

Effect of the Body Wall on Lithotripter Shock Waves

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Abstract

Purpose: Determine the influence of passage through the body wall on the properties of lithotripter shock waves (SWs) and the characteristics of the acoustic field of an electromagnetic lithotripter.

Methods: Full-thickness *ex vivo* segments of pig abdominal wall were secured against the acoustic window of a test tank coupled to the lithotripter. A fiber-optic probe hydrophone was used to measure SW pressures, determine shock rise time, and map the acoustic field in the focal plane.

Results: Peak positive pressure on axis was attenuated roughly proportional to tissue thickness—approximately 6% per cm. Irregularities in the tissue path affected the symmetry of SW focusing, shifting the maximum peak positive pressure laterally by as much as ~2 mm. Within the time resolution of the hydrophone (7–15 ns), shock rise time was unchanged, measuring ~17–21 ns with and without tissue present. Mapping of the field showed no effect of the body wall on focal width, regardless of thickness of the body wall.

Conclusions: Passage through the body wall has minimal effect on the characteristics of lithotripter SWs. Other than reducing pulse amplitude and having the potential to affect the symmetry of the focused wave, the body wall has little influence on the acoustic field. These findings help to validate laboratory assessment of lithotripter acoustic field and suggest that the properties of SWs in the body are much the same as have been measured *in vitro*.

Introduction

SHOCK WAVE LITHOTRIPSY (SWL) was introduced in the early 1980s and rapidly became the method of choice for treatment of urinary stones.¹ Although SWL has since proven to deliver a very low success rate (~50%),^{2,3} compared to other surgical interventions it remains the only noninvasive means to remove stones from the urinary tract.⁴ As such there has been a considerable investment of effort to identify the mechanisms of shock wave (SW) action in stone breakage, with the goal of improving this valuable technology.

Although the lithotripter industry has been somewhat slow to respond, it can be seen that data from the research community has influenced lithotripter design. Indeed, major trends in lithotripters can be linked to prevailing theories of SW action. For example, early in the development of lithotripsy when it was thought that stones broke primarily due to compressive failure and spallation, lithotripters were built to generate extremely high acoustic pressures delivered to a narrow focus. Subsequent understanding of the significant role of cavitation in the comminution of stone fragments⁵ and the demonstration that shear stress within stones is key to breakage and is enhanced when focal width exceeds stone diameter^{6–8} was followed by the introduction of broad focal zone, less powerful lithotripters.^{9,10} The translation of this to

practice is viewed in a positive light, whereas, it should be noted that the data that have influenced the evolution of lithotripters primarily come from *in vitro* laboratory testing. That is, our understanding of lithotripter acoustic fields does not consider the potential effects of the body wall tissue path on the propagation of SWs.

Measurement of the effect of biological tissues on SWs clearly presents a unique challenge and others have attempted this with limited success. Delius et al.¹¹ measured the SWs of a Dornier HM2 lithotripter using a polyvinylidene difluoride (PVDF) membrane implanted between the lung and diaphragm in dogs. Results showed waveforms to be similar in shape to SWs collected *in vitro*, with peak positive pressure (P^+) reduced about 20%. Vergunst et al.¹² measured SW pressures within the gallbladder of pigs and, likewise, saw a reduction in P^+ of about 15%–25%. Finney et al.¹³ used a needle hydrophone to measure lithotripter pulses passing through the biceps region of human upper arm, observing an ~80% drop in P^+ and a greater than 10-fold increase in shock rise time. Attempts have also been reported using optical fiber hydrophones to measure SWs *in vivo*. In tests with human patients undergoing SWL Coleman et al.¹⁴ introduced a fiber optic hydrophone (Fabry-Perot interferometric sensing principle) into the urinary tract through a ureteral catheter. To avoid damaging the optical fiber, readings were made with

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the tip in the ureter about 10 cm from the target point, giving understandably low values (0.5–5.0 MPa). As such, these first results in a human patient were difficult to interpret, but these illustrated the possibility of employing a fiber optic hydrophone within the urinary tract.

An informative study by Cleveland and colleagues¹⁵ sought to address the idea that tissue along the SW path could affect pulse amplitude and that inhomogeneities in biological tissue could scatter and distort SWs, affecting the properties of the acoustic field. The study involved surgical implantation of a PVDF membrane hydrophone in living pigs exposed to SWs in a water bath style Dornier HM3 lithotripter. The investigators constructed a small PVDF membrane hydrophone that was surgically implanted at the surface of the kidney. Fluoroscopy was used to align the hydrophone roughly perpendicular to the axis of SW propagation. Under these conditions it was observed that P^+ was reduced to ~70% of that in water and there was a substantial increase in the shock rise time. In addition, mapping of the acoustic field showed the focal width *in vivo* to be approximately twice that measured in the free field (20 mm vs 12 mm). As such, the data suggested potentially important differences between the acoustic field within the body and the acoustic profile that was measured when the lithotripter had previously been characterized.¹⁶ However, as the authors noted, this unique study system presented certain limitations that may have affected the findings. That is, the spatial orientation of the hydrophone to the SW axis could only be approximated, and for mapping of the acoustic field it was necessary to move the animal relative to the acoustic axis of the lithotripter, thus shifting the tissue along the acoustic path.

The objective of the current study was to assess the effect of *ex vivo* porcine body wall on the acoustic field of a Dornier Compact-S lithotripter under conditions that simulate *in vivo* SW exposure. We adopted an *ex vivo* model to allow precise orientation of the hydrophone for shock rise time measurement and to enable mapping of the acoustic field for determination of focal width with the body wall in fixed position. The findings suggest that apart from attenuation of the pulse and minor effects on the symmetry of focus, the body wall has minimal effect on SWs, such that the characteristics of the acoustic field are remarkably similar to values collected in the free field.

Materials and Methods

The *in vitro* test system consisted of a Dornier Compact-S electromagnetic lithotripter (Dornier MedTech, Kennesaw, GA) coupled to the acoustic window (0.13-mm-thick Mylar film, 20×20 cm) of an acrylic tank (length 50 cm×width 52 cm×depth 40 cm) containing deionized water (21°C–23°C) degassed to 25%–35% oxygen saturation using a multi-pinhole degasser^{17,18} (Fig. 1). Acoustic pressures were measured using a fiber-optic probe hydrophone (FOPH-500; RP Acoustics, Leutenbach, Germany) with the fiber tip oriented perpendicular to the axis of SW propagation, allowing for better longevity of the fiber. Perpendicular orientation, as opposed to aligning the fiber parallel to the axis of SW propagation, results in a slight (~5%) reduction in pressure rendition systematically. For measures of rise time the optical fiber tip was oriented parallel to the SW-path so that the wave front would hit the leading face of the fiber tip and give the

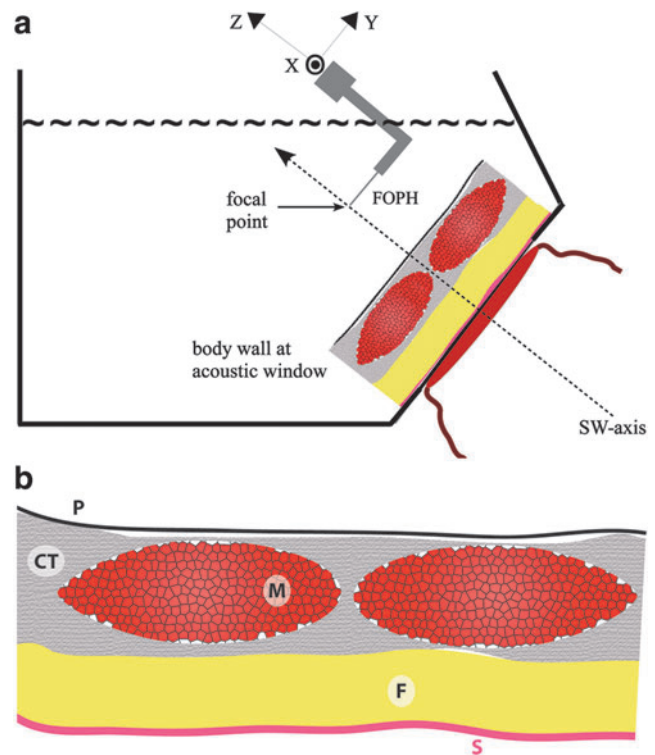


FIG. 1. *Ex vivo* test system: (a) Measurements were performed in a water-filled test tank using a fiber-optic probe hydrophone (FOPH) moved in the focal plane of the lithotripter by an X-Y-Z positioner. Specimens of pig body wall were held against the Mylar acoustic window of the tank and the treatment head of the lithotripter was coupled to the window using LithoClear[®] gel. (b) Full-thickness pieces of anterior abdominal wall were used. These consisted of skin (S) and subcutaneous fat (F), the paired rectus abdominis muscles (M) in cross-section view, surrounded by connective tissue fascia (CT) and apposed at the midline, and the peritoneum (P) and its subjacent fascia. Although specimens might be uniform in thickness, they were acoustically non-uniform.

shortest temporal resolution, limited only by the electronics of the hydrophone.¹⁹ An oblique angle of incidence due to even slight misalignment of the fiber tip artificially increased the rise time rendered by the FOPH. In these studies, direct visual access of the fiber tip allowed precise alignment, typically <2–3° off axis. If one assumes that a plane wave front hits the 0.12 mm diameter leading face of the hydrophone tip, the expected effect of a 2–3° misalignment will be an artificial increase of only ~3–4 ns in rise-time rendition.

The lithotripter was operated at power level 3 (peak positive pressure 52 ± 2 MPa with output of ~48–56 MPa from level 1 to 6), fired at a rate of 60 SW/min. Sets of 25 waveforms (8 ns sampling rate, 5000 data points per SW, shock to shock variation <±4%) were stored using a Tektronix digital oscilloscope (TDS 5034; Tektronix, Beaverton, OR) for post-processing.¹⁹ For mapping of the acoustic field the FOPH tip was moved in steps of 1 or 2 mm over a total lateral excursion of 10–12 mm in the focal plane of the lithotripter, with collection of 25 SWs per step. Waveforms distorted by strong cavitation are easily identified and rejected by visual

inspection, and average waveforms were calculated by aligning pulses to the coincidence of the half amplitude of the shock fronts.¹⁸

Full-thickness segments of abdominal body wall, shaved to remove hair, were harvested from pigs immediately after the animals were euthanized. All animal handling and surgical protocols were carried out 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. The pigs ranged in size from ~30 to ~80 kg, and specimens of body wall measured roughly 15 cm by 20 cm in size and ~2 cm to ~6 cm in thickness. Body wall segments were immersed in isotonic saline for transport (~5 minutes) to the lithotripsy laboratory. In a typical experiment the body wall was secured to a simple frame to hold the specimen centered against the inside surface of the Mylar acoustic window of the test tank (Fig. 1). As specimens were readily visible through the Mylar window it was possible to assure that bubbles did not get trapped at the tissue surface. Dimensions of the tissue specimens always overlapped the critical region (~7.0 cm diameter) of the acoustic window through which the majority of SW energy passes.²⁰ Repeated measures were performed with and without body wall positioned in the test tank and the tissue was returned to saline when not in the water tank.

Results

Waveforms were remarkably similar to measurements without tissue present, and exhibited a sharp shock front and similar pulse duration but with reduced amplitude (Fig. 2). Pulse amplitude was attenuated by passage through tissue. With the FOPH at the focal point of the lithotripter, measures with specimens of different thickness showed an increase in percent attenuation of P^+ as the thickness of the body wall increased (Fig. 3). Without accounting for differences in specimen composition (i.e., muscle vs fat), the data suggest an ~6.1% reduction in P^+ per centimeter of tissue. In these tests at least two consecutive sets of 25 waveforms were collected, first without tissue present and then with a specimen of body wall held at the acoustic window. High variability in the readings with tissue present (up to ± 5.0 MPa), compared to the free field, (< 2.0 MPa) was likely caused by variability in distortion of the acoustic field due to imprecise repositioning of the specimen at the acoustic window for repeated measures.

Mapping of the acoustic field, likewise, showed a reduction in P^+ when tissue was imposed in the SW-path and was further attenuated as tissue thickness increased. A specimen of anterior abdominal wall measuring ~5.0 cm in thickness reduced P^+ ~41% (Fig. 4). Similar measures for a segment of abdominal wall measuring about 2.5 cm in thickness showed only a slight ($< 10\%$) reduction in P^+ across the field (Fig. 4, inset). Measures of peak negative pressure (P^-) were noisy for all specimens, but were most consistent for the thicker segments of body wall, with a 5.0 cm thick specimen showing a reduction in P^- of ~25% (3.0 MPa vs 4.0 MPa in the focal zone) (Fig. 4).

By virtue of the normal anatomy, specimens of body wall were not uniform. They were consistent in overall thickness ($< \pm 0.5$ cm), but were always heterogeneous in composition. For example, the segments of abdominal wall consisted of

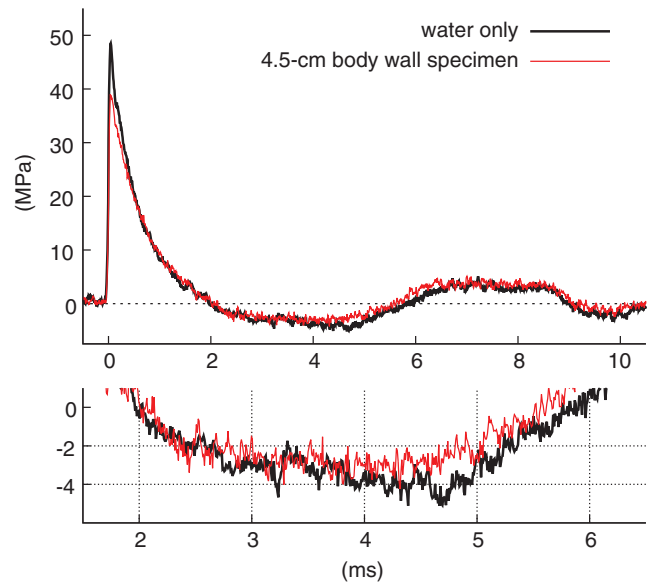


FIG. 2. Representative pressure waveforms for shock waves (SWs) passing through a 4.5-cm-thick *ex vivo* body wall. The FOPH probe was positioned at the lithotripter focal point during measurement and the two traces shown are the average over 25 SWs. Waveforms with and without the tissue were remarkably similar, showing only a reduction in amplitude.

paired rectus abdominis muscles that longitudinally joined the midline linea alba. For testing, these specimens were centered on the acoustic window with the midline roughly parallel to the Y-axis. As such, muscle was symmetric about the Y-axis but asymmetric about the X-axis, and mapping in X and Y directions showed distortion of the field with displacement of P^+ max up to 2 mm (Fig. 5). Regardless of this

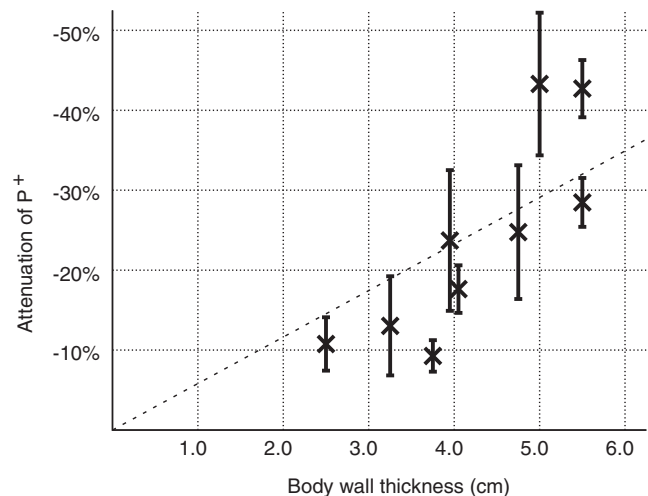


FIG. 3. Percent attenuation of peak positive pressure (P^+) as a function of body wall thickness. Maximum P^+ was measured at the lithotripter focal point with nine different body wall specimens (2.5 to 5.5 cm in thickness) at the acoustic window. Linear fit analysis estimates a 6.1% increase in attenuation per centimeter in thickness. Error bars indicate one standard deviation.

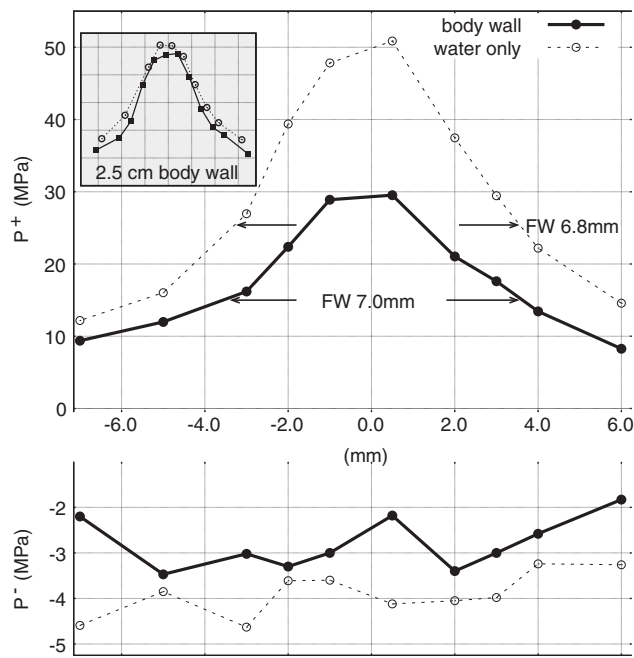


FIG. 4. Attenuation of acoustic pressures without an effect on focal width. Mapping of the pressure field along the Y-axis for passage of SWs through a 5.0 cm thick specimen of abdominal wall showed a reduction in both positive pressure ($\sim 41\%$) and negative pressure ($\sim 25\%$), but little effect on focal width. Inset: Trace of P^+ along the Y-axis for passage of SWs through a thinner (2.5 cm) specimen of body wall showed only a slight attenuation of the pulse and no apparent effect on focal width. The shock-to-shock variation in the 25 consecutive SWs acquired for typical data sets measured $< \pm 2.0$ MPa without tissue present and $< \pm 3.0$ MPa with the body wall.

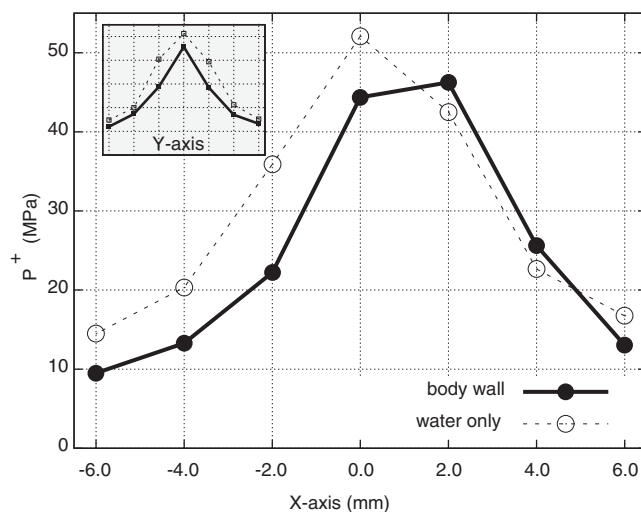


FIG. 5. Disruption in symmetry of the acoustic field by a 3.5 cm thick body wall. Mapping of the field in the X-axis showed lateral displacement of maximum P^+ by about 2 mm, while mapping in the Y-axis (inset) showed no such effect. The shock-to-shock variations measured $< \pm 2.0$ MPa without tissue present and $< \pm 3.0$ MPa with the tissue.

positional distortion there was minimal-to-no effect of the body wall on the width of the focal zone. Mapping of focal width was conducted for three specimens (2.5, 3.5, and 5.0 cm in thickness). The -6 dB zone measured ~ 6.5 mm with or without tissue in the path and was not affected by the thickness of the specimens (Fig. 4).

Shock rise time measured 15–19 ns (standard deviation $< \pm 1.0$ ns) *in vitro* and was not much affected by tissue. Multiple specimens measuring 3.5 to 5.5 cm in thickness all showed rise time between 17 and 21 ns ($n=5$, data not shown). In this experimental set up where the focal point sits ~ 7.5 cm from the acoustic window there was considerable distance between the tissue and the FOPH (~ 2 cm for a 5.5 cm specimen). As such, if the rise time increased due to attenuation by tissue, SWs would likely have ample distance to “heal,” recover a short rise time, before contacting the FOPH fiber tip.⁶ Therefore, a test was run in which a large specimen of 4.0 cm thick abdominal wall was halved and stacked (~ 8 cm thick) at the acoustic window. The fiber tip was advanced slowly toward the tissue surface until it was about 0.5 mm (estimated by eye) from the tissue surface (fiber tip currently at post-focal position $Z=8.12$ mm). Although the trailing negative portion of the waveforms was distorted when the tip-to-tissue distance was less than 1–2 mm, shock fronts were properly rendered by the hydrophone and the rise time did not change as SWs exited the tissue (Fig. 6).

Discussion

In an SWL session SWs pass through skin, muscle, and fat to reach the kidney. The length of this path depends on body habitus and in patients can be greater than 10 cm.²¹ The body wall occupies most of this path and because it includes muscle and fat it exhibits greater acoustic absorption than visceral organs such as the kidney.²² Indeed, the kidney has little effect on SWs as shown by Cleveland and colleagues¹⁵ who compared measures taken with a PVDF membrane hydrophone implanted on the anterior surface versus posterior surface of the kidney *in vivo*. Of the tissue types along the acoustic path, muscle exhibits the greatest acoustic absorption at the higher frequencies associated with a shock front. Muscle is also grossly nonuniform, tending to bulge toward the center and taper peripherally. Thus, the body wall overlying the kidney may be uniform in overall thickness, but it presents an acoustically non-uniform medium with the potential to alter SWs and, thereby, affect the acoustic field and the mechanisms of SW action. Our observations using *ex vivo* segments of body wall harvested from pigs show little effect of tissue on the acoustic field of the lithotripter. Other than attenuation in pulse amplitude and some degree of disruption in symmetry of the field there was minimal effect of the body wall on SWs.

We observed that the attenuation of focal P^+ at the focal point ranged from $\sim 10\%$ – 15% for thin segments of body wall (2.5–3.5 cm thick) to 40%–50% for thicker (5.0–5.5 cm thick) specimens, with a reduction in P^+ of $\sim 6\%$ per centimeter. Measurement of the negative pressure of lithotripter SWs is always difficult²³ but we obtained the most consistent readings with thicker specimens, and for a 5.0 cm thick segment of abdominal wall the reduction in P^- was roughly half that of the attenuation to P^+ ($\sim 25\%$ vs 41%). Some specimens induced a lateral shift in P^+ max of ~ 2 mm or more, possibly due to the non-uniformity of muscle in the

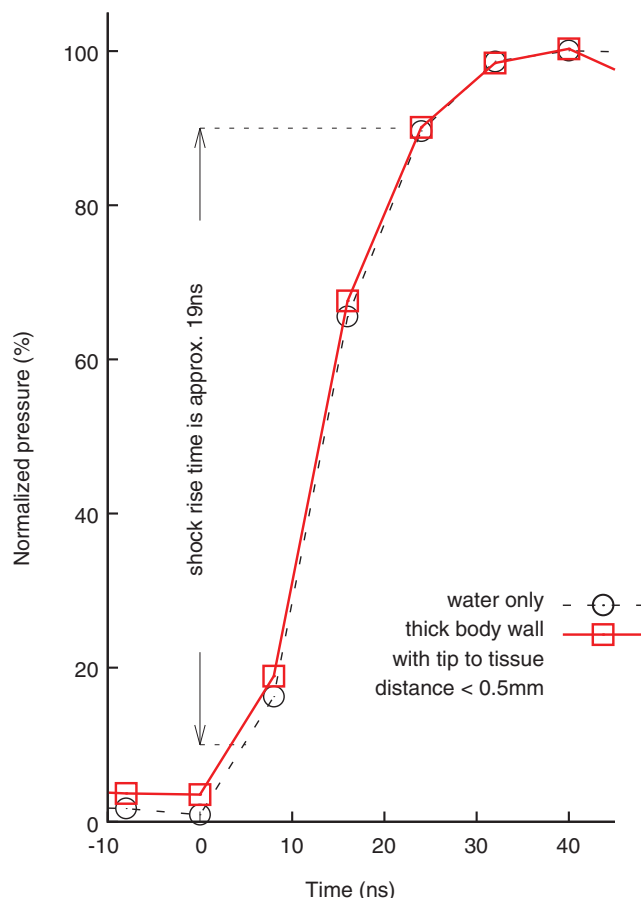


FIG. 6. Shock rise time for measures close to the tissue. Measures of shock rise time for body wall specimens of different thickness in which the FOPH fiber tip was $\sim 2\text{--}5\text{ cm}$ from the tissue all showed values of $\sim 17\text{--}21\text{ ns}$ (see text). To determine whether this lengthy distance between the FOPH and tissue permitted artifactual healing of the shock front, measures were conducted with the fiber tip in close proximity to the tissue. In this case a specimen of body wall $\sim 4\text{ cm}$ in thickness was halved and stacked to occupy the space between the acoustic window and the focal point, and the FOPH was advanced to within $< 0.5\text{ mm}$ of the tissue. Normalized pressure traces for measures with and without tissue show virtually no difference in the shock rise time. For these measures the FOPH was $\sim 8\text{--}9\text{ mm}$ post-focal due to the thickness of the stacked tissue.

body wall. In such cases P^+ at the lithotripter focus was noticeably less than the maximum P^+ displaced off axis, readily evident because the Compact-S has a nominal focal width of only $\sim 6.5\text{ mm}$.²⁰ Mapping of the acoustic field in the plane of the focal point showed virtually no effect of the body wall on focal width. Within the temporal resolution of the hydrophone ($7\text{--}15\text{ ns}$), even measures taken within 0.5 mm of a very thick specimen of body wall showed no effect of the tissue on rise time. In theory, the body wall is expected to dramatically lengthen the rise time (only $\sim 0.1\text{ ns}$ in water) due to the much higher absorption coefficients in the soft tissues, and the effect is only slightly offset by the opposing effect of nonlinearity.

Our measures of rise time and focal width for *ex vivo* specimens of body wall are not in agreement with what has

been observed using a PVDF membrane hydrophone surgically implanted at the surface of the kidney in living pigs.¹⁵ Cleveland and colleagues reported a substantial increase in rise time *in vivo* compared with the free field ($\sim 100\text{ ns}$ vs $\sim 25\text{ ns}$). Differences in the two experimental systems, including constraints imposed by the *in vivo* setting, likely explain these results. The PVDF membrane hydrophone used by Cleveland and colleagues was not readily visible by fluoroscopy and, therefore, difficult to align. The relatively large (0.5 mm) active area of the hydrophone made it prone to misalignment and this could considerably increase the rendition of measured rise time. The implication of an increase in rise time is a potential reduction in peak tensile stress within a targeted stone.⁶ That is, if passage through the body wall were to increase the shock rise time, this would reduce internal stresses within the stone that contribute to stone breakage. Again, we observed no effect of the body wall on shock rise time.

Cleveland and colleagues¹⁵ also reported a dramatic increase in focal width *in vivo* compared with measures collected in the open water bath of the lithotripter (20 mm vs 12 mm). However, for mapping of the acoustic field with the hydrophone affixed to the surface of the kidney it was necessary to move the entire animal stepwise across the field. Given the poor visibility of the hydrophone *in vivo*, precise positioning and orientation of the active area would have been difficult. In addition, moving the animal relative to the lithotripter axis would have changed the tissue path along the axis of SW propagation. As we observed, irregularities in the composition of the body wall can alter the symmetry of the acoustic field (Fig. 5). As such, if the *in vivo* measurement of P^+ max was underestimated due to shifting of the focus, this would have artificially broadened the focal width.

The effect of soft tissue on SWs is poorly understood, and measurement of SWs *in vivo* is extremely difficult. The current *ex vivo* approach avoids many of the obstacles encountered with *in vivo* measures, but is not without limitations. One potential concern is the non-physiologic conditions of the test system, with measurements being performed using tissue immersed in water. We used freshly excised tissue collected minutes after the animal was euthanized, and the time from harvest to immersion in the test tank was on average ~ 20 minutes. Data collection typically required less than 5 minutes for measurements at the focal point and $15\text{--}20$ minutes for mapping of the field before the tissue was returned to saline, but the need for repeated measures meant the specimen was returned to the water bath one or more times. Still, measurements were stable over time. For example, the focal P^+ at 2 hours (41.4 MPa) for a 3 cm thick specimen that had been returned to the test tank eight times for repeated measures (total time in water ~ 60 minutes) was not different from the value collected at the beginning of the experiment (40.2 MPa). When immersed in water these tissue specimens sat within a hypotonic environment that surely hastened cell death, particularly affecting cells at the cut edges. However, because these were specimens of intact abdominal wall that were covered on their exterior surface by skin, which has very low permeability to water, and on the opposite side by the parietal peritoneum, they were largely protected from osmotic insult, except at the cut edges. Since the cut edges did not overlap the acoustic window of the test tank, cell death in this region should not have affected the

integrity of the specimen. The fact that SW measurements did not change over time suggests that progression toward cell death in these specimens did not significantly alter the acoustic properties of the body wall. It is also reassuring that our values for attenuation of SW amplitude with *ex vivo* tissue were similar to those of Cleveland and co-workers observed in living pigs.¹⁵

To the extent that the component tissues are very similar, the pig body wall mimics the body wall of humans. The skin of pigs has a dermal–epidermal thickness ratio similar to that of humans and the epidermis contains the same layers and cell types as in human skin. Indeed, the pig is often used as a model for wound healing.²⁴ As in humans, the subcutaneous connective tissue can contain considerable adipose tissue that is similar in structure to that of humans. One obvious difference is that the musculature of the pig abdominal wall is not the same as the flank in humans. Considering that there can be substantial differences in the thickness of fat and muscle depending on body phenotype in patients, the specimens of abdominal wall we studied provided a reasonable approximation of the body wall overlying the kidneys.

Another potential limitation of the *ex vivo* body wall preparation is the static nature of the vasculature. The pigs were killed by lethal injection followed by exsanguination, and so the vasculature collapsed. This is not a condition that would lead to inclusion of large gas pockets, but if microbubbles were to form they would have remained in the field, possibly contributing to the attenuation of SWs. The fact that attenuation in these *ex vivo* specimens did not increase with multiple exposures to SWs over time and were similar in magnitude to the attenuation observed in living pigs¹⁵ suggests that cavitation was not an issue.

In conclusion, our observations suggest that passage through the body wall has minimal effect on lithotripter SWs. Other than reducing pulse amplitude and having the potential to affect the symmetry of the focused wave, the body wall has little influence on the acoustic field. Thus, the properties of SWs *in vivo* are likely not dramatically different from what has been characterized in the *in vitro* laboratory setting. These observations validate *in vitro* laboratory testing in SWL research. This may be particularly valuable to know in light of recent reports of the advantage of broad focal width in delivering SW energy to a stone moving due to respiratory excursion,^{25,26} and studies demonstrating that broad focal width enhances shear stress contributing to stone breakage.^{7,8}

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Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

FOPH = fiber-optic probe hydrophone

PVDF = polyvinylidene difluoride

SW = shock wave

SWL = shock wave lithotripsy