Clinical Experience with the Latest Generation Piezoelectric Extracorporeal Shockwave Lithotripsy System

a report by
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In recent years a number of review articles have been published on the current status of extracorporeal shockwave lithotripsy (ESWL) and the lithotripter technology used alongside it.[1–3] However, well-founded statements on the current piezoelectric ESWL systems can be missed entirely or are inaccurate, or the statements made are based on the piezoelectric systems of the first- and second-generation. In the meantime the piezoelectric shockwave technique, especially with the Piezolith 3000 from Richard Wolf, has developed to become one of the most innovative and flexible shockwave systems the ESWL market has to offer. Therefore it pays to consider this system and its efficiency more closely. Clinical results for the Piezolith 3000 and the first practical experience with its new triple-focus are presented in this report.

The Applied Piezoelectric ESWL System

Figure 1 shows the Piezolith 3000 with treatment table, ultrasound unit and X-ray unit with therapy source. A very compact piezoelectric shockwave source (SW) with an aperture diameter of 27cm sits in its centre. The SW source offers 165mm penetration depth and is therefore suitable for the treatment of deep-lying stones and adipose patients. A variety of settings offers the user the freedom of adapting to different treatment requirements. The SW source can be brought both into over- and under-table position by an isocentric swivel device. This means the best treatment access can be combined with the advantageous supine position of the patient, irrespective of what body calculi come into question. The supine position is clearly more pleasant for the patient and leads to a clear reduction of unwanted respiratory and patient movements during the treatment. With a peak pressure amplitude Pmax of 120MPa and a maximum energy E5Mpa of 115mj the SW source makes the sufficient power reserves available to guarantee a high disintegration efficiency. The use of innovative double-layer piezo technology is responsible for this. The triple-focus (F1, F2, F3), with 20 cadjustable energy levels each, grants the user full freedom for optimum dosage of the SW energy to the different requirements of the treatment situation such as hard ureteral stones, kidney stones of different size, salivary calculi, stones in children and SW therapy (ESWT) with a single ESWL unit. Fixed adaptation of the SW source to the X-ray unit ensures stable and precise assignment of the therapy focus to the X-ray isocentre and guarantees, for instance, optimum accuracy even for the small ureteral stones. An ultrasound probe, which can be rotated and shifted axially, is arranged in the centre of the SW source for realtime ultrasound localisation. Kidney stones in any position are localised without difficulty and effectively with inline ultrasound localisation, since the direction of view and therapy direction coincide.

Clinical Results

In a clinical study 254 patients with renal and ureteral stones were treated at the Urological Department of the Hospital of 'Barmherzige Brüder' with the Piezolith 3000 (focus setting F1). These were 148 renal stone treatments (58%) and 106 ureteral stone treatments *in situ* (42%). The stones were in the range less than 1.5cm. The localisation was performed for the kidney stones primarily by ultrasound. The ureteral stones were localised in addition with the integrated X-ray C-arm and, if visible with ultrasound, treated further under ultrasound control. All treatments were performed without analgesia or sedation. The average energy dose in 20 energy levels lays between level 12 and 15. Good fragmentation could be achieved in this way without essential sensations of pain being caused. Two thousand to 4,000 shockwaves were applied per session with a repetition rate of 3Hz.

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1. *Köhrmann K U, "Comparison of Lithotripters",* European Pharmacotherapy, *(2005);pp. 90–93.*
2. *Rassweiler J J, Tailly G G, Chaussy C, "Progress in Lithotriptor Technology",* EAU Update Series, *(2005);3: pp. 17–36.*
3. *Teichman J M H, Portis A J, Cecconi P P et al., "In vitro comparison of shock wave lithotripsy machines",* J. Urology, *(2000);164: pp.1,259–1,264. .*

Figure 1: Piezolith 3000 – System Overview

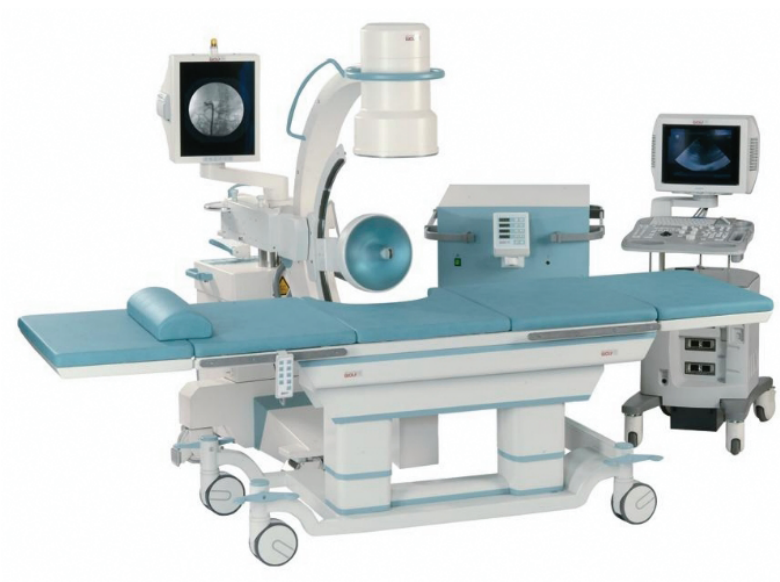
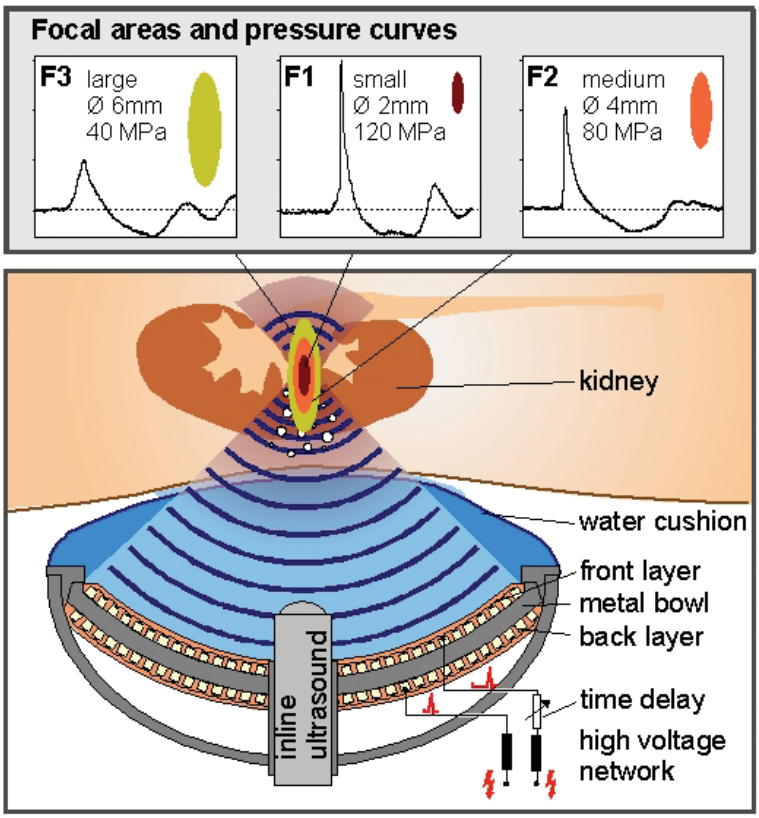


Figure 2: The New Triple-focus and the Double-layer Technology of the Piezolith 3000



All three settings (F1, F2, F3) use the same amount of radiated acoustic energy.

The duration of the treatment was between 15 and 30 minutes and electrocardiogram (ECG) monitoring was not necessary.

Out of 106 ureteral stones, 77 (73%) were treated *in situ*. In 29 patients (27%) a double-J stenting or a pushback of the stones was performed initially before the ESWL treatment took place because of acute obstruction. In this group 20 out of 29 patients (69%) were free of stones in the three-month follow-up. In the 77 patients with ureteral stones treated *in situ*, 52 patients (67%) were free of stones one week after treatment had taken place. Auxiliary measures were applied without further ESWL treatment to patients who were not free of stones.

The retreatment rate for kidney stones was 1.35. No complications requiring therapy such as larger perirenal haematoma, urosepsis or even loss of a treated kidney occurred. Of the 148 treated kidney stones, 141 patients (95%) were free of stones in the three-month follow-up after the last treatment, however, in seven patients (5%) auxiliary measures such as ureterorenoscopy and additional endourological lithotripsy for ureteral stone fragments were performed. The Piezolith 3000 achieved in the kidney stone treatments an efficiency quotient (EQ) of 0.68, making it one of the best ESWL systems worldwide.[2]

The Concept of the Triple-focus

A three-fold switchable focus zone was introduced in the latest generation of the Piezolith 3000 as a reaction to the findings from the area of ESWL research. ESWL has been employed successfully since the beginning of the 1980s, however, the fundamental mechanisms of the fragmentation effect and side effect are still the object of current research work. According to current thinking, it is generally recognised[4] that the effect is connected primarily with the energy applied in the stone and sound field variables, such as maximum pressure amplitude or maximum energy density play only a secondary role. The side effects on the other hand are linked directly with the sound field in the tissue, whereby high energy densities and cavitation effects are considered to be mainly responsible. The question as to whether a large focus or a small focus is better cannot be answered with general validity. Instead, an optimum form of treatment must be selected depending on the stone to be fragmented and its size, hardness, composition and position. These general considerations should indicate the importance of a controllable, flexible, focal sound field for future optimised ESWL treatments.

The double-layer technology (DLT) that is used in the Piezolith 3000 makes it possible to react to different and future sound field requirements. *Figure 2* shows a sectional representation of the therapy source. Two active piezoceramic layers, a front layer and a back layer, are applied to a metal bowl. Both the front layer and the back layer are

4. *Chaussy C, Haupt G, Jocham D, Köhrmann K U, Wilbert D, Therapeutic Energy Applications in Urology – Standards and Recent Developments, (2005)*

actuated through their own electronic circuit with controlled high-voltage pulses. The actuation for the focal zone F1 is such that the single pulses generated in the layers are superimposed constructively on the surface of the SW source. The focal zone F1 is therefore characterised by fine focusing at high energy density (6dB zone 2mm, Pmax 120MPa). The DLT has enabled selective modification of the focal sound field parameters to be acomplished. The guiding principle is to redistribute the focal acoustic energy spatially and in time under conservation of the total radiated acoustic energy. In this way, through triggering both active layers offset relatively in time, a reduction of the maximum occurring energy densities or pressure amplitudes and an enlargement of the focal zones is achieved. The focal zone F2 generated in this way has a 6dB diameter of 4mm at a maximum pressure Pmax of 80MPa and the focal zone F3 has a diameter of 6mm at maximum 40MPa.

In vitro experiments confirm that it is expedient to use different therapy focuses (F1, F2, F3) for different stone hardnesses. For this purpose 15mm gypsum balls were completely fragmented by a 3mm mesh. Gypsum balls of HMT served as substitute for soft body stones, gypsum balls made of Bego-Stone[4] for hard stones. A slight rise in the required number of shockwaves from F1 to F3 can be detected with the use of soft stones. F3 is similarly effective at the same energy level despite reduced energy density in comparison with F1, but in practice it is more conservative with a wider focal zone. The fragmentation in F1 is more than twice as effective as in F3 with hard stones.

The first clinical experiences with the triple-focus show that good disintegration capacities can be achieved even with the focus setting F3. The sensation of pain for the patient is also reduced by the sound field modification from F1 to F3. Whereas with the fine focus F1 at maximum applied energy an acute sharp pain is felt, the perception with F3 is changed to a rather dull pain that is more tolerable by the patient. In treatments without anaesthesia or sedation therapy could be performed with focus setting F3 around three to four energy levels higher. This is expected to lead to a further increase in effectiveness in comparison with the already good clinical results obtained with the fine focus F1.

Summary

The piezoelectric shockwave technique, as implemented in the Piezolith 3000, has developed further in recent years. The results of the clinical study demonstrate that this progress is limited not only to high-quality and long-life technology, but also shows positive practical effects. With a stone-free rate of 95% for kidney stones and an EQ of 0.68, the Piezolith 3000 is numbered among the most effective units on the market. The fact that sedation and analgesia, as well as ECG monitoring, can be dispensed with when using this unit predestines its use in the out-patient and interventional area. Patients who could choose in our clinic between an spark-gap lithotripter and the Piezolith 3000 decided in the majority for Piezolith treatment. Thanks to the new triple-focus the Piezolith 3000 offers absolute flexibility for therapy adapted individually to the needs of the treatment. ■

5. Liu Y, Zhong P, Acoust J, "BegoStone- new a stone phantom for shock wave lithotripsy research", Soc. Am. (2002);112/4: pp. 1,265–1,268.