

New noninvasive technique provides effective treatment for urinary stones

September 11 2024



Break Wave device. A, The imaging probe (left) and therapy probe (right). B, The imaging probe clicks into the center of therapy probe for treatment. C, The therapy probe and foot pedal are plugged into the therapy generator. D, The entire device required for treatment. E, An optional positioning arm may be attached to the clinic bed and used to assist in positioning. Credit: *Journal of Urology* (2024). DOI: 10.1097/JU.0000000000004091

A noninvasive ultrasound technology called Break Wave lithotripsy (BWL) offers a safe and effective new option for treatment of urinary stones, [reports](#) a clinical trial in the October issue of the *Journal of Urology*.

"In this initial experience, BWL provided a high treatment success rate, using a portable technology that can be used in a range of settings, without the need for anesthesia" comments lead author Ben H. Chew, MD, MSc, of the University of British Columbia, Vancouver, Canada.

Alternative approach to noninvasive treatment of urinary stones

Urinary stones are a common clinical problem and a major reason for emergency department (ED) visits. Treatment options include surgery (ureteroscopy), or for some patients, extracorporeal shockwave lithotripsy (SWL), which uses high-pressure ultrasound waves to fragment stones so they can pass through the urinary system. Although SWL is noninvasive and effective, it has some disadvantages: The equipment is large and expensive, and the procedure usually requires some kind of anesthesia and a surgical suite.

Rather than shockwaves, BWL uses low-pressure ultrasound waves to target and fragment urinary stones. Break Wave lithotripsy is delivered using a smaller and less costly mobile unit, allowing treatment to be performed in a range of locations outside of an operating room. In 2022, the BWL system received Breakthrough Device Designation from the US Food and Drug Administration.

Dr. Chew and colleagues report the "first-in-human" clinical trial of

BWL. The study included 44 patients at five hospitals across North America with stones located in the kidney (57% of patients) or ureter (43%). All patients chose to undergo BWL after discussion of other options (ureteroscopy or conventional SWL). Stones were treated for a total of 30 minutes under real-time ultrasound targeting.

BWL may lower costs and provide more timely care for urinary stones

Break Wave lithotripsy was effective, with evidence of fragmentation in 88% of patients. After treatment, most patients had fragments small enough to pass through the urinary system: four millimeters or less in 70% of patients, and two millimeters or less in 51%. On follow-up CT scans, 49% of patients were completely stone-free.

After the first several cases, 36 patients were treated with "optimized" ultrasound dose settings, achieving a fragmentation rate of 92%. Seventy-five percent of patients had fragments measuring four millimeters or less, while 58% were completely stone-free. As expected, success rates were higher for patients with stones located in the distal ureter, compared to stones in the lower pole of the kidney. Complications were generally mild, with no serious adverse events.

Through 90 days' follow-up, only 7% of patients required further treatment for the target [stone](#). In most patients, BWL could be performed without anesthesia—either with no medications or only a mild pain reliever. In four patients with severe, acute pain, BWL was successfully carried out in the ED.

In this initial clinical study, BWL appears to be a safe and effective new option for treatment of urinary stones. Treatment can be conveniently performed in the ED, medical office, or other settings, without the need

for anesthesia or sedation. Dr. Chew comments, "The BWL technique—together with other developing technologies such as ultrasonic propulsion—has the potential to provide effective, noninvasive treatment for patients with kidney and ureteral stones, reducing resource burdens and enabling more timely care."

More information: Ben H. Chew et al, Break Wave Lithotripsy for Urolithiasis: Results of the First-in-Human International Multi-Institutional Clinical Trial, *Journal of Urology* (2024). [DOI: 10.1097/JU.0000000000004091](https://doi.org/10.1097/JU.0000000000004091)

Provided by Wolters Kluwer Health

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