Extracorporeal Lithotripsy Overview of Technology

The first clinical application of extracorporeal shock-wave lithotripsy (ESWL) was reported by Chaussy et al in 1980, and during the ensuing two decades the urologic management of nephrolithiasis underwent a complete revolution. With the nearly simultaneous development of percutaneous and ureteroscopic techniques, open stone surgery, once a mainstay of treatment, is rarely indicated today. (30)

Historical Aspects

Shockwave technology was being developed in the late 1960’s by Dornier, a German aerospace firm, to study the effects of shock waves generated by supersonic aircraft. They originally found that aircraft metal was damaged by the shock waves created by rain drops and/or micrometeorites striking them when traveling at supersonic speeds. Chaussy and his co-workers (Munich) became interested in the applications of this new technology in medicine. The subsequent creation of an electro-hydraulic or spark gap generator allowed for the creation of reproducible shock waves that could be directed toward renal calculi. From 1969 to 1971, studies showed that shock waves generated in water could be transmitted into and through the body without appreciable energy loss. Only the lung tissue demonstrated vulnerability to the shock waves because of high acoustical impedance at the air-tissue interface. (42)

After initial experiments on dogs, the first human lithotripter prototype, the HM-1 (human machine), was introduced for clinical use on February 20, 1980. Four years later, the first widely available commercial
lithotripter, the Dornier HM-3 (Dornier, Germany), was on the market. The Dornier HM3 became the criterion standard when compared to newer devices. It was based on an electro-hydraulic shockwave. By placing the patient and generator in a water bath, the shock waves easily passed through tissue and were focused on a given stone. Localization was based on bi-planar fluoroscopy.\(^{(42)}\)

Modifications to increase the applicability of the technology and to minimize anesthesia requirements have resulted in machines in which both renal and ureteral stones can be localized and treated. The water bath employed with the Dornier HM3 has been replaced by a smaller generator and water cushions that coapts to the patient on many of the newest designs, allowing shockwave propagation into tissue. With the new designs, patients can be treated in a variety of positions to help in localization and to maximize the effect.\(^{(42)}\)

Piezoelectric (1986) and electromagnetic (1987) currently are the most common generators employed\(^{(50)}\). They have smaller focal zones than the Dornier HM3 and, as such, require less anesthesia. While they do produce acceptable pressure waves, the smaller zones require superior imaging to precisely place the shock waves. Thus, the newer shockwave generators have fewer margins for error and require better imaging for localization.\(^{(43)}\)

The combination of ultrasonic (1985) and fluoroscopic localizing in the same machine is preferred in the newer generation machines. This allows for the limitations of each modality to be compensated by the other. Ultrasound is especially useful for radiolucent renal calculi, while ureteral stones are localized efficiently with pulsed-progressive fluoroscopy\(^{(43)}\). With the use of fluoroscopy, the patient and to a lesser
extent the personnel of the ESWL team are exposed to hazards of radiation. Thus the operator must follow the generally accepted rule for protection from radiation energy ALARA: as low as reasonably achievable (42)

**Functional Components of ESWL**

Every lithotripter relies on the coordination of several components including:

*Shock-wave source

*Shock-wave focusing

*Shock-wave coupling

*Calculus imaging and localization

*Analgesia

**Shock wave Source**

There are several types of shock-wave generators available today, and lithotripters often are categorized on the basis of their energy source. The three forms of energy source used most frequently are electro-hydraulic, piezoelectric and electromagnetic sources. Another potential source is micro-explosive energy, but there is no commercially available lithotripter using this type of generator (40)

All shock wave generators are based on the geometric principle of an ellipse. Electro-hydraulic and micro-explosive generators often are referred to as **point-source generators**. Point-source generators create shock waves that diverge from the source (F1 focal point) and are
reflected subsequently and concentrated at a distant target (F2 focal point) \(^{(40)}\).

Electromagnetic and piezoelectric generators are *extended source generators*. In contrast to electro-hydraulic generators, extended source generators create a shock wave that is directly focused to a treatment point \((33)\) (F1 focal point).

*Electro-hydraulic lithotripters* were among the first lithotripters available clinically. This energy source relies upon an underwater spark-gap electrode to generate shock waves. A high-voltage discharge from the electrode vaporizes water at the (F1) focal point, and this sudden gaseous expansion generates a shock wave that diverges from the point of origin until it hits an ellipsoid or parabolic reflector. The shock waves then are reflected and redirected to a second focal point (F2), the point at which the stone is situated \((43)\). (Figure 20)

![Figure 20: The electro-hydraulic shockwave generator](image)

\[(43)\]
The next energy source developed was the piezoelectric generator, in 1986. In this system, numerous piezoelectric crystals line a hemispheric dish. If a high-voltage current is applied to the dish, the piezoelectric crystals expand simultaneously, thereby generating a shock wave. (Figure 21) The dish that houses the piezoelectric crystals is shaped in a fashion that permits the projection of the shock waves to converge at a focal point at which a calculus is targeted, often as a spherical or ellipsoid cup (40).

![Piezo-ceramic Shockwave Generator](image)

**Figure (21):** The piezo-ceramic shockwave generator (40)

The electromagnetic generator was first reported by Wilbert et al in 1987. These lithotripters use a water-filled shock tube (Figure 22 & 23). Inside the shock tube is a metallic membrane backed by a magnetic coil. If high-voltage current is applied to the coil, the resultant charge on the coil repels the oppositely charged metallic membrane, and this magnetic repulsion generates a shock wave. The shock wave then is focused with an acoustic lens or parabolic reflector to the focal point for treatment of the targeted calculus (40).
Figure (22): The electromagnetic shockwave generator with acoustic lens

Figure (23): The electro-magnetic shockwave generator with focusing reflector.
**Physical properties of shock waves:**

Regardless of their mode of generation, all shockwaves exhibit the following common characteristics:

1. Shockwaves can be transmitted freely and propagate through the body without energy loss if an appropriate transmission medium such as water is used.

2. In conjunction with suitable reflectors, shock waves can be focused and thus brought to bear on specific areas.

3. They do not cause damage on passing through body tissues.

4. Shockwaves give rise to mechanical stresses in brittle material like kidney and ureteric stones which exceed the strength limit of the stone.

5. Shockwaves are reliably reproduced.

**Shock wave Focusing:**

All shockwave lithotriptors require a focusing system in order to concentrate and direct the shock wave energy onto the stone, at F2, so that fragmentation can occur. Shock-wave focusing relies on various means to direct and concentrate shock wave energy to a defined focal point, and different energy sources rely on very different methods to achieve this. All of these methods, however, rely on some form of lens or reflector to alter the direction of the shock waves. The most important attributes of a given focusing device are aperture and focal zone.

The shock-wave aperture is the area of the acoustic lens, shock tube, or reflector and roughly corresponds to the body surface area of the
skin penetrated by the shock waves. Lithotripters with wide apertures, such as piezoelectric lithotripters, tend to have low energy density at the skin-entry point of the shock waves, because the same pressure is distributed over a wider area. This is believed to explain why patients treated with these devices experience less pain.\textsuperscript{(42)}

The \textit{focal zone} is the actual volume in which the shock waves are concentrated. Larger focal zones generally have more shock-wave energy and higher peak pressures. Higher peak pressure theoretically translates into more effective stone fragmentation; however, larger focal zones also result in more shock wave energy being delivered to surrounding body tissues.\textsuperscript{(42)}

\textbf{Shock wave Coupling}

Shock wave coupling refers to the medium through which the shock wave is propagated. A coupling system is needed to transmit the energy created by the shock wave generator and pressure wave to the skin surface and through body tissues to reach the stone. Ideally, this medium should dissipate shock wave energy as little as possible. A water bath filled with gasless water served as the coupling mechanism in the first-generation lithotripters (i.e., HM-3). Subsequently, membranes of appropriate acoustic density were developed that obviate the need for a water bath. Instead, water cushions coated with an acoustic gel are substituted. These "dry" lithotripters may deliver less shock wave energy to the target, but they make up for this in ease of patient positioning, including the ability to treat in the prone position\textsuperscript{(42)}. 
**Localization systems**

Imaging is employed for stone localization and placement of the shock waves onto the calculus. The commonly utilized methods are fluoroscopy and ultrasound localization. The first lithotripters relied on fluoroscopy to guide therapy.\(^{(40)}\)

Biplanar fluoroscopy, either using two tubes or one swinging C-arm, is the most commonly used system. The stone is brought to lie at the intersection of the central portion of the beams from the two planes. Precise localization of a stone down to a size of 1-2 mm is possible.\(^{(40)}\)

Monitoring of lithotripsy during the shock wave exposure is not difficult. A short learning curve and the ability to obtain documentation images during treatment without stopping constitute the main advantages of this method. Localizing problems consist chiefly of stones close to the vertebral column and radiolucent calculi. Besides the obvious elimination of radiation exposure, the potential advantages of ultrasound over conventional radiography include the ability for continuous real-time monitoring of treatment and the ability to treat radiolucent calculi without contrast injection. The disadvantages include, to most clinicians, suboptimal imaging, especially for ureteral calculi not associated with significant hydroureter. Ultrasound is less effective in assessing the degree of stone destruction \(^{(40)}\).

**Analgesia**

Initial ESWL treatment relied on general or regional anesthesia. Since then, a number of techniques have been developed to minimize the anesthetic requirement. Intravenous sedation with sedative hypnotics such as midazolam or short-acting narcotics, such as fentanyl, has proven to be
effective for ESWL. The addition of topical anesthetic agents, such as EMLA cream (Eutectic (easily dissolving) Mixture of Local Anesthetic), has been shown to decrease the amount of intravenous agent required in at least some studies, and even topical petroleum jelly has been shown to decrease the anesthetic requirement. The postulated mechanism of action is that the viscosity of the jelly prevents shock wave-induced cavitation at the skin level.\(^{(45)}\)

Regardless of the method of anesthesia chosen, children movement can hinder effective shock wave delivery. If the child is moving or breathing deeply, more shock waves need to be delivered to treat a given stone, and more shock waves and more frequent patient repositioning leads to increased treatment time and greater radiation exposure. High-frequency jet ventilation was developed to address the problems associated with respiratory excursion. In this method a continuous jet of air is sent to the patient hence eliminating the oscillatory movements caused by normal rhythmic inspiration/expiration cycles. Better fragmentation and shorter treatment times were obtained with this method. Altering the rate or depth of ventilation to the degree required for this modality, however, proved to be detrimental to patient oxygenation and this technique largely has been abandoned.\(^{(40)}\)

**Physics of Stone Fragmentation**

Two types of forces bring about the stone fragmentation with ESWL; *Compressive* forces and *Cavitation*. When the shock wave encounters the stone, part of the energy is reflected back at the source, part is absorbed, and the rest is transmitted through the stone. A resulting *compressive* force is created on the front surface of the stone as the shock wave encounters an interface between low and high acoustic impedance,
water and calculus, respectively. This compressive force will travel through the stone and create stress on the sides of the stone. The reflected portion of the wave is the tensile component of the shock wave. Another tensile force is created when the wave traverses the high/low impedance boundary at the posterior surface of the stone and has been termed ‘spalling’ (Figure 24).

The greater the impedance difference, the greater the force that is generated. The maximum force is theorized to be located at the front and back surfaces of the stone as the greatest interaction between the tensile and the compressive forces occur at these locations. The tensile portion of the shock wave will continue to reflect within the stone if faults are encountered and further stress is placed on the integrity of the stone. Fragmentation occurs when these forces overcome the innate forces holding the stone together. (42)

Another mechanical force that aids in stone fragmentation is cavitation. When microscopic bubbles on the surfaces of stones are subjected to the compression and expansion of shock waves, the bubbles expand to maximum size and then collapse. As this bubble collapses it creates a tiny jet of liquid, which generates a localized stress on the stone surface. This cavitation effect causes surface erosion by creating small craters in the stone. These pits form on imperfections on the stone surface and when they coalesce, fragmentation occurs. Studies have proposed that cavitation is the most important force in the destruction of stones from ESWL. This process can be noted on real-time sonography during treatment, and it appears as swirling fragments and liquid in the focal zone. Both cavitation and compression are illustrated in (Figure 24). (42)
Comparison of Lithotripters

In general, the differences among the various models of lithotripter available today are based primarily on the form of energy source employed.

*Electrohydraulic lithotripters*, the first lithotripters, have the advantage of large focal points, moderately high peak pressures, and flexible apertures \(^{(42)}\). The disadvantages of the electrohydraulic energy source include a relatively short functional lifespan and relatively inconsistent reproducibility of the shock waves. This lack of shock-wave

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Figure (24): Schematic representation of events leading to stone fragmentation \(^{(42)}\)
consistency results from the variable current pathway from the positive to negative tips on the electrode \(^{(40)}\)

As the electrode suffers wear, the distance between the positive and negative tips increases. Because of the geometry of the ellipsoid reflector, even small changes in this distance can translate into large differences in the width of the focal zone at \(F_2\). Therefore frequent electrode changes are often necessary. \(^{(40)}\)

**Piezoelectric lithotripters** have some advantages in that they have a long functional life span, cause less patient discomfort, and allow variable shock wave frequencies. The fact that piezoelectric lithotripters have the widest apertures is felt to account for the minimal pain experienced by patients.\(^{(51)}\) Unfortunately, this characteristic also results in relatively small focal zones. Despite delivering fairly high pressure pulses to the focal zone, the actual energy density delivered is relatively low, resulting from the small volume of the focal zone.\(^{(40)}\)

Fragmentation is limited further by the fact that a smaller focal zone also leaves a smaller margin of error for targeting a given calculus. Another disadvantage of piezoelectric generators is that they have a limited energy range. Despite of this disadvantage they are still preferred by some centres as they offer a more comfortable patient experience \(^{(40)}\)

**Electromagnetic lithotripters** also are distinguished from electrohydraulic lithotripters by the fact that they have long functional lives. They can deliver several hundred thousand shock waves between servicing, thereby obviating the need to replace electrodes continually. Also, they have a wide and continuous gradation of energy settings. The disadvantages of these machines, however, include the necessity to
change the metallic membrane, albeit not often \(^{(49)}\). It has been observed that different energy sources create different fragmentation patterns, at least in vitro. Electrohydraulic lithotripters produce shallow and wide craters; electromagnetic lithotripters create damage craters in the shape of a right angle circular cone; and piezoelectric lithotripters create narrow, deep craters. With electrohydraulic and piezoelectric lithotripters, maximal fragmentation has been achieved by placing the focal point on the anterior surface of the stone. In contrast, electromagnetic lithotripters worked best if the focal point targets the posterior surface of the stone. These findings, however, even if true, will not be clinically applicable until more accurate means of targeting and tracking calculi are available \(^{(40)}\).
**Complications of ESWL**

Despite SWL is considered a safe method to treat stones in the urinary tract, various side effects have been reported and studied, but most are rare and do not hamper the effectiveness of this technique\(^\text{(46)}\).

The complication profile of SWL is minor compared with other forms of urinary stone treatment such as PCNL or open stone surgery\(^\text{(47)}\).

**Complications after SWL are demonstrated in table (1):**

**Table (1):** List of complications after SWL.

<table>
<thead>
<tr>
<th>Immediate</th>
<th>Delayed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related to stone fragments</td>
<td>Renal function</td>
</tr>
<tr>
<td>Infectious</td>
<td>Hypertension</td>
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<tr>
<td>Tissue effects:</td>
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<tr>
<td>• Renal (heamatoma, heamorrhage)</td>
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<td>• Cardiovascular</td>
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<tr>
<td>• Gastrointestinal</td>
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<tr>
<td>• Genital system</td>
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**Complications related to stone fragments:**

Incomplete fragmentation, residual stone fragments, stein strasse, and obstruction are among the problems when SWL fails to completely disintegrate the stone treated\(^\text{(46)}\).
Growth of residual fragments <4mm has been documented in 21%-59% of patients who underwent SWL. Location of the residual fragments does not significantly influence stone clearance rate (48).

Predisposing factors to SWL failure are stone composition, size, location, and number, as well as renal morphology and shock wave rate and energy (49).

Overall stein strasse occurs in 1%-4% of patients who undergo SWL (48).

The rate increases in 5%-10% of patients with large stone burdens (> 2cm²) and in up to 40% of patients with partial or complete stag horn calculi (46).

These complications can be prevented by realizing the limitation of SWL for large stone burdens and by using PCNL or SWL followed by PCNL and repeat SWL (sandwich therapy), as an alternative. Stenting before SWL reduces complications caused by residual stone fragments, especially when a large stone is treated. (46).

**Infectious complications:**

The renal trauma and vascular disruption associated with SWL may allow bacteria in urine to enter the blood stream moreover, when infected calculi are disintegrated, bacteria are released from the stone into the urine and may be absorbed systemically (46).

As a consequence, bacteriuria, bacteremia, clinical urinary tract infection (UTI), urosepsis, perinephric abscess formation, endocarditis, candidal and klebsiella endophthalmitis, candida septiceamia, tuberculosis, and (rarely) death have been reported after SWL.
Bacteriuria has been found in 7.7% - 23.5% of patients who undergo SWL, including 7.7% in a group of patients without infection related stones \(^{(51)}\).

Clinical urinary tract infection is more common in patients with struvite stones, multiple or complex stones, or who underwent peri-procedural stone or urologic manipulation \(^{(51)}\).

Preoperative antibiotics should be given to patients with infection related stones (staghorn and struvite calculi), positive urine culture, or a history of recurrent UTIs and to those who undergo instrumentation at the time of SWL \(^{(52)}\).

**Tissue effects of SWL:**

Renal complications can subdivided into early effects on kidney anatomy that lead to haematuria and hematoma formation, and late complications that affect kidney function and cause systemic hypertension. Histopathological examination of human and animal kidneys showed endothelial cell damage to mid sized arteries, veins, and glomerular capillaries immediately after SWL \(^{(53)}\).

Thin walled arcuate veins in the cortico-medullary junction are especially vulnerable to shock wave exposure and are related to haematuria and haematoma. The lesion is usually a focal process; most of the renal parenchyma is unaffected \(^{(53)}\).

Hematoma is a rare complication of SWL and, when it occurs, typically involves the kidney. Gordetsky (2008) reported that subcapsular and perirenal hematomas may occur in as many as 15%–26% of cases \((\text{Fig. 25}).^{(53)}\)
Figure (25): CT scan following shock wave lithotripsy showing a 13×6cm subcapsular hepatic hematoma (53).

The incidence of hematoma due to kidney injury has been reported to occur in 0.2–0.7% of cases when examined by ultrasonography, and in 23–26% when examined by CT or magnetic resonance imaging (54).

Regions of hemorrhage are always near the site of F2, and these regions are typically characterized by the rupture of small vessels such as thin-walled veins, small arteries, and glomerular and peritubular capillaries. Evidence of extensive endothelial damage in these veins is noted by a loss of endothelial cells, the immediate attachment of numerous polymorphonuclear cells and activated platelets to the luminal surface of these vessels, and the appearance of vasculitis; damage to both the nephron and the vasculature is always seen first in the renal papilla and then in the cortex (56).
These observations demonstrate that both the microvasculature and nephron are susceptible to shock wave damage; however, the primary injury appears to be a vascular insult \(^{(55)}\).

Several groups have noted that as shock number is increased (1000 to 8000 shocks), a greater number of hematomas are formed and lesion size increases, although not as a direct correlation with shock number. An increased number of shock waves also was associated with larger hematomas, probably related to the fact that larger arteries are injured at high shock numbers. It appears that 1000 shock waves represents the threshold for tissue injury with the unmodified HM3 in that lesions begin to appear at this shock number and then grow rapidly in size as the shock number is increased \(^{(57)}\).

The most common clinical manifestation of renal trauma is gross haematuria that spontaneously resolves in few days \(^{(46)}\).

Symptomatic intrarenal, subcapsular, or perirenal fluid collection and haematomas are rare and occur in <1% of patients who undergo SWL. However, when computerized tomography or magnetic resonance imaging is performed routinely after ESWL, the hematoma rate may increase to 20%-25% \(^{(58)}\).

Potential risk factors for haematoma formation are hypertension, obesity, diabetes mellitus, and the number and intensity of shock waves \(^{(46)}\).

Treatment of haematoma is conservative in most cases; the most likely outcome is spontaneous radiographic resolution of haematoma without clinically evident adverse effects on blood pressure or renal function, however, a decrease in renal blood flow has been reported and
associated with acute renal failure and hypertension when there is bilateral involvement or in patients with a solitary kidney, so these high risk patients should be closely followed up (46).

**Impact on renal function after SWL:**

Strong evidence has developed that implicates SWL as a cause of transient acute renal damage and damage to surrounding tissues (59).

Studies on humans and animals reveal a reduction of glomerular filtration rate (GFR) and renal plasma flow soon after SWL, especially when pyelonephritis coexist (63).

However, SWL does not affect GFR over the long term, and immediate renal damage appears to resolve over days to couple of months (64).

Shock waves energy induces transient functional damage of tubular function in children (69). And the renal vasoconstriction induced by SWL is greater in small kidneys than in large ones (63).

On the other hand, assessment of long term effects of ESWL on GFR in children by renal scintigraphy revealed no significant decrease in mean ipsilateral and total GFR (46).

long term follow up studies could show no parenchymal damage in children who underwent SWL (67)

Regarding the concern that has been raised about potential damage to epiphyseal growth centers in children; no long term skeletal deformities to date having been demonstrated (46).
There is evidence that when cavitation is suppressed by minimizing the voltage and number of shocks may decrease the deleterious effect on the kidney (65)(66).

**Cardiovascular effect of SWL:**

*Zanetti et al. (1999)*, raised concerns about occurrence of cardiac arrhythmias during SWL, which usually represent minor, unifocal, premature ventricular contraction. However morbid cardiac events or biochemical evidence of myocardial injury are extremely rare. (46)

The incidence can be reduced with gating of the shock wave to the electrocardiogram pulse. SWL may be performed safely on patients with pacemakers with appropriate precaution. (68)

The treatment should be approved and supervised by a cardiologist. Dual-chamber pacemaker should be reprogrammed to single chamber mode, and single-chamber rate responsive devices should have the activity mode program off (46).

Patients with single chamber rate responsive devices implanted in the abdomen should not have SWL if the device will be close to shock wave focal point F2 (61).

*Neri et al. (2000)*, reported risk of rupture of abdominal aorticaneurysm after SWL. But experimental studies and clinical data indicate that patients with aortic and renal aneurysm can be treated safely and without complications according to (46).
**SWL and blood pressure:**

Hypertension following SWL has been an ongoing controversy since the original reports of acute onset hyper-tension following SWL were published in the mid to late 1980s \(^{(59)}\).

Randomized controlled trials failed to reveal any evidence that SWL cause changes in blood pressure \(^{(60)}\).

The suspected cause of hypertension after SWL is probably multifactorial and whether there is a direct causal link is unclear, blood pressure is more commonly affected by either rennin mediated or rennin independent mechanisms \(^{(46)}\).

_Erambeck et al. (2006),_ reported that renal stone disease rather than the type of treatment significantly increases blood pressure during a follow upperiod of 24 months However, in a case controlled study treating renal and proximal ureteral calculi with HM3 lithotripter was associated with DM and hypertension at 19 years of follow up and hypertension strongly correlated with bilateral SWL treatment \(^{(59)}\).

**Gastrointestinal injury 2ry to SWL:**

Pancreatitisis and pancreatic haematoma and liver and spleen subcapsular haematomas, have been reported in case studies \(^{(46)}\).

These adverse effects were associated with the increase in the number and energy of shock waves delivered and also with patient position \(^{(62)}\).

_Maker and Layke (2004)_ Reported that most GI perforations occurred when the patient was prone and received shock waves that
exceeded the U.S. Food and Drug Administration recommended numbers. The exact pathophysiology is not yet clear, but spallation, heat injury, and cavitation are possible injury mechanisms. (62)

**Karakayali et al. (2006)** reported acute necrotizing pancreatitis as a rare complication of shock wave lithotripsy. The cause exactly still controversy; **Abe et al. (2000)** have proposed postoperative adhesions between the pancreas and surrounding tissues as a facilitating factor in pancreatitis after SWL and have suggest that the adhesions might becaused by mechanical injury during SWL. While **Hassan and Zitlow (2002)** have proposed that cellular damage caused by cavitation and attending shear forces (produced by the shock waves as they pass through the surrounding tissues) might be the cause of pancreatic injury after SWL. Subcapsular hepatic hematoma as a rare complication of SWL. Prospective randomized studies are needed to determine the exact incidence of GI injury during SWL and to determine its true clinical impact on patients(46)