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Epochs in Endourology

Extracorporeal Shockwave Lithotripsy (ESWL®): A Chronology

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Through more than a quarter century of innovation and clinical application, SWL continues in its stride as the first minimally invasive therapy that helps alleviate the urinary calculus burden in millions of people worldwide. Evolution of SWL is a saga of scientific veracity based on human ingenuity and tenacity. The authors and their coworkers are to be commended for establishing a significant milestone of urology in the 20th Century.

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UROLITHIASIS is one of the most frequent diseases worldwide, with a prevalence of 2% to 3%. Within the industrialized countries, the frequency is still growing. The introduction of extracorporeal shockwave lithotripsy (ESWL® or SWL), which is the fragmentation of urinary stones by extracorporeal means, has become a medical milestone and a revolution in urology.

Initial research on this method started about 40 years ago, and 20 years later—on February 7, 1980—the first treatment of a patient with a kidney stone was carried out. With the acceptance and propagation of SWL, open surgical removal of urinary stones lost its place in urology. Today, there are more than 5000 lithotripters in use worldwide, and the more than a million treatments per year show the method's global acceptance. Extracorporeal lithotripsy remains the subject of scientific interest and research, as numerous publications per year illustrate (Fig. 1).

FROM THEORY TO EXPERIMENTAL SETUP: 1966–1972

In airplane and aerospace technology, the interaction of shockwaves with solid bodies, such as the impact of raindrops or micrometeorites on flying objects, are of great interest in order to clarify the mechanisms of damage to aircraft structures. In order to research these impacts, high-speed projectiles, which produce shockwaves imitating those engendered by micrometeorites, have been shot at a target. During these experiments, an engineer at Dornier noted the effect on biological tissue (pain as from an electrical shock) when in contact with the shockwave set-up. This phenomenon led to an experimental project to research the shockwave effect on biological structures, which was funded by the German Ministry of Defense. For metrology, the Institute for Short-time Physics and Electrical Engineering at the University of Saarland was included in the research. Obvious effects were detected at the interface between media of different sound wave impedances. Today, nobody is sure who had the first idea to destroy intracorporeal concretements by shockwaves.

In subsequent experiments with shockwaves created by high-speed water drops, it was proved that it was possible to destroy kidney stones within closed waveguides.[1] Shortly thereafter, physicists at Dornier were able to fragment kidney stones in an open waterbath using shockwaves generated with a light-gas gun.[2] The shockwave source, through its location in a semiellipsoid, allowed shockwave concentration on the kidney stone.

1973

At the end of 1972, W. Hepp and G. Hoff from Dornier Development and Research attempted to find a clinical partner for the application of SWL in humans. E. Schmiedt and F. Eisen-

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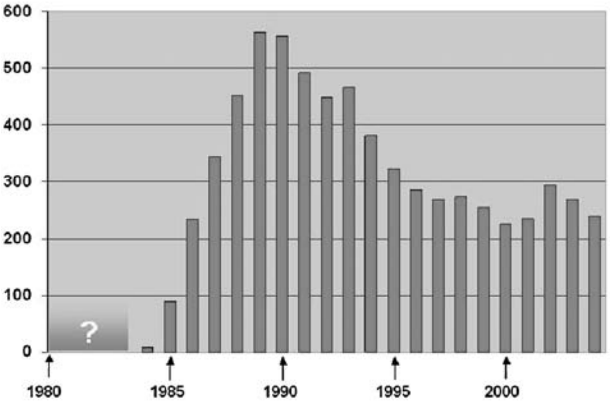

FIG. 1. Numbers of SWL publications by year.

berger (Dept. of Urology, Ludwig-Maximilians-Univ. Munich) agreed to join the project. It was agreed that the necessary preclinical and clinical research would be performed in cooperation with the Institute of Surgical Research (W. Brendel) That group, headed by Ch. Chaussy, applied for funding through the German Research and Technology Ministry (BMFT). To generate shockwaves, an underwater spark discharge was created, and shockwaves were focused on the kidney stone through a semiellipsoid. Planning the first human treatment for 1976 proved to be too optimistic by far.

EXPERIMENTAL PHASE

1974

The first experimental phase of researching the *in-vivo* and *in-vitro* effects of shockwaves was planned and conducted by Ch. Chaussy, F. Eisenberger, B. Forssmann, and W. Hepp. The idea was to destroy a kidney stone with just one extracorporeal shockwave exposure. Generation of shockwaves through spark discharge with water as the transmitter promised to provide the ideal acoustical interface with the human body. Irritating and harmful effects at the tissue entry point could practically be excluded. At the time, there was no suitable technology for measuring shockwave expansion and focusing within an ellipsoid. Consequently, piezoelectric pressure probes were developed in order to provide an estimate of the location of the second focal point for the relative pressure distribution within the waterbath. After the first positive results of generating and optimizing the focusing of shockwaves in the waterbath, it was only a short time till the first shockwave lithotripter (TM1; Fig. 2A) was built. In the TM1, the dimensions of the shockwave-generating system were already adapted to the anatomic dimensions of the human body. It was possible to place experimental objects for in-vitro or in-vivo experiments, via membrane or waterbath, in the apparatus. In the waterbath, kidney stones within the focal area could be fractured under direct vision and without any problems with the impact of high-energy shockwaves. The first ideas about the destruction mechanism had been developed. The main factors seemed to be the shear forces at the shockwave-entrance point and the tear forces at the shockwave-exit point, as well as the superimposition of tear and shear forces within the stone caused by focusing of the shockwave.[3,4] Even after repeated shockwave exposure, within the focus, there was no negative impact on erythrocytes or the proliferation of mixed lymphocyte cultures.[5–7]

1975

The next experimental stage was study with small animals. In these experiments, neither in eventerated organs nor in the waterbath could relevant macroscopic or microscopic pathologic changes be detected even after multiple exposures. The only exception was the lung, where severe lesions were found because of the multiple air–tissue interfaces. This was to some degree expected because of the different impedance levels; however, it was possible to avoid these lesions by interposition of protective materials (i.e., Styrofoam).[5–7]

The main topic for further research was the fragmentation of urinary stones in dogs and their necessary localization within the body. For these experiments, freshly harvested human kidney stones were implanted in the operatively dilated caliceal systems of dogs. Afterward, undisturbed urine flow was restored.[8,9] A further necessity at this stage of research was the solution of technical-material problems experienced with the underwater spark discharge and the reproducibility of shockwave generation. A significant element for this optimization was the striation optic experiments to focus with brass ellipsoids in different dimensions. This work led to more efficient

A

B

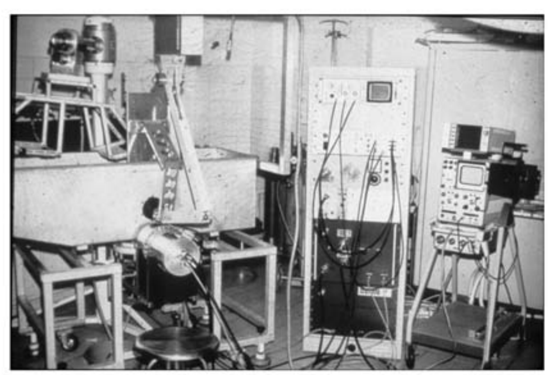

FIG. 2. Early lithotripters. (**A**) TM1 for *in-vitro* and *in-vivo* experiments. (**B**) TM2 with integrated ultrasound localization.

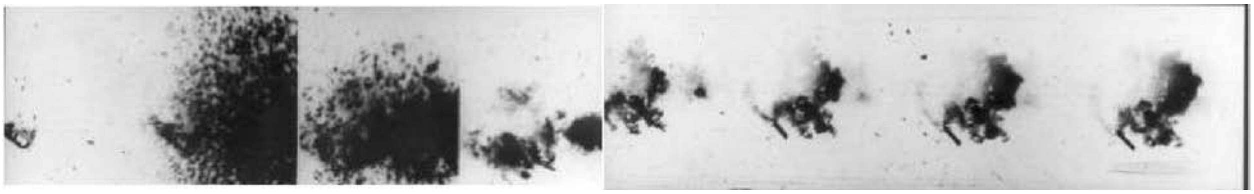

FIG. 3. High-speed sequence of kidney-stone destruction under water (SYCAM camera; 1000 pictures/sec).

shockwave generation for further animal experiments. Information on tissue-caused attenuation within the path of the shockwave was gained from the experimental data, and the effect of the kinetic energy of the fragments was determined from high-speed pictures (Fig. 3) in order to exclude damage to the caliceal system.[4,8–12] High expectations for improving the localization of concretements were raised by the new diagnostic ultrasound systems. In a newly developed experimental set-up (TM2), an improved shockwave generator was tested, and an ultrasound A scanner was integrated into the ellipsoid (Fig. 2B).

1976–1978

Because of problems with the ultrasound A scanner, *in-vivo* fragmentation of concretements was possible in only a few cases, even after positive *in-vitro* tests in the waterbath.[5,7,10,11] Hence, the funding ministry lost faith in the project and threatened to stop the support. Serendipitously, just before the review committee's further assessment, it proved possible to break down an implanted kidney stone into several fragments. This was the success urgently needed to gain further financial support. Also, the change to localization through ultrasound B scanning with the compound scanners then available did not allow definite localization of concretements because of multiple artefacts, but it showed the organ boundaries. Now, it was at least possible to research the effects of systemic exposures to high-energy shockwaves of the kidney parenchyma in a series with dogs without kidney stones. Histologic examination showed neither systemic nor pathological side effects on the kidney or adjacent organs. However, stone fragmentation still was not possible because of localization problems with the then-available ultrasound scanners. This problem was solved by a faster application of as many as 20 high-energy shockwaves in the area where the concretement was suspected to be. With this method, the first *in-vivo* destructions of implanted human stones through extracorporeally produced shockwaves were possible. In all cases, the implanted stones were fragmented, although larger pieces that were not passable remained. In four cases, though, we were successful in destroying a kidney stone into spontaneously dischargeable fragments.[5,6,11] Accordingly, the principal possibility of the method was proved; but the available ultrasound-guided localization systems were still a long way from clinical application. In the meantime, the method and the available results were presented for the first time at a symposium in Meersburg in presence of the Secretary for Research and Technology. This was more for political than for scientific reasons to show the feasibility of the method. The funding for the project by the Ministry of Research and Technology proceeded.

However, the same Ministry funded a competing project at the University of Saarland to fragment kidney stones in surgically exposed kidneys without localization. The aim of this project, in collaboration with the Institute for High-Frequency Technique and Electronics of the University of Karlsruhe, was to research the possibility of piezoelectric extracorporeal shockwave generation.[13]

Because of the above-mentioned difficulties of localization with ultrasound, we had to apply for funding for integration of an X-ray system. Initially, this idea was refused, not only because of the high cost, but also because of doubts about the possibility of achieving adequate, millimetre-precise concretement localization with a lithotripter. An additional problem presented itself in the fact that by the coupling of the shockwave through a waterbath, we had to expect a reduction of imaging quality by absorption of the X-rays passing through the water. In a laboratory study, it was possible to prove that with two independent, two-plane optical systems, three-dimensional localization was possible.[5,6,12,14] Now, the necessary financial support by the Ministry of Research and Technology was granted for the development of the TM4, an experimental device with an integrated X-ray system.

1979

Localization with the integrated three-dimensional X-ray system was reproducible. However, after shockwave discharge, there were fragments scattered over the caliceal system that were too large to pass spontaneously. Only the use of less-energetic shockwaves with an impulse series of as many as 500 single shots/sec led to dischargeable-fragment size. The energy dose for a complete fragmentation was, surprisingly, less than with the high-energy method. The strain on the kidney either through the shockwave or through scattered stone particles was clearly reduced.[5,12] With the new experimental set-up, reproducible destruction of kidney stones in one or two sessions with consequent spontaneous passage was possible.

Reduction of kidney function as a result of shockwave exposure was excluded by nuclear medicine methods and repeated laboratory tests. Neither macroscopic observation nor histologic examination of the organs from experimental animals showed impairments that would hinder the further development of the method. The results of these experimental series provided the prerequisites that justified human application.[5,6,15]

At this point, the development of the first clinical prototype of a lithotripter (HM1) started.[12] Technical tests that are standard requirements nowadays were not performed at that time. Even though technical security experts tested the device, they did not take the responsibility and declined to provide expertise regarding the security risk of the electrical spark gap with the patient immersed in a waterbath; therefore, the research team had to take full responsibility for the clinical application.

The Institute of Surgical Research offered to provide the necessary space where the Department of Urology could perform human treatments. There was a training program with stone-bearing volunteers in which localization tests were performed in the HM1 to pinpoint the position of the patient, as well as to test the technical procedure. These tests initiated necessary changes in the apparatus to take account of the buoyancy of the patient immersed in the waterbath.

The total costs for the whole project were 3.9 million DM (in 1979: US$2.12 million). The largest amount was expended on the development of the TM4 and HM1, both with integrated X-ray systems.

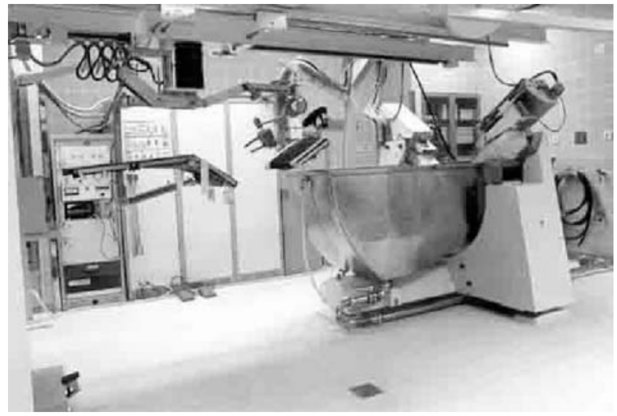

FIG. 4. Shockwave lithotripter HM1 used for first human treatment.

CLINICAL EVALUATION

1980

On February 7, 1980, Ch. Chaussy, B. Forssmann, and D. Jocham treated the first patient ever on an extracorporeal lithotripter only after applying intense selection criteria (Fig. 4). The patient was suffering from a fourth recurrence of a renal pelvic stone. The treatment was performed with intrathecal narcotic anesthesia (ITN). The stone was broken into spontaneously dischargeable fragments, and follow-up showed passage of the fragments without any significant problems. During the first patient treatments, an unexpected problem arose, namely, induction of extrasystoles by the shockwaves. This phenomenon was later avoided by the introduction of EKG triggering of the shockwave impulse. The cause of induction of extrasystoles by shockwaves is still not understood.

Motivated by the first successful treatments, we proceeded routinely. In December 1980, the first clinical results were published in *The Lancet*.[16] Interestingly enough, the American Urological Association refused a submitted presentation about the results. However, 1 year later, SWL as a topic was acceptable, and another 9 years later, the AUA presented the Distinguished Contribution Award to Ch. Chaussy, F. Eisenberger, and E. Schmiedt.

1981

Now, it was possible to extend the indications for SWL to the treatment of ureteral and partial staghorn stones. Contraindications, which are still valid today, were defined.[6,17,18] The first treatments were performed with ITN; fortunately, it soon became evident that peridural anesthesia was sufficient. In an early clinical study, 206 patients were treated under strict selection criteria with extracorporeally produced shockwaves. Later that year, the method was named "ESWL"* = extracorporeal shockwave lithotripsy or SWL.

Critical analysis showed that there were no serious complications, either through the treatment itself or through the discharge of the debris. Conservatively treatable colic or pain was in some cases caused by fragment discharge. None of the patients had to undergo emergency surgery. Follow-up to 1 year showed no significant biochemical changes in blood or urine. Nuclear isotope studies performed on these patients did not discern any alterations in renal function.[6,19,20] Further clinical experience prompted the need for technological advances such as improvements in shockwave generation, optimization of the X-ray system, and adaptation of the patient support for possible emergency situations. These modifications were tested in the HM1 and verified in the HM2.

CLINICAL SUCCESS

1981

The installation of the HM2 in Munich required a space allocation plan. The investment of 2.1 million DM (in 1981 US$855,000) was possible only with the help of the Bavarian insurance companies and the Committee for Home Dialysis (Kuratorium für Heimdialyse [KfH]). Without their dedication, the project would not have been possible at all.

1982

On May 20, 1982, the first lithotripsy center was launched in Munich under the supervision of Ch. Chaussy of the Department of Urology, University of Munich. With this set-up, fast further clinical evaluation of the extension of indications was possible. The treatment of staghorn stones by fractionated shockwave exposition in multiple sessions, of infected stones with antibiotic pretreatment, and of multiple stones proved possible. Also, high-risk patients were accepted. Furthermore, percutaneous nephrolithotomy,[21] which was regarded initially as competition, was introduced as an auxiliary procedure for SWL. After these successful extensions of the indications for SWL, operative indications for stone removal were limited to 10% to 15% of stone patients.[6,19,22–25]

1983

The success of SWL sparked enormous interest in Germany and worldwide. In 1983, the second lithotripsy center was opened in Stuttgart (F. Eisenberger).[26–28]

*ESWL is a registered trademark of Dornier MedTech Systems.

A study necessary for approval of SWL by the U.S. Food and Drug Administration was planned at six centers. In spite of the great interest displayed by radiologists, it was possible to keep the procedure in the hands of urologists, the main reason being that all principal investigators had to be trained in Munich, and the Munich urologists refused to train radiologists.

1984

The first device in the US was installed in February in Indianapolis (D. Newman, J. Lingeman); another five clinics soon followed. The study required for marketing approval was monitored by G. Drach.

Because of the method's success, the Food and Drug Administration granted approval for general marketing in December 1984. This fast decision was attributable mainly to the acceptance of the data from the clinical study conducted by the Munich Urology Clinic The results of the US study were not published until 2 years later.[29]

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