

Extracorporeal shock wave lithotripsy: An opinion on its future

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ABSTRACT

The development of miniaturized nephroscopes which allow one-stage stone clearance with minimal morbidity has brought the role of shock wave lithotripsy (SWL) in stone management into question. Design innovations in SWL machines over the last decade have attempted to address this problem. We reviewed the recent literature on SWL using a MEDLINE/PUBMED research. For commenting on the future of SWL, we took the subjective opinion of two senior urologists, one mid-level expert, and an upcoming junior fellow. There have been a number of recent changes in lithotripter design and techniques. This includes the use of multiple focus machines and improved coupling designs. Additional changes involve better localization real-time monitoring. The main goal of stone treatment today seems to be to get rid of the stone in one session rather than being treated multiple times non-invasively. Stone treatment in the future will be individualized by genetic screening of stone formers, using improved SWL devices for small stones only. However, there is still no consensus about the design of the ideal lithotripter. Innovative concepts such as emergency SWL for ureteric stones may be implemented in clinical routine.

Key words: Endourology, extracorporeal shock wave lithotripsy, urolithiasis

INTRODUCTION

Within the last 25 years, the management of urinary stones has seen innovations such as percutaneous stone removal in the late 1970s, followed by extracorporeal shock wave lithotripsy (SWL) in 1980.^[1-4] SWL held the sway in the 90s, but continuing developments in endourological equipment meant that percutaneous stone removal progressively became more attractive due to its potential of one-time complete clearance. There have been some recent innovations in lithotripter design and technique, which may improve outcomes with this non-invasive treatment modality.

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We reviewed recent literature on SWL using a MEDLINE/PUBMED search using the key words “extracorporeal shock wave lithotripsy,” “shock wave lithotripsy,” “lithotripter,” and “shock wave generation.” Since the use of one modality over another also depends on surgeon preference, we took the subjective opinion of two senior urologists, one mid-level consultant, and one junior fellow (2nd year resident) to comment on the potential future role of SWL in stone management.

THE DECLINING ROLE OF SWL IN THE LAST DECADE

In the last decade, open surgery was almost completely replaced by the non-invasive SWL and endourologic techniques such as ureteroscopy (URS) and percutaneous nephrolithotomy (PCNL).^[5] Renal stones less than 1-2 cm were treated by shock waves, whereas complicated kidney stones were managed by a combination of PCNL and SWL.^[6,7] Ureteral stones were treated either by SWL or by URS, depending on stone size and localization. In 1988, 70% of stones were located in the kidney and 30% in the ureter,^[8] and there was an enthusiastic attitude toward the use of SWL for all types of urinary calculi.^[9]

The significant improvement of armamentarium meant that endourological techniques became more attractive

and effective in stone management,^[10] whereas technical improvement of SWL was minimal.^[11] Miniaturization of endoscopes with significant improvement of video technology and techniques of stone fragmentation such as lasers accelerated the success of endourological approaches.^[12-15] Moreover, the size and localization of urinary calculi changed with an increase of ureteral calculi to 50-60%. All this resulted in a decrease of SWL and an increase of URS, whereas PCNL use remained stable [Figure 1]. The main argument in favor of endourological techniques was that the stone could be removed in one session with minor sequelae in contrast to SWL which has a 20-30% re-treatment rate and the problems associated with passage of fragments.^[12-18]

RECENT DEVELOPMENTS IN LITHOTRIPTERS

Recent studies on the mechanisms of stone disintegration, shock wave focusing, coupling, and application have appeared, which may address some of the problems associated with lithotripters.^[11] Moreover, manufacturers have introduced new devices with significant modifications [Table 1] which, if used appropriately, may be helpful in rekindling an interest in SWL.^[14] The introduction of new lithotripters appears to have increased the potential problems of shock wave application compared to first-

generation devices, mainly due to the use of water cushion — based coupling of shock wave energy, ultrasound-based localization systems, and small focal sizes of the shockwave sources.^[11,14]

Clinical lithotripters are based on four different principles of shock wave generation. In *electrohydraulic (EHL)* lithotripters, spark discharge between two electrodes produces the shock wave. EHL devices have a shot-to-shot

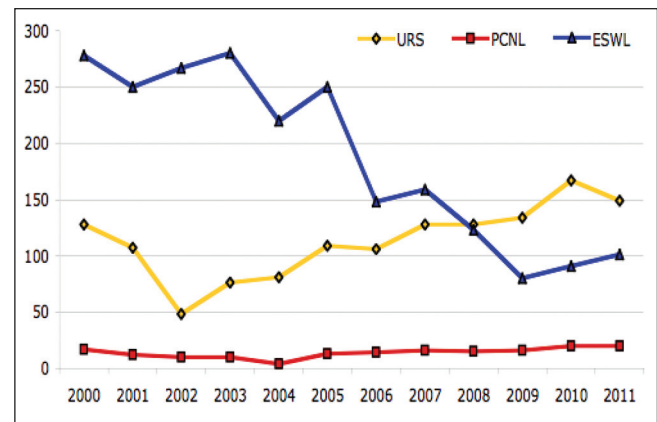


Figure 1: Development of primary treatment strategies for urolithiasis at Department of Urology, SLK Kliniken Heilbronn, showing an increase of URS and decline of ESWL

Table 1: Comparison of technical details of new lithotripters

Lithotripter	SW generation	Focal size (-6 dB) Lateral (mm)	Focal depth (mm)	Max. pressure (MPa)	Localization system	Features
Siemens Lithoskop	Electromagnetic (coil; Pulso™)	12	160	75*	Isocentric fluoro-C-arm In-line ultrasound	SW source on parallel isocentric C-arm Multifunctional working station
Dornier DoLi-S II	Electromagnetic (coil, EMSE 220F-XXP)	5.4	150	110	Isocentric fluoro-C-arm In-line ultrasound Lateral ultrasound	Three simultaneous localization options (tri-mode)
Dornier Gemini	Electromagnetic (coil, EMSE 220F-XXP)	6	170	110	Isocentric fluoro-C-arm In-line ultrasound Lateral ultrasound	Dual simultaneous imaging Autopositioning
Storz Modulith SLX-F2	Electromagnetic (cylinder)	F1: 6 F2: 9	180	150 90	In-line fluoroscopy In-line ultrasound	Two focal sizes Multifunctional working station
Xinin XX-ES	Electromagnetic (self-focusing)	18	180	30	Lateral ultrasound	Low-pressure SWL Large focus
EDAP/TMS Sonolith i-sys	Electroconductive (Diatron IV™)	14	170 (155-210)	n.a.	Isocentric fluoro-C-arm Isocentric ultrasound	No jitter effect Automatic pressure regulator
LithoGold 380	Electrohydraulic (Smarttrode™)	16	165	40	Adaptable to C-arm	Low-pressure SWL Large focus
AST LithoSpace	Electrohydraulic	17	140	38	Adaptable to C-arm and ultrasound	Navigation with acoustic tracking (SuperVision™)
Wolf Piezolith 3000	Piezoelectric (two self-focusing layers)	F1: 2 F2: 4 F3: 8	165	126 119 48	Isocentric fluoro-C-arm In-line Ultrasound	Three focal sizes Dual simultaneous localization

*E_{12mm} 8-117 mJ per impulse

variability as the spark location changes as the electrodes wear down; the significance of this “jitter-effect” is under debate, with some suggesting it might be less relevant in large-focus sources.^[19] The *electroconductive system* (EDAP-TMS, Lyon, France) employs electrodes immersed in a highly conductive solution, resulting in repeatable spark location due to shorter and self-adjusting inter-electrode distance to compensate for electrode wear.^[11,20] Electrode lifetime exceeds 40,000 impulses. The idea of a dual-EHL system (Direx Duet, Tel Aviv, Israel) represents an interesting concept of distributing the shock wave energy on two applicators. *In vitro*, more impulses were required using the alternate mode (679 vs. 601), and in the kidney model, there was no advantage concerning renal injury.^[21] However, clinically, there is only a small amount of data which confirms safety but no advantage over single-source SWL. The main reason for this are the problems with adequate coupling and acoustic windows to the calculus.^[22] *Electromagnetic* and *piezoelectric* sources provide stable shock wave release lasting for >1 million shocks; however, instability of acoustic output may occur.^[23]

Adaptation of the focal zone to stone size and localization seems to be another reasonable innovation.^[24] A 1 cm distal ureteric stone may need to be treated with a relatively small focus, whereas a 1.5 cm stone in the renal pelvis may require a larger focus. Some lithotripter manufacturers have found ways to adjust focal width to suit such clinical applications. In Modulith SLX-F2 (Storz Medical, Germany), two focal sizes are obtained by modifying pulse duration using the same electromagnetic source. The larger focal zone (50 × 9 mm) is recommended for renal stones and the smaller focus (28 × 6 mm) for ureteral stones. However, no improvement of clinical efficacy has been shown. There is no clinical study that analyzes the impact of the F2 concept. De Sio *et al.*^[25] evaluated only the smaller (original) focus size, and in the comparative study from Berne,^[26] only the larger focus was taken. In this randomized controlled trial, the 3-month stone-free rate of HM3 was slightly higher compared to the use of F2 focus of the Modulith (90% vs. 81%). However, there are no data when using the standard smaller focus. Earlier studies showed a disintegration rate of 85% with Modulith SL 20.^[27] Tiselius reported stone-free rates over 97% for ureteric stones using the classic and F2 machines. For 90 patients treated using the F2 focus, the success rates were similar to those of patients treated with the standard focus of the classic device.^[28]

Double-layer arrangement of piezoelectric elements in Piezolith 3000 (Richard Wolf GmbH) increased shock wave energy after reducing the aperture from 50 to 30 cm.^[29,30] Modifying the synchronization of both traveling waves allows variation of delay and pulse formation, resulting in three focal zones. However, the treatment has to be performed under intravenous analgesia. Retreatment rates are lower (10%), but so are the stone-free and success

rates of 45% and 64%, respectively.^[31,32] In contrast, the results obtained in children (using the small focal size) are excellent.^[33] Nevertheless, there are no studies focusing on the use of three different focal zones as proposed by the manufacturer.

Broad-focus, low-pressure lithotripters (LithoSpace, LithoGold 380, Xinin XX-ES) have recently attracted attention as research showed that focal width affects stone breakage in several ways^[11,34] [Table 1]. *In vitro*,^[35] the disintegrative efficiency of Xinin XX-ES was superior to HM3 (634 vs. 831 SW). Early clinical results show that treatment is possible without any anesthesia and with minimal renal trauma (i.e. hematuria) [Figure 2a, b]. However, handling of lateral ultrasound device proved to be difficult and needs definitive improvement. Siemens^[36] and Dornier^[37] also aimed at creating larger focal zones by prolonged pulse duration, but do not offer different focal sizes. Arrabal-Polo^[38] applied the focal applied energy quotient (FAEQ) to assess the efficacy of SWL with the DoLi-S (EMSE 220-XXP) device and observed equivalent results of SWL versus endoscopic lithotripsy with holmium laser in ureteral stones (94%) when FAEQ exceeded 10. This indicates better fluoroscopic localization and increase of shock wave energy delivered to the stone.

CLINICAL SWL TODAY

Young urologists favor endourology and are less interested in SWL. At several centers, only specially trained technicians, rather than urologists, perform SWL.^[11] In some countries, reimbursement of SWL has become a problem, for example, in Germany, only one treatment per year is financed as outpatient. All this has resulted in a decrease of SWL procedures and a restriction of indications, particularly to renal stones larger than 1 cm and all kinds of ureteral calculi. SWL efficacy depends on various acoustic properties [Table 2]. Manufacturers and clinicians have addressed some of them (i.e. quality of coupling using a water cushion, ramping strategies), but for others (i.e. size of focal zone, amount of shock wave pressure), there is still no consensus.

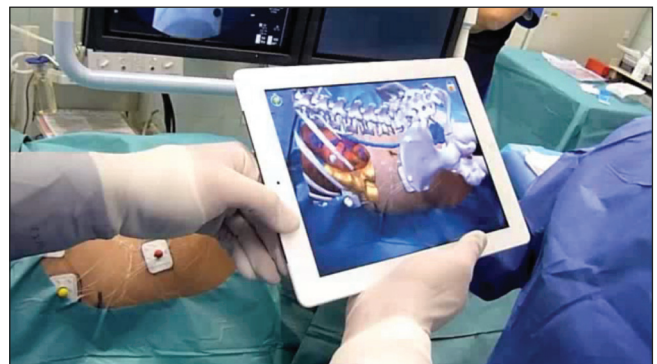


Figure 2: The use of iPad-assisted percutaneous access to the collecting system. In the future, tablet-based navigation might be also useful during ESWL

Bohris *et al.*^[39] used a camera as a tool to control coupling quality and found imperfect coupling in 67% of the cases. In-line ultrasound probes enable an intraoperative check of coupling quality.^[11] Unfortunately, the ideal lithotripter has not yet been constructed.

The reliable production of 2 mm dust, instead of fragmentation, is possible with SWL.^[40] This would be possible with better shock wave generators (i.e. with larger focal zones), combination of different sources (i.e. piezoelectric plus EHL), respiratory regulated, color doppler ultrasound monitored hit-control [Figure 3], and computer-assisted shock wave navigation adapted to the individual anatomy, improving the quality of stone disintegration with almost complete pulverization of the stone and basically no side-effects applying shock wave without anesthesia [Figure 2a, b]. The non-invasive nature of SWL could be further supported by ultrasound-induced repositioning of renal stones, that is, from

unfavorable locations like the lower calyx to the renal pelvis.^[41]

OPINION

Even if the lifetime of knowledge becomes shorter and shorter, it takes usually 5-10 years for a novel technique to become accepted worldwide. For implementation of guidelines, it may take even longer. For example, the first patient was treated by SWL in 1980 and it was not approved by the US Food and Drug Administration (FDA) until 1986. Accordingly, some of the novel techniques being introduced today may not become commonly accepted for a number of years.^[16]

In general, to understand the predictable future of SWL in the management of urolithiasis, it is necessary to review three areas [Table 3]; imaging and diagnostics, evolving technology including the ideal lithotripter, and treatment strategies.

Table 2: Factors influencing the success of extracorporeal shock wave lithotripsy

Factor of success	Options	Specific modifications	Advantages	Comments/problems
Shock wave generation and focusing	Electrohydraulic with ellipsoid reflector	Spark electrode	Large focus	Variability of pulses One electrode per session
		Twin head	Less energy density	Coupling from two sites difficult
		Electroconductive	No variability of pulses 40,000 shock waves	–
	Electromagnetic	Coil-membrane with acoustic lens	Extension of focal zone by prolonged pulse duration	Advantage of larger focal zone not clinically proven
		Cylinder with paraboloid reflector	Dual focus by different pulse duration (i.e. for renal and ureter stones)	Advantage of dual focus not clinically proven
		Spherical element	Very large focal zone	Not available in Europe
Piezoelectric	Spherical alignment with two layers	Three focal sizes	Advantage of triple focus not clinically proven	
	Coupling of shock wave	Water bath	Complete (Dornier HM3) Partial (Sonolith 2000, Piezolith 2200)	Ideal coupling No multifunctional use Not manufactured anymore
Water cushion		Gel-pad (abandoned) Coupling gel	Multifunctional use	20% attenuation of SW energy Warm ultrasound gel from container High amounts on cushion Shave skin of patient Check quality of coupling by in-line ultrasound
Localization of stone	Fluoroscopic C-arm In-line fluoroscopy	Automated positioning	Reduction of X-ray exposure	Fluoroscopy first choice worldwide
		Optical tracking	Reduction of X-ray exposure	Camera checks position of SW source
		Acoustic tracking	Adaptation to external C-arm	Five piezoelements track the position of SW source
	In-line ultrasound	–	Real-time SW application Control of coupling quality	Difficult in obese patients and mid-ureteral stones
	Lateral ultrasound	Tri-mode localization system (isocentric)		5 (3-9) mm tolerance to in-line ultrasound

Imaging and diagnostics

Static imaging will not be enough in the process of decision-making. All information has to be available during surgery in a way to guide the surgeon during the procedure (i.e. navigation). For this purpose, image fusion, virtual reality, molecular imaging, and marker-based navigation with miniaturized computers (i.e. iPad = surgical pad) will play an important role in the near future [Figure 4]. The development of these modalities will provide an information-rich anatomic platform that may well feed data into a truly robotic assembly such that tissue marked by the surgeon will then be neatly targeted.^[42-46]

Technology

Novel technology is the key for new treatment strategies. The principle of extracorporeal SWL revolutionized the treatment of urolithiasis. However, this principle has to be continuously elaborated. The progress in lithotripter technology focused mainly on the integration of the shock wave source into multifunctional fluoroscopic tables, rather than improving the efficacy of SWL. There are

recent promising new data regarding increased efficacy and minimal trauma of SW sources with large focus [Figure 2, Table 1]. If they prove to be highly efficient, reducing the numbers of re-treatment by pulverization of the stone, this might induce resurgence in SWL.^[14]

It is interesting that even after more than 30 years of intensive research, the ideal device has not been presented. Even worse, there is no general consensus about the criteria. It is obvious that the ideal device should be highly efficient in stone disintegration with minimal associated side effects. This could be evaluated using the Efficacy Quotient (EQ) in its different modifications.^[9,14] However, there are other criteria; the treatment should be performed under intravenous analgesia or even without anesthesia and the lithotripter should represent a multifunctional endourological workstation. Evidently, some of these criteria are difficult to realize simultaneously. The water bath represents the optimal coupling method, but cannot be used in multifunctional tables. Larger aperture systems enable treatment almost without anesthesia; however, such systems have a very small focal zone requiring multiple sessions. Furthermore, such devices cannot be used as multifunctional workstations. Moreover, with the changing demands on the security of medical devices, the handling of the lithotripters has become more complicated.^[14]

New theories for stone disintegration favor the use of shock wave sources with larger focal zones. Use of slower pulse rates, ramping strategies, and adequate coupling of the shock wave head can significantly increase the efficacy and safety of SWL [Table 2]. It seems difficult to realize “the ideal lithotripter”; however, manufacturers should keep in mind that SWL has to fight against endourology. All these procedures require general anesthesia, but offer immediate removal of the calculus. Indeed, some of the large focus lithotripters already enable SWL without any anesthesia or analgesia. However, these energy sources have to be combined with sophisticated localization systems. Early trials with charge-coupled device CCD-ultrasound indicate that the duplex signal may show when the stone is adequately hit by the shock wave and, probably also, when the stone starts to fragment [Figure 3].

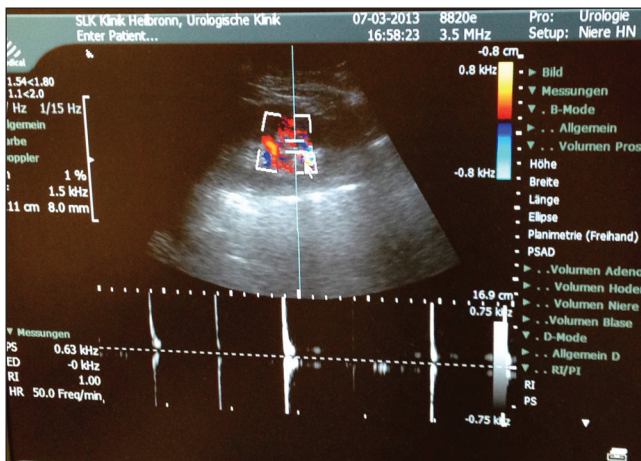


Figure 3: The use of color-coded duplex ultrasonography for localization of stones during ESWL. The CCD signal indicates by sound and graphics when the stone is hit by the shock wave. Moreover, the change of the signal may indicate breakage of the stone

Table 3: Trends in minimally invasive management of urolithiasis — The role of ESWL

Issues	Last century	Actually	Future
Diagnostics	Risk factors in urine	Risk factors in urine	Genome-related disorders
Imaging	KUB, IVP	Ultrasound, CT	Ultrasound, low-dose CT (i.e. Dyna-CT)
Stone distribution	Large stones 80% renal	Small stones 40% renal	Small stones 20% renal
Treatment option	ESWL	(Flexible) URS	Hit-controlled ESWL
	URS	ESWL	Robotic URS
	PCNL	Mini-PCNL	Navigated PCNL
			Dietary dissolution
			Microbiomic stone dissolution

Treatment strategies

The most important issue for a lithotripter today is good disintegration with a minimal number of sessions. Additionally, innovative concepts such as emergency SWL for ureteric stones should be implemented in clinical routine, even for children.^[47,48] All urologists should be aware of the new trends and latest results of SWL research as basics in their training to optimize the clinical application. The strategies in the management of urinary calculi will not change significantly. Non-invasive SWL will survive for <1.5 cm stones in the renal pelvis and upper calices. However, the method is under pressure due to miniaturized endourology

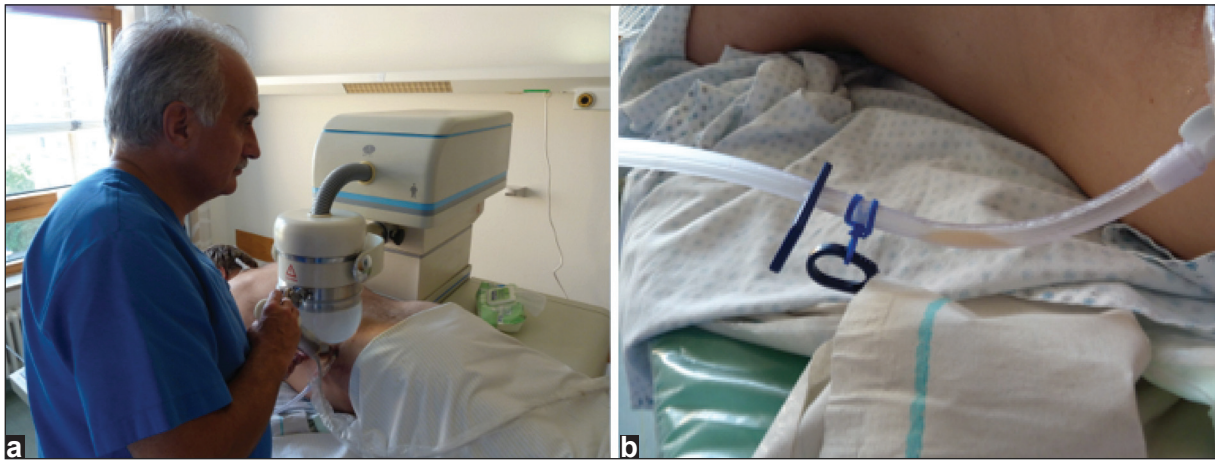


Figure 4: Early experience with the Xinin XX-ES lithotripter providing a self-focusing electromagnetic shock wave source with a large focal zone and lateral ultrasound localization. (a) ESWL for residual stones after PCNL with patient in prone position, no anesthesia or analgesia. (b) Urine output during ESWL shows no hematuria

and, thus, to provide rapid cure of the stone disease in a single session. Otherwise, patients will prefer the minimally invasive percutaneous or transurethral techniques.

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