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A Randomized Controlled Trial of Ultrasonic Propulsion–Facilitated Clearance of Residual Renal Stone Fragments vs Observation

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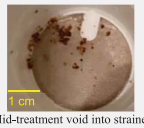
Study Need and Importance: Ultrasonic propulsion (UP) is a noninvasive, office-based treatment for awake patients with residual fragments after kidney stone treatment. An earlier study showed that UP increased the fragment passage rate by 58% and reduced risk of relapse by 70% vs untreated controls with minor associated adverse events (AEs). This study presents a second, independent trial of UP to demonstrate replication of those results and effective training of a novice team of users.

What We Found: The Figure presents the outcomes of this multicenter, open-label, randomized, controlled trial. Repositioning of residual fragments $\leq$ 5 mm resulted in a 66% difference in fragment passage rate between the treatment group and the control group. These fragments remained a median of 6 months after surgery before study enrollment and, thus, were unlikely to pass spontaneously. AEs were mild and self-resolving, and all participants tolerated the procedure well.

Limitations: This was a small study of 24 participants, and few of the participants were non-White, which attenuates generalization of the results. However, our objective was replication of the short-term results from a larger study, and no significant difference in outcomes or AEs was noted. The urologists and participants in this study were not blinded.

Endpoint	Treatment N = 12	Control N = 12	Risk Estimate OR (95% CI) [P value]*
Primary Effectiveness: Fragment passage within 3 weeks – n (%)  Mid-treatment void into strainer	10 (83.3)	2 (16.7)	24.9 (2.9-214) [P=0.003] 66% increase in passage rate
Decrease in stone burden on imaging within 90 days – n (%)  Pre-treatment Post-treatment	9 (75.0)	1 (9.1)**	29.9 (2.6-343) [P=0.003]
Primary Safety: Serious Adverse Events (SAEs) – n	0	0	N/A***

*Odds ratio – OR, confidence interval – CI. P-value calculated by Fisher's exact test.
**One subject in the control group failed to obtain follow-up imaging.
*** Too few events to calculate OR.

Figure. Outcomes. N/A indicates not applicable.

Interpretation for Patient Care: UP has been previously shown to be safe and effective. Here, a group of clinicians and ultrasonographers newly trained to the technique replicated these results following the same research protocol. These results contributed to Food and Drug Administration clearance of the first UP device, and with trials by others, lay the groundwork for broad clinical use. UP is part of a new generation of ultrasound-based stone treatment that includes burst wave lithotripsy to fragment stones before clearing the fragments with UP.

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A Randomized Controlled Trial of Ultrasonic Propulsion–Facilitated Clearance of Residual Renal Stone Fragments vs Observation

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Conflict of Interest Disclosures: The Authors have no conflicts of interest to disclose.

Ethics Statement: This study received Institutional Review Board approval (University of Washington IRB No. 00002746; VA IRB No. 01671).

Author Contributions:

Conception and design: Yang.

Data acquisition: Yang, Keating, Honssinger, Managuli.

Data analysis and interpretation: Desai, Yang, Holt.

Drafting the manuscript: Desai, Yang, Managuli.

Critical revision of the manuscript for scientific and factual content: Desai, Yang, Keating, Honssinger, Holt.

Supervision: Desai, Yang, Keating, Honssinger.

Statistical analysis: Yang, Holt.

Image analysis and clinical study: Managuli.

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Purpose: In patients with residual stone fragments, ultrasonic propulsion (UP) increased the fragment passage rate by 58% and reduced risk of relapse by 70% vs untreated controls with minor associated adverse events (AEs). This study presents a second, independent trial of UP to demonstrate replication of those results and effective training of a novice team of users.

Materials and Methods: This was a multicenter, prospective, open-label, randomized, controlled trial. Adults with residual fragments $\leq$ 5 mm seen on clinical imaging at least 4 weeks post lithotripsy were enrolled. The treatment group underwent UP; the control group did not. The effectiveness end points included the proportion of subjects reporting visual observation of stone passage within 3 weeks post procedure (treatment group) or randomization (controls) and the reduction in stone burden on follow-up imaging captured within 90 days post procedure/randomization. The safety end points were AEs within 3 weeks post procedure/randomization. The Fisher exact test was used for comparison.

Results: The trial was conducted April to October 2024. Fragments remained a median of 6 months after surgery before study enrollment. Ten of 12 treated participants passed fragments vs 2 of 12 controls ($P = .003$). Nine of 12 treated participants saw stone burden reduction on imaging vs 1 of 11 controls ($P = .003$). All AEs were mild, occurring in 7 of 12 treated participants and 4 of 12 controls.

Conclusions: Consistent with the index study, UP conducted by an independent group of operators demonstrated a higher rate of fragment passage and greater reduction in stone burden after UP compared with controls, with minor associated risk.

Key Words: kidney stones, ultrasound, lithotripsy, residual fragments, renal calculi

Lithotripsy treatments for nephrolithiasis commonly leave residual fragments[1,2] and those remaining in the upper collecting system longer than 3 months are unlikely to spontaneously pass.[3] Upward of 39% of lithotripsy procedures are repeated within 120 days, for residual stones,[4] and 21% to 59% of patients with untreated residual stones return for additional care within 5 years.[1]

Given these data, better clearance of residual fragments would be expected to minimize the need for additional care, including surgical intervention. Nonsurgical, noninvasive techniques

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such as diuresis, postural inversion, and flank percussion have shown mixed results in facilitating residual stone passage and reduction in fragment burden.[5,6] Shock wave lithotripsy has also been applied at low amplitude to facilitate passage of residual fragments by "stirring up" fragments rather than breaking them.[7] At the time of this study, ultrasonic propulsion (UP) was an investigational procedure that used real-time ultrasound imaging and transcutaneous, focused ultrasound waves to move fragments out of calyces where they have collected and into the renal pelvis to facilitate stone passage.[8-11] A UP device has since been cleared by the US Food and Drug Administration for this indication in adults after stone breaking surgery.[12] The procedure can be performed in the clinic, without anesthesia. A recent study showed that UP increased the fragment passage rate by 58% and reduced 3-year stone-related events by 70% in the treatment group relative to the concurrent control group, with minimal added risk.[13] We sought to test in a randomized controlled trial whether the (short-term) fragment passage results could be replicated in a separate cohort of patients and with a group of UP operators distinct from the index study.

MATERIALS AND METHODS

This study was an investigator-initiated, multicenter, open-label, randomized, controlled trial (ClinicalTrials.gov, NCT02028559). The trial was approved by the Institutional Review Boards at the participating institutions (University of Washington, 00002746; VA Puget Sound Heath Care System, 01671). The device was made by the University of Washington (UW) team, and the study was conducted under an investigational device exemption from the US Food and Drug Administration and sponsored by a UW investigator. Although the principal investigator and investigational device exemption sponsor remained the same as in the study by Sorensen et al,[13] an entirely new research team of clinicians and ultrasonographers was trained by the sponsor and conducted this study.

Eligibility Criteria

We enrolled ambulatory participants of age older than 18 with residual kidney stone fragments visible on a recent (within 6 months of enrollment, mean 70 days) clinical imaging examination. Participants were at least 4 weeks after stone surgery, which included ureteroscopy, shock wave lithotripsy, or percutaneous nephrolithotomy. It was confirmed with the referring physician or through operative notes that all stones were broken into individual fragment sizes smaller than 5 mm, although collections larger than 5 mm of small (<5 mm individual) fragments were eligible. Persons taking anticoagulants were excluded. Although not specifically excluded, no person with a solitary kidney or a ureteral stent was enrolled.

Procedures

We performed a screening ultrasound examination with the investigational device on all participants to confirm an ultrasonic view of fragments within the target depth (4 cm-10 cm from the skin surface). Participants without stone visualization were excluded. Eligible participants were then randomized 1:1 to the treatment or control group per one central computer-generated schedule. The study team was blinded to the randomization schedule and block size, which was 4. Once the randomization envelope was opened, the study team and participant were unblinded to the group assignment. For the treatment group, the day of the procedure was defined as the procedure day; per protocol, this was to be within 3 days of randomization. For the control group, the day of randomization was defined as the procedure day. All participants were encouraged to drink fluids before the ultrasound (screen) imaging and before the UP procedure (treatment-group only). Pain was assessed from 0 (no pain) to 10 (maximum pain) before screening, after screening, and before/after the investigational procedure (treatment group only), and the participants' skin at the ultrasound transducer site was observed before screening, after screening, and before/after the investigational procedure (treatment-group only). All participants were provided urinary strainers and instructed to monitor for fragments, including during the study session.

We contacted participants weekly for 3 weeks post procedure to assess for adverse events (AEs) and stone passage. AEs were queried using a script of 10 common surgery and stone-related symptoms, along with any other reported events.[14] Clinical imaging was scheduled at least 4 weeks but within 90 days post procedure to detect hydronephrosis or hematoma. Stone burden was also noted and compared with preprocedure imaging. If feasible, the same imaging modality (ultrasound, plain film X-ray, plain film X-ray plus ultrasound, or CT) was used pre procedure and post procedure to enable direct comparison. Participants' medical records were reviewed out to 90 days post procedure for additional AEs related to the procedure or stone disease. A stopping rule was in place if any device-related significant AEs were experienced. Three independent experts blinded to the participants' randomization group adjudicated imaging (radiologist), safety (nephrologist), and stone passage (urologist) events. As part of their clinical care, participants were offered metabolic evaluation and education on appropriate dietary, medical, and fluid consumption interventions for stone prevention.

Intervention

The investigational device included a central, in-line commercial imaging transducer coaxially aligned with a surrounding, 55 mm diameter, annular therapy transducer.[8] The entire assembly was hand-held. The device operated similarly to a diagnostic ultrasound instrument.[15] Gel and transducer were placed against the participant's skin. The target fragment collection was visualized with conventional ultrasound imaging techniques and positioned within the target zone.[11] When a switch was depressed, 25 ms, 350 kHz ultrasound pulses at a maximum pulse intensity of 200 W/cm^2 were delivered. The therapy pulses were interleaved with imaging pulses for real-time image guidance; a single pulse ensemble could be delivered up to 3 seconds.[8] The

scattering of therapy pulses from the fragments introduces a force on the fragments that causes them to move away from the transducer.[8] The operator retargets and repeats the process as needed.[9] The total ultrasound therapy exposure was limited to 5 minutes. Participants were most often positioned in a lateral decubitus position with the bed tilted head down and the transducer on their abdomen under the ribs; however, several participant and transducer positions were used during each treatment. Since the participant and study team could visualize fragment motion on the ultrasound screen, there were no masking and no attempt at sham treatment.

UP Training

Two training sessions were conducted before the trial that included a 20-minute slide presentation by the sponsor and hands-on demonstration. The sonographers participated in one of 2 training sessions before the trial. The urologists participated in both. Under guidance from an expert sonographer, the trainees each completed stone expulsion on a mannequin phantom and proficiency in the alignment technique on a volunteer. An experienced sonographer was present with each trainee during the first several procedures for guidance, and afterward as needed.

Outcomes

The primary effectiveness end point was the proportion of participants who reported visual observation of stone passage within 3 weeks of the procedure (treatment group) or randomization (control group). In the index study, visualized stone fragment passage within 3 weeks of UP treatment was associated with long-term reduction of stone relapse events.[13] Documenting stone passage was cumulative, so a participant reporting fragment passage at week 2 but not at week 3 was classified as having successfully passed fragments. In addition, effectiveness was evaluated by the reduction in stone burden on follow-up imaging as adjudicated by an independent radiologist blinded to the treatment group.

The primary safety end point was the number of participants reporting any procedure or device-related event meeting the definition of serious adverse events (SAEs) with onset within 3 weeks after the procedure (treatment group) or randomization (control group). A priori SAEs of interest included, but were not limited to, skin burn, clinically significant hematuria, renal injury requiring intervention, or sepsis. The secondary safety end point was the number of participants reporting any AEs with onset within 3 weeks after the procedure (treatment group) or randomization (control group).

Sample Size Calculation

The power calculations are based on stone passage results of a previous UP study that showed a stone passage rate of 63% in the treatment group vs 5% in the control group.[12] Power calculations and statistical simulations identified that a minimum of 12 participants per group would provide the replicate trial a statistical power of 83% with a type 1 error rate of 0.05 under a χ^2 test assumption. This accounts for measuring association in a small sample size through the Fisher exact test.

Statistical Analysis

Demographic and clinical variables were summarized by count and percentage for categorical variables and by median and IQR for continuous variables.

The effectiveness end points were binary end points calculated as the number of participants who reported passage of stone fragments during the 3-week follow-up or who showed a stone burden reduction on follow-up imaging, divided by the total number of participants randomized to that group. The proportion was calculated for both the treatment and control groups and evaluated using a Fisher exact test. Risk estimates for likelihood of effectiveness end points were determined using logistic regression.

The primary safety end point was a binary end point, calculated as the participant-level presence or absence of procedure or device-related SAEs through 3 weeks post procedure.

The secondary safety end point was the tabulation of participant-level presence or absence of any AEs without statistical analysis. Risk estimates for likelihood of SAE/AE end points were determined using logistic regression. All analyses were performed with SAS software, version 9.4 (SAS Institute).

RESULTS

Participant Disposition and Baseline Characteristics

The trial was conducted from April 3, 2024, through October 21, 2024. A total of 27 participants were enrolled (Figure). Three participants were withdrawn from study before randomization for the reasons listed. Complete end point data were available from all randomized participants except a single-control subject without follow-up imaging, precluding stone burden assessment. A protocol deviation occurred because of 2 participants in the control group receiving imaging within 4 weeks for clinical concerns. A protocol deviation also occurred for a participant in the treatment group due to the UP procedure delayed more than 3 days after randomization for clinical concerns.

Overall, the baseline characteristics (Table 1) were representative of the population following up from stone surgery (Supplementary Material, Table S1, https://www.jurology.com).

Outcomes

Outcomes are given in Table 2. For the primary effectiveness end point, 8 more participants passed fragments in the treatment group than in the control group ($P = .003$). Eight more participants had a reduction in stone burden in the treatment group compared with the control group ($P = .002$). Movies showing fragment motion captured from the UP device in real time and photographs of fragments passed by the participants are included in the Supplementary Video. One subject in the control

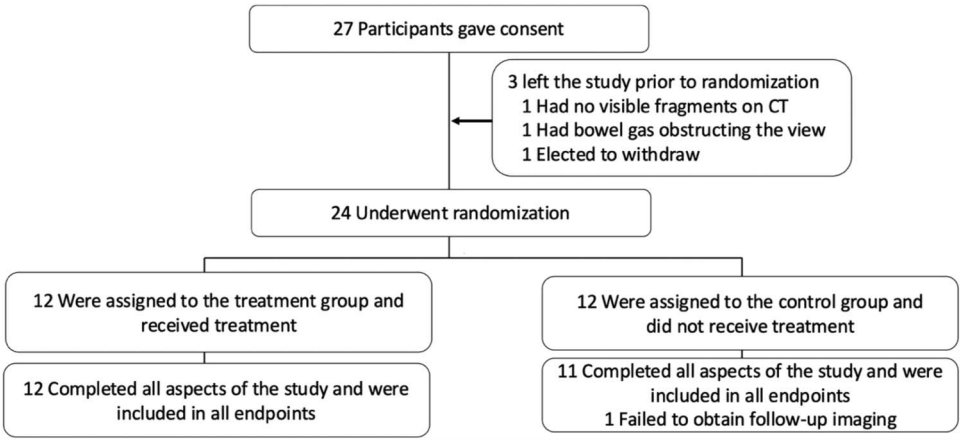

Figure. Enrollment and randomization.

group reported passing fragments without photographic confirmation, and postprocedural imaging did not identify a reduction in stone burden. Two subjects in the treatment group passed fragments without a measured reduction in stone burden on postprocedural imaging. This included one subject who passed in clinic the considerable fragment collection shown in Supplementary Video. The mean screening time was 11 ± 4 minutes, and the mean procedure duration was 64 ± 34 minutes.

Table 1. *Baseline Clinical Characteristics*

	Treatment (N = 12)		Control (N = 12)	
Age, median (IQR), y	70	(70-75)	64	(55-67)
Female sex, No. (%)	6	(50)	6	(50)
Ethnicity, Hispanic, No. (%)	1	(8.3)	0	(0)
Race, No. (%)				
White	9	(75)	10	(83.3)
Black/African American	1	(8.3)		
Asian			2	(16.7)
Pacific Islander/Native American	1	(8.3)		
More than 1 race	1	(8.3)		
BMI, median (IQR), kg/m^2	27.7	(24.4-30.2)	27.9	(24.3-30.9)
Stone history, No. (%)				
Bilateral stones on pre-enrollment imaging	8	(66.7)	7	(58.3)
Recurrent stones on enrollment	6	(50)	11	(91.7)
On medications for stone prevention	3	(25)	5	(41.7)
Primary surgery, No. (%)				
Ureteroscopy	9	(75)	9	(75)
Shock wave lithotripsy	3	(25)	1	(8.3)
Percutaneous nephrolithotomy			2	(16.7)
Median days between surgery and randomization (IQR)	181	(146-414)	188	(177-230)
Target fragment clusters				
Upper pole location[a], No. (%)	0	(0.0)	3	(25.0)
Interpole location[a], No. (%)	4	(33.3)	4	(33.3)
Lower pole location[a], No. (%)	11	(91.7)	9	(75)
Left side, No. (%)	9	(75)	7	(58.3)
Maximum size, median (IQR), mm[b]	7.7	(6.4-9.4)	6.8	(5.0-8.8)
No. of clusters, median (IQR)	1	(1-2)	2	(1-2)
Most recent preprocedure imaging, No. (%)				
CT	8	(66.7)	5	(41.7)
Ultrasound	1	(8.3)	2	(16.7)
Ultrasound and plain film x-ray	3	(25.0)	5	(41.7)
Stone composition, No. (%)				
Calcium oxalate	9	(75)	7	(58.3)
Calcium phosphate	2	(16.7)	1	(8.3)
Uric acid			1	(8.3)
Other/unknown	1	(8.3)	3	(25)

Data were obtained from participants' medical records.
[a] Subjects could have fragment collections in more than 1 pole.
[b] Size of the collection of fragments. Fragments within the collection were confirmed <5 mm.

For the primary safety end point, there were no subjects in either group with skin burn, clinically significant hematuria, renal injury requiring intervention, clinically significant hematoma, sepsis, or any other procedure-related or device-related event meeting the definition of a SAE. AEs were mild and self-resolving and did not differ between groups affecting 7 of 12 participants in the treatment group and 4 of 12 participants in the control group ($P = .22$). All AEs were classified as Clavien-Dindo Grade 1. Pain and hematuria were more common in those who passed fragments vs those who did not (16.7% and 8.3%, respectively), but these rates were not statistically different. Two participants in the treatment group reported mild discomfort during the procedure. Two additional participants in the treatment group reported a mild (1) and moderate (1) increase in their pain level after the procedure vs none in the control group after screening. After the procedure, one treated participant-reported instant relief from 4 months of discomfort, which continued though the 3-week follow-up.

No cases of hydronephrosis or hematoma were identified in the follow-up imaging. In the 90-day follow-up, no participants in the treatment group compared with 3 participants in the control group had an unscheduled health care encounter for stone-related events, including symptomatic events and stone growth.

DISCUSSION

In this multicenter, randomized, controlled trial, participants with small, residual kidney stone

Table 2. *Outcomes*

	Treatment n = 12	Control n = 12	Risk estimate OR (95% CI)
Primary effectiveness: fragment passage, No. (%)	10(83.3)	2(16.7)	24.9 (2.9-214)
Decrease in stone burden on imaging, No. (%)	9(75.0)	1 (9.1)[a]	29.9 (2.6-343)
Primary safety: SAEs, No.	0	0	N/A[b]
Secondary safety: adverse event (any), No.	7	4	2.80 (0.53-14.73)
Specific type (not mutually exclusive), No.			
Pain	6	4	
Skin bruise	1	0	
Hematuria	1	0	
Constipation	1	0	
Voiding difficulty	0	0	

Abbreviations: N/A, not applicable; OR, odds ratio; SAEs, serious adverse events.
[a] One subject in the control group failed to obtain follow-up imaging.
[b] Too few events to calculate odds ratio.

fragments after lithotripsy were assigned to a treatment group in which they received the investigative UP procedure to reposition residual stone fragments for the purpose of facilitating passage, or to a control group, in which they did not receive the UP procedure. Fragments remained a median of 6 months post lithotripsy, so the fragments were unlikely to pass spontaneously. We found that the repositioning of residual fragments resulted in a 66 percentage point difference in fragment passage rate (83% vs 17%) between the treatment group and the control group. Correspondingly, 75% of participants in the treatment group showed a reduction in stone burden on follow-up imaging compared with 9% of participants in the control group. These short-term metrics correspond to long-term reduction in risk for stone-related events.[13] AEs were mild and self-resolving in both groups. In no cases did a repositioned fragment cause obstruction. All procedures were conducted in a clinic setting with subjects awake. All participants tolerated the procedure well and drove themselves home after treatment. No medications were given during or after the procedure.

UP is an investigational procedure that has been previously shown to be safe and effective for facilitating passage of residual fragments that remain at least 4 weeks after lithotripsy.[13] Here, a separate group of clinicians and ultrasonographers replicated these results following the same research protocol. The 66 percentage point difference in rate of fragment passage between the treatment and control groups reported herein is consistent with the 58 percentage point difference reported in the first randomized control trial by Sorensen et al.[13] Of note, none of the UP operators in this study had previous experience with UP for the clearance of renal stone fragments. However, with training, they collectively obtained similar results to the original study by a team of experienced device users. The research procedures were 64 minutes on average. It is expected that the procedure time will be shorter in clinical practice with improved workflow efficiency compared with a research study.

The rate of AEs was comparable between treatment and control groups in both studies with 50% of participants in the treatment group experiencing an AE in the current cohort and 63% in the first study.[12] In the current cohort, all AEs were grade 1, mild, and self-resolving. Two AEs in the control group in the study by Sorensen et al[13] were moderate and classified as Clavien-Dindo Grade II. The AEs were similar in both studies with the majority including mild discomfort associated with the procedure, discomfort/pain associated with passage of fragments, and hematuria.

This study was relatively small, and few of the participants were non-White, which attenuates generalization of the results. However, our objective was replication of the short-term results from a larger study,[13] and no significant difference in outcomes or AEs was noted. The urologists and participants in this study were not blinded. However, fragments were photographed in all treatment cases, and follow-up imaging demonstrated a greater decrease in overall stone burden in the treatment group, confirming the reported stone passage results.

UP is part of a new generation of ultrasound-based stone treatment modalities for awake patients that includes burst wave lithotripsy (BWL). BWL is used to fragment stones and has been demonstrated to be safe and effective for stones up to 12 mm in size.[15,16] UP is used to reposition small stone fragments to facilitate their passage.[11,15,16] Both technologies can be performed with the same machine and are synergistic.[11,17] The ultrasound pulses are shorter duration and higher amplitude in BWL, compared with UP.[11] The ultrasound technologies, which are in their early phases of commercialization,[12] hold the promise of safe, effective, clinic-based stone treatment.

CONCLUSIONS

Participants who underwent UP showed a higher rate of passage of residual kidney stone fragments and reduction in stone burden compared with those who received no treatment. The increase in stone fragment passage rate with the UP procedure was comparable with an index study that also showed the long-term benefit of reduced occurrence of future stone events.

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REFERENCES

1. EAU Guidelines. Edn. presented at the EAU Annual Congress Amsterdam. 2020. ISBN 978-94-92671-07-3.
2. Assimos D, Krambeck A, Miller NL, et al. Surgical management of stones: American Urological Association/Endourological Society Guideline, part I. *J Urol.* 2016;196(4):1153-1160. doi:10.1016/j.juro.2016.05.090
3. Osman MM, Alfano Y, Kamp S, et al. 5-Year-follow-up of patients with clinically insignificant residual fragments after extracorporeal shockwave lithotripsy. *Eur Urol.* 2005;47(6):860-864. doi:10.1016/j.eururo.2005.01.005
4. Kidney Stones 2017. In: Feinstein L, Matlaga B, eds. *Urologic Diseases in America. US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases*. US Government Printing Office; 2018; NIH Publication No. 12-7865.
5. Pace KT, Tariq N, Dyer SJ, Weir MJ, D'A Honey RJ. Mechanical percussion, inversion and diuresis for residual lower pole fragments after shock wave lithotripsy: a prospective, single blind, randomized controlled trial. *J Urol.* 2001;166(6):2065-2071. doi:10.1016/s0022-5347(05)65507-3
6. Chiong E, Hwee ST, Kay LM, Liang S, Kamaraj R, Esuvaranathan K. Randomized controlled study of mechanical percussion, diuresis, and inversion therapy to assist passage of lower pole renal calculi after shock wave lithotripsy. *Urology.* 2005;65(6):1070-1074. doi:10.1016/j.urology.2004.12.045
7. Keeley FX Jr, Tilling K, Elves A, et al. Preliminary results of a randomized controlled trial of prophylactic shock wave lithotripsy for small asymptomatic renal calyceal stones. *BJU Int.* 2001;87(1):1-8. doi:10.1046/j.1464-410x.2001.00781.x
8. Janssen KM, Brand TC, Cunitz BW, et al. Safety and effectiveness of a longer focal beam and burst duration in ultrasonic propulsion for repositioning urinary stones and fragments. *J Endourol.* 2017;31(8):793-799. doi:10.1089/end.2017.0167
9. Harper JD, Cunitz BW, Dunmire B, et al. First-in-human clinical trial of ultrasonic propulsion of kidney stones. *J Urol.* 2016;195(4 pt 1):956-964. doi:10.1016/j.juro.2015.10.131
10. Dai JC, Sorensen MD, Chang HC, et al. Quantitative assessment of effectiveness of ultrasonic propulsion of kidney stones. *J Endourol.* 2019;33(10):850-857. doi:10.1089/end.2019.0340
11. Hall MK, Thiel J, Dunmire B, et al. First series using ultrasonic propulsion and burst wave lithotripsy to treat ureteral stones. *J Urol.* 2022;208(5):1075-1082. doi:10.1097/JU.0000000000002864
12. Device Classification Under Section 513(f)(2)(De Novo). 2024. Accessed November 7, 2024. U.S. Food and Drug Administration. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN230082
13. Sorensen MD, Dunmire B, Thiel J, et al. Randomized controlled trial of ultrasonic propulsion-facilitated clearance of residual kidney stone fragments vs observation. *J Urol.* 2024;212(6):811-820. doi:10.1097/JU.0000000000004186
14. The U.S. Food and Drug Administration (FDA). ESWL 510(k) Guidance Document Entitled "Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi," issued August 9, 2000.
15. Harper JD, Lingeman JE, Sweet RM, et al. Fragmentation of stones by burst wave lithotripsy in the first 19 humans. *J Urol.* 2022;207(5):1067-1076. doi:10.1097/JU.0000000000002446
16. Chew BH, Harper JD, Sur RL, et al. Break wave lithotripsy for urolithiasis: results of the first-in-human International multi-institutional clinical trial. *J Urol.* 2024;212(4):580-589. doi:10.1097/JU.0000000000004091
17. Harper JD, Dunmire B, Thiel J, et al. Facilitated clearance of small, asymptomatic renal stones with burst wave lithotripsy and ultrasonic propulsion. *J Urol.* 2025;214(1):41-47. doi:10.1097/JU.0000000000004533