JOURNAL OF ENDOUROLOGY
Volume 27, Number 5, May 2013
© Mary Ann Liebert, Inc.
Pp. 631–639
DOI: 10.1089/end.2012.0611

Evaluation of the LithoGold LG-380 Lithotripter: *In Vitro* Acoustic Characterization and Assessment of Renal Injury in the Pig Model

Yuri A. Pishchalnikov, PhD,[1] James A. McAteer, PhD,[1] James C. Williams, Jr., PhD,[1] Bret A. Connors, PhD,[1]
Rajash K. Handa, PhD,[1] James E. Lingeman, MD,[2] and Andrew P. Evan, PhD[1]

Abstract

Purpose: Conduct a laboratory evaluation of a novel low-pressure, broad focal zone electrohydraulic lithotripter (TRT LG-380).

Methods: Mapping of the acoustic field of the LG-380, along with a Dornier HM3, a Storz Modulith SLX, and a XiXin CS2012 (XX-ES) lithotripter was performed using a fiberoptic hydrophone. A pig model was used to assess renal response to 3000 shockwaves (SW) administered by a multistep power ramping protocol at 60 SW/min, and when animals were treated at the maximum power setting at 120 SW/min. Injury to the kidney was assessed by quantitation of lesion size and routine measures of renal function.

Results: SW amplitudes for the LG-380 ranged from (P^+/P^-) 7/-1.8 MPa at PL-1 to 21/-4 MPa at PL-11 while focal width measured ~20 mm, wider than the HM3 (8 mm), SLX (2.6 mm), or XX-ES (18 mm). For the LG-380, there was gradual narrowing of the focal width to ~10 mm after 5000 SWs, but this had negligible effect on breakage of model stones, because stones positioned at the periphery of the focal volume (10 mm off-axis) broke nearly as well as stones at the target point. Kidney injury measured less than 0.1% FRV (functional renal volume) for pigs treated using a gradual power ramping protocol at 60 SW/min and when SWs were delivered at maximum power at 120 SW/min.

Conclusions: The LG-380 exhibits the acoustic characteristics of a low-pressure, wide focal zone lithotripter and has the broadest focal width of any lithotripter yet reported. Although there was a gradual narrowing of focal width as the electrode aged, the efficiency of stone breakage was not affected. Because injury to the kidney was minimal when treatment followed either the recommended slow SW-rate multistep ramping protocol or when all SWs were delivered at fast SW-rate using maximum power, this appears to be a relatively safe lithotripter.

Introduction

SHOCKWAVE LITHOTRIPTERS are relatively simple devices consisting of a shockwave (SW) generator, a mechanism such as a lens or reflector to focus the acoustic pulse, a means to couple the shock source to the patient, and an imaging system for targeting. For the most part, the properties of the SWs produced by different lithotripters, regardless of the type of SW generator used (i.e., electrohydraulic, electromagnetic, piezoelectric), are fundamentally the same.[1,2] What distinguishes one lithotripter from the next is its acoustic output, which is described primarily by the magnitude of the acoustic pressures produced and the dimensions of the focal zone.

The focal zone (or focal volume) is the region of high pressure where the stone is targeted for treatment, and by definition is the region where the magnitude of the positive pressure (P^+) is at least half of its maximum amplitude. The width of the focal zone has come to be a critical feature often used in comparing one lithotripter with another. Most lithotripters have a focal width of less than 10 mm. For example, the focal width of the Storz SLX measures 2.6 mm; the Siemens Multiline and Dornier DoLi, Delta, and Compact series lithotripters have focal widths of ~5 mm; the focal width of the Storz SLX-F2 is selectable at 6 mm or 9 mm; and the Dornier HM3 and Healthtronics Lithotron lithotripters have focal widths of ~8 mm.

In practice, if the focal zone is narrow, it can be more difficult to hit the stone, particularly when the kidney is moving because of respiratory excursion.[3–5] In addition, the generation of stress waves understood to play an important role in

---

[1] Department of Anatomy and Cell Biology, Indiana University School of Medicine, Indianapolis, Indiana.
[2] Department of Urology, Indiana University School of Medicine and Methodist Hospital Institute for Kidney Stone Disease, Indianapolis, Indiana.

stone fragmentation is enhanced when the width of the high pressure region (focal volume) is wider than the stone.[6–8] As such, focal width is one factor that may contribute to differences in treatment outcomes observed with different lithotripters.[9–14] In addition, laboratory studies have shown that the renal lesion produced by a narrow focal width lithotripter can be more intense than that produced by a wider focal width machine, and clinical reports have suggested that a narrow focal width may be linked to an increase in the occurrence of adverse effects.[15–17]

Previously, we undertook an evaluation of the XiXin CS2012 (or XX-ES) lithotripter.[18] This lithotripter represents a novel concept, a departure from the higher pressure, narrower focal width lithotripters that are most commonly in use.[19] The purpose of our assessment was to provide an independent characterization of the acoustic output of the machine and, because safety in SWL is an essential consideration, we also ran tests with a pig model to assess for SW-induced injury to the kidney. The results confirmed the manufacturer's assertion that this lithotripter has a particularly wide focal zone (18 mm) and that it generates very low acoustic pressures (less than 20 MPa). Analysis of waveforms showed a very broad pulse width and the absence of a true shock front.[20] Still, the XX-ES broke model stones effectively, with efficiency comparable to the Dornier HM3 operated at approximately the same pressure amplitude. Analysis of injury to the renal parenchyma showed only small sites of histologically detectable hemorrhage that proved to be too slight to be quantifiable.

The TRT LithoGold LG-380 (TRT Tissue Regeneration Technologies, Woodstock, GA) is also marketed as a wide focal zone, low-pressure lithotripter. This is an electrohydraulic device described as having a long-life self-adjusting spark gap electrode. The LG-380 has been used to treat patients in the United States since 2006, but little has been reported about the characteristics of this lithotripter.[21] From the perspective that it is important to critically evaluate new lithotripters to identify their advantages and limitations and build experience in how to use these instruments safely and effectively, we undertook a thorough laboratory assessment of the LG-380 lithotripsy system.

Methods

Acoustic output of the LG-380 lithotripter

Shockwave pressure measurements and mapping of the acoustic field of the TRT LG-380 LithoGold lithotripter were performed in degassed water (dissolved gas 10%–30% saturation) using a fiberoptic probe hydrophone FOPH-500 (RP Acoustics, Leutenbach, Germany) within a ~100 L acrylic test tank. The Mylar acoustic window (0.13 mm) of the tank was coupled to the therapy head of the lithotripter using Litho-Clear gel (Sonotech Inc., Bellingham, WA).[22] Waveforms were collected in sets of 10 to 30 shockwaves using the Fast Frame setup of a Tektronix oscilloscope (TDS 5034).[23] Waveforms that did not exhibit artifact because of cavitation interference along the fiberoptic cable were averaged after alignment to the half amplitude of the shock fronts.[24]

For mapping to determine the width of the focal zone, the tip of the hydrophone was positioned in the plane of the target point of the lithotripter (140 mm distal to the spark source, 35 mm proximal to the maximum P^+ focal point).[21] Focal width was defined by the dimensions of the –6dB zone (pressure half-maximum of the acoustic field).[25] The fiber tip of the FOPH was moved in 1 to 2 mm steps, over a 15 mm radius in the x and y plane. At least 10 pulses at power level 9 (PL-9) were collected for each position. Mapping of the acoustic field to determine focal width was also performed for an unmodified Dornier HM3 lithotripter (Dornier Med-Tech America, Inc., Kennesaw, GA) and a Storz Modulith SLX electromagnetic lithotripter.[15] Mapping along the acoustic axis (Z-axis) was also performed for the LG-380 and the HM3.

In vitro *stone breakage*

Breakage of U-30 gypsum model stones held in a 2-mm mesh basket was used to assess lithotripter performance, by counting the number of shockwaves to complete fragmentation—until no fragments remained in the basket.[26]

Animal studies

The surgical and animal treatment protocols used to assess renal injury in this study were performed in accordance with the *National Institutes of Health Guide for the Care and Use of Laboratory Animals* and were approved by the Institutional Animal Care and Use Committee of the Indiana University School of Medicine. Surgical procedures for the placement of vascular and ureteral catheters have been described previously,[27] as have procedures for morphologic evaluation,[28] quantitation of lesion volume,[29] and measures of renal function in shockwave lithotripsy (SWL).[18]

Eight female farm pigs, weighing 70 kg each (Hardin Farms, Danville, IN), were divided into two groups (n = 4, each group) for treatment using the LG-380 lithotripter. One group received 3000 SWs using an uninterrupted multistep power ramping protocol at 60 SWs/min (PL 1–8 with 50 SWs each level, followed by 2600 SWs at PL 9), as recommended by the manufacturer (TRT) for treatment of patients. A second group was treated with a nonramping protocol in which all 3000 SWs were administered at maximum power (PL-11) at a SW-rate of 120 SW/min. In all cases, the lithotripter was targeted on a lower pole calyx of the left kidney.

Coupling of the therapy head to the animal followed a protocol shown to minimize the formation of air pockets.[30] The skin overlying the kidney was shaved, and the animal was placed supine on the treatment table. The water cushion of the therapy head was inflated, a mound of gel was applied to the cushion, and the table was lowered to bring the treatment head in contact with the skin of the pig. Once coupling was accomplished, contrast medium (Renografin 60% or Isovue 300, Bracco Diagnostics, Princeton, NJ) was injected through a ureteral catheter to highlight the renal collecting system, and a lower pole calyx was targeted using biplanar x-ray fluoroscopy. SWs were administered without stopping. Targeting was checked every 500 SWs (on-the-fly) and, if needed, adjustments in position were made with slight movements of the treatment table. A new electrode was used for each animal.

Kidney function was determined immediately before and at 1 hour after SW treatment. Urine and plasma samples were analyzed for inulin and para-aminohippurate concentrations, used to calculate glomerular filtration rate (GFR) and effective renal plasma flow (ERPF).[18]

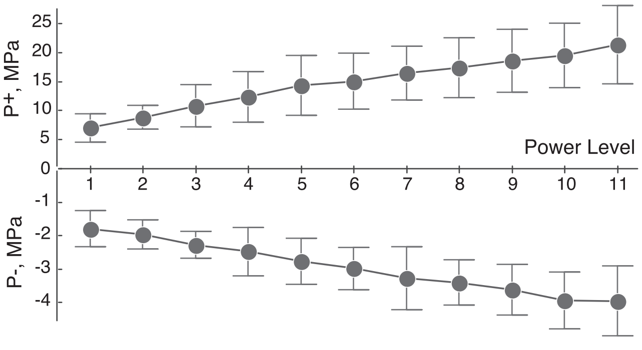

FIG. 1. Peak positive (P^+, top) and negative (P^-, bottom) pressure as a function of power level (PL1–11) for the LG-380 lithotripter. Each point shows the mean and standard deviation for 10 sets of SWs (20–30 SWs per set) from pooled data collected using five different LG-380 lithotripters. Shockwaves were measured at the target point. Average P^+ at the highest power level (PL-11) was ~21 MPa.

Five hours after treatment with SWs, the kidneys were perfusion-fixed *in situ* with 2.5% glutaraldehyde in 0.1 M cacodylate buffer (pH = 7.4), quickly removed, and submerged in fresh fixative before processing for histologic determination of lesion size. The area of hemorrhagic lesion in systematically selected sections was used to determine lesion volume expressed as percent total functional renal volume (FRV) within the renal parenchyma.[29]

Statistical analysis

Body weight, blood pressure, and renal function measures were summarized as mean and standard errors of the mean. Baseline measures were compared using a *t* test with pooled variances. Changes in blood pressure and renal function measures from baseline to 1-hour postlithotripsy were examined using paired *t* tests within each group. For data on stone breakage, means were compared using the *t* test or the Tukey-Kramer HSD test. The criterion for statistical significance was set at $P < 0.05$.

Results

Acoustic characterization of the LG-380

Peak positive pressure measured at the target point of the LG-380 lithotripter ranged from 7 ± 3 MPa at PL-1 to 19 ± 5 MPa at PL-9 (Fig. 1). Because the treatment protocol recommended by the manufacturer calls for starting at PL-1 with delivery of 50 SWs at each successive upward step through PL-8, followed by 2600 (or fewer) SWs at PL-9, the majority of SWs delivered to a patient by such a regimen will be at pressures less than or equal to 20 MPa. Even at the maximum power setting (PL-11), average peak positive pressure was only 21 ± 7 MPa. Peak negative pressure was relatively low in magnitude, increasing from 1.8 ± 0.5 MPa at PL-1 to 4 ± 1 MPa at PL-11.

Acoustic output of the LG-380 was stable over the 6000 SW lifetime of the electrode (Fig. 2). The LG-380 uses an open caged electrode with a self-advancing tip that adjusts the spark-gap for power level and to compensate for wear. Figure 2 plots averaged values of peak positive (P^+) and negative (P^-) pressure for 100 SW sets fired at PL-9 for the LG-380, compared with SWs fired at 18kV with the Dornier HM3. While P^+ for the HM3 dropped ~25% and showed increasing variability over the 2000 SW lifetime of the electrode, output for the LG-380 was consistent for 6000 SWs.

The focal width (-6dB width or pressure half-maximum amplitude) of the LG-380 measured ~20 mm, about two times wider than for the HM3 (~8–10 mm) and more than 7.5 times wider than for the SLX (~2.6 mm) (Fig. 3). With

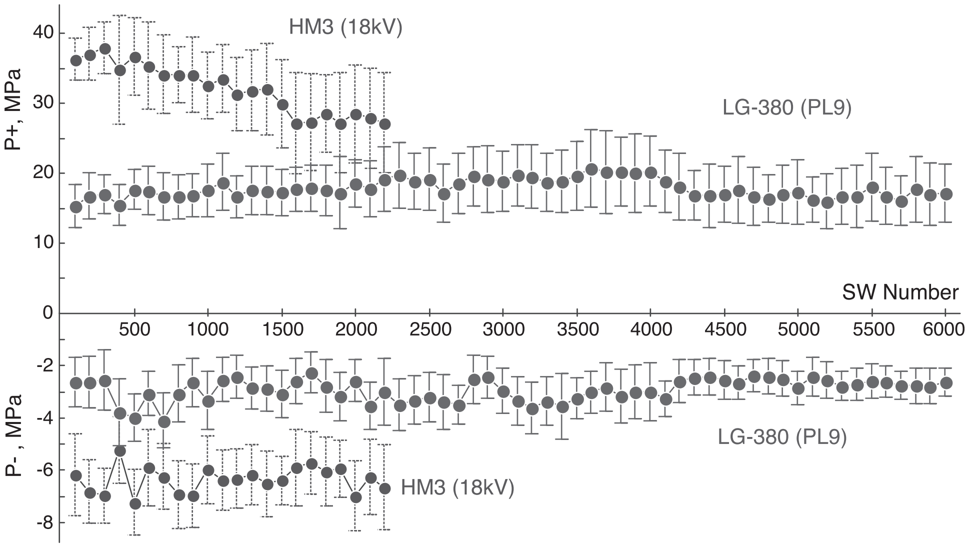

FIG. 2. Acoustic output over electrode lifetime for the TRT LG-380 and Dornier HM3 lithotripters. Each point is the average of 100 shockwaves (SWs). Whiskers indicate standard deviation of the mean. Trace for LG-380 begins after 365 SWs had been fired, while data for HM3 begin with SW#1 and are aligned opposite LG-380 points for convenience. Mean peak positive (P^+, top) and negative (P^-, bottom) pressures for the LG-380 (uses a self-adjusting spark-gap electrode) were consistent over 6000 SWs. Mean P^+ for the HM3 fell ~25% over 2200 SWs. Recommended lifetime for Dornier-style electrodes is 1000 to 2000 SWs, depending on kV.

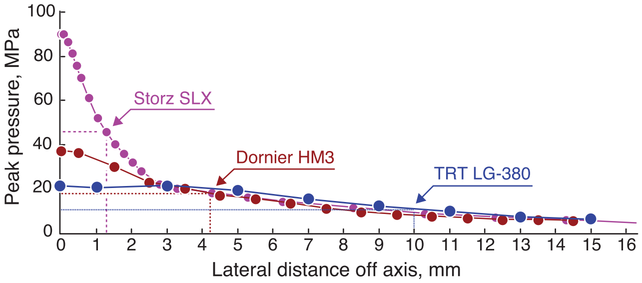

FIG. 3. The lateral distribution of peak positive pressure (P^+) for the TRT LG-380 (at PL-9), the Dornier HM3 (at 18 kV), and Storz-SLX (PL-9) lithotripters. Measures were in the plane of the treatment focal point of each lithotripter (target point for LG-380, F2 focal point for HM3, focus of SLX). The focal width (i.e., −6dB width; pressure half maximum amplitude; radius indicated by intersection of dashed lines with x-axis) was ~20 mm for the LG-380, ~8 mm for the HM3, and ~2.6 mm for the SLX. Data points are averaged values for at least 10 SWs collected at steps lateral to the axis of SW propagation.

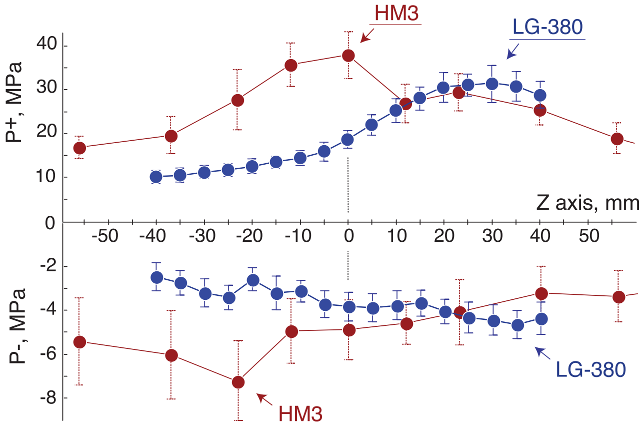

FIG. 4. Peak positive (P^+) and negative (P^-) pressures for SWs collected at steps along the acoustic axis (Z-axis) for the LG-380 and HM3 lithotripters. Data are for SWs (mean of 30–40 SWs) fired during the working lifetime of the electrodes (SWs 900–1500, PL-9 for LG-380; SWs 500–900, 18 kV for HM3). Zero on the Z-axis marks the target point of the LG-380 and the F2 focal point of the HM3. Maximum P^+ (~30 MPa) and P^- (~−4.5 MPa) for the LG-380 was located ~30–35 mm postfocal. Maximum P^+ (~38 MPa) for the HM3 was at the F2 focal point, while the greatest negative pressure (~−7.5 MPa) was located ~20–25 mm prefocal. This illustrates key differences in the acoustic properties of the two lithotripters.

consideration for how these lithotripters are used in the clinical setting, values for focal width were determined from measures of the lateral distribution of P^+ in the plane where the stone is targeted for treatment. That is, mapping was performed in the plane of maximum P^+ for the HM3 and SLX, and 30 mm proximal to the point of highest P^+ for the LG-380.[21,25] The focal width of the LG-380 was observed to narrow as the electrode aged. That is, when the electrode was new and had been fired about 1000 times, the focal width measured ~20 mm, but after 5000 SWs, the pressure half-maximum width measured only ~10 mm.

Measurements taken at 5 mm steps along the acoustic axis (Z-axis) of the LG-380 showed that, whereas P^+ at the stone target point was relatively low amplitude (~20 MPa), the acoustic pressure 30 mm beyond the target was considerably higher (~30 MPa) (Figs. 4, 5). This was the case when the electrode was new. As the number of SWs increased, the position of maximum P^+ on the Z-axis shifted toward the target point (i.e., toward the SW source), moving ~ 10 mm during the first 1000 SWs and ~ 30 mm after 6000 SWs had been fired. This was accompanied by a gradual reduction in maximum P^+ postfocally, such that P^+ at the target point remained relatively constant throughout the lifetime of the electrode (Fig. 2).

The LG-380 was nearly as effective in breaking stones located 10 mm off-axis as when the stones were positioned directly on the acoustic axis, with stones at 10 mm lateral position needing on average only 31% more SWs than at the

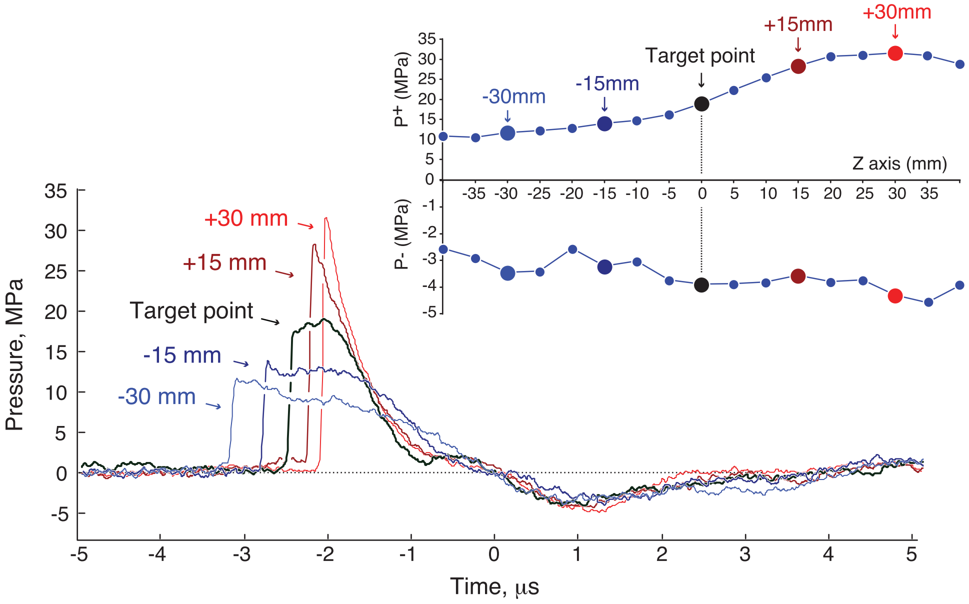

FIG. 5. LG-380 waveforms at selected locations relative to the target point. SWs were collected during mapping along the acoustic axis (Z-axis, see inset) early in the lifetime (SWs 900–1500, PL-9) of the electrode, and waveforms (mean of 30 SWs) are aligned so that the transition from positive to negative pressure is at the zero point on the time scale. This illustrates the evolution of the focused shockwave along the Z-axis, showing that SWs are relatively low amplitude (~20 MPa) at the point where the stone is targeted (target point, Z = 0 in inset), but achieve much higher amplitude (~30 MPa) at ~35 mm beyond the target point.

target point on axis (Fig. 6). Breakage efficiency was similar to that of the wide focal zone XX-ES. The SLX was significantly ($P < 0.01$) more effective in breaking stones on-axis than either the LG-380 or XX-ES, but breakage for the narrow focal width SLX fell faster off-axis, needing ~three times more SWs at 5 mm and ~five times more SWs at 10 mm off-axis than at the focal point. The breakage of stones for the LG-380 on-axis was similar in efficiency to that seen with the Dornier HM3 with mean values of 879 SW and 831 SW, respectively.[18]

For the LG-380, the proximal shift in P+ and narrowing of the focal width as the electrode aged had a negligible effect on breakage. Also, although acoustic pressures for the LG-380 were somewhat higher beyond the target point (Figs. 4, 5), stones positioned 35 mm postfocally broke no better than at the target point. It is worth noting that stones located 50 mm postfocally showed breakage equivalent to stones at the target point; this suggests that the depth of the effective focal zone for the LG-380 is at least 50 mm.

Renal response to shockwaves

Body weights, and baseline values for blood pressure, GFR, and ERPF were similar in both pig groups with combined values of 67 ± 2 kg, 77 ± 3 mmHg, 16.1 ± 1.7 mL/min, and 229 ± 16 mL/min, respectively. Three of four pigs in each group had similar post-treatment reductions in GFR and ERPF that averaged 34% and 24%, respectively, whereas one pig in each group showed minimal change in renal function after SWL. Blood pressure remained unchanged in both groups during renal function measurements, but had fallen by ~12 mm Hg at the time of nephrectomy.

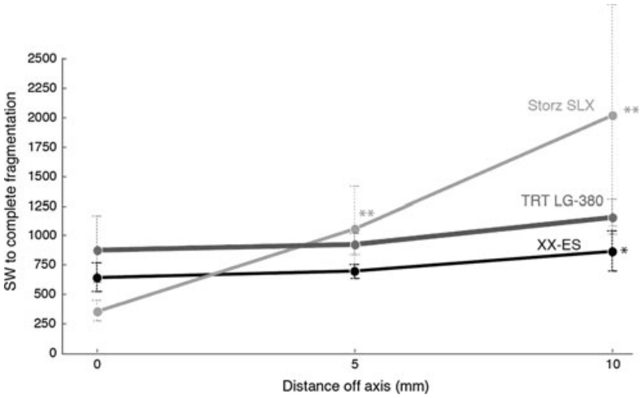

FIG. 6. Stone breakage for wide and narrow focal zone lithotripters. Gypsum model stones held in a 2-mm mesh basket were positioned on-axis and at 5 mm and 10 mm off-axis in the plane of the target point of the lithotripter. SWs were fired at settings in the range of clinical treatment for the LG-380 (PL-9, 19 MPa), XX-ES (9.3 kV, 17 MPa), and Storz SLX (PL-9, 90 MPa) at 60 SW/min until no fragments remained in the basket. The Storz SLX was more effective at breaking stones positioned on-axis than either the LG-380 or the XX-ES ($P < 0.01$). Breakage efficiency fell faster, however, for the narrow focal width SLX than for either of the two wide focal width lithotripters, with the SLX needing three times as many SWs to break stones positioned 5 mm off-axis as at the focus ($P < 0.001$ *vs* on-axis). For the XX-ES, stones had to be moved to 10 mm off-axis for a significant increase in number of SWs to breakage ($P < 0.05$), but this needed on average 34% more SWs than on-axis. The LG-380 needed a similar increase in number of SWs at 10 mm, on average 31% more than on-axis. *$P < 0.05$, **$P < 0.001$ *vs* SWs on-axis (distance = 0).

Histologic assessment of renal injury in pigs treated using the multistep power ramping protocol with the LG-380 showed small, isolated sites of hemorrhage primarily in the renal medulla (Fig. 7). Lesion volume measured < 0.1% FRV. This pattern of diffuse renal parenchymal injury with a very low volume of hemorrhage was similar to that previously observed in pigs treated with a comparable, but not equivalent, dose of SWs delivered at slow SW-rate (2000 SW, 24 kV, 60 SW/min) using the Dornier HM3 (Fig. 7).[31] Pig kidneys treated using the LG-380 with all SWs at the maximum power setting (PL-11) and at fast SW-rate (120 SW/min), likewise, showed injury limited to isolated spots of hemorrhage in the medullary parenchyma, with a lesion volume of < 0.1% FRV (data not shown). This is in contrast to the much higher lesion volume (3.29 ± 1.07% FRV) observed in pigs treated at 120 SW/min using the HM3 (Fig. 7).[32,33]

Discussion

Lithotripters have been categorized by the magnitude of the acoustic pressure they generate, in particular their peak positive pressure (P^+). The descriptors "low" and "high" pressure tend to be used, but these are relative terms and ill defined. Typically, lithotripters have a broad range of power settings, and there can be a substantial difference in the P^+ produced at the lowest *vs* the highest settings. For example, pressures for the Dornier HM3 range from ~25 MPa at 12 kV to ~45 MPa at 24 kV, and for the Storz SLX, the values are ~12 MPa at PL-1 to ~90 MPa at PL-9.[15,24,34] It is also true that most lithotripters are not recommended for use at their maximum output, so P^+ at the highest setting may not be representative of how the lithotripter is used.

Lithotripter models currently in use, which include the Dornier HM3, span a very broad range in P^+. The XiXin-Eisenmenger CS2012 (XX-ES) is used at < 20 MPa, the Storz SLX achieves much higher pressures in the clinical treatment range (~50 MPa, PL-7), and the Dornier HM3 falls between these two (~38 MPa at 18 kV).[15,18,19,34] It is tempting to refer to these as "low," "moderate," and "high" pressure lithotripters. Based on available data for acoustic output measured at the power setting for delivery of the main dose of SWs as recommended by the manufacturer, or as is typically selected by users, we suggest it is reasonable to consider a lithotripter to be low pressure if it operates at ~20 MPa, moderate pressure to be a lithotripter used at ~35–45 MPa, and high pressure if the P^+ is > 50 MPa. If so, the LG-380 would fall into the low pressure category.

The LG-380 was found to have a very broad focal zone. In practical terms, the focal zone (or focal volume) of a lithotripter is the region of highest pressure within the acoustic field. The pressure amplitudes and dimensions of the focal zone are dependent on numerous factors such as the focusing mechanism and the power setting at which the SWs are fired.[1] It is also true that measures of focal width are affected by the type of hydrophone used, and this may account in part for differences in values reported for a given lithotripter. By convention, the focal width is the diameter of the zone (focal zone) spanning the acoustic axis, where the positive pressure is at least half the maximum pressure. Our comparison of the lateral distribution of P^+ for the LG-380, the Dornier HM3, and the Storz SLX lithotripters (Fig. 3) showed the LG-380 to

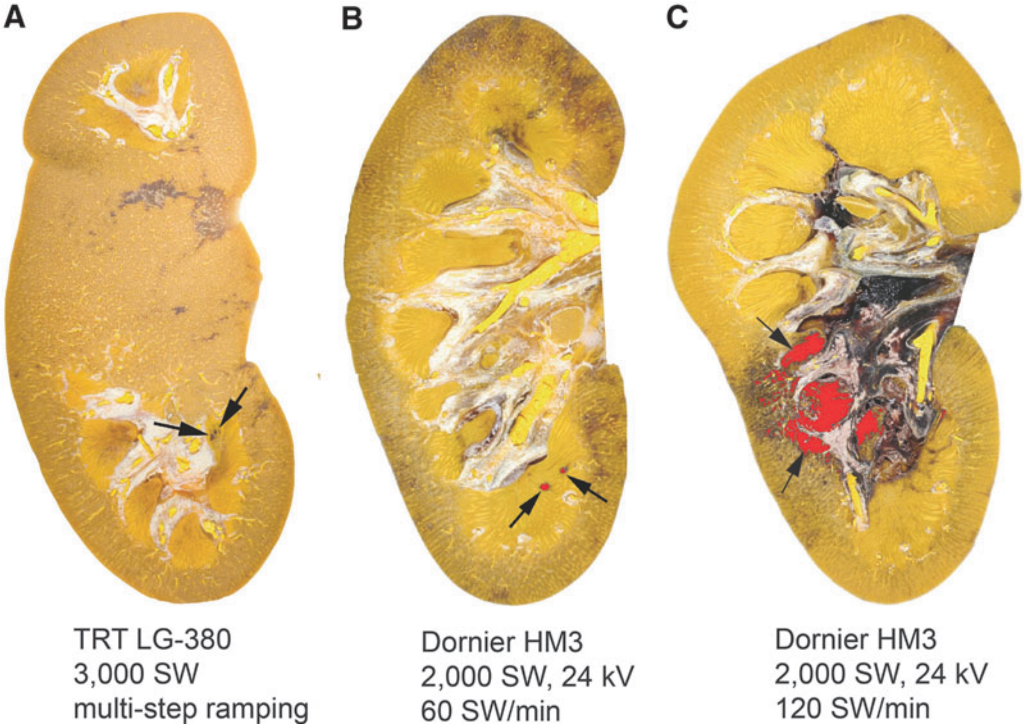

FIG. 7. Renal parenchymal lesion in pig kidneys treated using the TRT LG-380 and Dornier HM3 lithotriptors. Frame **A** shows small foci of hemorrhage (arrows) in the lower pole medulla of a pig kidney treated using the multistep power ramping protocol (PL 1–8 @50, PL-9 2600 SW, 60 SW/min) recommended by TRT. Lesion volume in this group of animals measured $<0.1\%$ FRV ($n=4$). Frame **B** shows lower pole medullary lesions (arrows) in the kidney of a pig treated using the Dornier HM3 fired at 60 SW/min (2000 SW, 24 kV), while frame **C** shows a larger region of hemorrhage (arrows) extending from the cortex to medulla in a kidney treated at the same dose (2000 SW, 24 kV) but at 120 SW/min. Lesion volume of renal parenchyma, expressed as functional renal volume, in these representative sections measured 0.42% and 3.9% FRV, respectively. Data for renal injury with the Dornier HM3 have been reported previously.[31–33,38]

have by far the widest focal width of the three. Indeed, at ~20 mm the focal zone of this lithotripter is wider than any other lithotripter for which characterization data have been reported. This includes the XX-ES electromagnetic lithotripter having a focal width of ~18 mm.[18,19]

Just as lithotripters can be categorized as low, moderate, or high pressure, they have also been described as broad (or wide) or narrow focal width machines. Our assessment shows that whereas focal width spans a very broad range (~2.6–20 mm), there are lithotripters such as the Dornier HM3 that have a focal zone of intermediate width (~8 mm). Focal width is not entirely dependent on the mode of SW generation. Electromagnetic lithotripters such as the Storz SLX (FW 2.6 mm) tend to have a narrow focal width, but the XX-ES (FW ~18 mm) is also an electromagnetic lithotripter. For some lithotripters such as the Wolf Piezolith 3000 (piezoelectric) and the Storz SLX-F2 (electromagnetic), focal width can be selected. The Piezolith 3000 offers focal width settings of 2.1 mm, 3.7 mm, and 8.1 mm, while the SLX-F2 can be operated with a focal width of 6 mm or 9 mm. It seems reasonable that based on reported data, lithotripters can be described by focal width as narrow (FW < ~7mm), intermediate (FW 8–14 mm), and wide (FW >15 mm), with the understanding that lithotripters such as the Piezolith-3000 and the SLX-F2 can be adjusted to operate as narrow or intermediate focal width machines.

Focal width is clinically relevant because a kidney stone is a moving target. The kidney moves with the respiratory cycle, and the excursion of a stone can be many centimeters. A recent patient study using diagnostic ultrasonography to detect when stones were hit by SWs indicated that ~40% of SWs miss the stone entirely.[5] The wider the focal width of the lithotripter, the better the chance of hitting the stone.[3,35] A broad focal width may also play a role in initiating stone breakage. *In vitro* studies and numeric modeling have demonstrated that when the focal width is greater than the diameter of the stone, internal shear stresses are maximized and breakage occurs in fewer SWs.[6–8] Thus, there are potential advantages to a broad focal width lithotripter.

We observed that the focal width of the LG-380 became narrower as the number of shots on the electrode increased, such that after 5000 SWs, the focal width had narrowed from ~20 mm to ~10 mm. This appears to be a unique characteristic of the LG-380 related to the design of its electrode. The electrode of the LG-380 is centered within the reflector and aligned on the acoustic axis. It has a proprietary mechanism to adjust the width of the spark-gap, in which the proximal tip is advanced by a motor in incremental turns of screw threads. This system adjusts the gap for different power settings and to compensate for erosion of the electrode tips. As the tips erode, the gap width is maintained, but the location of the spark-gap moves progressively away from its original position near the base of the reflector. This slight movement of the gap toward the patient alters slightly the focusing of the shockwave in space, changing the dimensions and properties of the focal volume of the lithotripter. The rate of this shift was greater when the electrode was new, likely because the sharp conical tips of a new electrode erode faster than the rounded tips of a used electrode. As a result of movement in position of the spark-gap along the acoustic axis, the point of maximum positive pressure (P^+max) also shifted progressively toward the lithotripter, moving ∼10 mm during the first 1000 SWs (from 35 mm to 25 mm distal to target point) and did not align with the target point of the lithotripter until about 5000 SWs had been fired.

The LG-380 was very effective in breaking stones positioned a considerable distance lateral to the target point. Indeed, breakage efficiency was not statistically different for stones at the periphery of the focal zone (10 mm lateral position) compared with stones directly on-axis. These were static tests that, in principle, assessed the effect of respiratory motion; that is, the ability to break a stone that has moved away from the target point. The result suggests that the LG-380 would not be much affected by 10 mm of respiratory excursion. The same can be said for the XX-ES, which also has a wide focal zone, but would not hold true for the SLX. Although the SLX broke stones at the target point more effectively than either the LG-380 or the XX-ES, the breakage efficiency of this narrow focal zone lithotripter fell off rapidly as the stones were moved laterally (Fig. 6). This suggests that the SLX would be highly efficient when targeting is precise, and progressively more ineffective as the stone is carried off axis. Such was a finding of a study in which a motorized apparatus was used to move stones in and out of the focal zone of an SLX lithotripter, where movement of just 5 mm resulted in a 50% decrease in breakage efficiency.[3] Our observations also suggest that there may be more latitude in stone targeting with a wide focal zone lithotripter, and that during treatment there would be less concern with minor, incidental movements of the patient. One might speculate that if, with a wide focal zone lithotripter, it is not as critical to keep the stone precisely at the target point, this could also prove to reduce imaging time and, thus, x-ray exposure to the patient.

In this study, we compared the acoustic characteristics of the LG-380 and the Dornier HM3. These two lithotripters have certain obvious similarities in that they are both electrohydraulic machines that use open-caged electrodes and use hemiellipsoidal reflectors to focus shockwaves to the target. In other respects, they are quite different. The focal width of the HM3 is much narrower than that of the LG-380 (HM3 ∼8 mm; LG-380 ∼20 mm), and the HM3 is capable of generating much higher acoustic pressures (HM3 ∼40 MPa P^+, ∼ −8 MPa P^-; LG-380 ∼20 MPa P^+, −4.5 MPa P^-). The data for mapping along the acoustic axis (Fig. 4) also illustrate that the distribution of positive and negative pressure is different. For the HM3, the point of greatest negative pressure is ∼20 mm proximal to the focal point. Laboratory studies with the HM3 have shown that stone breakage is more efficient prefocally and that this corresponds to enhanced cavitation in this region of the focal zone.[36] In the HM3, maximum P^+ is at the F2 focal point and falls quickly postfocally, but for the LG-380, the positive pressure is higher beyond the target point (maximum P^+ at ∼30 mm postfocal) and remains high for a considerable distance. One potential advantage of a long zone of robust pressure would be in the treatment of obese patients in which the skin to stone distance prevents positioning the stone at the focal point of the lithotripter.[37] There are no clinical data, however, to suggest that the LG-380 is advantageous for such patients.

Kidney injury was quite low with the LG-380, limited to very small spots of hemorrhage in the renal medulla. This was the case when treatment followed the slow SW-rate (60 SW/min), stepwise power ramping protocol recommended by the manufacturer and, also, when all SWs were delivered at the maximum power setting (PL-11) at fast SW-rate (120 SW/min). Because injury was minimal when SWs were administered at both the recommended settings and at the highest settings available for treatment, these findings suggest that the LG-380 is a relatively safe lithotripter.

In previous work, we performed a similar injury assessment for the XiXin XX-ES lithotripter, another low pressure (17 MPa), broad focal zone (18 mm) machine and, likewise, observed an impressively low level of renal trauma.[18] In pigs treated with the XX-ES, the volume of the hemorrhagic lesion was too small to be quantifiable. SW-rate used with the XX-ES, selected to match the manufacturer's recommendation, was very slow (27 SW/min), and pigs treated with the same number of SWs (1500 SW) using the HM3 at a comparable SW-rate (30 SW/min) but at higher acoustic pressure (∼37 MPa) also produced a very small lesion (∼0.1% FRV). Limitations of the shock generator in the XX-ES prevented firing any faster, so the effect of SW-rate on injury could not be investigated. Maximum acoustic pressures with the LG-380 were only slightly higher than with the XX-ES (∼21 MPa *vs* ∼17 MPa), and the shock source was capable of consistent output at 120 SW/min. This allowed us to look for an effect of SWs administered at 120 SW/min and showed that renal injury was not sensitive to SW-rate in the range routinely used in clinical SWL.

It may be tempting to suggest that the broad focal width of the LG-380 or XX-ES contributed to the reduced renal injury we observed with these lithotripters, but this is not a direct outcome of these studies. Granted, these lithotripters have very wide focal zones, but they are also extremely low-pressure machines and cannot be operated above ∼20 MPa. Therefore, unlike other lithotripters, a wide range of acoustic output cannot be tested in the LG-380. An early study with the HM3 showed that when pigs were treated with 2000 SWs at low amplitude (12 kV, ∼25 MPa, 120 SW/min), lesion size was also very low (0.27% FRV), close to values observed with the LG-380. Thus, under similar but not equivalent conditions of operation, the intermediate focal width HM3 (FW ∼8 mm) produced a lesion volume comparable to that of the broad focal width LG-380 (FW ∼20 mm). That is, a small lesion volume was attainable with a focal width less than half that of a wide focal width lithotripter. This suggests that at low SW amplitude, focal width may not play a significant role in tissue injury. This may well not be the case for lithotripters that generate very high acoustic pressures, as in a recent study of the Storz Modulith SLX (FW 2.6 mm) treatment of the pig model with SWs at ∼90 MPa generated a highly focused zone of injury in which tissue disruption was far more complete than occurred with a comparable dose of SWs with the Dornier HM3.[15]

Conclusions

This assessment shows the electrohydraulic TRT LG-380 to be a low-pressure, wide focal zone lithotripter. The shock source is relatively consistent, with a small range in amplitude over settings recommended for clinical use (7 MPa at PL-1 to 19 MPa at PL-9) and low maximum pressure (21 MPa at PL-11). Focal width is very broad (20 mm) allowing effective breakage of stones located off axis. Treatment of the pig model with the maximum dose of SWs allowable for treatment of patients produced very minor injury to the renal parenchyma. Further study will be needed to determine clinical success rates and the occurrence of clinically significant adverse effects with this lithotripter.

Acknowledgments

This investigation was supported by grants from the National Institutes of Health (DK43881, DK67133). The authors thank Philip Blomgren, Cynthia Johnson, Jonathan VonDerHaar, and Anthony Zancanaro for valuable technical assistance.

Disclosure Statement

Dr. Lingeman has financial interests in Midwest Mobile Lithotripsy and Midstate Mobile Lithotripsy. For the remaining authors, no competing financial interests exist.

References

1. Cleveland RO, McAteer JA. The physics of shock wave lithotripsy. In: Smith AD, Badlani GH, Preminger GM, Kavoussi LR, eds. Smith's Textbook on Endourology. 3rd ed. Oxford, UK: Medical Books, Wiley-Blackwell, Chapter 49, Vol. 1, 2012, pp 529–558.
2. Leighton TG, Cleveland RO. Lithotripsy. In: Proceedings of the Institute of Mechanical Engineers, Part H: J Engineering Med 2010;224:317–342.
3. Cleveland RO, Anglade R, Babayan RK. Effect of stone motion on in vitro comminution efficiency of Storz Modulith SLX. J Endourol 2004;18:629–633.
4. Cleveland RO. The advantage of a broad focal zone in SWL. In: Evan AP, Lingeman JE, McAteer, JA, Williams JC, (eds). Renal Stone Disease 2: Proceedings of the 2nd International Urolithiasis Research Symposium. Melville, NY: American Institute of Physics IP Proceedings, 2008, 1049, pp 219–225.
5. Sorensen MD, Bailey MR, Shah AR, et al. Quantitative assessment of shock wave lithotripsy accuracy and the effect of respiratory motion. J Endourol 2012;26:1070–1074.
6. Eisenmenger W. The mechanisms of stone fragmentation in ESWL. Ultrasound Med Biol 2001;27:683–693.
7. Cleveland RO, Sapozhnikov OA. Modeling elastic wave propagation in kidney stones with application to shock wave lithotripsy. J Acoust Soc Am 2005;118:2667–2676.
8. Sapozhnikov OA, Maxwell AD, MacConaghy B, Bailey, MR. A mechanistic analysis of stone fracture in lithotripsy. J Acoust Soc Am 2007;121:1190–1202
9. Tan EC, Tung KH, Foo KT. Comparative studies of extracorporeal shock wave lithotripsy by Dornier HM3, EDAP LT 01 and Sonolith 2000 devices. J Urol 1991;146:294–297.
10. Bierkens AF, Hendrikx AJ, de Kort VJ, et al. Efficacy of second generation lithotriptors: A multicenter comparative study of 2,206 extracorporeal shock wave lithotripsy treatments with the Siemens Lithostar, Dornier HM4, Wolf Piezolith 2300, Direx Tripter X-1 and Breakstone lithotriptors. J Urol 1992;148:1052–1057.
11. Gerber R, Studer UE, Danuser H. Is newer always better? A comparative study of 3 lithotriptor generations. J Urol 2005;173:2013–2016.
12. Ng CF, Thompson TJ, McLornan L, Tolley DA. Single-center experience using three shockwave lithotripters with different generator designs in management of urinary calculi. J Endourol 2006;20:1–8.
13. Hoag CC, Taylor WN, Rowley VA. The efficacy of the Dornier Doli S lithotripter for renal stones. Can J Urol 2006; 13:3358–3363.
14. Alanee S, Ugarte R, Monga M. The effectiveness of shock wave lithotripters: A case matched comparison. J Urol 2010;184:2364–2367.
15. Connors BA, McAteer JA, Evan AP, et al. Evaluation of shock wave lithotripsy injury in the pig using a narrow focal zone lithotriptor. BJU Int 2012;110:1376–1385.
16. Ueda S, Matsuoka K, Yamashita T, et al. Perirenal hematomas caused by SWL with EDAP LT-01 lithotripter. J Endourol 1993;7:11–15.
17. Dhar NB, Thornton J, Karafa MT, Streem SB. A multivariate analysis of risk factors associated with subcapsular hematoma formation following electromagnetic shock wave lithotripsy. J Urol 2004;172:2271–2274.
18. Evan AP, McAteer JA, Connors BA, et al. Independent assessment of a wide-focus, low-pressure electromagnetic lithotripter: Absence of renal bioeffects in the pig. BJU Int 2008;101:382–388.
19. Eisenmenger W, Du XX, Tang C, et al. The first clinical results of "wide-focus and low-pressure" ESWL. Ultrasound Med Biol 2002;28:769–774.
20. Pishchalnikov YA, McAteer JA, Williams JC Jr. Effect of firing rate on the performance of shock wave lithotriptors. BJU Int 2008;102:1681–1686.
21. Schultheiss R, Doerffel M. Standards for lithotripter performance. In: Evan AP, Lingeman JE, McAteer, JA, Williams JC, eds. Renal Stone Disease 2: Proceedings of the 2nd International Urolithiasis Research Symposium. Melville, NY: American Institute of Physics Proceedings, 2008, 1049, pp 226–237.
22. Pishchalnikov YA, Neucks JS, VonDerHaar RJ, et al. Air pockets trapped during routine coupling in dry-head lithotripsy can significantly decrease the delivery of shock wave energy. J Urol 2006;176:2706–2710.
23. Pishchalnikov YA, McAteer JA, VonDerHaar RJ, et al. Detection of significant variation in acoustic output of an electromagnetic lithotripter. J Urol 2006;176: 2294–2298.
24. Pishchalnikov YA, Sapozhnikov OA, Bailey MR, et al. Cavitation selectively reduces the negative-pressure phase of lithotripter shock pulses. Acoust Res Lett Online 2005;6:280–286.
25. IEC-Technical Committee-87, IEC Standard 61846 Ultrasonics - Pressure pulse lithotripters - Characteristics of fields. Geneva, Switzerland: International Electrotechnical Commission, 1998.
26. McAteer JA, Williams JC Jr., Cleveland RO, et al. Ultracal-30 gypsum artificial stones for research on the mechanisms of stone breakage in shock wave lithotripsy. Urol Res 2005; 33:429–434.
27. Willis LR, Evan AP, Connors BA, et al. Relationship between kidney size, renal injury, and renal impairment induced by shock wave lithotripsy. J Am Soc Nephrol 1999;10:1753–1762.
28. Shao Y, Connors BA, Evan AP, et al. Morphological changes induced in the pig kidney by extracorporeal shock wave lithotripsy: Nephron injury. Anat Rec 2003;275: 979–989.
29. Blomgren PM, Connors BA, Lingeman JE, et al. Quantitation of shock wave lithotripsy-induced lesion in small and large pig kidneys. Anat Rec 1997;249:341–348.

30. Neucks JS, Pishchalnikov YA, Zancanaro AJ, et al. Improved acoustic coupling for shock wave lithotripsy. Urol Res 2008; 36:61–66.
31. Connors BA, Evan AP, Blomgren PM, et al. Extracorporeal shock wave lithotripsy at 60 shock waves/min reduces renal injury in a porcine model. BJU Int 2009; 104:1004–1008.
32. Handa RK, McAteer JA, Connors BA, et al. Optimising an escalating shockwave amplitude treatment strategy to protect the kidney from injury during shockwave lithotripsy. BJU Int 2012;110:E1041–E1047.
33. Evan AP, McAteer JA, Connors BA, et al. Renal injury during shock wave lithotripsy is significantly reduced by slowing the rate of shock wave delivery. BJU Int 2007;100: 624–628.
34. Cleveland RO, Bailey MR, Fineberg N, et al. Design and characterization of a research electrohydraulic lithotripter patterned after the Dornier HM3. Rev Sci Instr 2000;71:2514–2525.
35. Qin J, Simmons WN, Sankin G, Zhong P. Effect of lithotripter focal width on stone comminution in shock wave lithotripsy. J Acoust Soc Am 2010;127:2635–2645.
36. Sokolov DL, Bailey MR, Crum LA, et al. Prefocal alignment improves stone comminution in shockwave lithotripsy. J Endourol 2002;16:709–715.
37. Pareek G, Hedican SP, Lee FT Jr, Nakada SY. Shock wave lithotripsy success determined by skin-to-stone distance on computed tomography. Urology 2005;66:941–944.
38. Connors BA, Evan AP, Willis LR, et al. The effect of discharge voltage on renal injury and impairment caused by lithotripsy in the pig. J Am Soc Nephrol 2000;11:310–318.

Address correspondence to:
James A. McAteer, PhD
Department of Anatomy and Cell Biology
Indiana University School of Medicine
635 Barnhill Dr., MS-5055
Indianapolis, IN 46202-5120

E-mail: jmcateer@iupui.edu

Abbreviations Used

EPRF = effective renal plasma flow
FRV = functional renal volume
GFR = glomerular filtration rate
SW = shockwave
SWL = shockwave lithotripsy