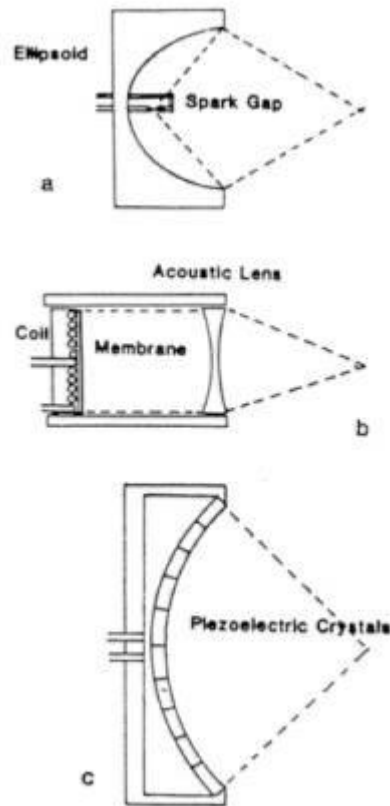


Fig. 1a to 1c: Principles of shock wave generation. a. electrohydraulic, b. electromagnetic, c. piezoelectric. Extracted from [2].

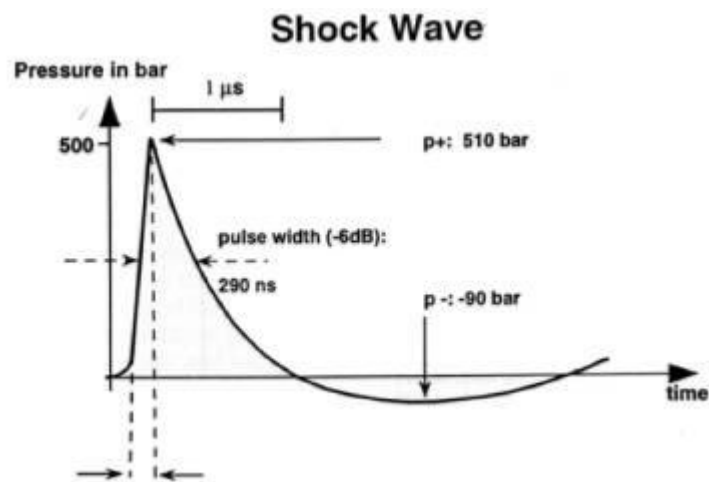


Fig. 2: Typical shock wave (pressure vs. time) in the focus F2 of an electrohydraulic shock wave system. Schematic representation of the pressure amplitude of the shock wave as a function of time. Positive pressure amplitude is followed by a tensile wave.

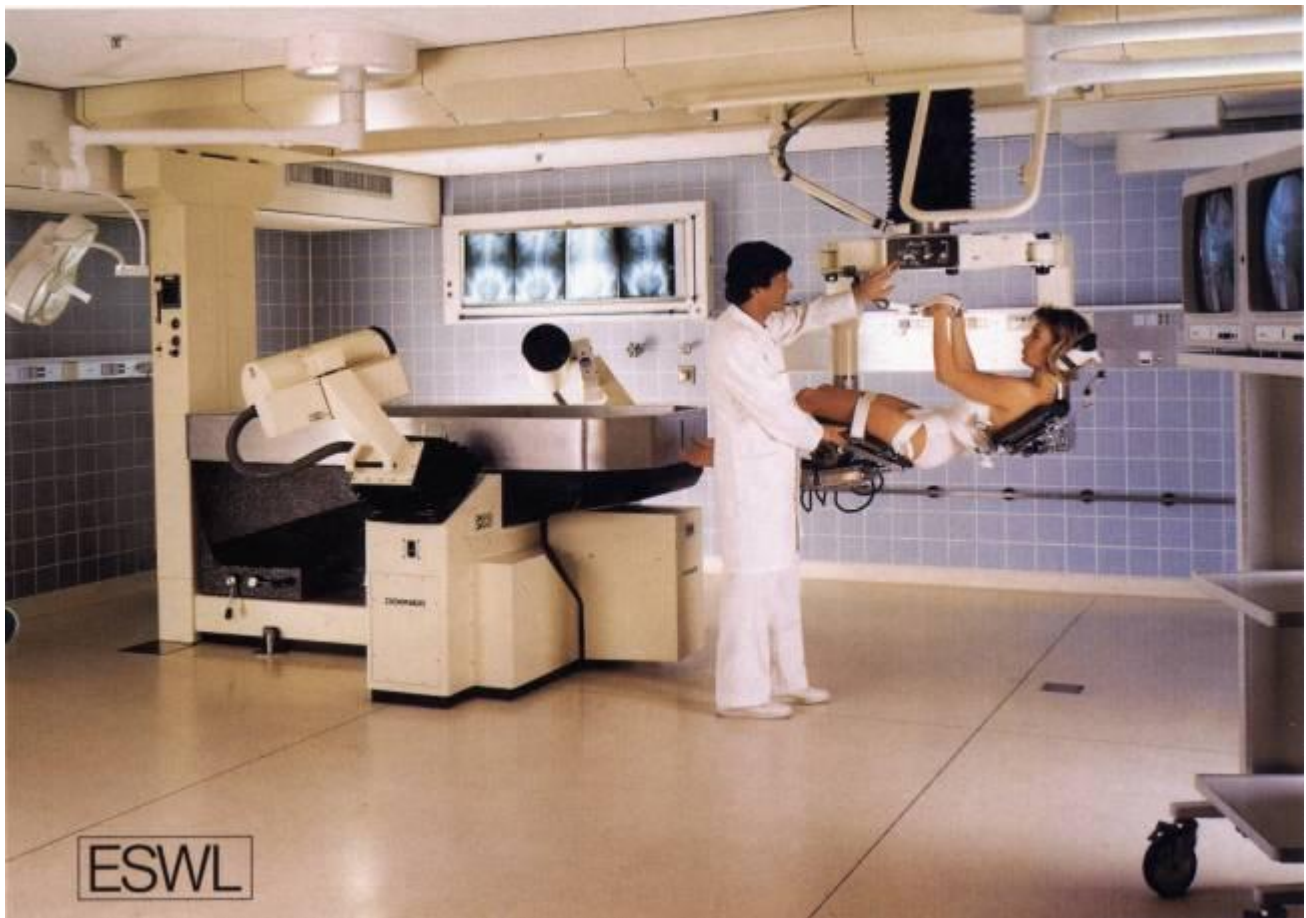


Fig.3: First commercial lithotripter HM3 (Dornier) with bathtub.

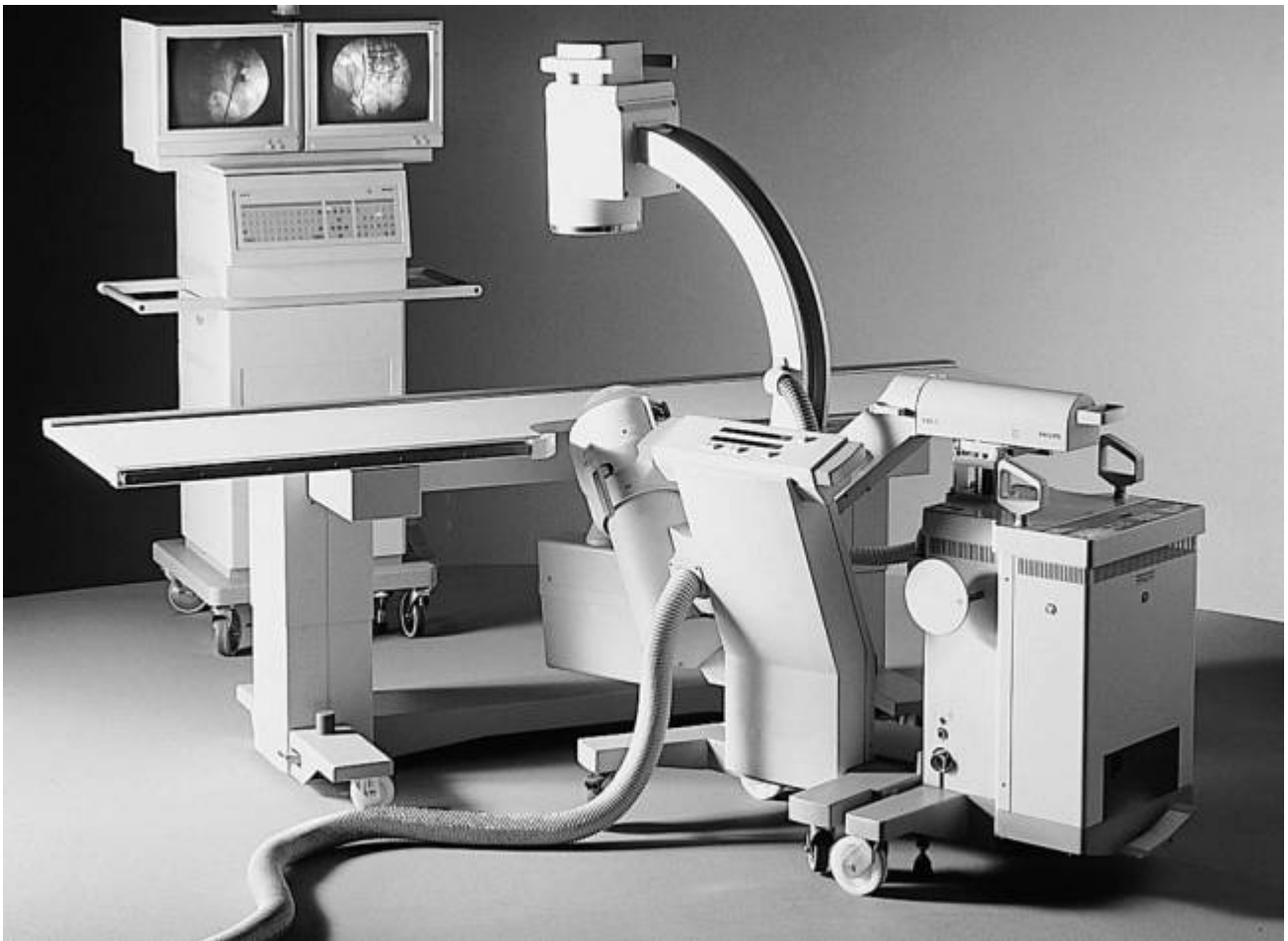


Fig.4: Today's lithotripters (LithoTron, HMT) are mobile, flexible and easy to use.



Fig.5: Special orthopedic shock wave device OssaTron (HMT High Medical Technologies AG) with movable therapy head of about 350° degree for the different localization of orthopedic diseases.



Fig.6: The ReflecTron (HMT AG) is an orthopedic shock wave device especially designed for soft tissue diseases

Fig.7: Combination of direct and indirect shock wave effect to disintegrate a kidney stone [1].

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