

Toward Comprehensive Kidney Stone Disease Management Detection, Propulsion + Comminution of Kidney Stones with Ultrasound

Kennedy Hall: Kidney stones are so common in the emergency department. Responsible for over a million visits a year.

Narrator: Kidney stones – small, but very painful, often requiring emergency treatment and surgery.

Hall: One in ten adult males can expect to develop a kidney stone over their lifetime. It's excruciating pain.

Kenneth Jaffe: Many years ago, I was diagnosed with having idiopathic hypercalcaemia, which has resulted in quite a burden of kidney stones over the last thirty years."

Narrator: In 2014, Ken Jaffe participated in the first-ever FDA-approved human clinical trial of non-invasive focused ultrasound used to push, or reposition, kidney stones. Ken Jaffe came to the trial with kidney stones.

Jaffe: There was no pain involved and at the conclusion of our first session, I myself, as well as the other investigators in the room, had a chance to see the stones move from their initial position.

Mike Bailey: These are your stones, Dr. Jaffe, that you gave to us immediately following the procedure. So that was about 45 minutes after we started."

Narrator: In the trials, ultrasound techniques developed at the Applied Physics Laboratory at the University of Washington succeeded in imaging and moving kidney stones in 14 of 15 human subjects, including one large stone measuring 10 mm, all with no pain or adverse events.

Four out of six post-surgery subjects successfully passed more than 30 stone fragments.

And in four subjects, what appeared to be a single large unpassable stone was shown to be smaller fragments – also successfully passed.

Hunter Wessells: Only one patient or maybe two felt anything at all and it was only a momentary twinge. The more exciting thing really was that we could move stones. And in almost every patient, we could reposition stones.

Barbrina Dunmire: This is a new application that the FDA has not seen before. And so we need to demonstrate that it is safe and effective for use in humans, that there is no injury to the tissue, there's no discomfort to the patient and that there's no lasting effects after the procedure.

Narrator: At APL's Center for Industrial and Medical Ultrasound, research continues on how to improve ultrasound imaging of kidney stones.

Julianna Simon: I'm working on improving kidney stone detection through this ultrasound twinkling artifact – which, if you image the stone with color, shows the stone as rapidly changing color. So it makes it really easy for a non-expert reviewer to say that's a kidney stone.

Jeff Thiel: In the last couple of years, we have improved the twinkling signal on the stones to readily identify them. And be more confident that we are looking at a kidney stone."

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Narrator: Another target goal: breaking up kidney stones.

Adam Maxwell: We've developed a technology called burst-wave lithotripsy. It's a new experimental procedure that we think can be used non-invasively to fragment kidney stones. If you have a large stone, you may want to break the stone into smaller fragments and then push those fragments out of the kidney – all non-invasively. So our eventual goal is to develop a platform technology that will bring these different ideas together to be able not only to break stones but to use ultrasonic propulsion and imaging technologies to detect and target stones all into one ultrasound unit that can be used for comprehensive stone management.

Narrator: The success of the 2014 human subjects trials was a major step forward. It was made possible in large measure by continued support from NASA. The space agency envisions a small, easy-to-use, hand-held device capable of diagnosing and treating kidney stones in astronauts in space – where there is no hospital emergency room down the street.

Dorit Donoviel: It's been a real honor and a pleasure to work with the Applied Physics Lab here and Larry Crum and Mike Bailey and the group. I think the tax dollars spent by NASA in this project really are not just helpful for the space program but also patients on Earth and the clinicians doing their best to help them.

Larence Crum: We have been privileged for many years to be involved with the National Space Biomedical Research Institute. The thing that we're most interested in is medical ultrasound and how it applies to a clinical situation. We consider this a revolution in medicine.

Hall: Ultrasonic propulsion changes the game. It gives us the opportunity to reposition the stone or relieve the obstruction and potentially make somebody feel no pain.

Craig Mundie: I had no pain.

Narrator: Trials subject Craig Mundie felt no pain.

Mundie: There was almost no sensation at all. The only thing I recall was sort of a warming sensation.

Jaffe: I knew I was going to continue to have this burden of kidney stones. This was going to go on. So this was technology that was extremely relevant to my personal life.

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This is APL — The Applied Physics Laboratory at the University of Washington in Seattle.