

## ESWL '90 – state of the art

### Limitations and future trends of shock-wave lithotripsy

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After a decade of clinical experience, extracorporeal shock-wave lithotripsy (ESWL) has proved to be the safest treatment modality for urinary stones with minimal morbidity and side effects. Despite this fact, it is of great importance that the limitations of this procedure be pointed out with the aim of further improving its efficacy.

#### Limitations of ESWL

##### *Persisting fragments*

The follow-up series after 2 and 3 years show a stone-free rate of 67%–78% and a recurrence rate of 6%–11% [61, 81, 82, 97, 98]. The stone-free rate does not exceed 60% for calculi in the lower calix. This correlates with the results after percutaneous nephrolithotomy (PCNL) plus ESWL for staghorn stones [42].

Most stone remnants are asymptomatic. Therefore, in the majority of cases, no further treatment is recommended. However, residual fragments represent a persisting risk factor for future complications (i.e. infection, fever, colics) and can even cause redevelopment of calculi. In the first instance, the management of persisting fragments (i.e. > 6 months) should include a short-interval follow-up. In the case of symptoms and regrowth, percutaneous removal of the stone debris should be performed [16]. A surgical approach might be indicated if additional anatomical disorders exist (i.e. caliceal diverticulum, infundibular stenosis).

##### *Criteria for the selection of adjuvant procedures*

Correct patient selection is the main means of avoiding ESWL treatment failure. Although lithotripters have been further improved (i.e. ultrasound stone location), the criteria for patient selection have remained the same: Stone burden/distribution, stone composition/radiodensity, renal function, and collecting system. Of course, the

use of *indwelling stents* has contributed to the extension of indication for ESWL monotherapy, even for staghorn calculi, as acute morbidity is reduced. It must be noted, however, that double-J stents do not increase the stone-free rate, and double-J morbidity (4%–10%) should not be neglected [48, 101, 163, 168].

The use of ultrasound probes for stone localization has enabled ESWL treatment of even *non-opaque or slightly opaque calculi* [156]. The follow-up of such patients remains problematic, particularly in cases with larger calculi: it is often difficult to determine the degree of stone disintegration as well as the passage of fragments [42]. Thus, especially for larger non-opaque or slightly opaque stones, PCNL seems to be the method of choice [42].

*Decreased renal function* is accompanied by reduced urinary outflow and perfusion of the kidney. Additional anatomical disorders and urinary tract infection frequently exist. These factors greatly limit the effectiveness of ESWL due to the increasing risk of complications (i.e. septicemia). The same applies to percutaneous stone removal. Therefore, in most cases such kidneys should be excluded from ESWL [17]. *Stenosis of the collecting system* also reduces the success rate of ESWL. However, calculi in a caliceal diverticulum have a 50% chance of being successfully disintegrated [134]. Therefore, a trial session of shock-wave lithotripsy is indicated. In the case of ESWL failure, percutaneous removal can be performed using a short ureteroscope via a small percutaneous tract (18 F). Open plastic renal surgery is indicated for nephrolithiasis in connection with major anatomical disorders, whereas the effectiveness of percutaneous technique and ESWL should not be overestimated.

In summary, the final success of ESWL cannot be predicted in all cases. The existence of residual fragments in about 30% of cases [95, 97] requires an adequate follow-up. Undesirable failure of this elegant method can be avoided by correct patient selection for ESWL (instead of uncritical “bang and see” [121]) and the use of additional methods (endourology, surgery).

**Table 1.** Advantages and disadvantages of the different methods of shock-wave generation

Method	Advantage	Disadvantage
Electrode elements	Wide range of energy, twin-pulse technique, flexible size of aperture (15–26 cm)	Short life span (3,000–4,000 SW), only ellipsoid for focussing, no continuous gradation of energy (min. generator volt)
Piezo-electric elements	Very long life span (> 1,000,000 SW), variation of frequency (1–100 Hz) target control	Limited range of energy, large aperture necessary (> 30 cm)
Electromagnetic elements	With range and continuous gradation of energy, flexible size of aperture, long life span (200,000–400,000 SW), multiple focussing principles (membrane + acoustic lens, cylinder + paraboloid, spherical shape)	Metal membrane must be changed

SW = shock waves

### Future lithotripter technology

The technical progress of second-generation lithotripters has involved all of the basic principles of ESWL such as shock-wave generation, focussing, energy coupling and stone localization [8, 60, 64, 65, 69, 76, 80, 91, 93, 102–106, 112, 127, 133, 135, 139, 141, 144, 148, 152, 166, 170, 176, 180, 187, 189, 193, 196, 197]. In the meantime, with respect to general clinical experience with second-generation lithotripters, the results of the first series have been reproduced by other centers on most of the machines. The successful stone-disintegration rate ranges between 80% and 95%. Unfortunately, this sometimes includes a considerable retreatment rate (Wolf Piezolith 2300 = 45%). Some common principles could be implemented in future lithotripters, despite the various technical disadvantages involved (Table 1).

### Shock-wave generation

*Electromagnetic elements* [81, 112, 143, 144, 184, 190] may be preferred as the shock-wave source in the future, as they are more durable than electrodes, enable continuous gradation of shock-wave energy and provide sufficient shock-wave pressure, even with a smaller aperture in the focussing system. They can therefore be integrated in multifunctional tables. The shape of the electromagnetic membrane can be modified and enables different focussing principles. The fact that the *electrodes* must be changed after each treatment, causing inconvenience to the operator and higher maintenance costs, poses a major disadvantage. The twin-pulse technique compensates for the time lost during renewal of the electrodes between treatments [65].

The greatest disadvantage of *piezo-electric elements*, despite technical improvement (Wolf Piezolith 2500), is

the restricted energy of each element [148], affording a large aperture for the focussing system. An adjustable frequency scale is of minor importance for lithotripsy, as high frequencies (> 2.5 Hz) are less effective and cause severe tissue damage. A theoretically possible “hit control”, which converts the echo signal of the stone that is recorded by one of the piezo-electric elements, has not yet been realized in clinical lithotripters [93, 152].

An *electromagnetic cylinder for shock-wave generation together with a paraboloid metal reflector* is an interesting modification of an electromagnetic element. As a self-focussing system without an energy-absorbing acoustic lens, it produces a high range of shock-wave pressure. In contrast electrohydraulic systems, the cylinder in this system enables the coaxial integration of an ultrasound probe that does not lie in the blast path [143, 144, 149]. No advantage is gained from other modifications to shock-wave generation, such as pulsed laser or microexplosion with lead acetate pellets and these can be disregarded for future use [91, 106].

### Shock-wave coupling

As with the shock-wave source, there are some technical alternatives, but the coupling of shock-wave energy will be carried out only via a *water cushion* and *ultrasonic gel* in all future lithotripters. Only one of the new machines [176] has retained a partial water bath (Sonolith 3000). Owing to the membrane of the water cushion, the attenuation of shock-wave energy amounts to approx. 15% as compared with that obtained using a water bath [45, 80], and this can easily be compensated by an increase in generator voltage. The result is an enormous reduction in the size of lithotripters and more favourable maintenance costs.

**Table 2.** Demands and characteristics of third-generation lithotripters

Demand	Characteristic
Biliary and urinary calculi	Fluoroscopy and ultrasound
Better efficacy than Dornier HM3	Wide energy range of the shock-wave source
Anesthesia-free treatment (max. i.v. analgesia)	Large aperture in the focussing system
Multifunctional use of table	Integrated fluoro-table for endoscopy
Economical machine	Low costs and maintenance

### Positioning

Because of the water cushion, the energy source can be included in an ordinary treatment table. As a result, special positioning techniques (i.e. sitting position for distal ureteral stones) have become less important. The patient must be in the supine position, as for a normal intravenous pyelogram (IVP), if *fluoroscopic stone localization* is used for renal and upper calculi. A prone position is recommended for mid- and lower ureteral stones [113, 114, 116, 138]. Oblique positioning of the patient is favourable for the *purely ultrasonic localization* of upper ureteral stones and prone positioning with the patient's bladder being semi-filled, for that of distal ureteral stones [128, 141].

### Stone localization

Many of the new lithotripters use *ultrasound* for stone localization. The reasons for this are: (1) the large aperture of the focussing system has prevented easy integration of the X-ray, (2) cost reduction, and (3) to enable the treatment of gallbladder stones. A major advantage of *ultrasound* is real-time monitoring, which avoids radiation exposure during treatment and enables "autofocussing" of the stone by the patient's own breathing [141]. This regulation of the patient's breathing is much more effective and far cheaper than a computerized respiratory gating or even a "hit control" by a piezo-electric element [8, 80, 93, 189].

Despite its low cost and wider range of indications for ESWL (i.e. radiolucent calculi, biliary stones), ultrasound also has some disadvantages. Ultrasound localization of calculi in the mid-ureter is almost impossible, and multiple stones can be problematic. The lengthy learning curve is another disadvantage. A sonographically experienced urologist requires considerable time to distinguish between actual fragmentation of secondary artifacts and intrarenal gas formation such as air bubbles released by shock waves or cavitation [94].

*Fluoroscopic stone localization* is much safer, as the chance of missing radiopaque calculi is minimal. This results in a shorter learning curve. Furthermore, fluoroscopy guarantees a wide range of indications for in situ treatment (eventual application of contrast dye) and enables multifunctional use of X-rays (diagnostic, endo-

urologic). Fluoroscopic localization of stones close to the vertebral column and of radiolucent calculi is especially difficult. The adequate treatment of gallbladder stones, in particular, is not possible.

The highest demand on future interdisciplinary lithotripters ("third-generation lithotripters") is the *combination of ultrasound and fluoroscopy* (Table 2). The following are the present technical alternatives to this localization method (Table 3):

1. In-line ultrasound probe with integrated C-arm for fluoroscopic localization using a virtual focus ( $F_v$ ) and moving the patient on the shock-wave source (Storz Modulith SL20, Dasonics Therasonic Lithotripter); parallel to ultrasound, with oblique coupling of the shock-wave source (Dornier MPL 9000); and using an in-line C-arm integrated in the shock-wave source (Wolf Piezolith 2500)
2. One rotating X-ray tube with an integrated lateral computer-assisted ultrasound scanner (Dornier MFL 5000-u, Medstone 1000-s)
3. Two fixed X-ray tubes with two independent shock-wave sources and an overhead module consisting of a third shock-wave source with coaxial ultrasound probe (Siemens Lithostar Plus)

The compact form of a unit that uses a *virtual focus* ( $F_v$ ), enabling easy handling and multifunctional use of the lithotripter, is very advantageous [144]. Unfortunately, real-time fluoroscopy during treatment is not possible. It should be stressed that due to accurate mechanical design and calibration, exact focussing is possible unless the patient is moved on the shock-wave source after fluoroscopy. Simultaneous fluoroscopy and ultrasound can be carried out by *parallel use of a C-arm* [139]. The combination of two C-arms (shock-wave head and fluoroscopy), however, makes handling complicated (i.e. treatment is not possible with the patient in the prone position). *Integration of the fluoroscopic system in the large aperture of the shock-wave generator* provides an interesting and compact lithotripter design [128]. On the other hand, this type of machine cannot be used for multifunctional purposes.

Both of the basically X-ray-guided systems provide the widest spectrum for multifunktional use. The implementation of a *lateral computer-assisted ultrasound probe* [8] enables easy handling, but focussing is restricted due to (1) deviation of lateral ultrasound owing to diffraction and declination, amounting to approx. 5 mm on the x- and y-axes; and (2) the inadequate precision of computer-assisted positioning of the patient after ultrasound determination of the stone coordinates. Alternatively, the installation of an *independent ultrasound-guided overhead module* is a quite expensive solution [185]. Almost all types of stones can be treated on such a machine, but there is no provision for the simultaneous use of ultrasound and fluoroscopy. The most appropriate concept for interdisciplinary lithotripsy will be determined in the time to come.

### Comparison of lithotripters

The introduction of new lithotripters has made comparison of the different machines necessary [133, 148]. Where-

**Table 3.** Third-generation lithotripter: comparison of the main technical concepts combining ultrasound and fluoroscopy for stone localization

Localization concept	Multifunctional use	Simultaneous X-ray and ultrasound	Real-time fluoroscopy	Handling	Machine	Reliability of focussing
1. In-line ultrasound with integrated C-arm:						
External fluoroscopy with virtual focus (Modulith SL20)	++	No	No	Easy	Compact	++ <sup>b</sup>
Parallel fluoroscopy (MPL 9000-x)	++	Yes	Yes	Complicated (positioning)	Complex	+++
In-line fluoroscopy (Piezolith 2500)	+	No <sup>a</sup>	Yes	Easy	Compact	+++
2. One rotating X-ray tube with lateral ultrasound (MFL 5000-u)	+++	Yes	Yes	Easy	Expensive (space required, computer-assisted ultrasound)	++ <sup>c</sup>
3. Two X-ray converters plus independent shock-wave head with coaxial ultrasound (Lithostar plus)	+++	No	Yes	Easy	Expensive (3 shock-wave sources)	+++

+ = insufficient; ++ = sufficient; +++ = excellent; <sup>a</sup> inflation of X-ray balloon necessary; <sup>b</sup> with respect to integrated C-arm; <sup>c</sup> with respect to lateral ultrasound

as the technical differentiation of the lithotripters, i.e. shock-wave generation, focussing, coupling and localization, is simple, classification of the disintegrative efficacy remains problematic. The development of new shock-wave sources, in particular, requires a *standardized classification* to determine the range of shock-wave pressure (or generator voltage) that is safe for clinical use. This can be accomplished by physical measurements, stone models, and animal studies.

#### Physical measurements

Ideally, shock-wave generators should be classified with acoustic measurements [25–27, 45, 73]. Theoretically, they can be defined by the rise time, peak positive pressure, peak negative pressure, duration of impulse, spectrum of frequencies, size of the focal area, and acoustic energy of each impulse.

At present *no standardized hydrophones* are available. Accurate measurement requires a durable and sensitive pressure probe with adequate rapid response time to record the fast-rising peak pressures. Previously, shock-wave measurement was carried out using a narrow band width and was therefore, less accurate [65]. The use of a broad-band (PVDF) needle probe ensures more reliable data [184]. Recently, Coleman et al. demonstrated significant differences in frequency response between needle probes, even between those from the same manufacturer, leading to varying statistics in the focal zone [26]. As Coleman and Saunders have shown, this unreliable measurement method is of minor importance when different shock-wave sources are tested using the *same* hydrophone [27]. Nevertheless, it is understood that a significant comparison of lithotripters can be made only using a

reliable, well-defined standard for measuring shock waves. The laser hydrophone could possibly become such a standard instrument [45].

#### Stone models

The problem of physically classifying shock waves is the main reason why the exact impact of each of the different parameters for stone disintegration with minimal tissue traumatization has not been adequately defined and, as a result, is not yet completely understood. Standardized in vitro stone models have therefore, become important for the classification and comparison of shock-wave efficacy [148, 149].

Stones, chalk pieces, plaster cubes and pellets made of dental cement were used in preliminary studies to measure both the number of impulses for complete disintegration and the cavity produced after a defined number of shock waves. The possibility of determining a characteristic curve plotting impulses vs generator voltage for different shock-wave sources was demonstrated. The movement of the curve (to the left of right) along the x-axis was caused by the hardness of the stone tested or by shock-wave attenuation (use of a water cushion). These characteristic curves could be useful for determining the optimal generator-voltage range for effective stone fragmentation and comparing the therapeutic broad band of different shock-wave sources [143, 184].

An easy check of the actual machine power can also be made, particularly in less successful clinical cases. Any decrease in disintegrative efficacy, i.e. owing to defective transducers, can be demonstrated on a standardized stone model by increasing the impulses for fragmentation. Plaster cubes can also be used for the exact regulation of

**Table 4.** Comparison of clinical results obtained with the most important second-generation lithotripters using the efficiency quotient<sup>a</sup>

	SFR	RE-TX	AUX	EQ
Stones measuring < 1 cm:				
Dornier HM3	77%	5%	12%	0.66
Dornier HM4	85%	38%	4%	0.60
Direx	75%	24%	7%	0.57
EDAP	72%	29%	2%	0.55
Siemens	74%	7%	16%	0.60
Technomed	81%	13%	7%	0.68
Wolf	86%	16%	4%	0.72
Stones measuring 1–2 cm:				
Dornier HM3	75%	10%	11%	0.62
EDAP	64%	68%	6%	0.37
Siemens	65%	12%	12%	0.52
Wolf	69%	27%	2%	0.53

<sup>a</sup> From [133]

SFR = Stone-free rate; RE-TX = retreatment rate; AUX = percentage of auxiliary measures; EQ = efficiency quotient

the focussing and localization system. It is important that a considerable deviation of shock-wave focus and geometrical focus, amounting to approx. 2–3 mm in the electrode ellipsoid system as well as in the electromagnetic membrane-acoustic lens device, is possible [184]. This deviation is less important in shock-wave sources with a large focal zone (12 or 9 mm, respectively, on the x- or y-axis) than in those with a small focal area (3 or 5 mm on the x- or y axis) [164]. In comparison with the geometrical focus determined by fluoroscopic localization, the focal zone of the shock wave can be depicted by means of a plaster cube, making time-consuming pressure measurements unnecessary.

### Animal studies

At present, the degree of tissue trauma produced by shock waves cannot be predicted by physical measurements or in vitro stone models, as pertinent standards are missing. It has been well documented that only focal and reversible intrarenal hematomas occur when a medium range of shock-wave energy is applied [1, 3, 5, 13, 19, 32–34, 53, 56, 74, 90, 99, 123, 124, 130, 143, 173, 185, 188]. The introduction of shock-wave sources that produce higher pressure levels (i.e. Storz Modulith SL20, Lithostar overhead, Dornier MPL 9000, Piezolith 2500) has made the characterization of renal trauma that occurs at higher energy levels a matter of great importance in avoiding severe clinical complications.

Three animal models can be used (canine, New Zealand rabbit and mini-pig), and at least two of them should be standardized with respect to the experimental design (i.e. number of shocks, localization, positioning) for future studies [56, 143]. Nevertheless, a well-defined standard of physical measurements should be achieved using standardized, reliable hydrophones. The correlation of this standard to in vitro and in vivo studies should finally make animal experiments unnecessary.

### Clinical trials

Despite the fact that in vitro stone models have been correlated with clinical experience (i.e. the number of impulses and the retreatment rate vs the number of shocks for disintegration of a test stone), only clinical trials can estimate the exact capability of a lithotripter. A prospective, randomized phase III study at one center would be the best method of clinically comparing different stone machines. Unfortunately, very few centers have more than one lithotripter. Diverse stone distribution and the treatment strategies of each ESWL unit make a simple comparison of the available clinical data difficult. As phase III studies cannot be performed in most cases, the following represents a suitable method for comparing clinical results:

1. Definition of treatment strategy (i.e. in situ ESWL for ureteral calculi or “push and bang”)
2. Determination of stone size and localization and adjustment procedures before ESWL.
3. Definition of success (i.e. degree of disintegration and stone-free rate after 3–6 months)

Taking these criteria into consideration, it is possible to make a reasonable comparison of clinical results obtained using different lithotripters. The “efficiency quotient” EQ, (Table 4) recently defined by Preminger and Clayman [133] enables the determination of a specific figure that expresses the clinical efficacy of a stone machine:

$$EQ = \frac{\% \text{ of stone-free patients}}{100\% + \% \text{ retreated patients} + \% \text{ secondary procedures}}$$

It is interesting to compare the similarity of EQs obtained for small stones between the most important second-generation lithotripters and the Dornier HM3. The EQ obtained for larger calculi using the Dornier HM3 is much higher (Table 4). Future clinical trials based on the above-mentioned criteria must confirm the theoretical advantages of the new (third-generation) interdisciplinary lithotripters in clinical practice.

### Choice of lithotripters

The rapid development of new lithotripters has initiated a worldwide boom of these machines. This mainly the case in the *United States and West Germany* and has led to an abundance of stone machines. In West Germany, 22 urologic ESWL centers were installed in 1986 and this number was considered to be sufficient. At present, > 75 lithotripters are being used for interdisciplinary ESWL, and additional installations are planned. In the United States > 25 stone machines are in use in Los Angeles alone. This increase in ESWL centers has led to a marked change in the indications. Whereas ureteral stones were treated in 15% of all ESWL patients in 1984, ureteral calculi were treated in 45% of ESWL cases in 1989. In general, most larger stones were disintegrated [18, 22, 42].

As a result, decentralization of ESWL will become established in the future and an increasing number of urologists will treat fewer stones. This could affect the quality of treatment for the following reasons: (1) an increase in the use of *mobile lithotripters* would make necessary retreatment on the following day difficult, and (2) *out-patient treatment of ESWL* would complicate follow-up [168]. Moreover, as a result of this trend toward decentralization urologists will no longer be classified into two groups (those with and those without a lithotripter).

In *developing countries* (e.g. India, South America, Africa), ESWL has just started and a very large number of patients require stone treatment. Thus, ESWL and endourology will be the chief means of stone management in such countries. Financial problems will limit the number of lithotripters available in these countries for the next few years.

For these reasons, it is obvious that no specific choice among lithotripters can be made. The following are the important factors to be considered:

1. The *size of the unit*, allowing for the number of patients, the financial support, and the choice of a urological or an interdisciplinary stone center
2. The *distribution of calculi*, i.e. the localization (renal vs ureteral) and size of stones
3. *Experience of the urologist* with ESWL and ultrasound

*Small urology units* can choose from three alternatives: (1) a "low-cost lithotripter" based mainly on ultrasound stone localization; (2) a more expensive multifunctional table based on fluoroscopy, which could also be used for other urological purposes; and (3) a mobile lithotripter with the above-mentioned disadvantages. The aim of *larger urology units* with a substantial number of patients should be a third-generation lithotripter encompassing all ESWL requirements. If necessary, interdisciplinary lithotripsy could also be performed. A third-generation lithotripter should also be the first choice of an *interdisciplinary stone center*. However, if the center has a standard lithotripter with fluoroscopic stone localization (i.e. Dornier HM3, MFL 5000 or Siemens Lithostar), an ultrasound-based stone machine could be a good addition; 7–10 patients/day must be treated at such "two-machine stone centers" before the acquisition of both lithotripters is worthwhile [139].

### Further applications of shock waves

Clinically, the most interesting extension of indications for ESWL is the treatment of *pancreatic duct and salivary duct stones* [72], as extensive surgery can be avoided in both cases. To date, the treatment of stones in the salivary gland (i.e. submandibular, parotid gland) has been performed by glandectomy, with the possibility of significant injury and postoperative complications (i.e. paresis of the facial nerve).

Another possible clinical application of shock waves involves the treatment of *pseudoarthrosis*. In 1989,

Valchanov et al. [179] presented their first experience with 53 patients who had suffered from pseudoarthrosis of fractures for an average of 20 months. On shock-waves treatment, the pseudoarthrosis was brought to a stillstand for an average of 81 days; this therapy was successful in 88% of the patients.

In contrast, the *treatment of tumors with shock waves* remains at an early experimental stage. The clinical relevance of such treatment is unknown, despite the fact that early investigations demonstrated that significant dose-dependent damage was caused by high-energy shock waves. Only a temporary effect was determined in most studies, and very little information exists on the tumor-specific effect of shock waves [6, 9, 10, 12, 14, 15, 20, 21, 55, 59, 70, 100, 132, 159, 160, 191]. Shock waves will have to be modified for any future treatment of neoplasms. Whereas shock waves were developed for ESWL sources with the aim of minimal tissue trauma, maximal traumatization is the aim of tumor treatment. The increase in cavitation and the use of higher frequencies are important factors in this respect. Using normal tissue, in 1989, Peschke et al. [132] demonstrated that 5-Hz impulses caused more distinct damage to Dunning Ly/Lu prostate carcinoma of the rat than did 1-Hz impulses. Due to essential differences in shock-wave quality, all experimental studies concerning the treatment of tumor cells – including chemotherapy – are elementary. The same applies to *shock-wave treatment of benign prostatic hypertrophy* [46].

*Aiming shock waves at drug carriers* could be another interesting application. In 1989, Jones et al. loaded autologous erythrocytes with [<sup>3</sup>H]-methotrexate and demonstrated a 107% increase in the cytotoxic drug in the shocked area [183]. Such techniques could reduce the toxic side effects of cancer chemotherapy. All of the above-mentioned methods are far from being ready for clinical application.

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