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Assessment of a Modified Acoustic Lens for Electromagnetic Shock Wave Lithotripters in a Swine Model

John G. Mancini^{1,†}, Andreas Neisius^{1,2,†}, Nathan Smith³, Georgy Sankin³, Gaston M. Astroza¹, Michael E. Lipkin¹, Walther N. Simmons³, Glenn M. Preminger¹, and Pei Zhong^{1,3,**}

¹Duke University Medical Center, Division of Urologic Surgery, 200 Trent Drive, DUMC 3707, Durham, NC 27710, USA

²Johannes Gutenberg University Mainz, Department of Urology, Langenbeckstrasse 1, 55131 Mainz, Germany

³Department of Mechanical Engineering and Materials Science, Duke University, P.O. Box 90300, Durham, North Carolina 27708, USA

Abstract

Purpose—The acoustic lens of the Siemens Modularis electromagnetic (EM) shock wave lithotripter has been modified to produce a pressure waveform and focal zone more closely resembling that of the original Dornier HM3 device. Herein, we assess the newly designed acoustic lens *in vivo* in an animal model.

Materials and Methods—Stone fragmentation and tissue injury produced by the original and modified lenses of a Siemens lithotripter were evaluated in a swine model under equivalent acoustic pulse energy (~45 mJ) at 1 Hz pulse repetition frequency. Stone fragmentation was determined by the weight percent of stone fragments less than 2 mm. For tissue injury assessment, shock wave-treated kidneys were perfused, dehydrated, cast in paraffin wax and sectioned. Digital images were captured every 120 μ m and processed to determine the functional renal volume damage.

Results—After 500 shocks, stone fragmentation efficiency produced by the original and modified lenses was $48 \pm 12\%$ and $52 \pm 17\%$ ($p=0.60$), respectively. However, after 2000 shocks, the modified lens showed significantly improved stone fragmentation of $86 \pm 10\%$, compared to $72 \pm 12\%$ for the original lens ($p=0.02$). Tissue injury caused by the original and modified lenses was minimal at $0.57 \pm 0.44\%$ and $0.25 \pm 0.25\%$ ($p=0.27$), respectively.

Conclusions—With lens modification, the Siemens Modularis lithotripter demonstrates significantly improved stone fragmentation with minimal tissue injury at clinically relevant acoustic pulse energy. This new lens design could potentially be retrofitted to existing lithotripters, thereby improving the effectiveness of EM lithotripters.

Keywords

Lens modification; Electromagnetic Lithotripter; *in vivo*; Swine model

**corresponding author: Phone: (919) 660-5336, Fax: (919) 660-8963, pzhong@duke.edu.

†These authors (John G. Mancini and Andreas Neisius) contributed equally to this work (i.e. shared first authorship).

INTRODUCTION

Shock wave lithotripsy (SWL) has advanced significantly since the introduction of the 1st-generation HM3 lithotripter in the early 1980's.^{1,2} Although a majority of lithotripter improvements made in the past two decades have been driven by patient comfort and operator convenience, the most notable technical change is the shift from electrohydraulic (EH) to electromagnetic (EM) shock wave sources. In particular, the EM shock wave platform provides consistent and reproducible output pressure and focal zone dimensions with no consumable parts, in marked contrast to the original HM3 and other EH lithotripters. Moreover, coupling between the shockwave head and the patient in contemporary lithotripters is achieved with an inflatable bellow instead of the bath tub of the HM3, and general or regional anesthesia is no longer mandatory.^{3,4}

Despite the aforementioned technical improvements, growing evidence suggests that the 2nd- and 3rd- generation EM lithotripters are not as clinically effective as the HM3.⁵⁻⁷ Two key features associated with the current design of EM lithotripters (i.e., pulse profile and beam width) have been speculated to be responsible for the observed low efficiency.⁸ Firstly, all EM lithotripters produce a second compressive wave immediately following the leading shockwave (i.e., the first compressive and tensile wave). The second compressive wave, caused by the current oscillation in the EM coil, can suppress cavitation activity in the lithotripter field,⁸ which is critical for the disintegration of calculi into small dischargeable fragments.⁹ Secondly, the beam widths of most modern EM lithotripters ($\approx 4\text{--}7$ mm) are considerably narrower than beam widths measured with the HM3 ($\approx 10\text{--}12$ mm).¹⁰ It has been demonstrated on the HM3 that for the same total effective acoustic energy a lithotripter field with broad focal width and low peak pressure produces better stone comminution than its counterpart with narrow focal width and high peak pressure.^{10,11}

To overcome these drawbacks, we have modified the acoustic lens of an EM lithotripter to produce a broader focal zone and an idealized pressure waveform more closely resembling that of the HM3. Evaluation of this modified lens *in vitro* has demonstrated significantly improved stone fragmentation.⁸ Herein we seek to assess the performance of the modified lens design in a swine model in terms of stone comminution and tissue injury *in vivo*.

MATERIALS AND METHODS

A contemporary EM shock wave lithotripter (Modularis, Siemens, Malvern, PA, 19355, USA) fitted either with the original or a modified acoustic lens was used. Acoustic fields produced by the different lenses were characterized by using a fiber optic probe hydrophone (FOPH 500, RP Acoustics, Leutenbach, Germany), following the IEC 61846 lithotripter field characterization protocol (International Electrotechnical Commission 1998). The original lens of the EM lithotripter was modified with an annular ring cut of 14 mm in depth (h) to its lower surface (near the source) and a corresponding uncut lens area to total lens area ratio (AR) of 60%. Relevant radii (R_i , R_u and R_{tot}) for determining AR are shown in Figure 1. The uncut area produces a main shock wave and the cut area generates a delayed wave from a single EM impulse. Destructive superposition of the second compressive component of the main shock wave with the tensile component of the delayed wave at the beam focus results in a modified pressure waveform with minimal second compressive wave (Figure 2). Moreover, the cut was made in the outer region of the original lens, which reduces the aperture of the main shock wave and thus broadening concomitantly the focal width of the lithotripter field from ~ 7 to ~ 10 mm.⁸

Stone Fragmentation Experiments

Seventeen juvenile female farm swine weighing approximately 36 kg^{12,13} were used to compare the fragmentation of surgically implanted stone phantoms between the modified and original lenses in a Siemens Modularis lithotripter. The study protocol was approved by the Institutional Animal Care & Use Committee (IACUC Protocol Nr. A164-05-06) of Duke University. After induction of general endotracheal anesthesia, the flank of the animal was shaved to provide adequate coupling of the lithotripter shock head to the skin. The animal was placed in the supine position on an operating table; a standard midline laparotomy incision was made to expose the right kidney, renal pelvis, and proximal ureter. A 1 cm ureterotomy was made in the anterior wall of the proximal ureter, and a cylindrical (5 × 10 mm in diameter and length) Begostone[®] phantom fabricated using 5:2 powder to water mixing ratio¹⁴ was introduced into the lumen and then advanced into the renal pelvis. A 6-french polyurethane double J ureteral stent (Boston Scientific, Boston, MA) was placed through the ureterotomy and advanced into the renal pelvis to prevent stone migration down the ureter. The ureterotomy was closed in one layer with a running suture. The same procedure was repeated on the left side. After surgical implantation of bilateral artificial stones, the laparotomy was closed and the animals transferred to the lithotripsy suite. The type of lens used was randomized (original or modified) for each OR day (2 pigs) to prevent bias, however, treatment of the two kidneys in each pig was not randomized after stone implantation due to complexity of changing lenses intra-operatively.

The implanted stones were aligned with the lithotripter focus under fluoroscopic guidance. Ultrasound gel (Medline, Mundelein, IL, USA) was applied to the lithotripter coupling balloon, which was held a constant average pressure throughout the study.¹⁵ SWL treatment was performed using either the original or modified lens, operated at a clinically relevant pulse energy of ~45 mJ with a pulse repetition frequency (PRF) of 1 Hz. Each kidney was exposed to either 500 or 2000 lithotripter shock waves. Stone movement and fragments spreading were recorded *in situ* using fluoroscopy after 50, 500, 1000, 1500, and 2000 shocks. During SWL, the lithotripter was not realigned after initial ramp (<500 shocks) to keep the bias of tracking spread fragments low. After completion of the SWL treatment, the animals were euthanized and bilateral nephrectomies were performed. The kidneys were harvested and carefully dissected to open the collecting system and expose the residual fragments. The stone comminution pattern was photographed, and all visible fragments were collected. The fragments were allowed to dry in air at room temperature for 24 hours and then sieved with decreasing mesh size of 4, 2.8, and 2 mm. Final stone fragmentation efficiencies were determined as the percentage (by weight) of fragments less than 2 mm normalized to the pre-treatment weight. An unpaired two-tailed student's t-test was used to compare fragmentation results.

Tissue Injury experiments

In a separate cohort, 12 female farm swine, similar to those from the fragmentation study, were used to compare renal injury produced by the original and modified lenses. Only one renal unit per pig was treated with SWL to avoid any bias in tissue injury assessment. Since there is no known side preference, only the right kidney of each animal was treated. After induction of general anesthesia, a 21-french cystoscope was used to place a 6-french 70 cm open-ended ureteral stent (Cook Medical, Bloomington, IL, USA) into the renal pelvis under fluoroscopic guidance. Fluoroscopic contrast agent (Isoview-300, Bracco Diagnostics, Princeton, NJ, USA) was injected to ensure accurate alignment of lithotripter focus with the lower pole of the kidney. After the contrast agent was no longer visible on the fluoroscopic images, 2000 shock waves were delivered at 1 Hz PRF with either the original or modified lens at comparable acoustic pulse energies (~45 mJ). The total accumulated acoustic energy

delivered to each renal unit was ~90 J. To mimic a “worst case” treatment scenario, no energy ramping procedure was performed.

The analysis of tissue injury was conducted following the protocol previously described by Blomgren and colleagues.¹⁶ The animals were euthanized on day 0, two hours after completing the SWL treatment. Vascular perfusion and fixation was performed *in situ*, and the kidneys were removed en bloc. The renal vasculature was then filled with yellow Microfil (Flowtech, Carver, MA), and the kidneys were dehydrated in 100% ethanol and chloroform and subsequently embedded in barium sulfate-filled paraffin. After paraffin infiltration, each kidney was sliced using a horizontal sliding microtome (Model 860, American Optical Corp, Southbridge, MA), in which the blade level remains constant and the tissue block is incrementally raised with each successive advancement of the blade. The sectioning of the kidney was performed in a sagittal technique with cuts of 40 μ m in thickness. Digital images of the kidney surface were captured every 120 μ m. A typical juvenile pig kidney generated 180–190 images. Each recorded digital image was traced to delineate the boundaries of the collecting system and the injured regions. The traced images were processed using MATLAB (MathWorks, Natick, MA) and Adobe Photoshop to determine the percentage of functional renal volume (FRV) damaged. In addition, MATLAB was used to reconstruct a 3D model of the kidney anatomy and damaged regions (Figure 3). Final data are presented as mean value $\pm$ SD. Again, an unpaired t-test was used to compare the data between the two experimental groups, with $p < 0.05$ considered to be statistically significant.

RESULTS

After 500 shocks the original and modified lenses produced similar fragmentation efficiencies of $48 \pm 12\%$ and $52 \pm 17\%$ ($p=0.60$), respectively (Figure 4). In comparison, after 2000 shocks the modified lens showed significantly improved fragmentation efficiency of $86 \pm 10\%$, compared to $72 \pm 12\%$ for the original lens ($p=0.02$). Given the comparable standard deviation and similar digitalized sample pictures between the two groups, the fraction of spread fragments between calyces appeared to be similar.

Gross inspection immediately after nephrectomy did not reveal sub capsular hematomas or other significant signs of gross renal trauma using either lens. Additionally, no areas of injury were noted on exploration of the perirenal, peritoneal, or retroperitoneal spaces. Six kidneys from each group underwent processing and were analyzed by two urologists (JGM and AN) and one senior pathologist; however two kidneys from the “original lens” group were excluded from the computerized tissue injury analysis due to poor microfil casting. Nevertheless, macroscopic inspection of these samples after slicing with the same methodology, revealed no significant tissue injury in renal parenchyma. In the remaining four kidneys from the original lens group and the six kidneys from the modified lens group, sectioning and subsequent image analysis revealed lower pole injury in the renal papillae, outer medulla, and cortex in the focal region, except 1 kidney in the original lens group and 1 kidney in the new lens group which showed no detectable damage (Table 1). Representative images of the kidney slices before and after processing are shown in Figure 3. The tissue injury associated with the original lens was calculated to be $0.57 \pm 0.44\%$ in FRV, compared to $0.25 \pm 0.25\%$ ($p=0.27$) for the modified lens. At 45 mJ pulse energy and 1 Hz PRF, tissue injury produced by either lens after 2000 shocks was minimal.

DISCUSSION

Contemporary EM lithotripters, currently used in clinical practice, have benefited greatly from numerous technological advances over the past 25 years. Yet in terms of their stone

fragmentation ability, these devices appear to be inferior to the original Dornier HM3 device.¹⁷ In particular, clinical studies have shown that the HM3 produces better stone fragmentation, higher stone-free rates, and lower rates of retreatment compared to newer-generation EM devices.^{18,19}

In terms of acoustic field characteristics, the HM3 produces a significantly broader focal width (or larger focal zone) with a pressure wave profile that allows strong cavitation activity. Conventional EM lithotripters produce a second compressive peak that is absent in EH devices (approximately 7 μ s from the leading shock front, marked with an arrow in Figure 2a), which suppresses cavitation activity and thus negatively impacts stone fragmentation during SWL.⁹ Cavitation bubbles induced by the tensile component in a lithotripter shock wave can grow to several hundred times their original size, then collapse violently causing pittings on nearby stone surfaces from either high-speed liquid microjets or emitted shock waves.^{20,21} It has been shown that stress waves and cavitation act synergistically to produce effective stone fragmentation during SWL.⁹

The modified lens was developed to simultaneously broaden the focal zone and idealize the pressure waveform for cavitation enhancement. The results of this study support the notion that a broad focal zone and enhanced cavitation activity become increasingly important as SWL treatment progresses. After 500 shocks, fragmentation was essentially equivalent between the original and modified lenses; however, after 2000 shocks the modified lens produced significantly improved fragmentation. It is plausible that as treatment progresses, residual fragments spread out in the collecting system to an area larger than that occupied by the original stone. Furthermore, respiratory motion can move stones 5 cm or more between maximal inspiration and expiration. Depending on the focal width of the lithotripter, it is believed that up to 50% of the shocks can miss the targeted stone during the SWL treatment.^{6,22}

Yet, previous studies under clinically relevant *in vitro* test conditions have demonstrated that a broad focal zone is able to treat a stone target that is continuously changing, resulting in overall improved stone fragmentation. For example, stone comminution experiments with target stones in a membrane holder (which allows dispersion of stone fragments) or under simulated respiratory motion using a finger cot holder have resulted in greatly reduced fragmentation efficiencies for lithotripters with a high peak pressure and a narrow beam size.^{23,24} Therefore, a lithotripter field with broad focal zone will be advantageous in targeting stone and residual fragmentation during SWL.

Other recent studies have also supported the use of a wide focal zone for improved stone fragmentation *in vivo*. In a clinical study from Eisenmenger et al, a self-focusing EM lithotripter with a low peak pressure (25 MPa) and a wide focal zone (=18 mm) has produced a stone free rate of 86% after 3 months of follow up.²⁵ These results were obtained using a very low PRF of 0.3 Hz, which may also contribute to the high comminution efficiency.^{26–28} In addition, experiments *in vitro* using a modified HM3 lithotripter have shown that a broad beam size of 10 to 12 mm produced improved fragmentation as compared to a narrower beam size of 3 to 4 mm under otherwise similar experimental conditions.¹⁰ These findings support our hypothesis that stone spreading is responsible in part for the higher comminution results of the modified lens, which has a ~47% enlarged focal width compared to the original lens. However, the amount of spreading *in vivo* cannot be easily quantified. Stone fragments are not visible with fluoroscopic imaging after approximately 800 – 1000 shocks, except in instances where one big fragment moves permanently outside of the lithotripter focal region. Following SWL, fragments spreading inside the harvested kidneys can be seen which provides a plausible explanation of the differences in stone comminution between the two lenses. However, it should be noted that

the process of kidney harvesting and sectioning may artificially displace residual fragments within the kidney. Therefore, it is unreliable to quantify fragments spreading after bivalving the kidney.

Of equal importance to stone fragmentation and clearance are the tissue injury results, which demonstrate that the modified lens produces a very low level of renal damage, similar to the outcome of the original lithotripter lens. The energy setting (cumulated total energy dose of ~90 J) used for this study was at an intermediate level of clinical SWL.²⁹ At high energy and PRF, the enhancement of cavitation activity may increase the propensity of renal injury from rupture of small vessels during bubble expansion.³⁰ Additional studies at higher energy settings and PRFs >1 Hz will be needed to define the safety limit of acoustic pulse energy and total dose applicable to the treatment of kidney and ureteral stones. Image resolution of sectioned kidneys was high enough to detect any hematoma > 1mm, though it is worth noting that further investigation using high power microscopy on an additional cohort of animals may improve detection of renal injury.

The current studies suggest that the modified lens design does not increase the risk of renal injury while improving stone comminution efficiency of the lithotripter.

CONCLUSIONS

The modified acoustic lens for the Siemens Modularis lithotripter produces a broader focal zone (by 47%) and an idealized pressure waveform for significant reduction of the secondary compressive wave when compared to the original lens. As a result, stone fragmentation is significantly improved *in vivo*, while differences in tissue injury are minimal compared to that produced by the original lens at an intermediate energy output setting. This lens modification is simple and cost-effective, and has the potential to be retrofitted on existing EM lithotripters to improve their effectiveness. Further clinical studies are warranted for the translation of this new lens design to SWL treatment of stone patients.

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Abbreviations used in this text

SWL	Shock Wave Lithotripsy
PRF	Pulse Repetition Frequency
EH	electrohydraulic
EM	electromagnetic
J	Joule
mJ	Milli Joule
FRV	Functional Renal Volume
MPa	Mega Pasqual
dB	decibel

Figure 1.

Modification of the geometry of the original Modularis lens to generate two temporally separated (Δt) acoustic waves. (a) Picture of the backside of the two lenses; (b) Schematic plot of the original lens; (c) Schematic plot of the modified lens (with a cut on the outer part of the backside) mounted on a shock source (electromagnetic transducer). h : Depth of the cut = 14 mm; R_i , R_u and R_{tot} are the relevant radii for determining area ratio between the uncut and original lens surface $AR = 60\%$.

Figure 2.
Averaged ($n=4$) pressure waveforms produced by (a) the original lens and (b) the modified lens as measured by a fiber optic probe hydrophone at the geometric focus of the lithotripter.

Figure 3.
Representative tissue slices before and after image analysis. The collecting system is shown in blue and injury in green: (a) Original Lens and (b) Modified Lens

Figure 4. Fragmentation efficiencies produced by the original and modified lenses after 500 and 2000 shocks using a PRF of 1 Hz and an equivalent acoustic pulse energy of ~45 mJ.

Table 1**Tissue injury by sample**

Six kidneys from each group underwent processing; samples with 0.0% tissue injury were under the detectable threshold. Statistical comparison did not reveal a significant difference for tissue injury between the lenses.

	Original Lens	Modified Lens	p-Value
Sample	Tissue Injury (%)	Tissue Injury (%)	
1	0.0	0.65	
2	0.75	0.0	
3	Excluded *	0.09	
4	1.04	0.10	
5	0.47	0.46	
6	Excluded *	0.22	
Mean %	0.57	0.25	0.27
SD	0.44	0.25	

* Excluded due to poor quality of microfil casting during sample preparation.