

Urology Times®

The Leading News Source for Urologists

UrologyTimes.com | NOVEMBER 2015 VOL. 43, NO. 12

BREAKING NEW GROUND (& kidney stones) WITH ULTRASOUND

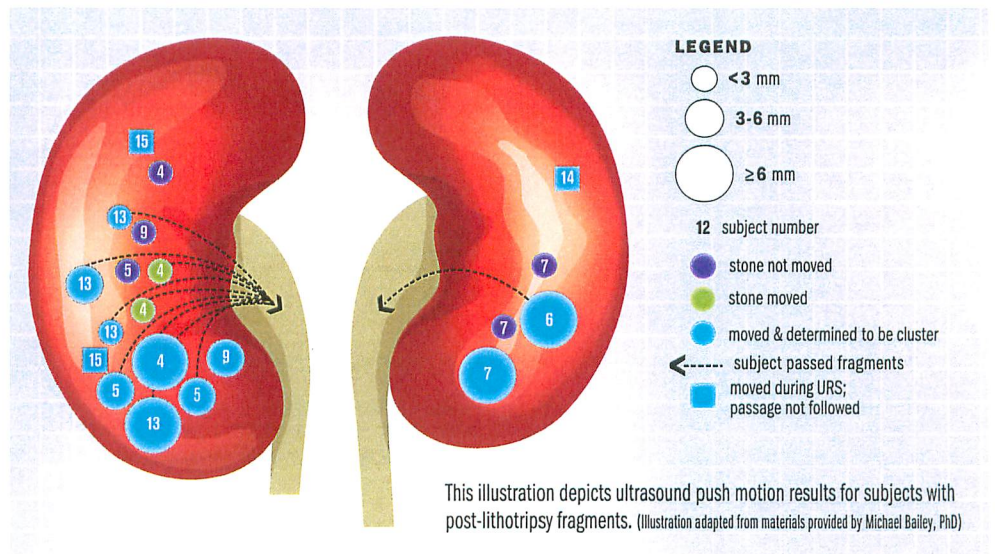
Q&A | Ultrasound for Stones

Michael Bailey, PhD



Novel ultrasound-based techniques for propelling and breaking kidney stones could soon join ESWL and URS in the urologist's treatment armamentarium. Michael Bailey, PhD, discusses how these technologies work, what they're capable of, and where they are in development. Dr. Bailey is assistant professor of mechanical engineering and adjunct assistant professor of urology at the University of Washington, Seattle.

For the full article, please turn to page 24



PRIVATE PRACTICE vs. EMPLOYMENT: 12 LESSONS LEARNED

Lisette Hilton | UT CORRESPONDENT

National Report—The pressure is on for many U.S. urologists to take a hard look at whether to practice privately or as part of a hospital system.

We asked two urologists to weigh in about the lessons they learned in transitioning from one practice type to another. They tackled six topics important to all urologists, ranging from administrative woes to the impact on patients of choosing one model over the other.

Our experts spoke on the topic at the 2015 American Association of Clinical Urologists' Annual State Advocacy Conference.



In hospital-based practice

Brian Jumper, MD, is employed by Maine Medical Partners Urology, which is part of Maine Medical Center in Portland and part of the state-wide Maine Health hospital system. Dr. Jumper has been in hospital-based practice as a full-time faculty member in Maine Medical Center's urology residency program for 7 years.

Before that, he was in private practice for 19 years.



Back in private practice

Michael Fabrizio, MD, CEO of the 30-urologist group Urology of Virginia, joined a health system in Virginia in 2008 amid what he calls an acquisition war between rival hospitals. Dr. Fabrizio said becoming employed seemed logical at the time, given his concerns about the complex and costly administrative aspects of remaining in private practice, such as electronic medical

Please see **PRIVATE V. EMPLOYED**, on page 26

Inside NOVEMBER 2015 • VOL. 43, NO. 12

ROBOTICS

6 Robotic prolapse repair found safe, durable

MEN'S HEALTH

14 The 5 keys to a successful men's health center

CODING Q&A

16 How ICD-10 is changing how you do Dx coding



MICHAEL BAILEY, PhD

Dr. Bailey was interviewed by *Urology Times* Editorial Consultant **Stephen Y. Nakada, MD**, The Uehling Professor and founding chairman of urology at the University of Wisconsin, Madison.

Breaking new ground (and kidney stones) with ultrasound

Q: How did you become involved with stone disease?

A: I have a PhD in mechanical engineering, and I've studied sound. I've always had an interest in medical ultrasound. I'm on the Executive Council of the Acoustical Society of America, and I served on the American Institute of Ultrasound in Medicine's Bioeffects Committee.

As someone interested in sound, I think shock wave lithotripsy is an amazing technology for breaking kidney stones. About 25 years ago, when lithotripsy was still new, I became involved with Dr. James Lingeman's research group, studying who lithotripsy was most effective with and what its safety limits were. That research program, which was funded by the National Institute of Diabetes and Digestive and Kidney Diseases, was a collaboration among clinicians, basic science anatomists, and biologists at Indiana University as well as shock wave physicists at the California Institute of Technology and engineers from the University of Washington who knew ultrasound and acoustics.

Q: Please describe how you're using ultrasound to propel and break up stones.

A: We have two new technologies we're developing, and they come out of the 20 years of lithotripsy research we've done.

With the first technology—ultrasonic propulsion—the user places the handheld probe

against the patient's skin, and the probe emits an ultrasound wave to reposition stones and to create real-time ultrasound imaging to target and observe stone movement. When the user touches the screen in the location of the stone, in between imaging pulses, a longer duration push pulse is focused on the stone. The push pulse reflects from and imparts momentum into the stone, which makes the stone hop. We want to use this technology to expel small stones and fragments from the kidney to avoid surgery, to dislodge larger stones from an obstructing position in the ureteropelvic junction or possibly ureterovesical junction to relieve pain and avoid urgent surgery, and to improve access in a procedure like percutaneous nephrolithotomy.

With the second technology—burst wave lithotripsy (BWL)—broadly focused ultrasound is used to crumble stones into uniform small fragments. We took lessons we've learned from lithotripsy that enabled us to make a different device that pulverizes even the hardest stones quickly and completely in preliminary experiments. We use a broad beam width and longer duration pulse. We try to minimize cavitation in the tissue and limit cavitation to the surface of the stone. Even the hardest stones seem to be breaking.

Q: That's really fascinating and in many ways potentially groundbreaking. However, is the technique safe, and how do you know that?

A: The stone-breaking technology, BWL, is not as far along in development, but it utilizes low pressure—about 5 to 10 MPa—compared to lithotripters, which operate at 50 to 100 MPa. We have done limited animal studies, and we feel we have a safe range where we can break stones and not cause injury. We also have ultrasound feedback that allows us to see when cavitation that may cause injury occurs in the tissue. When cavitation is detected, the output is turned off, allowing cavitation to dissipate before resuming.

With ultrasonic propulsion, we have completed a clinical trial with 15 subjects and that

manuscript is in press in the *Journal of Urology*. There were no adverse events associated with the treatment. It's basically a diagnostic probe with diagnostic ultrasound output levels. So I think you would appreciate that it would probably be safe. It was performed in patients who were awake. They did not experience pain. There were two patients who felt some sensation in the kidney, but did not require stopping the procedure.

Q: That's great. Who should be performing these procedures?

A: Our primary "target audience" is urologists, who have been supportive of this technology from the beginning. This has grown out of urology research supported by the AUA and NIH/National Institute of Diabetes and Digestive and Kidney Diseases. We even have NASA funding because stones are a concern in space.

We do think it is urologists who are going to be responsible for the movement of the stones for any obstructions that could occur. In addition, though, if its effectiveness is established, there could be applications in the emergency department; emergency medicine physicians might use the technology to dislodge a large stone obstructing the ureteropelvic junction retrograde into the kidney to relieve pain and avoid the need for urgent intervention. The urologists would then schedule any necessary intervention for the stone and potentially use either of these new technologies.

Q: Of the potential uses for this technology, which do you think will have the greatest impact, and why?

A: I tend to follow what urologists tell me. For ultrasonic propulsion, I think interest is split almost equally between moving a large stone to relieve symptoms of obstruction and delay intervention and expelling small de novo stones or small fragments that might remain after lithotripsy to avoid additional intervention. We have also heard a list of other uses in which urologists are interested, such as accessing stones during surgery or facilitating lithotripsy in various ways.

UT EXCLUSIVE AUDIO

urologytimes.com/Bailey-interview

Listen to an excerpt from Dr. Nakada's interview with Dr. Bailey online.

We spun off a company out of the University of Washington called SonoMotion. I think the company will probably first focus on expelling fragments. Personally, I hope this comes to be seen like a toothbrush; you do this every so often and clean people out before they need surgery.

Q: What are the limitations of this technology?

A: It's still early, so we'll learn more about limitations. BWL in particular is in the early stages, but a lot of our effort is on feedback for when the stone is fully comminuted. For ultrasonic propulsion, we learned a great deal in the clinical trial. We learned we wanted to move more stone material more quickly. I don't think we appreciated how much debris might be left after lithotripsy. We built a system originally to steer one stone through a maze. In the trial, we saw we just needed to move more stone mass in the right direction and then the kidney could take it from there.

We had patients get off the table and pass stones immediately. Our post-lithotripsy patients passed over 30 fragments among them. There was a lot of small (about 2-mm) material that we were getting them to pass.

In terms of limitations for ultrasonic propulsion, although urologists are well trained in ultrasound, they're still not as familiar with it as computed tomography. The biggest challenge is aligning the direction of push with a path where the stone can travel. Finding the correct acoustic window can be challenging, as you have to work around the ribs. However, the lower pole is a pretty nice target because it's below the ribs and you're pushing in a favorable direction.

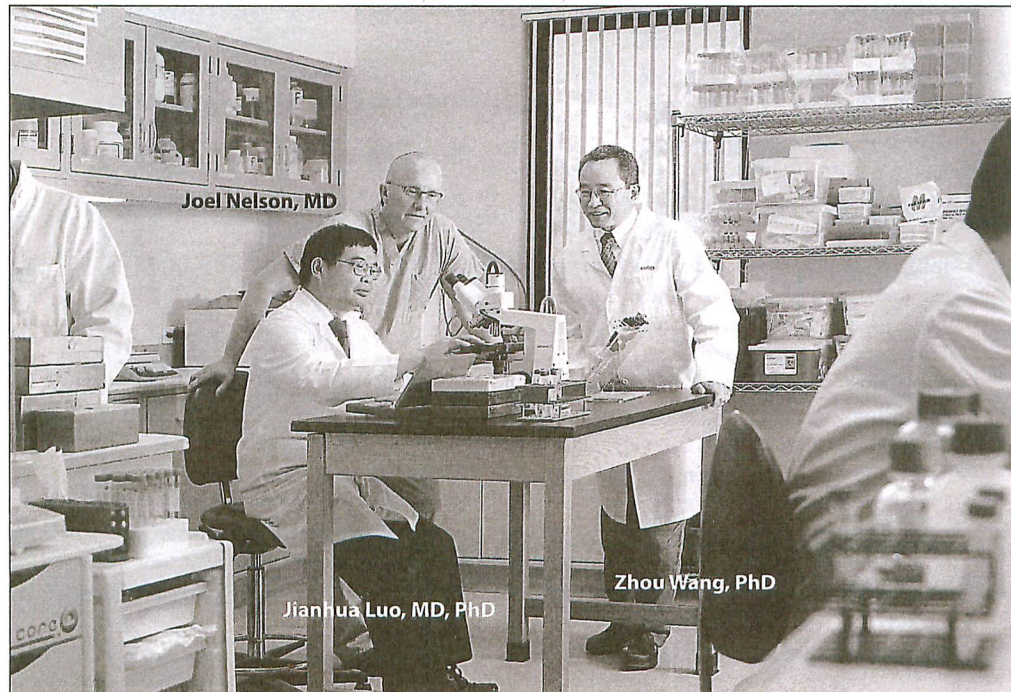
Q: What's next for this technology?

A: For ultrasonic propulsion, we have been

approved by the FDA for another 15 subjects at our institution. Our research group clearly learned a lot; we have safety headroom and we have clear steps we can take to improve the system based on what we learned. That gave us the confidence to let the university spin off the technology to SonoMotion Inc. We hope that will enable us to move quickly to get this in the hands of more users and obtain more

feedback on exactly where ultrasonic propulsion fits best in the management of stones. We hope this will take off commercially, so it can be used to help patients.

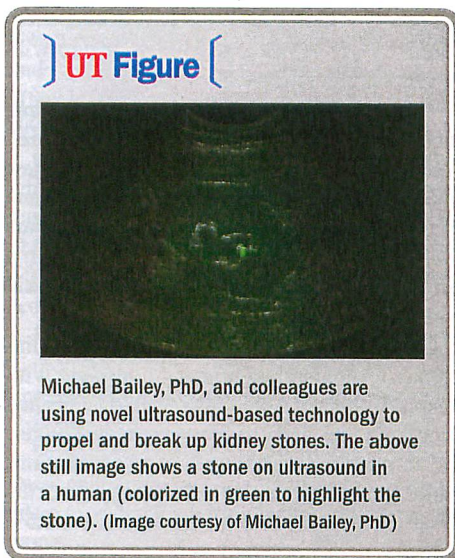
In addition, we're continuing to work on breaking stones, and we hope that in a couple of years BWL moves into a clinical trial so we can test if we have a better way of breaking stones. **UT**



Leading the way in finding new treatment models for prostate cancer.



At UPMC, our physician and researcher teams are working to better understand the mechanisms of prostate carcinogenesis and progression by studying major pathways, such as androgen receptor signaling, and developing new, targeted small molecule therapeutics. In addition, we are defining prostate cancer from a genomic perspective, and have discovered novel genomic abnormalities and genetic fusions associated with disease recurrence. Our ultimate goal is to find new prostate cancer treatments directed at those who require treatment to improve survival and quality of life. To learn more, visit UPMCPhysicianResources.com/Urology.



Michael Bailey, PhD, and colleagues are using novel ultrasound-based technology to propel and break up kidney stones. The above still image shows a stone on ultrasound in a human (colorized in green to highlight the stone). (Image courtesy of Michael Bailey, PhD)

UPMC LIFE CHANGING MEDICINE