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Shock wave lithotripsy: advances in technology and technique

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Abstract

Shock wave lithotripsy (SWL) is the only noninvasive method for stone removal. Once considered as a primary option for the treatment of virtually all stones, SWL is now recognized to have important limitations that restrict its use. In particular, the effectiveness of SWL is severely limited by stone burden, and treatment with shock waves carries the risk of acute injury with the potential for long-term adverse effects. Research aiming to characterize the renal response to shock waves and to determine the mechanisms of shock wave action in stone breakage and renal injury has begun to suggest new treatment strategies to improve success rates and safety. Urologists can achieve better outcomes by treating at slower shock wave rate using a step-wise protocol. The aim is to achieve stone comminution using as few shock waves and at as low a power level as possible. Important challenges remain, including the need to improve acoustic coupling, enhance stone targeting, better determine when stone breakage is complete, and minimize the occurrence of residual stone fragments. New technologies have begun to address many of these issues, and hold considerable promise for the future.

Introduction

Before the introduction of shock wave lithotripsy (SWL) to clinical practice in the early 1980s, the vast majority of urinary stones were removed by open surgery—often via challenging procedures with considerable potential for complications, and frequently involving a long in-hospital recovery period. As stone disease is typically recurrent, stone formers often underwent multiple, highly invasive surgeries over time. SWL, which utilizes high-intensity acoustic pulses to break up urinary tract stones, offered an entirely noninvasive means to remove stones and held the promise of eliminating virtually any stone without injury to the kidney or urinary tract.

Early reports enthusiastically promoted this new technology and SWL found application in even complex cases such as multiple stones, bilateral stones, stones in solitary kidneys and staghorn calculi.^{1–3} However, as experience with lithotripsy grew, urologists began to recognize its limitations. Some stone types (for example, brushite, calcium oxalate monohydrate, and cysteine stones) could be resistant to SWL.^{4–7} Among stones that could be readily broken, breakage was not always complete, and the presence of residual fragments often necessitated re-treatment. Also, aspects of renal anatomy (lower pole calyx, acute infundibulopelvic angle, calyceal diverticula) could pose a barrier to the clearance of stone debris.⁸ In addition, the relatively limited capacity of the ureter to discharge stone fragments restricted SWL treatment to a stone burden of less than about 2.5 cm.⁹

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Competing interests

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Reports also began to describe unexpected and sometimes serious adverse effects of SWL.^{10–12} It became apparent that shock waves could rupture blood vessels and that the resultant bleeding could be severe. Case studies reported the occurrence of intraparenchymal hemorrhage and massive renal hematomas requiring transfusion, or even nephrectomy. Extrarenal damage such as intra-abdominal bleeding, splenic rupture and hematomas of the liver and pancreas were also reported.

Thus, against the background of countless successful cases were problems too significant to ignore. In response, basic research was undertaken, first to characterize the acute renal lesion induced by SWL.¹³ Studies conducted primarily in the pig model using the Dornier HM3 lithotripter (Dornier MedTech Europe, Wessling, Germany) found that the lesion was focal but not limited to the dimensions of the focal zone, that lesion size was dose-dependent (both number and amplitude of shock waves), and that the renal papilla was particularly susceptible to shock wave damage.^{14,15} These studies showed that the lesion could involve a broad range of vessels, that tubular injury could occur but was often secondary to vessel rupture, and that bleeding initiated an inflammatory response that could result in scarring with permanent loss of functional renal volume. Thorough assessments of renal function found that although glomerular and tubular function was affected in the short term, the kidney rebounded quickly. A salient observation was that even brief exposure to shock waves could initiate a vaso-constrictive response in the kidney.^{16,17} These observations have led to the development of treatment strategies that can significantly reduce tissue damage in SWL.^{16,18,19} Thus, studies of the acute response to treatment drove home the reality that shock waves can be injurious, and helped to emphasize the importance of optimizing technique to improve outcomes.

Relatively little is known about the potential for lasting injury as a consequence of SWL. Long-term studies of the adverse effects of shock waves have never been adequately pursued in animal models. The best data on the potential for chronic effects in SWL come from clinical studies (reviewed elsewhere¹²). Although the published findings are not unanimous, there is sufficient evidence to raise concern that some patients, particularly older individuals and those who have undergone multiple lithotripsies, are at increased risk of developing lasting and significant chronic conditions including new-onset hypertension and diabetes mellitus.^{20–22} There might also be a link between multiple treatment sessions, injury to the renal papilla, and progression in the complexity and severity of stone disease.²³

Overall, lithotripsy offers important advantages for the treatment of renal and ureteral stones. In particular, SWL is noninvasive, is readily performed on an out-patient basis and can be very effective in treating solitary uncomplicated stones. SWL also presents a number of limitations—some stone types are difficult to break with shock waves, stone breakage can be incomplete necessitating re-treatment or an ancillary procedure to remove clinically significant residual fragments, and treatment is limited to a maximum stone burden of around 2.5 cm as the ureter has a limited capacity to discharge stone fragments. A further limitation is the potential for severe acute renal and extrarenal injury as a consequence of shock wave exposure, with concern that in some cases acute injury can progress to lasting damage.

In this Review we aim to place these advantages and limitations in perspective, assess the current role of SWL in stone management, and discuss recent advances in lithotripsy technology and treatment strategies, which will influence how SWL is used in the future.

Trends in surgical management

SWL, percutaneous nephrolithotomy (PCNL) and ureteroscopic stone removal (URS) are all effective methods to remove renal or ureteral stones in given clinical situations. PCNL is

superior to SWL or ureterorenoscopy in the treatment of large stone burdens and staghorn calculi.²⁴ SWL is efficacious in fragmenting and clearing most renal stones up to 2.5 cm in size.²⁵ The optimum management of lower pole renal calculi is controversial;^{8,26} the only prospective, randomized trial of SWL and PCNL reported that for lower pole stones of 1 cm or less in size the stone-free rates were 63% and 100%, respectively.²⁶ For stones larger than 1 cm, the stone-free rates were only 21% for SWL and 91% for PCNL. Although PCNL resulted in a higher stone-free rate and less need for re-treatment compared with SWL, the complication rate was higher and hospital stay was longer. For smaller lower pole stones, URS or SWL provide comparable stone-free rates of 35% and 50%, respectively, and both are acceptable options.²⁷ The low success rates achieved with stones in the lower pole are attributable to the effects of renal anatomy and gravity on the retention of fragments, and probably have little to do with the efficiency of stone breakage. For non-lower-pole stones, SWL success rate varies, being in the range of 62–92% for small stones and 33–84% for larger stones.^{8,28} Many factors affect the selection of treatment modality, and several scenarios predict poor outcomes with SWL. For example, obesity (high BMI or large skin-to-stone distance) negatively affects the success rate of SWL.^{29,30} Other anatomic features, including uretero-pelvic obstruction, calyceal diverticulum and fusion anomalies such as horseshoe kidney, can also negatively affect outcome.⁸ As a general rule, if the stone problem is simple, the renal anatomy is normal and the stone is around 2.5 cm or smaller, SWL should be the primary treatment modality.

The two main surgical options for ureteral stones are SWL and URS. Alternative procedures include antegrade percutaneous ureteroscopy and laparoscopic uretero-lithotomy.³¹ Improvements in ureteroscopic technology has enabled retrograde ureteroscopy to become a first-line option for most ureteral stones. The literature base for the 1997 American Urological Association (AUA) Guidelines indicated that for proximal ureteral stones less than 1 cm in size, URS provided a median success rate of only 56%, while SWL was the preferred treatment modality with a stone-free rate of 84%.³² By contrast, the 2007 AUA–European Association of Urology (EAU) Ureteral Stone Guidelines Panel highlighted the advances in URS in the previous decade and reported that the stone-free rates with SWL and URS for small (<1 cm) proximal ureteral stones were 90% and 80%, respectively.³³ Generally, for small ureteral stones, URS is preferred in the distal ureter and either SWL or URS is acceptable in the proximal ureter.³¹ For larger stones, URS seems to result in a higher stone-free rate and less need for re-treatment compared with SWL, but has a slightly higher complication rate and longer hospital stay.³³

Analysis of health-care costs has been used to estimate surgical trends in the handling of stones. Pearle and colleagues³⁴ suggest that throughout the 1990s in the USA SWL was used in about 50% of cases, URS in 40% and PCNL in about 4%, with not much change in this distribution over time. In a similar assessment covering approximately the same period, Kerbl and co-authors³⁵ found a similar rate for PCNL (4–6%), but a somewhat higher prevalence of SWL (70–80%) and a lower rate for URS (14–22%), although this represented a nearly 60% increase in the use of URS over the study period. Analysis of treatment records for the investigators' hospital showed that over approximately the same period the use of URS increased by 53% while that of SWL decreased by 15%. The number of stone treatment procedures at that center remained reasonably constant. By contrast, Medicare data for this period showed a 75% increase in the number of stone procedures with an increase in SWL use of around 60%. These data suggest that a substantial increase in the use of SWL at the national level was not reflected in practice at this particular academic center.

Whether or not this increase in the use of URS at one center reflects trends at other academic centers is difficult to answer. Nevertheless, the use of endourological stone procedures is commonly perceived to be on the rise, at least at some academic centers. A recent study

suggests that this may be the case, and presents evidence of a generational shift in surgical technique.³⁶ Most urologists would agree that many facets of physician preference affect the choice of treatment modality for a given case. The study by Matlaga³⁶ examined the surgical practice logs submitted to the American Board of Urology by candidates for initial certification and recertification between 2003 and 2008. Urologists in the initial certification cohort performed URS in 52% of cases, whereas more-senior urologists performed SWL in up to 60.5% of cases. There are several possible explanations for this trend, including the dramatic advances in endoscopic technology that have occurred in the past decade, the limited progress in SWL technology during the same period, and the fact that young urologists are now introduced to state-of-the-art endoscopic techniques during their training at academic centers. In addition, some senior urologists might be less likely to be exposed to technical innovations or are reluctant to devote time to learning newer, more-advanced technologies.

Another factor that might affect the choice of treatment, at least in the USA, is the widespread migration of many common surgical procedures from hospitals to ambulatory surgery centers.^{36–38} In particular, the increase in physician ownership of these centers and the financial incentives involved might contribute to the preferential selection of outpatient procedures.³⁹ Ownership of ambulatory surgery centers might even affect the indications for surgical intervention as has been seen in other medical fields.^{40,41} For example, a patient with a large, asymptomatic renal stone that might best be treated with PCNL might be more likely to be treated by SWL—regardless of the lower success rate—when the lithotripsy facility is owned by a doctor who works within that facility.

Thus, among the available surgical options to treat urinary stones, SWL is currently used most often. However, younger urologists prefer the more technically challenging endourological methods with their more-certain outcomes and this trend might affect the rates at which procedures are applied in the future. It also seems likely that financial considerations will influence choice of modality.

Current status of SWL in the clinic

It is widely appreciated that treatment protocols for SWL differ depending on the clinical setting. Practice patterns in the choice of treatment modality are affected by factors such as access to facilities and the proficiency and preference of the individual urologist; how lithotripsy is performed depends, at least in part, on similar factors. Lithotripsy is not performed the same way at all institutions, or at all sites. It is understandable that variations in protocol exist, but local practice often deviates from what is recognized as 'best practice'.²⁵

How shock waves are delivered can have a significant effect on outcomes and the occurrence of adverse effects. In brief, well-substantiated evidence indicates that the shock wave dose should be kept as low as possible and that treatment should be performed at a slow shock wave rate.^{19,25,42} Damage to the kidney in a single session is dose-dependent for pulse amplitude and shock wave number, and an increased risk of long-term adverse effects is associated with multiple lithotripsies.^{12,14,22,23,43–45} Success rates have been shown to be significantly better when treatment is performed at a rate of 60 shock waves per min (or slower) compared to the typical rate of 120 shock waves per min.^{46–52} In addition, the risk of injury can be reduced by slowing the shock wave rate, and incorporating a brief pause after the initiation of treatment protects against injury.^{14–19} Thus, the current standard is treatment at low-to-moderate acoustic pressures with as few shock waves as possible, to minimize acute and lasting tissue injury, and at a slow shock wave rate (60 shock waves per

min or slower), to enhance stone breakage and reduce tissue damage.²⁵ It is difficult to know how widely these standards are followed in practice.

Shock wave rate is a good example of the difficulty of translating ‘best practice’ recommendations to actual practice, and might serve to illustrate how the competing demands of the clinical setting can influence treatment protocol. Despite sound evidence that slowing the shock wave rate is beneficial, few urologists have been able to adopt this simple but effective measure in practice. Slowing the shock wave rate increases the treatment time. For a high-volume stone center that sees a dozen or more cases a day, slowing the shock wave rate might not be a feasible option. Also, many urologists and SWL technicians are mandated to follow a set protocol specified by their institution or service. Such is the case for many private hospitals and sites serviced by certain mobile providers, and it effectively takes a critical aspect of treatment out of the hands of the urologist. In addition, some urologists and technicians are likely to be unaware of the concepts and supporting data that represent advances in the field. One would expect that urologists at academic centers would be least likely to fall into this category, but an inadequate knowledge base could be a factor in any setting.

Total shock wave dose is another parameter that is likely to differ by clinical setting. In situations in which there is limited access to a lithotripter, which curtails the opportunity for re-treatment, there is a natural tendency to deliver the maximum number of shock waves allowable so as to increase the chances of complete comminution in a single session. Similarly, ready access to lithotripsy makes it feasible to re-treat, which increases the total number of shock waves delivered.

Arguably, the best treatment will be administered in a setting in which the urologist has the freedom to determine the shock wave delivery protocol and to adopt strategies that objectively-determined data have shown to improve outcomes and minimize adverse effects.

Practical steps to improve outcomes

As more is learned about the mechanisms of shock wave action in stone breakage and tissue injury and as the biological response to shock waves becomes better characterized and better understood, the procedural steps that constitute ‘best practice’ in SWL are sure to change. In the past few years alone significant advances in research have identified several key factors that can affect outcomes of SWL and have the potential to reduce the incidence of adverse effects (Table 1). In short, they have provided new insight into the importance of basic technique—how best to couple the shock head to the patient, and how stone breakage and tissue injury can be affected by treatment settings for shock wave rate and power, and the sequence of shock wave delivery.

Improving acoustic coupling

Unlike the water-tub style Dornier HM3, modern lithotripters are dry-head devices in which the treatment head is brought into contact with the patient. Among current machines the only exception is the Storz SLX (Storz Medical, Tägerwil, Switzerland), which uses a partial water bath for coupling to the shock head. The typical protocol for coupling is to apply a handful of gel onto the cushion of the treatment head, and to the contact area on the patient’s skin. The treatment head is pressed against the skin, the stone is targeted and treatment is initiated. There is usually little concern about the quality of coupling. However, air pockets can get caught at the coupling interface and the likelihood of these defects increases the more the gel is handled. Shock waves propagate very well through water and through coupling gels, but not through air. Indeed, over 99% of a lithotripter shock wave will be reflected at an air pocket.⁵³ Even very minor coupling defects can affect stone breakage. *In*

vitro experiments using a test tank with a Mylar membrane as a surrogate body wall showed that defects of only 2% coverage reduced the breakage of model stones by 20–40%.⁵⁴ Breaking and re-establishing contact reduced the transmission of acoustic energy measured at the focal point by more than 50%. The quality of coupling can be improved by the way the gel is handled and applied.⁵⁵ An effective method is to apply the gel directly from the stock jug as a mound to the center of the treatment head, then press the cushion against the patient. The gel can be further spread out, by increasing the water inflation pressure of the cushion. The issue of coupling may seem mundane, but it is essential, as poor coupling and variability in coupling are likely to contribute to poor and variable outcomes.

Slowing the shock wave rate

It is easy to appreciate that stone breakage and tissue injury are dose-dependent. It seems less intuitive that shock wave rate should similarly affect outcomes. However, three prospective clinical trials and an independent meta-analysis have concluded that stone breakage outcomes are improved at 60 shock waves per min compared to 120 shock waves per min, and recent studies of acute renal injury in the pig model show a reduction in tissue damage at 60 shock waves per min (or slower).^{52,56–58}

Laboratory studies suggest that the mechanisms of action involved in the effect of shock wave rate are different for stone breakage and tissue injury. In stone breakage, cavitation bubbles collapse at the stone surface and act primarily to erode fragments that are too small to be acted on by internal shear stresses generated by passage of the shock front.^{53,59} Cavitation, the formation and violent collapse of bubbles, is dependent on the amplitude and duration of the negative pressure phase of the shock wave. At a fast shock wave rate, cavitation increases because microbubbles generated at bubble collapse persist between pulses, acting to seed the formation of new bubbles.⁶⁰ The growth of these small bubbles reduces the negative pressure of the shock wave and the increase in number of bubbles alters bubble dynamics, affecting delivery of energy to the stone.⁶¹ Thus, at a fast shock wave rate, more bubbles form but they are less effective in attacking the stone surface.

Cavitation also contributes to tissue damage, but in a very different way. Bubbles that form within the blood are thought to damage the vessel wall either as they expand or upon collapse.⁶² Fortunately cavitation does not occur readily within patent vessels,⁶³ otherwise vascular damage in SWL might occur far more frequently. An alternative hypothesis is that cavitation within tissue is secondary to injury initiated by shear. Stress might accumulate within kidney tissue if the shock wave rate is faster than the displacement relaxation time of the tissue.⁶⁴ In such a scenario, vessel rupture might be induced by shear and the resultant extravasation and pooling of blood could provide a site for intense cavitation, exacerbating tissue damage. Numerical modeling suggests that the shock wave rate threshold for tissue relaxation is about 1 Hz, such that rates faster than 60 shock waves per min would be expected to drive tissue deformation leading to injury.⁶⁵ Recent studies in the pig model indicate that slowing the rate of shock wave delivery can significantly reduce renal injury (Figure 1).^{56,58} In separate studies, pigs were treated with either 120, 60 or 30 shock waves per min using a Dornier HM3 lithotripter operated at 24 kV. The animals treated at the slower rates had significantly smaller lesions compared to the pigs treated at the faster rate. This finding is potentially very important as it implies that protecting against SWL trauma is as simple as slowing the firing rate of the lithotripter. Most centers have experienced practical difficulties in adopting a slow shock wave rate, but the notion that reduced rate is both protective and improves stone breakage makes this an attractive treatment strategy.

Sequence of shock wave delivery

How shock waves are administered to the patient—the sequence with regard to timing and shock wave number at a given power level—can influence stone breakage and have a dramatic effect on tissue injury. The practice of ‘power ramping’ in which shock wave intensity is gradually increased was introduced over 20 years ago for anesthesia-free lithotripsy, as a means to acclimate the patient to treatment. Such a protocol is still followed in one form or another at most institutions—regardless of the regimen used for anesthesia. No standard ramping (or step-wise) protocol exists, and urologists and technicians tend to use whatever works for their particular setting. This approach often involves two or more steps of a nominal number of shots, increasing the power setting on-the-fly, then settling in at some higher level—below the maximum setting for the lithotripter—for the remainder of treatment. Power ramping has been observed to improve stone breakage *in vitro* and with model stones that were surgically implanted in pigs, and ramping has been reported to improve success rates in patients.^{66–68} Step-wise treatment might also contribute to low hematoma rates.⁶⁹

Studies in the pig model show that a two-step power ramping protocol can significantly reduce renal injury, but that it is not the low-to-high step that imparts protection.^{16–18} Treatment with 100 shock waves at 18 kV followed by 2,000 shock waves at 24 kV significantly reduced lesion size compared to 2,000 shock waves at 24 kV—but so did 100 shock waves at 24 kV followed by 2,000 shock waves at 24 kV. The key to the protective effect was the inclusion of a brief pause (~3 min) between the two doses. The degree of protection was impressive. Animals treated at 24 kV without pause showed a mean lesion size of approximately 4% of functional renal volume, whereas pigs treated using a ‘pause protocol’ had a lesion affecting around 0.5% of functional volume or less. This finding is strongly supportive of the idea that step-wise treatment is beneficial. Inclusion of a brief pause in treatment should be feasible in most clinical settings, and as step-wise protocols have been shown to improve success rates it seems reasonable to recommend a pause protocol to promote safety.

Lithotripter technology

Several technological advances promise to improve the effectiveness and safety of SWL. These developments include the introduction of lithotripters with dual shock wave sources, the use of lithotripters that produce a broad focal width, and the development of new devices—many of which are in the experimental stage—that aid in tracking and targeting of stones, help determine when stone breakage is complete and improve the clearance of residual fragments (Table 2). The application of such technology has great potential for improving the outcomes of SWL treatment in the clinic.

The first lithotripter to be introduced widely to clinical practice, the Dornier HM3, was an electrohydraulic device in which shock waves were generated by underwater spark discharge using an electrode near the base of a hemi-ellipsoidal reflector.^{1–3,8} The patient reclined in the chair of an XYZ gantry and was immersed in the water bath (filled with degassed, deionized water). The stone was localized by fluoroscopy and positioned for treatment at the focal point of the lithotripter. The HM3 generated fairly robust (~40 MPa) shock waves and the focal volume was about 12 mm in width.^{70,71} Acoustic coupling was excellent as water is a superb medium for propagation of shock waves.⁵³ Stone-free rates with the HM3 were also excellent: approximately 90% or better for uncomplicated non-lower-pole stones.⁸

Nonetheless, as the large water bath and water processing plant of the HM3 required a dedicated facility, manufacturers developed dry-head devices in which the shock source is

enclosed by a rubber boot. In an attempt to engineer machines that could be used to perform lithotripsy under minimal anesthesia, the aperture of the shock source was widened. This modification spread the energy over a broader area of the patient's skin to reduce discomfort during treatment, but resulted in a narrower focal zone.⁵³ Many such lithotripters have a focal width of around 5 mm. Also, some lithotripters generate acoustic pressures of the order of 100 MPa or higher.^{53,71}

Most lithotripters developed in the 1990s moved away from spark gap technology in favor of durable, highly reproducible electromagnetic shock sources; yet, some manufacturers continued to pursue electrohydraulic technology including the development of encapsulated electrodes to improve longevity and consistency.⁷² Piezoelectric lithotripters that employ multiple piezo-ceramic elements to generate shock waves were also developed. Outcomes for the most part have been poor with these machines.⁷³ Nevertheless, piezoelectric sources have not been entirely abandoned as this modality offers the potential to manipulate the waveform, to steer the acoustic axis to track the stone during treatment and, when paired with another shock generator, has been used to produce tandem pulses in rapid succession as a means to enhance the effect of cavitation in stone breakage.^{74–76}

Tandem-pulse and dual-head lithotripters

Recognition of the role of cavitation in stone comminution has led to efforts to enhance the action of cavitation bubbles at the stone surface. A novel idea has been to use two shock waves in rapid succession to drive the forceful collapse of bubbles against the stone. A number of approaches have been reported, such as fitting a lithotripter with an auxiliary piezoelectric array to generate a second, trailing shock wave along the same acoustic axis.^{74–76} Tandem shock waves have also been generated using a piezoelectric lithotripter fitted with an additional charging and discharge circuit to produce the second pulse.⁷⁷ Tandem-pulse lithotripsy is an area of active investigation and shows promise as a means to enhance stone breakage while minimizing injury.

A related concept is the delivery of closely timed shock waves from separate treatment heads aligned to the same focal point.^{78,79} Dual-head lithotripters are already being used to treat patients and despite the inherent complexity associated with twin shock sources—two potential sources of variability in coupling and acoustic output—plus concern that treatment at very fast shock-wave rate (up to 240 shock waves per min) might be injurious, initial reports suggest that such machines can be used safely and effectively.^{80,81} Dual-head lithotripters are not currently in widespread use, but the concept has merit and with continued refinement and further study such machines may be applied more widely in the future.

Wide focal zone lithotripters

A main feature that distinguishes one lithotripter from another is its acoustic output; that is, the amplitude and spatial distribution of acoustic energy delivered to the focal volume.⁵³ In terms of acoustic output, it is difficult to describe what constitutes a 'typical' lithotripter, because the range of amplitudes and focal widths is so great. The Dornier HM3, arguably the most widely studied and well-characterized lithotripter, produces peak positive pressures of about 40 MPa within a focal width of approximately 10–12 mm (reports describe 8–15 mm²⁵). Most lithotripters, however, generate higher pressures (~60–160 MPa) delivered to a much narrower focal zone (~3–6 mm). One class of machines also produce considerably lower pressures (~20 MPa) and have very broad focal zones (~18–20 mm). Two such lithotripters are the XX-ES CS-2012A (Xi Xin Medical Instruments Co. Ltd, Suhou, China) and the LithoGold LG-380 (Tissue Regeneration Technologies, Woodstock, GA, USA). Both machines have been found to have very broad focal zones and generate relatively low

acoustic pressures at power settings used for clinical treatment (XX-ES ~18 mm, 16–20 MPa; LG-380 ~20 mm, 20–25 MPa).^{57,82} These broad-focus, low-pressure lithotripters have been commercially available for only a short time, but have begun to attract attention as research has shown that focal width affects stone breakage in several ways.

Respiratory movement can move a stone into and out of the focal zone, and, therefore, a wider focal zone offers a better chance of hitting the stone. This effect has been illustrated in an *in vitro* study that compared the stone breakage efficiency of a lithotripter with a focal width of approximately 5 mm (Dornier DoLi-50) to that of a lithotripter with a focal width of around 18 mm (XiXin XX-ES). When model stones were positioned at set distances lateral to the acoustic axis, breakage efficiency with increasing distance fell faster for the DoLi-50, but was not significantly different until 15 mm lateral, at which point the DoLi-50 required almost twice the number of shock waves as the XX-ES to break stones to completion ($3,006 \pm 780$ shock waves versus $1,726 \pm 972$ shock waves; $P < 0.006$), even though the XX-ES generated substantially lower acoustic pressure (DoLi-50 58 MPa versus XX-ES 16 MPa).⁸³ The implication is that when stone motion occurs owing to respiratory motion, a broader focal zone will increase the likelihood of hitting and breaking the stone.⁸⁴

Focal width also seems to have a critical role in the mechanism of stone comminution, particularly the initial fragmentation of a stone and the breakage of large fragments; at least two effects have been reported (discussed thoroughly elsewhere²⁵).^{85–87} First, when the focal width is narrower than the stone, the energy deposited into the stone is reduced. A focal width of 10 mm will deliver five times more energy to a 10 mm stone than will a focal width of 4 mm.²⁵ Second, shear stresses generated within a stone during passage of the shock wave have a critical role in stone breakage. Numerical modeling studies have shown that the shear waves necessary to produce large internal stresses within the stone launch from the surface of the stone and occur when the focal width is greater than the diameter of the stone;^{85,86} that is, the exterior surface of the stone must be subjected to high pressures in order to generate significant internal stress.

Safety and efficacy are important issues in SWL, and evidence suggests that the use of more powerful, narrow focal zone machines is associated with higher re-treatment rates and a greater incidence of adverse effects than use of devices with a broader focal zone.^{88–92} This is not to imply, however, that wide focal zone lithotripters are inherently safer machines. Indeed, one might think that a wider focal zone would expose a larger region of tissue to potentially damaging shock wave energy. However, studies in pigs show that when a clinical dose of shock waves is delivered using the treatment protocols recommended by the respective manufacturers, both the XX-ES and the LG-380 broad focal zone machines produce relatively small (~0.1% functional renal volume) lesions in the renal parenchyma.^{57,82} The protocols used in these studies applied treatment at a slow shock wave rate (27 shock waves per min with the XX-ES, and 60 shock waves per min with the LG-380). Both these slow-rate regimens have been shown in studies using the HM3 to produce significantly less injury than treatment at the conventional rate of 120 shock waves per min.^{56,58} Until a study appropriately assesses the effect of fast versus slow shock wave rate using a broad focal zone machine, one must assume that the low level of injury observed to date with these lithotripters is a product of the protection afforded by treatment at a slow shock wave rate.

Assessment of stone breakage

Most patients are treated with the maximum dose of shock waves allowable for the lithotripter being used. This is the case despite laboratory studies showing that virtually all stone types can be broken by administration of hundreds of shock waves, rather than thousands.⁹³ Missed shots caused by respiratory motion, and a reduction in effective energy at the target owing to poor acoustic coupling surely contribute to the higher shock wave

counts. However, the principal reason that patients are overtreated is because conventional imaging does not show when the stone is broken to completion. The fluoroscopic and ultrasound imaging modalities used with lithotripters have improved substantially over the years and are effective for stone localization, but remain unreliable for precise determination of the treatment end point. Experienced urologists know to look for softening of margins, loss of density and movement of particles as signs of fragmentation, but such features are hard to judge and difficult to qualify.²⁵

Recent progress includes the development of an acoustic feedback system to monitor stone comminution and determine the breakage end point.⁹⁴ A broadband receiver is used as a microphone to monitor shock waves reflected off the stone. The signal includes reflection of the incident shock wave and reverberation of the acoustic wave transmitted into the stone. As the stone breaks up, reverberations within smaller fragments generate higher-frequency signals. *In vitro* tests with model stones have shown that even the first fracture can be detected in real time and that breakage is more evident with the signal converted in the frequency domain. The END system can discriminate between fragments that differ in size by just 1–2 mm. Proof of concept is well demonstrated and the system requires further refinement before *in vivo* testing.

A similar system developed by Leighton and co-workers⁹⁵ utilizes an acoustic sensor to detect emissions generated by each shot at the focal point of the lithotripter. This passive listening device monitors cavitation at the target area. The quality of the cavitation signal is affected by the immediate fluid environment, and was found to correlate with the degree of breakage of the stone. A computer display tells the operator if the shock wave hits the stone, and whether fragmentation is progressing. A clinical trial with the device showed promise, predicting the outcome in 95% of cases in which therapy was successful.⁹⁵

Acoustic tracking for stone targeting

Respiratory motion can move stones 5 cm or more with each breath, and this movement is not in line with the acoustic axis of the lithotripter. Thus, the stone is a moving target that is carried in and out of the focal zone of the lithotripter. Depending on respiratory rate, the length of excursion, and the focal width and shock wave rate of the lithotripter, the stone can be outside the focal zone when 50% or more of the shots are fired.^{53,84} Thus, many shots miss the intended target, but hit the surrounding tissue. If a means to track the moving stone and to trigger the lithotripter only when the stone is on target were available, then it would shorten treatment time and reduce exposure to shock waves.

Several targeting systems have been developed to track stones during treatment. These include the use of sophisticated ultrasound imagers and tracking algorithms, and a system built into a piezoelectric lithotripter to actively steer the beam to hit the moving stone.^{96–99} None of these systems is currently in clinical use, but they demonstrate proof of concept that tracking can improve the hit rate by about 50%.

Owen and colleagues¹⁰⁰ have reported a real-time tracking and triggering system in which short ultrasonic pulses are delivered to the focal point of the lithotripter, and the scattered pulse—scattered by the stone when on target—is detected by a receiver–transducer. Signal scattered by a stone is much higher in amplitude than that scattered by tissue, and a threshold for stone above background is used to trigger the lithotripter. *In vitro* tests using a motorized positioner to simulate 4 cm of respiratory excursion through the test tank of an HM3-clone lithotripter showed that the system improved stone breakage approximately two-fold.¹⁰⁰

Clearance of residual stone fragments

One of the recognized limitations of SWL is the retention of stone fragments within the kidney, particularly the lower pole. Fortunately, the majority of fine particles clear fairly well, but larger fragments, of the order of one to several millimeters, can be slow to wash out or can be retained. As such fragments can be symptomatic or act as a nidus for stone formation, there has long been interest in finding ways to remove them. In some instances ureteroscopy may be an option, but noninvasive methods such as percussion, diuresis, or inversion of the patient have broader appeal. Recently, a method has been described in which stone fragments in the renal pelvis can be moved using transcutaneous focused ultrasound.^{101,102} The system employs a focused ultrasound therapy probe, which generates acoustic radiation forces and acoustic streaming sufficient to push stone fragments over a distance of several centimeters. The therapy probe has an inline ultrasound imaging probe, which is used to localize the fragments and to help the operator move them in a desired direction. The system is independent of the lithotripter and operates below the threshold for thermal injury. Such a device holds considerable promise not only for moving and clearing stone fragments, but also for dispersal of clusters of fragments to help in determining if a stone is adequately broken to completion.

Other challenges

Some additional issues in SWL seem well suited to being addressed through new technology. These problems include ensuring adequate acoustic coupling, and the difficulty posed by obese patients.

Acoustic coupling

As discussed previously, acoustic coupling with modern dry-head lithotripters is inefficient and highly variable. Defects (air pockets) at the coupling interface arise when coupling is first established and worsen if the patient is moved or contact is broken and hastily reinitiated. Such defects interfere with the transmission of shock wave energy to the target and reduce the efficiency of stone breakage.⁵⁴ Poor coupling, therefore, necessitates an increased number of shock waves for effective treatment, but because the shock waves still exhibit an ample negative pressure phase they retain the potential to contribute to tissue injury. Even under well-controlled conditions *in vitro*, coupling by the typical method of applying gel is highly variable, with defects ranging from 1.5% to 19% of the coupling interface.⁵⁵ The quality of coupling *in vitro* can be improved by using proper technique to apply the gel, but when working with a patient the urologist has no way to know if coupling is adequate. What is needed is a means to assess the integrity of the coupling interface in preparation for treatment and throughout the SWL session. Direct imaging is a possible solution, and could give immediate feedback. Some lithotripters are equipped with inline ultrasound probes and monitoring the integrity of coupling could be a useful application of this existing hardware.

The obese patient

Obese patients typically have poor outcomes with lithotripsy, and treatment often fails in cases in which the skin-to-stone distance is greater than 9–10 cm.²⁹ When the skin-to-stone distance is large, the stone cannot be positioned precisely at the focal point of the lithotripter without inverting the cushion of the treatment head—a situation almost certain to produce very poor coupling. Data on the trade-off between coupling and positioning of the stone along the axis of a lithotripter in obese patients have never been reported, although tellingly a recent study found no effect of skin-to-stone distance when using the HM3, a lithotripter for which coupling is not an issue.¹⁰³ With many lithotripters, however, the stone can be broken even if it is positioned distal to the focal point.¹⁰⁴ Indeed, for some lithotripters, such

as the LithoGold LG-380, breakage is actually best several centimeters distal to the focus.¹⁰⁵ Thus, the obese patient presents at least two potential problems: overcoming ineffective coupling; and ensuring that the stone is accurately localized along the acoustic axis. Perhaps a typical dry treatment head could be fitted with a partial water bath (an attractive feature of the Storz SLX). As for targeting when the focal point falls proximal to the stone, a positive step would be an algorithm to aid alignment so that the stone lies on the acoustic axis.

Conclusions

SWL remains the only entirely noninvasive surgical treatment to remove urinary stones. This fact is key in influencing urologists and patients to opt for lithotripsy rather than more-invasive endourological procedures. SWL has noteworthy limitations including a spectrum of potentially serious adverse effects. However, significant advances are being made in SWL technology and technique that have begun to improve success rates and reduce the potential for adverse effects—a keen attention to shock wave parameters and treatment protocols will improve success rates and help to enhance safety.

Key points

- Shock wave lithotripsy (SWL) is the only noninvasive surgical technique to remove urinary stones, and is the most common treatment for solitary, uncomplicated, small upper urinary tract calculi
- Some stone types can be highly resistant to shock waves; clinically relevant residual fragments are common in SWL, and re-treatment following SWL is common
- Shock wave treatment can rupture blood vessels, and acute renal injury can be severe; inflammation in the kidney following SWL can lead to scarring with permanent loss of functional renal mass
- Success rate in SWL is significantly increased by treating at a slow shock wave rate; renal injury is also reduced by treatment at slow shock wave rate, and by step-wise treatment employing a pause between steps
- Lithotripter focal width affects stone breakage, and a wide focal zone is an advantage
- Most urologists are likely to overtreat with shock waves because the breakage end point is hard to judge; new technologies are being developed to target stones, assess breakage and clear fragments

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Figure 1.

Protective effect of a slow shock wave rate in shock wave lithotripsy (SWL). Kidneys from three pigs treated by SWL. The top row shows surface views and the bottom row is the corresponding tissue section. **a** | This kidney received the dose of shock waves recommended for clinical treatment (1,500 shock waves, 9.3 kV, 27 shock waves per min) using the Xi Xin XX-ES CS-2012A lithotripter. No surface or parenchymal bleeding was observed, and lesion size was 0% of functional renal volume (FRV). The XX-ES is currently the only lithotripter recommended for use at a firing rate of less than 60 shock waves per min.⁸⁷ **b** | This kidney also received 1,500 shock waves, but with a Dornier HM3 lithotripter at 30 shock waves per min (18 kV). No surface bleeding was observed, but several small

sites of hemorrhage could be seen isolated to the renal papillae (arrows). Lesion size was 0.1% FRV. **c** | This kidney was treated with the HM3 lithotripter at 120 shock waves per min (2,000 shock waves, 24 kV). Injury included a subcapsular hematoma (asterisk) and sites of cortical and papillary hemorrhage (arrows). Lesion size in this kidney measured 1.5% FRV. A study using the pig model has shown that treatment with the HM3 lithotripter at 60 shock waves per min is also protective compared to 120 shock waves per min (lesion size: 0.42% FRV and 3.93% FRV, respectively).⁵⁸

Table 1

Treatment strategies to improve outcomes and reduce adverse effects

Strategy	Effect	References
Slow shock wave rate (<120 shock waves per min)	Improved success rates	Pace <i>et al.</i> (2005) ⁴⁶ Yilmaz <i>et al.</i> (2005) ⁴⁷ Madbouly <i>et al.</i> (2005) ⁴⁸ Chacko <i>et al.</i> (2006) ⁴⁹ Kato <i>et al.</i> (2006) ⁵⁰ Weiland <i>et al.</i> (2007) ⁵¹ Meta-analysis: Semins <i>et al.</i> (2008) ⁵²
Slow shock wave rate	Reduced renal injury	Animal studies: Evan <i>et al.</i> (2007) ⁵⁶ Evan <i>et al.</i> (2007) ⁵⁷
Step-wise power ramping	Low complication rate	Mobley <i>et al.</i> (1993) ⁶⁹
Two-step power ramping	Reduced kidney injury	Animal study: Willis <i>et al.</i> (2006) ¹⁶
Brief pause between ramping steps	Reduced renal injury	Animal study: Connors <i>et al.</i> (2009) ¹⁸ Vasoconstriction as potential mechanism: Handa <i>et al.</i> (2009) ¹⁷
Minimal handling of gel; proper method of applying gel	Reduced coupling defects	<i>In vitro</i> study: Neucks <i>et al.</i> (2008) ⁵⁵

Table 2

Technical innovations in shock wave lithotripsy

Results	References
<i>Increased focal width lithotripters</i>	
Proof of concept	Eisenmenger <i>et al.</i> (2002) ⁸⁷
Enhanced potential to hit targeted stone	<i>In vitro</i> studies: Pishchalnikov <i>et al.</i> (2008) ⁸³ Cleveland <i>et al.</i> (2004) ⁸⁴
Improved breakage of large stone fragments	<i>In vitro</i> studies and numerical modeling: Cleveland and Sapozhnikov (2005) ⁸⁵ Sapozhnikov <i>et al.</i> (2007) ⁸⁶
<i>Dual-head lithotripters</i>	
Improved safety and efficacy	Prospective clinical trial: Sheir <i>et al.</i> (2008) ⁸¹
Improved stone breakage	<i>In vitro</i> studies: Sokolov <i>et al.</i> (2001) ⁷⁹
Minimal renal injury	Animal study: Handa <i>et al.</i> (2009) ⁸⁰
<i>Tandem-pulse shock sources</i>	
Enhanced cavitation in stone comminution	Laboratory studies: Xi and Zhong (2000) ⁷⁴ Zhou <i>et al.</i> (2004) ⁷⁵
Reduced time to breakage	Laboratory study: Fernandez <i>et al.</i> (2009) ⁷⁷
<i>Acoustic detection for targeting and breakage assessment</i>	
In development	Leighton <i>et al.</i> (2008) ⁹⁵ Owen <i>et al.</i> (2007, 2004) ^{94, 100}
<i>Focused ultrasound to enhance clearance of residual fragments</i>	
Proof of concept	Laboratory studies: Shah <i>et al.</i> (2009) ¹⁰¹ Sapozhnikov <i>et al.</i> (2009) ¹⁰²