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Ultrasonic propulsion of kidney stones

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Abstract

Purpose of review—Ultrasonic propulsion is a novel technique that uses short bursts of focused ultrasonic pulses to reposition stones transcutaneously within the renal collecting system and ureter. The purpose of this review is to discuss the initial testing of effectiveness and safety, directions for refinement of technique and technology, and opinions on clinical application.

Recent findings—Preclinical studies with a range of probes, interfaces, and outputs have demonstrated feasibility and consistent safety of ultrasonic propulsion with room for increased outputs and refinement toward specific applications. Ultrasonic propulsion was used painlessly and without adverse events to reposition stones in 14 of 15 human study participants without restrictions on patient size, stone size, or stone location. The initial feasibility study showed applicability in a range of clinically relevant situations, including facilitating passage of residual fragments following ureteroscopy or shock wave lithotripsy, moving a large stone at the UPJ with relief of pain, and differentiating large stones from a collection of small fragments.

Summary—Ultrasonic propulsion shows promise as an office-based system for transcutaneously repositioning kidney stones. Potential applications include facilitating expulsion of residual fragments following ureteroscopy or shock wave lithotripsy, repositioning stones prior to treatment, and repositioning obstructing UPJ stones into the kidney to alleviate acute renal colic.

Keywords

kidney calculi; lithotripsy; residual fragment; ultrasonic propulsion; ultrasound

INTRODUCTION

One in 11 Americans will have a urinary stone over the course of their lifetime, and the incidence appears to be increasing [1]. Up to 50% of patients with a stone event will recur within 5 years [2]. Owing to the recurrent and debilitating nature of renal stone disease, it is reported to be the most expensive benign urologic condition [3,4]. Surgery options have remained relatively stable and include shock wave lithotripsy (SWL), ureteroscopy (URS),

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Conflicts of interest

M.R.B. has equity in SonoMotion, Inc., which has licensed this technology from the University of Washington.

and percutaneous nephrolithotomy. Although there have been incremental improvements in technology, some studies suggest newer SWL machines are less efficacious than the original Dornier HM-3 lithotripter [5–7]. Ultrasonic propulsion is a novel technology that uses short bursts of ultrasonic pulses to relocate stones within the renal collecting system. The user controls a handheld transducer producing a real-time ultrasound image, directing ultrasound waves toward a stone to reposition it in a controlled fashion.

There remain open questions in the surgical management of kidney stones, including that regarding residual fragments. All stone treatments are associated with risk of residual fragments, with up to 50% becoming symptomatic or requiring repeat procedures [8–11]. The ability to clear residual fragments is particularly important in the lower pole, where pelvicalyceal anatomy is least favorable for spontaneous clearance [12]. As laser technologies improve and stone dusting gains favor as a management strategy, the management of residual fragments will continue to be important [13]. Ultrasonic propulsion has demonstrated promise in expulsion of small fragments in both animal and human models, and is a potentially useful technology in this setting.

Ultrasound is increasingly used in a point-of-care fashion by a variety of medical specialists [14]. A recent study supports the use of point-of-care ultrasound for first line diagnosis of stones in the emergency department setting [15]. The integration of ultrasonic propulsion capabilities to point-of-care ultrasound may allow repositioning of obstructing UPJ stones to relieve acute renal colic.

In addition to clearance of residual stone fragments and repositioning obstructing stones, ultrasonic propulsion has other potential uses, including expulsion of asymptomatic small *de novo* stones and repositioning stones before surgery to improve stone-free rates. This article reports the capabilities and safety profile of ultrasonic propulsion, comments on the potential for improvement and refinements, and offers opinion on its clinical applications.

DEVELOPMENT OF ULTRASONIC PROPULSION

Ultrasonic propulsion has been developed and tested at the University of Washington with NIH and NASA/NSBRI funding and was first described in 2010. *Shah et al.* [16] described the development of a prototype device that utilized ultrasound force to move stones within a tissue phantom. The device consisted of a large 2 MHz 8 cm annular probe around a separate imaging probe. Glass beads and calculi up to 8 mm were successfully repositioned within the artificial collecting system. The treatment parameters were an instantaneous acoustic power of 5–40 W, duty cycle 50% duration of pulse 2–5 s.

In the study by *Shah et al.* [17] in 2012, ultrasonic propulsion was tested *in vivo* using this previously described system. Stones or beads were moved from renal calyces to the renal pelvis and UPJ in all six pigs. There was no difference in the ability to move stones of varying compositions. There was no evidence of histologic injury in regions exposed to 325 W/cm²; areas exposed to 1900 W/cm² had thermal injury 1 cm in maximal dimension in six of seven samples.

Harper *et al.* [18] reported on the second-generation device that used a single-probe for both imaging and therapy. The pushing pulse was longer, broadened by electronic focusing, and could be focused anywhere in the B-mode image. Lower acoustic energy and pressure were used in comparison to the initial preclinical studies, with a peak pressure of 20 MPa (vs. 37–115 on commercial lithotripters). The time average intensity was much lower, as short pulses were distributed over a 1-s burst for a 3% duty cycle. Artificial or calcium oxalate stones of 2–8 mm were implanted in eight pigs. Total 65% of stones were successfully repositioned from the calyces to the renal pelvis [3], UPJ [2], or ureter [12] with average net stone displacement 6 cm. Although seven stones were not successfully repositioned to the renal pelvis, they were observed to move within the calyx. Stones as large as 11 mm could be moved. No study animals experienced a complication, including gross hematuria, and there was no histologic injury.

In these early studies, stones were observed to move from the ultrasound focus prior to completion of the 1-s ultrasound pulse, resulting in misplaced energy. In Harper *et al.* [19] 2014, the outputs were refined from 1 s of sparsely distributed pulses to a concentrated burst of pulses 50 ms long. Effectiveness studies using 2–5 mm calcium oxalate stones were performed as described previously with successful repositioning of all six stones from the lower pole to the UPJ or proximal ureter. Average procedure time was 14 ± 8 min, using an average of 13 ± 6 bursts. Seven-day survival studies were also performed without complications, evidence of injury on blood and urine tests, or evidence of renal injury on histologic analysis.

To assess the effectiveness in the setting of a larger skin-to-stone distance and potentially adherent *de novo* stones, ultrasonic propulsion was performed in 190–210 kg pigs with diet-induced hyperoxaluria [20,21] in collaboration with the University of Wisconsin. Two calcium oxalate stones under 3 mm were identified and repositioned within the renal collecting system at a mean depth of 10 ± 1 cm with a mean treatment time of 20 ± 13 min [22].

Ultrasonic propulsion requires that providers be familiar with both the principles of ultrasonic imaging as well as the features of renal anatomy as viewed on ultrasound. Hsi *et al.* [23] piloted a training curriculum on the fundamentals of renal ultrasound and ultrasonic propulsion and enrolled 10 board-certified urologists. Total 90% of participants did not perform renal ultrasounds before the study. After the 90-min curriculum, all participants were able to move lower pole stones within a renal tissue phantom, and 90% of stones were successfully repositioned into the renal pelvis with a mean time of 4.6 ± 2.2 min. This study further demonstrated the clinical applicability of this technology, with the goal of a clinic-based system used by practicing urologists to reposition stones.

PRECLINICAL INVESTIGATION OF SAFETY

Ultrasound dose thresholds for injury have been delineated in a number of studies [24–26]. Two areas of particular importance are the effect of ultrasonic propulsion on renal parenchyma and functional renal volume, and periprocedural risks, including hemorrhage, hematuria, and pain. Multiple studies have been performed to investigate the safety of

ultrasonic propulsion and these indicate that the technology is associated with minimal risk across a wide-range of exposures.

Connors *et al.* [27] quantified renal injury associated with ultrasonic propulsion and SWL. Porcine kidneys were examined following ultrasonic propulsion using clinical settings, after very high dose to simulate excessive treatment parameters, and following SWL. Injury was analyzed via a previously described technique [28]. There was no detectable lesion in kidneys exposed to simulated clinical treatment parameters or at an extreme exposure. Only with the probe placed directly on the kidney did the extreme dose produce a hemorrhagic lesion, which was less than 1% of total renal functional volume (mean $0.46 \pm 0.37\%$). This was one-third the mean lesion size of kidneys treated with SWL (mean $1.56 \pm 0.45\%$). These results are consistent with ultrasound bioeffects studies [24–26].

The threshold for renal injury was further investigated by Wang *et al.* [29]. At a duty cycle of 3.3%, the anticipated parameter for clinical stone propulsion, a spatial peak intensity of $16\ 620\ \text{W}/\text{cm}^2$ was required to demonstrate significant injury. This intensity was approximately seven times the maximal power output and over 200 times the average pulse intensity of the clinical prototype device.

Although the potential for renal injury exists with inappropriately high treatment parameters or device malfunction, ultrasonic propulsion using clinical treatment parameters does not produce identifiable renal lesions, and appears comparatively less injurious than SWL. The threshold required to consistently produce renal injury using clinical treatment settings is beyond the power output capabilities of the current clinical prototype device.

HUMAN STUDY PARTICIPANTS TRIAL

Harper *et al.* [30] reported the findings from the first human investigational trial of ultrasonic propulsion toward the applications of expelling small stones and dislodging large obstructing stones. This was a Food and Drug Administration approved feasibility study to assess if renal stones could be repositioned in human study participants. There were no restrictions on stone size, position, or patient BMI. As an initial feasibility study enrollment was restricted to 15 study participants.

All study participants underwent ultrasonic propulsion either without sedation in clinic [13], or under general anesthesia during URS [2]. Ultrasound imaging and a pain questionnaire were completed before, during, and after propulsion. The primary outcome was to reposition stones within the collecting system. Secondary outcomes included safety, controllable movement of stones, and movement of stones less than 5 mm and at least 5 mm. Adverse events were assessed weekly for 3 weeks.

Kidney stones were successfully repositioned in 14 of 15 study participants. Fig. 1 shows ureteroscopic and B-mode ultrasound images of ultrasonic propulsion. Of the 43 targets, 28 (65%) showed some level of movement whereas 13 (30%) were displaced more than 3 mm to a new location. See Table 1 and Fig. 2 for details of stone propulsion and passage. There were no adverse events associated with the treatment. Discomfort during the procedure was rare, mild, brief, and self-limited. Stones were moved in a controlled direction with over 30

fragments being passed by four of six study participants, who had retained fragments several weeks after SWL or URS. One patient experienced pain relief during treatment of a large stone at the UPJ. The largest successfully moved stone was 10 mm. In four study participants, a seemingly large stone was determined to be a cluster of smaller, passable stones once treated with ultrasonic propulsion.

OPINIONS ON CLINICAL USE

The clinical trial, combined with the extensive *in vivo* evidence of safety and effectiveness in porcine models, shows that ultrasonic propulsion can be a successful strategy in the management of nephrolithiasis. The ultimate goal of this work is to create an ultrasound-based system that integrates ultrasonic propulsion, burst wave lithotripsy (BWL), and stone-specific imaging algorithms designed to improve stone detection and sizing. BWL uses short, broadly focused bursts of ultrasound to fragment stones [31²²]. This technology has been shown to fragment stones *in vitro* at lower pressures than SWL. Research to improve the sensitivity, specificity, and stone sizing accuracy of B-mode ultrasound with stone-specific algorithms designed to improve stone to soft tissue resolution is ongoing [32]. Potential clinical scenarios for the use of ultrasonic propulsion are outlined below.

Expulsion of fragments following lithotripsy

SWL, URS, and percutaneous nephrolithotomy may leave residual stone fragments, and in up to 50% of cases these fragments become symptomatic or require a repeat intervention [8–11]. Any of these treatment modalities could be followed with ultrasonic propulsion to facilitate higher stone-free rates. Of the six study participants with postlithotripsy fragments in the clinical trial, four reported passing over 30 stones following the procedure where no stones had passed spontaneously in the weeks prior to ultrasonic propulsion. Although the overall number of study participants was small, the individual cases are compelling. One study participant noted the passage of two small stones within an hour of the start of treatment, and another study participant with limited mobility passed an estimated 10 fragments following propulsion when no fragments were seen previously.

Although success was noted, the treatment of large collections of smaller stones was limited by the narrow ultrasound focus. These collections were more time-consuming to treat, as the small stones needed to be targeted and repositioned individually. A new probe with a wider and longer focus, as seen in Fig. 3, is under development to improve the effectiveness of expelling these collections of fragments [33].

Relief of obstruction

Three study participants had large stones in the renal pelvis. One study participant had a pain level of 5 before treatment, which decreased to three following ultrasonic propulsion. With an increase in power output – felt to be safe for the reasons described previously – these large, obstructing, and proximal stones could possibly be repositioned into the kidney to alleviate renal colic. Based on the familiarity with both point-of-care ultrasound and management of acute stone events, ultrasonic propulsion for repositioning proximal stones is

particularly appealing in the emergency department setting [15]. Trials investigating this application are currently being pursued.

Stone diagnosis and characterization

In four study participants what appeared as a single, large stone on B-mode ultrasound was observed to be a collection of fragments after ultrasonic propulsion. The potential diagnostic value of this technology is as unique as its interventional value, and could be used to both improve the accuracy of ultrasound for diagnosing renal stones, as well as assist in more accurate characterization of stone burden for surgery planning, or help determine the end point of SWL.

Special populations

There are populations that would gain particular benefit from ultrasonic propulsion technologies, including children, pregnant women, and those with occupational risk from an acute stone event. Ultrasound is without ionizing radiation and would thus be particularly suitable for children or pregnant women. Certain professions, including piloting aircraft, cannot be performed with active or recurrent urinary stone disease because of the risk of incapacitation from acute renal colic [34]. These patients could benefit from propulsion of small, asymptomatic stones out of the kidney to pass in a controlled fashion. Astronauts have an increased risk of stones while in space because of bone demineralization, dehydration, and stasis, and there are currently few options for treatment of an acute stone event in space [35,36]. For this reason NASA/NSBRI has participated in the funding of this research, and integration of ultrasonic propulsion technology with existing ultrasound systems in space is being pursued. Between 2001 and 2011, 60 soldiers were evacuated from combat zones per year for renal colic [37]. Ultrasonic propulsion could reduce the burden of acute stone events in soldiers because of its portability, ease of use, and lack of anesthesia requirement.

Other potential uses

As ultrasonic propulsion becomes available for clinical use and subject to broader testing the indications are expected to expand. Expulsion of small, asymptomatic, *de novo* stones would allow predictable timing of stone passage and reduced patient anxiety. Propulsion of *de novo* stones is challenging because they are potentially adherent to the collecting system, and initial evidence from the clinical feasibility trial showed limited success with these stones. However, as ultrasonic propulsion technology develops and utilizes higher output levels, displacement, and passage of these stones may be possible. An additional potential use is repositioning stones just prior to or during surgery (e.g., SWL) to improve stone-free rates.

CONCLUSION

Ultrasonic propulsion of kidney stones is a safe, effective, and easy-to-learn method of transcutaneously repositioning stones within the kidney. The technology continues to be optimized, and future directions include fusion of the technology with BWL and stone-specific ultrasound imaging algorithms. This technology has a well defined clinical niche as

a standalone technology for both treating and staging renal stones, as well as an adjunct to existing therapies.

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KEY POINTS

- Preclinical studies with a range of probes, interfaces, and outputs have demonstrated feasibility and consistent safety of ultrasonic propulsion.
- Ultrasonic propulsion was used painlessly and without adverse events to reposition stones in 14 of 15 human study participants without restrictions on patient size, stone size, or stone location.
- Ultrasonic propulsion of kidney stones shows great promise as a point-of-care system for transcutaneously repositioning stones within the kidney.
- Potential applications include facilitating expulsion of residual fragments following URS or SWL, repositioning difficult to access lower pole stones, and repositioning obstructing UPJ stones to alleviate acute renal colic.
- Future direction include broader beam, more powerful system, additional trials directed at clinically relevant endpoints, and integration with a suite of ultrasound technologies, including BWL.

FIGURE 1.

Ultrasonic propulsion of stone in human study participant. (a) Ureteroscopic images immediately before one push burst of intraoperative ultrasonic propulsion with region of repositioned stone in red. (b) Ureteroscopic images immediately after one push burst of intraoperative ultrasonic propulsion with region of repositioned stone in red. (c) A cluster of stones (encircled in red) on B-mode ultrasound before ultrasonic propulsion in a human study participant. (d) Successful repositioning of a fragment marked in red.

FIGURE 2. Ultrasonic propulsion of residual fragments following lithotripsy. Summary of results of facilitation of passage of residual fragments remaining after URS or SWL. Green represents stone movement and the green arrow highlights study participants that reported passing stones. The number next to each target indicates the study participant number. Different sized circles represent stone target sizes. The hash mark corresponds to a target that was identified as a single large stone on clinical imaging but determined to be a cluster of small stones with ultrasonic propulsion. Adapted from [30*].

FIGURE 3.

Numerical simulations of acoustic beam width. Acoustic beam width for clinical system (left) in comparison to new, broader beam designs (center, right). The goal of this broader beam is to move entire clusters of stone fragments in a single Push and to apply more force to large stones [33]. Simulations performed by B.W. Cunitz.

Table 1

Summary of stone motion based on subject management group from clinical feasibility trial

	Postlithotripsy (Group 1)	<i>De novo</i> (Group 2)	Pre-URS (Group 3)	Peri-URS (Group 4)
Study participants, n	6	3	4	2
Stones, range, <i>n</i>	5 to many	2–5	1–3	3
Stone size (mm)	3	1–5	1–2, 7–14	1–2, 8–12
Pushes, mean (range)	39 (37–40)	30 (27–40)	23 (17–32)	28 (22–34)
% of push w/motion ^b				
Grade 1	35	75	81	58
Grade 2	47	25	19	30
Grade 3	18	0	0	12
Stones passed, <i>n</i>	4 of 6	0 of 3	N/A	N/A

N/A, not applicable; URS, ureteroscopy. Adapted from [30[■]].

^a Group 1 = postlithotripsy fragments; Group 2 = *de novo* less than 5 mm stones, Group 3 = *de novo* more than 5 mm treated before surgery, and Group 4 = *de novo* stones treated during ureteroscopy.

^b Grade 1 = no movement; grade 2 = movement less than 3 mm; grade 3 = movement at least 3 mm or new location.