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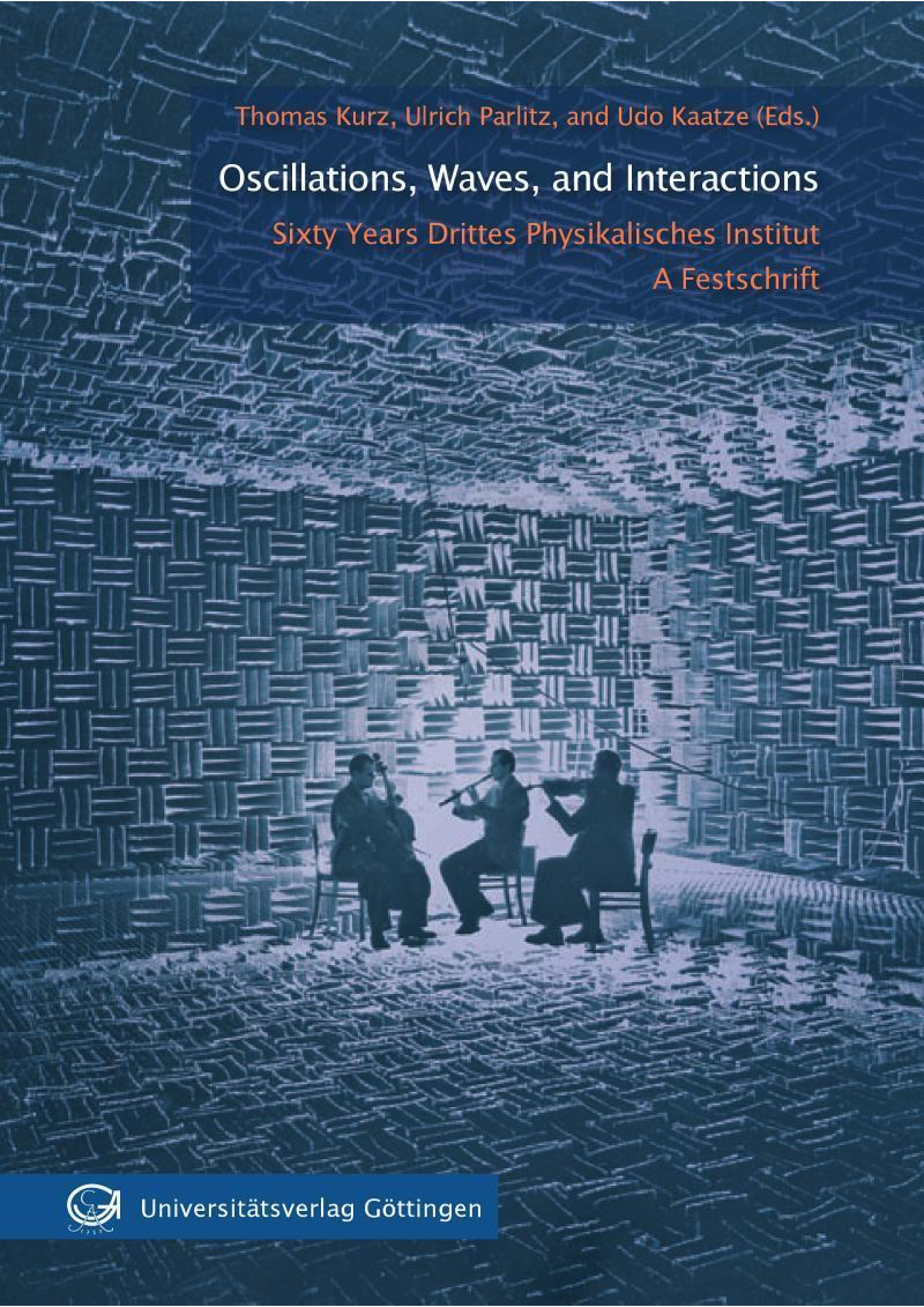

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Physics of stone fragmentation and new concept of wide-focus and low-pressure extracorporeal shock wave lithotripsy

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Abstract. In this contribution a new fragmentation mechanism by circumferential quasistatic compression using evanescent waves in a stone is described. The high efficiency of such "squeezing" process in fragmentation experiments, utilizing a self-focussing electromagnetic shock wave generator developed at the University of Stuttgart, is shown for artificial stones as well as for clinical applications. The method relies on the wide focus of the generator, with focal diameter comparable to or larger than the stone diameter. It comprises a significantly smaller peak pressure of the shock waves, with many substantial advantages for the extracorporeal shock wave lithotripsy (ESWL). A first clinical study at seven hospitals in China, in which a total of 297 patients has been treated with wide-focus and low-pressure ESWL, revealed (i) a beneficial average number of only 1532 shock pulses for successful teratment, (ii) a small mean of 1.39 sessions per patient, (iii) a high stone-free rate of 86 per cent after a follow-up of three months, and no necessity for pain medication and auxiliary measures. Additionally, with respect to the conventional narrow-focus ESWL, larger focal width involves reduced aperture and increased positional flexibility. It also enables the treatment of larger stones with a wider spatial distribution of fragments and it avoids the necessity of X-ray control during treatment, because ultrasonic positioning appears to be sufficient.

1 Introduction

Almost three per cent of the adult population is affected by kidney stones. Kidney stones are polycrystalline concrements that form from minerals and proteins in the urine. Stones come in various compositions and in sizes varying between one millimeter and some centimeters. Until about three decades ago, stones too large to pass through the urinary tract have been removed by surgery, called lithotomy. For centuries the operations bore a serious risk. In the middle of the nineteenth century, about fourteen per cent of operations resulted in the patient's death. The introduction of general anaesthesia and aseptic conditions reduced the risk of lithotomy significantly.

The successful extracorporeal disintegration of stones in the seventies of the last century, using acoustical waves or shock waves in Saarbrücken [1] and Friedrichshafen [2], has revolutionized the treatment of urinary lithiasis. Extracorporeal shock wave lithotripsy (ESWL) has received rapid acceptance, because of its noninvasive nature, high efficiency, and ease of use. Lithotripsy is the most effective non-surgical procedure for the disintegration of kidney stones ever developed. It is an alternative to surgery for seventy to eighty per cent of patients with kidney stones. Therefore, within a very few years, ESWL became the standard treatment for stones in the kidney and ureter worldwide. Stones are comminuted into small fragments which are passed with the urine during the weeks after treatment. The risk for patients to suffer major complications is distinctly lower than with surgical stone removal. The unique development of ESWL has been described in various review articles and textbooks [3–8].

Despite increasing perfection in the lithotripter generations that followed the first Dornier HM3 device, there is currently only limited agreement on the relevant stone breaking mechanisms. Some authors consider cavitation, besides shear and spalling, as the most important force for the ultimate stone fragmentation in applications of conventional lithotripters [8,9]. Cavitation is believed to cause trauma to thin-walled vessels in the kidney and in adjacent tissue as side effects, leading to short-term complications and to scar and chronic loss of tissue function [8]. Alternatively, in experiments with focal diameters on the order of the stone diameter, evidence for a squeezing mechanism has been found [10]. In addition to the question of the stone fragmentation mechanism, it has become obvious that, since the promising introduction of the Dornier HM3, progress in ESWL techniques has been unexpectedly slow [11]. The further optimization of the physical parameters of the pressure shock waves with respect to fragmentation efficiency and avoidance of side effects has been scarce and is still matter of a lively scientific debate [7,12].

In this article we summarize the results on the efficient mechanism of stone fragmentation by wide-focus and low-pressure shock waves, which one of us has obtained at the University of Stuttgart [10]. We also review clinical studies [13,14] demonstrating successful treatment of a large group of patients with kidney stones, without necessity for preventive measures, using an advanced ESWL conception. It involves a wide-focus low-pressure lithotripter that had been developed in cooperation between the Erstes Physikalisches Institut of the University of Stuttgart and the Xixin Medical Instruments Co. Ltd., Suzhou, China.

2 Lithotripter shock wave generation

Shock wave lithotripters are currently produced by more than ten companies. As an example, Fig. 1 shows the Xixin instrument, meanwhile named XX-ES lithotripter [15], as it has been used in the clinical studies which we report here. During treatment the patient rests on an examination couch which is provided with X-ray equipment and/or ultrasonic B-scan facilities for the optimum positioning. For the treatment of the patient in either dorsal or face-down position the lithotripter is equipped with a shock wave generator in an overcouch or undercouch arrangement. The shock wave

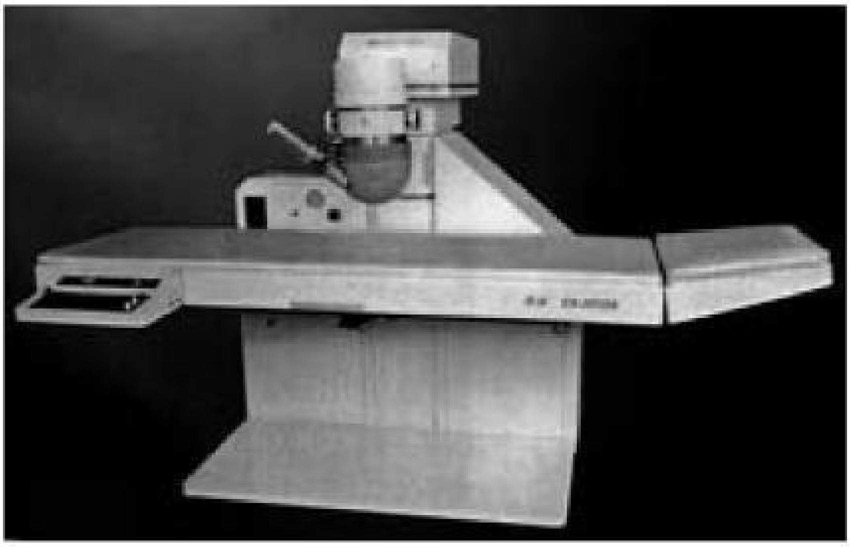

Figure 1. Lithotripter of Xixin Medical Instruments Co. Ltd., China, equipped with self-focussing electromagnetic shock wave generator from the University of Stuttgart.

is normally coupled to the patient's body via a water-filled cushion and a gel coat.

Various principles of shock wave generation are used [4]. In the electrohydraulic, or spark-gap, technology the wave is created under water by generation of an electrical discharge between two tips of an electrode (Fig. 2). The discharge produces a vaporization bubble which expands and immediately collapses, generating a high-energy pressure wave thereby. The electrode tips are located in the first focus of an ellipsoidal reflector made of suitable metal. Hence the high-energy pressure waves created in this point converge at the second focal point of the ellipse where pressure is sufficiently high for fragmentation of stones.

In the piezoelectric method a shock wave is generated by an array of some tens to thousands of piezoelectric elements stimulated with high-energy electrical pulses

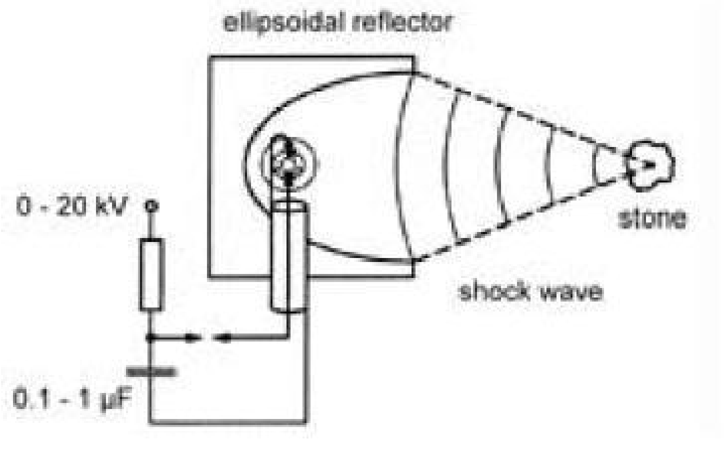

Figure 2. Sketch of electromagnetic shock wave generation with a high-voltage electrical current passing across a spark-gap electrode system that is located within a water-filled container.

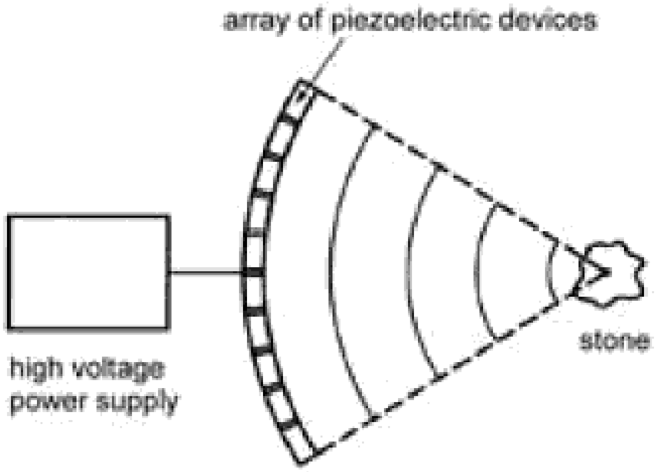

Figure 3. Principle of self-focussing piezoelectric shock wave generation.

(Fig. 3). The dome-shaped arrangement of elements in a water-filled container leads to a self-focussing shock wave.

Electromagnetic shock wave generators are based on an electromagnetic coil, positioned within a water-filled cylinder. Application of an electrical pulse results in a magnetic field which induces an opposing current in the adjacent metallic membrane, causing repulsion and pressure pulse radiation [16–18]. The membrane motions, due to nonlinearities in the wave propagation within the overlying water bath, generate shaped pressure waves. These waves are focused by either an acoustic lens (Fig. 4) or by a cylindrical reflector.

Electromagnetic generators are in favour because of their robustness, durability, reproducibility of signals, and flexibility in the choice of pulse parameters. The lens may be avoided by a self-focussing spherical shape of the coil [19] as sketched in Fig. 5. The steepening of the shock waves and the pressure profile at a series of distances from the self-focussing electromagnetic generator is shown in Fig. 6 [20].

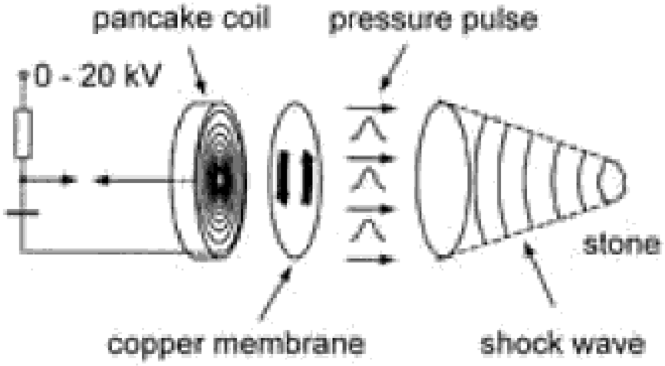

Figure 4. Electromagnetic shock wave generation using a magnetic coil to drive a metallic membrane and an acoustic lens to focus the resulting waves.

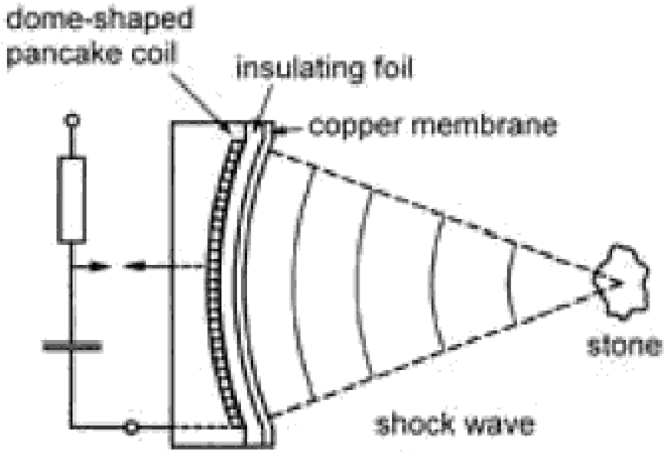

Figure 5. Self-focussing electromagnetic shock wave generation with the aid of a concavely shaped coil and membrane.

The signals have been measured with a fibre-optic probe hydrophone that basically determines optically the change in the density of the material as the pressure wave passes [21]. As revealed by the signal traces in Fig. 6, a positive pressure pulse is followed by a tensile wave. Such a profile is characteristic to almost all lithotripters. In the focus the peak amplitude of the positive pressure may vary from 10 to 120 MPa. The rise time of the shock front is in the range of nanoseconds [17,18]. The duration of the positive pressure pulse amounts to some microseconds. The amplitude of the negative pulse may reach 10 MPa. Spectral analysis of the pulses yields broad frequency bands with their centre frequencies in the range from 200 to 600 kHz.

3 Accepted stone fragmentation mechanisms

Fragmentation needs tensile stess or strain. The positive part in the pressure profile of the shock wave (Fig. 6) results in noticeable tensile stress only if it displays significant variations in space over extensions that are smaller than the stone dimensions. Pressure gradients, shear stress, as well as tensile stress and strain is then produced within the renal and urinary calculi, leading to pulverization into the desired smaller fragments. Pressure gradients are particularly high if the focus diameter of the shock waves is small as compared to the stone size. A crater-like first fragmentation erosion [22,23], as illustrated by Fig. 7, is therefore often observed with sharply focussed pressure waves.

Less sharply focussed shock waves with a pulse duration shorter than the traveling time within the stones are transmitted through the material and are reflected with pressure inversion at the rear face of the stone where the acoustical impedance changes from the large value of the solid to the smaller one of the aqueous environment. Stone material is split off [5] by the tensile stress in the reflected wave, as sketched in Fig. 8. This mechanism is known as Hopkinson effect.

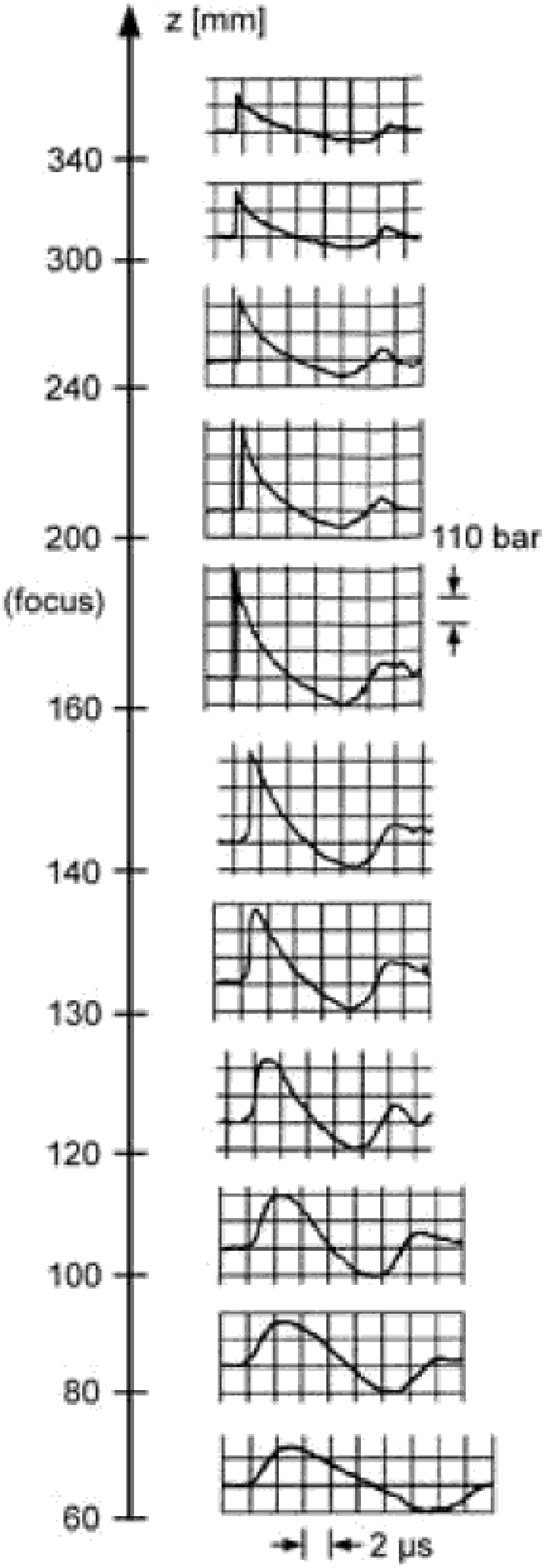

Figure 6. Steepening and focussing of shock wave profiles in dependence of the distance z from the generator [20]. The signals, produced with a self-focussing electromagnetic generator, have been recorded with the aid of a fibre-optic probe hydrophone [21].

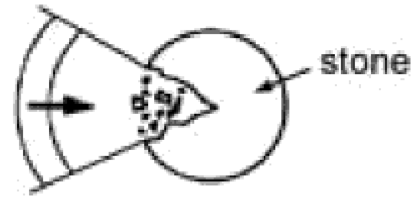

Figure 7. Scheme of crater-like fragmentation erosion of larger stones by pressure inhomogeneities of narrow-focus shock waves (-6-dB width of the focus between 2 and 6 mm).

For both above fragmentation mechanisms, which are related to the positive pressure pulse, no indications for noticeable side effects, such as tissue damage and vessel injury, exist. The situation is quite different with the action of the negative part of the shock wave profile. In addition to the direct action on the stones, the negative pressure causes cavitation in the aqueous environment and also in the liquid enclosed in microcracks [24] and cleavage interfaces of the calculi (Fig. 9). Strong evidence for significant contributions of fragmentation by cavitation exist [25].

Cavitation erosion is especially observed at the anterior and posterior side of stones [22,23]. If, however, cavitation occurs in adjacent tissues or vessels severe damage may result because, after the low pressure period of some microseconds duration, cavitation bubbles of some millimetre size are formed within some hundred microseconds (Fig. 10). These bubbles collapse rapidly, producing locally pressures of many MPa which are accompanied by high temperatures, sonoluminescence and emission of secondary shock waves [26]. Cells are ruptured upon bubble collapse [27].

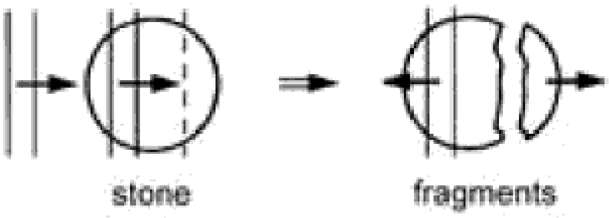

Figure 8. Principle of spalling by tensile stress in the reflected wave within the stone (Hopkinson effect).

4 Cleavage by squeezing

Crater-like stone erosions, spalling of material by tensile stress within the stone, in particular the Hopkinson effect, and cavitation are considered for a long time the dominating causes of fragmentation. Each of the mechanisms has been observed under certain conditions. The relative importance of either of the mechanisms, however, is still unclear presently. More recently it has been shown both, experimentally and theoretically [10], that binary fragmentation by quasistatic squeezing is most efficient in ESWL. Squeezing leading to stone cleavage involves shock wave focus diameters

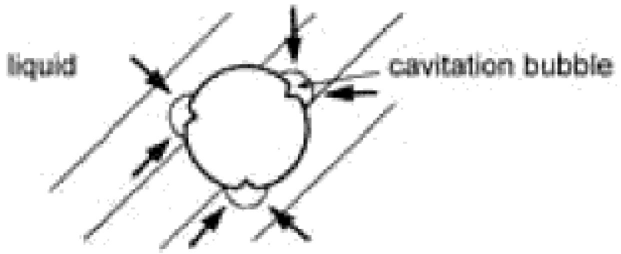

Figure 9. Erosion by cavitation at the surface of the stone.

comparable to or larger than the stone diameter. Fragmentation studies on artificial stones, using a self-focussing electromagnetic shock wave generator (Fig. 5) yielded cleavage in planes parallel to the wave vector, in experiments with positive pulse-pressure amplitudes of 20 MPa, and in planes perpendicular to the wave vector, in experiments with lower pressure (10 MPa). These observations are strikingly reproducible and are in conformity with results from other authors [24,25,28]. They are also in accordance with a squeezing model [29] as sketched in Fig. 11. The model proceeds from the part of the pressure wave that propagates outside the stone and that exerts a circular pressure to cause a compression zone inside the stone. The zone propagates with the sound velocity of the surrounding aqueous liquid which is distinctly smaller than the propagation velocities of the elastic waves within the stone. Corresponding with the pulse width in the aqueous liquid, the width of the resulting inhomogeneous pressure region amounts to 1 to 3 mm and causes tensile stress in the adjoining nonpressurised stone areas.

In the case for which the squeezing situation is depicted in Fig. 11 the situation of wave position at the centre plane of the originally globular stone is given. In Fig. 12 the first cleavage parallel to the direction of wave propagation is shown for an artificial stone of 15 mm diameter that had been exposed to seven shock wave pulses

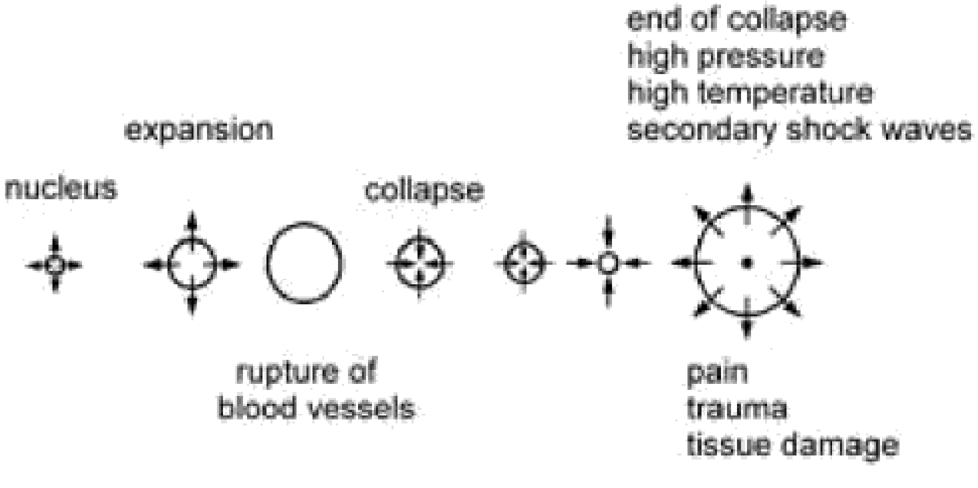

Figure 10. Cavitation bubble and its potential effects on tissue.

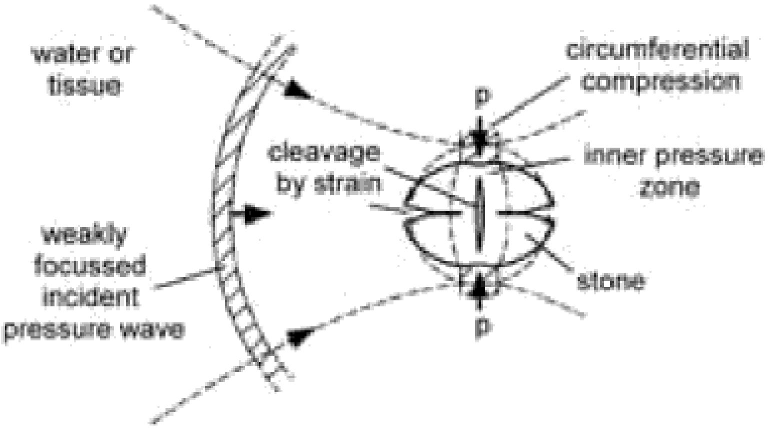

Figure 11. Orientations of cleavage planes resulting from circumferential compression (squeezing) of an originally globular stone. Within the stone the resulting strain is parallel to the direction of wave propagation. At the anterior and posterior surfaces, respectively, the resuling strain is perpendicular to that direction.

of 32.5 MPa positive amplitude, a pulse duration of 1.5 μs, and 17 mm focal diameter according to the -6 dB criterion. Fig. 13 presents the first cleavage of a similar stone in which an increased pulse pressure of 37 MPa resulted in three cleavage surfaces. With further increase of pulse pressure up to five first cleavage planes parallel to the wave vector have been observed [10].

Here we are interested in lower pressure amplitudes rather than in an immediate fragmentation into particles of 2 mm diameter or even smaller sizes. Such small fragments, that are able to pass the ureter without difficulty, are obtained from a larger number of shock wave pulses. In Fig. 14 the development of fragmentation is shown for four individual artificial stones of 15 mm diameter at varying number of pulses. The positive pressure amplitude was 25 MPa throughout, the pulse width was 1 μs and the -6-dB focal diameter was 22 mm. The series of experiments indicates an increasing number of smaller fragments with fairly narrow size distribution as the number of pulses is increased. This result is in nice accordance with a binary fragmentation mechanism [29] of large focus ESWL.

A quantitative model of the cleaving process has been developed to verify binary fragmentation by quasistatic squeezing [10]. In principle, cleaving can be described by nucleation, growth, and coalescence [12,31] of microflaws or microcracks under the repeated action of strain pulses (Fig. 15). The process proceeds until a complete crack or fragmentation interface is generated. Preexisting microflaws in kidney stones, as in many composite materials, act as nuclei for the growth of microcracks [32]. At repeated application of pressure pulses, with amplitudes just above the breaking threshold, microcracks grow and, after a number of pulses, coalesce to larger fissures. This coalescence leads to disintegration of the stone into two parts. When applying pressure shock waves of comparatively low amplitudes, coalescence of growing microcracks is caused by mechanical interaction and is controlled by stronger growth of microcracks in one single plane perpendicular to the strain direction.

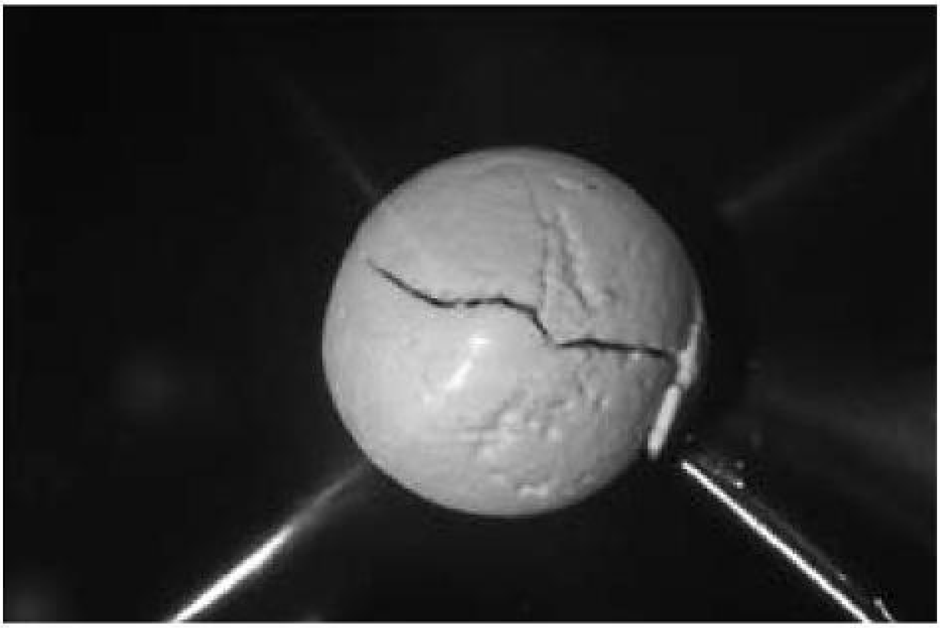

Figure 12. First cleavage parallel to the direction of wave propagation: artificial stone supplied by High Medical Technologies A.G., Switzerland; stone diameter 15 mm; 7 shock wave exposures at 32.5 MPa positive pressure amplitude, 1.5 μs pulse duration, and 17 mm focal diameter, according to the -6-dB criterion, observed parallel to the direction of wave propagation.

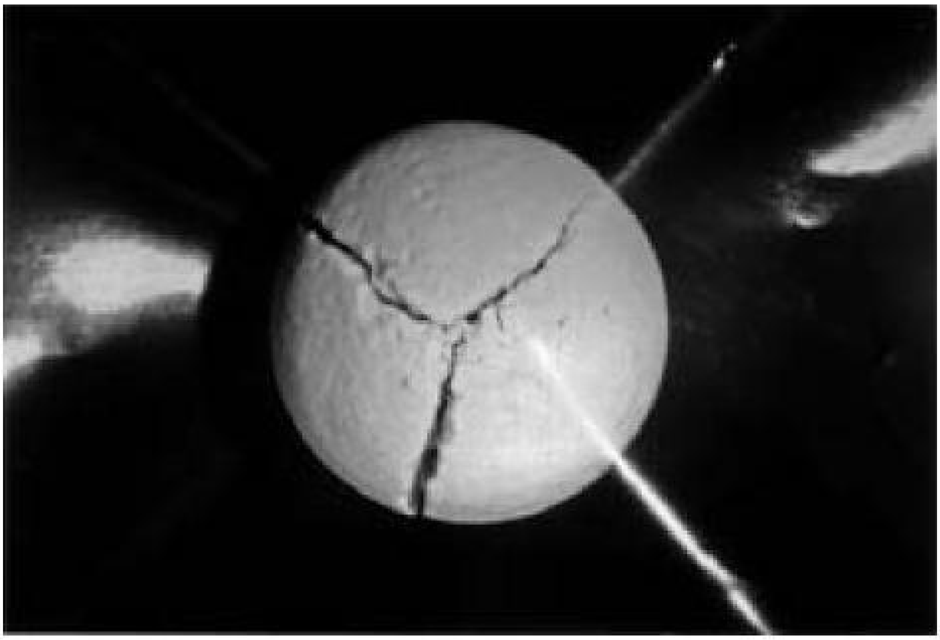

Figure 13. First cleavage of a 15 mm diameter stone as in Fig. 12 but in three cleavage surfaces. The positive pulse pressure amplitude was 37 MPa in the experiment. The direction of wave propagation was perpendicular to the figure plane.

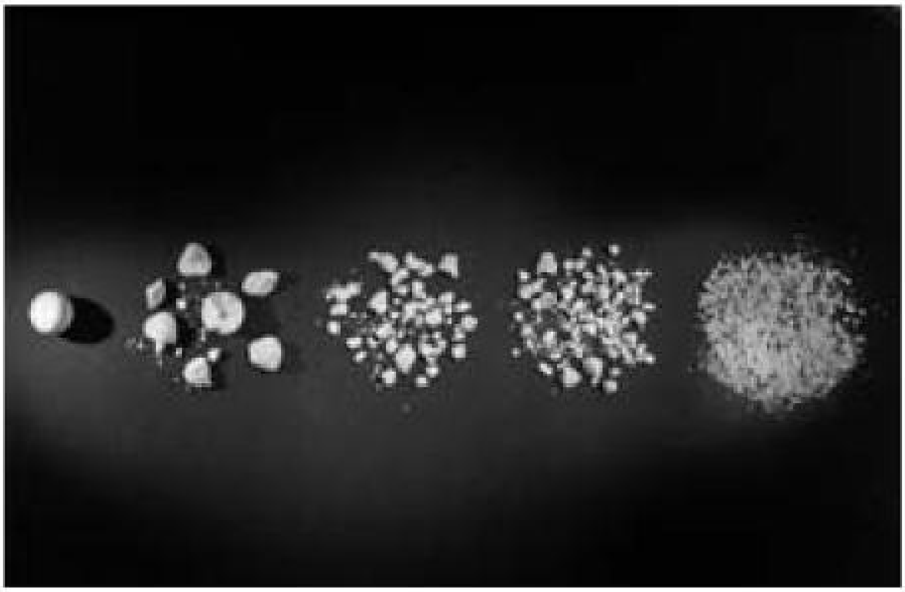

Figure 14. Results of fragmentation experiments with 15 mm diameter artificial stone as in Figs. 12 and 13, shown for different number of shock wave exposures. From left to right the figure shows first the original stone and then fragmentation after 7, 60, 120, and 500 pulses. In these experiments shock waves with positive pulse pressure of 25 MPa, pulse duration of 1 μs, and -6-dB focal diameter of 22 mm were applied. Each fragmentation result has been obtained with an extra stone. The particle size after 500 pulses was smaller than 2 mm.

The theoretical description proceeds from the observed cleavage orientations which suggest the positive part of the pressure pulse to act on the stone and its fragments by quasistatic squeezing as outlined above. It is additionally presumed that the inhomogeneous strain distribution (Fig. 11) inside the stone and the fragments does not significantly change until the lower limit of the clinically relevant size of 2 mm is reached. Equivalence of the quasistatic squeezing energy for fragmentation and the surface generation energy leads to the following expression for the number m of steps for binary fragmentation to end up with fragments of diameter d_m:

$$m = 3\ln(d_0/d_m)/\ln(2)\,, \tag{1}$$

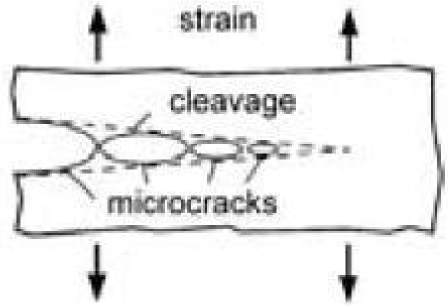

Figure 15. Scematic representation of the growth of microcracks at the repeated action of strain pulses and the resulting coalescence to a macroscopic fissure.

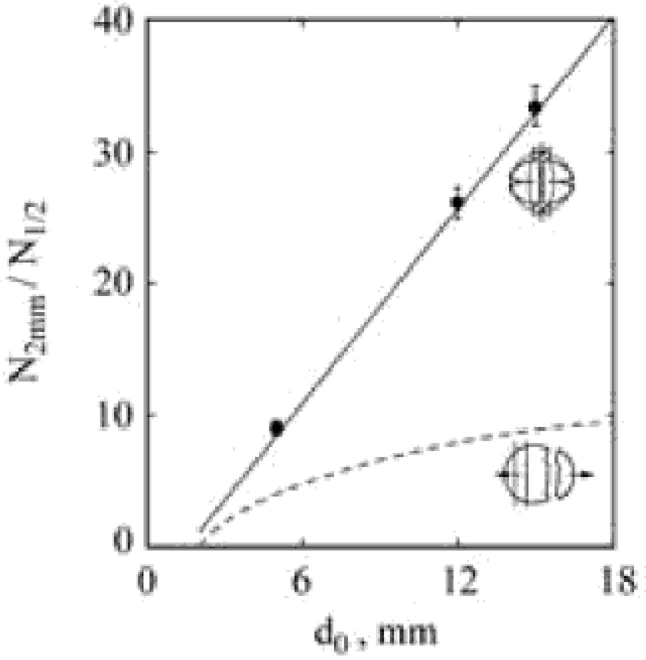

Figure 16. Ratio of the number of pulses for a 2 mm size fragmentation to that for the first cleavage displayed as a fuction of stone diameter. Figure symbols show experimemtal results for artificial stones with errors referring to measurements of 12 stones of 5 mm diameter, 10 stones of 12 mm diameter, and 7 stones of 15 mm diameter. The full line represents the theoretical relation as predicted by the quasielastic squeezing model [10]. Assuming binary fragmentation by a Hopkinson mechanism (Fig. 8) the dependence indicated by the dashed line follows.

where d_0 denotes the diameter of the original stone. In deriving this relation it has been assumed that binary fragmentation on average results in fragment volumes half the original particle volume and that the fragments can be simply considered globular particles with reduced radius. The fragmentation ratio, defined as the number of shock wave pulses needed for the production of particles with diameter d_m, divided by the number of pulses for the first cleavage, is then given by the relation [10]

$$\frac{N_{d_m}}{N_{1/2}} = \frac{2^{1/3} d_0/d_m - 1}{2^{1/3} - 1} \,. \tag{2}$$

For a final particle diameter $d_m = 2\,\mathrm{mm}$ Fig. 16 shows the fragmentation ratio as a function of d_0. The full line represents the theoretical predictions based on the assumption of a squeezing mechanism (Eq. 2).

Experimental data for three sizes of artificial stones nicely agree with theory, thus confirming the idea of binary fragmentation due to quasistatic squeezing. Obviously, crater-like stone erosion, cavitation, and spalling of material by tensile stress within the stone are of minor importance at small pressure amplitudes. For the latter effect the theoretical dependence (Eq. 1) is shown for comparison by the dashed line in Fig. 16. It predicts a significantly smaller fragmentation ratio at a given stone diameter.

5 Clinical results with wide-focus low-pressure lithotripter

The above results show that binary fragmentation by squeezing is a very efficient mechanism for kidney stone disintegration. Consequently, wide-focus and low-pressure extracorporeal shock wave lithotripsy appears to be in favour when compared to conventional treatment using sharply focused pulses. The requirements in the aperture and in the placement of the generator are much lower and, in addition, the reliability to hit the stones and their fragments is considerably higher when applying wide focus waves. Most important for clinical use is the option of relatively low positive pressure and, consequently, of negative pressure amplitudes smaller than 5 MPa. Adverse reactions, such as tissue damage and pain can be avoided thereby. A short rise time of shock wave pulsesappears to be less important in applications, whereas the pulse width can be increased to a duration of 2 μs.

The conception of using an increased focus and a reduced pressure was the basis of a clincal study which has been performed in a scientific cooperation between the University of Stuttgart, the Xixin Medical Instruments Co. Ltd., and seven hospitals in China [13]. In these first studies into the reliability of the method, about three hundred patients have been treated using a lithotripter as shown in Fig. 1, equipped with the self-focussing wide-focus electromagnetic shock wave generator from the University of Stuttgart [10]. Its apperture is 120 mm and its distance of the geometrical focus is adjusted at 200 mm. At pressure amplitudes between 10 and 25 MPa in the positive pulse range, the -6-dB focal width is 1.8 μs as determined at the focus with 10 MPa positive pulse pressure. When the pressure is increased to 27.5 MPa, the -6-dB pulse duration is reduced to 1 μs in the focus. Laterally displaced from the focus, however, the -6-dB pulse length is still 1.8 μs. Figure 17 shows an example of a pressure pulse at the geometrical focus and also in the focal plane but 9 mm off axis. The pressure amplitudes depend on the generator voltage. In Table 1 the positive and negative focal peak pressure values of the generator are displayed for some generator volages. The pulse repitition rate of the generator can be adjusted in the range from $0.3\,\mathrm{s}^{-1}$ to $2\,\mathrm{s}^{-1}$.

A detailed protocol has been kept for each patient during treatment. It involved fifty items, most of them in correspondence with a former clinical ESWL study [33], but with additional details for pain. For stone disease diagnosis as well as for stone position and for the determination of the stone size X-rays have been used throughout. The stone-free rate was checked in part by X-rays but mostly by sonography

U(kV)	P^+(MPa)	P^-(MPa)
8	11.6	-4.0
9	17.7	-4.6
10	26.1	-5.6
11	31.3	-6.4
12	33.8	-7.2

Table 1. Positive (P^+) and negative (P^-) focal peak pressures of the self-focussing electromagnetic shock wave generator at some generator voltages U.

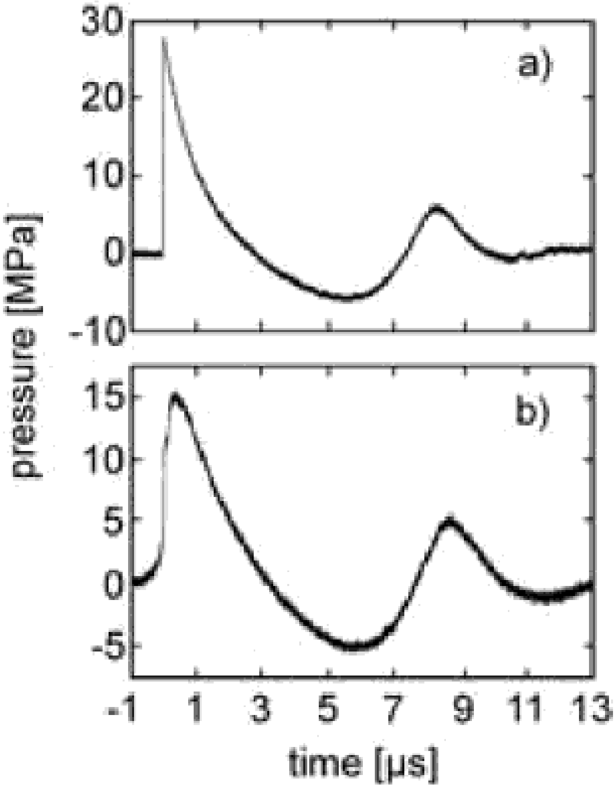

Figure 17. Shock wave pulse with positive pressure amplitude of 27.5 MPa and maximum negative presure of -6 MPa, measured with fibre-optic probe hydrophone [21] at the geometrical focus (a) and in the focal plane but 9 mm off axis (b). Corresponding with the -6-dB focal width of the pulse, the pulse pressure outside the axis is reduced to one half, but the pulse duration is close to 1.8 μs in both cases. In (b) the shock wave front has not yet developed.

after a follow-up of one week, one month, and also three months. The study included 297 patients and altogether 398 stones of which 41.6 % were smaller than 1 cm in diameter and 3.2 % were larger than 2 cm. About 32 % of the stones were located in the calyx, 30 % in the lower ureter , and 21.5 % in the upper ureter. The remaining parts were distributed across the pelvis (7 %), the middle ureter (5.5 %), and the bladder (4 %). The treatment time per session was 77 min during which the patient was exposed to a mean of 1532 shock waves with 20.8 MPa pulse pressure. The most important results of the study are summarized in Table 2 where comparison is made with clinical results obtained with narrow-focus lithotripters.

The finding that wide-focus lithotripsy required the remarkably small number of 1532 shock waves per session attracts attention, in particular as an acceptable part of only 33 % patients needed repeated ESWL and as the number of 1.39 sessions per patient was pretty small. There was no standardisation treatment procedure, but, typically, after a start with lower pressures the pulse amplitude was increased to an upper limit between 15 and 25 MPa. As a rule one thousand shock wave pulses have been applied in one session. With respect to the number of patients, as well as the number, the size distribution, and the location of stones the wide-focus low-pressure lithotripsy study resembles a previous study by Rassweiler et al. [33] in which two narrow-focus lihotripters had been used (Table 2). Quite remarkably, in that treatment the average shock wave number was 3288 and 3457, respectively, thus more than twice the number needed with low-pressure ESWL. Additionally, the agreeable small pulse pressure of only 20.8 MPa, as a mean, applied in the wide-focus study underlines the high efficiacy of binary stone fragmentation by squeezing.

The stone-free rate of 86.3 % after three months for the treatment in all seven Chinese hospitals compares with 68 % and 70 %, respectively, in the narrow-focus lithotripsy study [33]. The figures are even more in favour of wide-focus ESWL if only the 176 patients are considered who were treated in four selected hospitals out of all seven. Just an average of 1331 shock-wave pulses was applied, with a requirement of repeated ESWL for just 22 % of the patients and a mean number of 1.24 sessions per patient. The stone-free rate was as high as 97.7 % after three months follow-up (Table 2).

The treatment time of 77 min is longer than reported for the narrow-focus lithotripters. This longer treatment time is due to the large time intervals of 3 s chosen between succeeding pressure pulses. Residual bubbles after cavitation are allowed to become progressively resorbed thereby, as has been observed by sonography. These measures reduce the contributions of bubbles to repeated cavitation events at the next pressure pulse. In the first clinical study of wide-focus low-pressure ESWL the large time interval setting aimed at a reduction of pain, traumatisation and uneasiness of the patients to the largest possible extent. In principle, the pulse repetition time can be reduced to 0.5 s.

In contrast to the narrow-focus lithotripsy study [33], for which 80 % and 77 %, respectively, of IV analgesida/sedation and 6 % general anaesthesia were reported, analgossedation was required only with 1 % of the patients treated with wide-focus ESWL (Table 2). No auxiliary measures were necessary, as compared to 38 % and 42 %, respectively, of invasive measures with conventional ESWL. Severe complications, such as the perirenal haematoma, were not reported, compared with 1.4 and 2.3 per cent of patients treated with narrow-focus lithotripsy. These results again reveal the favourable attributes of wide-focus ESWL treatment utilizing stone fragmentation by quasistatic squeezing.

Feature	Modulith SL 20	Lithostar Plus	Wide-Focus Low-Pressure	
Number of Patients	287	258	297	(176)
Number of Sessions	3288	3457	1532	(1331)
IV Analgosedation, %	80	77	1	(1)
Auxiliary Measures, %	38	42	0	(0)
Severe Complications, %	1.4	2.3	0	(0)
Stone-free Rate, %	68	70	86.2	(97.7)

Table 2. Comparison of clinical results obtained with narrow-focus lithotripters "Modulith SL20" and "Lithostar Plus" [33] as well as with the Xixin wide-focus low-pressure instrument. Figures in parentheses refer to four selected ones out of altogether seven hospitals. The stone-free rate refers to a three-months follow-up.

6 Conclusions

Based on predominant fragmentation by sqeezing, wide-focus and low-pressure extracorporeal shock wave lithotripsy has the potential of high fragmentation efficiency. A significantly reduced shock wave number is required at agreeably low pressure amplitude. At the comparatively small negative pressure range of -5 MPa and the low pulse repetition rate of $0.33\,\mathrm{s}^{-1}$, adverse effects of cavitation are less strong and do not cause severe pain. In accordance with the reduction of cavitation, as compared to conventional ESWL, only minor complications have been observed in the clinical study comprising 297 patients. Petechia and pain at the skin can be largely avoided by careful bubble-free application of the ultrasound coupling gel [10]. Missing evidence of perirenal haematoma is again in accordance with the moderate negative pressure and the thus reduced effects of cavitation. As fragmentation with wide focus results in a more homogeneous and narrow fragment-particle size distribution, auxiliary measures are necessary neither before nor after the shock wave applications.

An acceptable side effect of using a wide focus is the lower precision that is required in the localisation of stones. It is less difficult to hit the stone and its fragments during treatment. Despite of being compacted under prestress of the ureter and/or bladder entrance, middle and lower ureter stones can be easily fragmented. Also bladder stones of sizes larger than 3 cm in diameter can be sucessfully treated, provided the bladder is sufficiently filled with liquid.

Due to the many advantages offered by the wide-focus low-pressure shock-wave lithotripter, the Xixin instrument, equipped with the self-focussing electromagnetic shock wave generator of the University of Stuttgart, was given clinical approval in China.

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