Fiscal Year:	FY 2017	**Task Last Updated:**	FY 05/11/2017
PI Name:	Bailey, Michael R. Ph.D.		
Project Title:	Prevention of Renal Stone Complications in Space Exploration		
Division Name:	Human Research		
Program/Discipline:	NSBRI		
Program/Discipline--Element/Subdiscipline:	NSBRI--Smart Medical Systems and Technology Team		
Joint Agency Name:		**TechPort:**	Yes
Human Research Program Elements:	(1) **ExMC**:Exploration Medical Capabilities		
Human Research Program Risks:	(1) **Medical**:Risk of Adverse Health Outcomes & Decrements in Performance due to Inflight Medical Conditions (IRP Rev I) (2) **Renal**:Risk of Renal Stone Formation		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
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Zip Code:	98105-6698	**Congressional District:**	7
Comments:			
Project Type:	GROUND	**Solicitation:**	2012 Crew Health NNJ12ZSA002N
Start Date:	06/01/2013	**End Date:**	12/31/2016
No. of Post Docs:	12	**No. of PhD Degrees:**	2
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No. of Master's Candidates:	2	**No. of Bachelor's Degrees:**	4
No. of Bachelor's Candidates:	9	**Monitoring Center:**	NSBRI
Contact Monitor:		**Contact Phone:**	
Contact Email:			
Flight Program:			
Flight Assignment:	NOTE: Extended to 12/31/2016 per NSBRI (Ed., 3/11/16)		
Key Personnel Changes/Previous PI:			
COI Name (Institution):	Wang, Yak-Nam (University of Washington) Sorensen, Mathew (University of Washington) Khohklova, Vera (M.V.Lomonosov Moscow State University) Sapozhnikov, Oleg (University of Washington) Crum, Lawrence (University of Washington) Harper, Jonathan David (University of Washington) Kreider, Wayne (University of Washington)		
Grant/Contract No.:	NCC 9-58-SMST03402		
Performance Goal No.:			
Performance Goal Text:			

Task Description:

1. Specific aims
We will refine and validate probes to integrate with the NASA Flexible Ultrasound System (FUS) to address Exploration Medical Capabilities (ExMC) Gap 4.02 Nephrolithiasis.

AIM 1. Refine ultrasound probes to detect, reposition, and fragment kidney stones. AIM 2. Validate probes to visualize, reposition, and fragment stones. AIM 3. Refine and validate imaging to guide therapy.

2. Key Findings

A probe and software to image and reposition kidney stones were developed and integrated on a radiation hardened flexible ultrasound system (FUS) and demonstrated effectively on human subjects. A probe to image, reposition, and fragment stones was designed, fabricated, and integrated into an FUS and is currently in clinical trials to expel stone fragments. Software was developed and integrated on an FUS and validated in human subjects to improve kidney stone detection and size determination. The ability to reposition stones was also integrated into the partially completed NASA FUS with the NASA FUS probes and demonstrated. The work has garnered attention. Reports have been sent to NSBRI (National Space Biomedical Research Institute), FDA (Food & Drug Administration), NIH (National Institutes of Health), NASA, and OMB (Office of Management and Budget). Demonstrations have been conducted at American Urological Association (AUA) annual meetings each year, Congress twice, and several other professional societies. Over 40 papers have been published. Over 40 patent applications have been submitted. Students, residents, and fellows have trained on the project. Technology developed in this research has been licensed to a spin-off company SonoMotion Inc.

3. Impact

We have invented a technology to reposition kidney stones and demonstrated it works in people. In four of the cases, what appeared as one large stone on x-ray was two or three small passable stones. This had direct diagnostic benefit to these subjects and changed their course of treatment. In four other subjects, we moved stones out of the kidney, which they passed. This result was a direct therapeutic benefit to these subjects. One subject felt relief from a painful obstructing stone. We have shown we can produce a working prototype, develop sufficiently high-quality imaging to guide treatment, train new users, and conduct a successful clinical trial. We refined the system design, submitted for publication in vitro results quantifying the improvement, and entered a second clinical trial. The refined design also has the capability to fragment stones. This design is being commercialized. Specifically, we have now implemented our technologies with different probes making it efficient to add the probes NASA selects or to continue to refine the probes we can provide. Our imaging software can be added to an FUS or commercial imager. Our pushing capability has been added as a software upgrade to the FUS. Our advanced repositioning and fragmenting probe is readily integrated with any standard or FUS imager with minimal additional mass and software change to the system. Our final system and the system being commercialized, when validated in human in a flight analog, largely close the gap of nephrolithiasis or exploration mission and extends application to the emergency department on Earth. Our new stone sizing technique can be used on any imager by any user to improve the accuracy of stone size determination with ultrasound. Overestimated stone size leads to unnecessary surgeries, and underestimated stone size leads to obstructions and ER (emergency room) visits. Stone size similarly determines risk and course of action in space.

4. Proposed Research

We are conducting a clinical trial of S-mode software for automatic stone detection and stone sizing. We are conducting a clinical trial of expelling stone fragments. We have received approval and set up the infrastructure for an test of ultrasonic propulsion in an Emergency Department (ED) analog to a space emergency, and seek funding for that trial. We are testing safety and effectiveness in clinical simulation in animal studies of stone breaking to add this capability to our ED trial. The technology is also being tested for gallstones.

Rationale for HRP Directed Research:

Research Impact/Earth Benefits:

Kidney stones have long been near the top of NASA's list of concerns; mitigating Gap 4.02 medical condition Nephrolithiasis is a shall for all missions beyond the International Space Station (ISS). Likewise, stones have plagued humans since ancient Egypt. Currently, one in eleven Americans has suffered from stones -- more than have diabetes or cardiovascular disease. Dehydration, stasis, and bone demineralization are strong contributors to kidney stones, and occur in microgravity, increasing the risk of stones in space. Stones are often debilitating, and pilots cannot fly with stones. Stones occurred on a Russian space mission, and the mission was nearly aborted before the stone passed. Over 30 stones have occurred shortly following even short duration space flights. NASA has collected compelling evidence for concern on its website https:// . Additionally, since the website publication, the total number of astronaut stone episodes has more than doubled, and a drug introduced to combat visual impairment/intracranial pressure has exacerbated the risk. Science, experience, and the negative medical consequences support concern for the risk of stones in space. NASA and NSBRI have focused considerable attention on stones and made progress. However, there are many types of stone disease, and it is unlikely that stone disease will ever be completely prevented on Earth or in space. We propose a way to prevent or minimize the consequences of any stones that form while in space. The treatment for most kidney stones is to encourage natural passage. To quote NASA's expectations in space Based on current Lifetime Surveillance of Astronaut Health (LSAH) data, 80 to 85% of in-flight cases of nephrolithiasis are expected to be best case scenarios (defined as a renal stone that responds to conservative treatment, e.g., analgesics and hydration), and 15 to 20% would be worst case scenarios (defined as a renal stone that does not respond to conservative treatment, e.g., requires lithotripsy or surgical treatment). Even surgery leaves residual fragments that must pass. Our technology provides the capability to reposition stones within the kidney and ureter, which will enhance conservative treatment or surgery by accelerating and facilitating passage of stones or fragments. However, this does not have to be the only use. The technology can also be used to reposition a stone to a non-obstructing location within the kidney to postpone surgery or to accelerate passage through the ureter, as proposed here. Finally, the technology proposed in this grant also provides the capability to comminute the stone as in shock wave lithotripsy (SWL) with what we call burst wave lithotripsy (BWL).

Task Progress:	All tasks were completed. AIM 1. Refine the ultrasound probes to detect, reposition, and fragment kidney stones. Task 1.1. Select imaging probe for stone repositioning. We enabled the capability to push stones on the as yet incomplete NASA FUS system with the NASA GE C1-6 abdominal imaging probe. These results were reported in an NSBRI Advanced Technology Demonstration: Prevention of Renal Stone Complications in Space Exploration in August 2016. Deliverable of the grant The capability to reposition kidney stones noninvasively has been added to the NASA flexible ultrasound system. Task 1.2. Custom design probe to image, reposition, and fragment stones. We invented Burst Wave Lithotripsy which has fully comminuted stones of all compositions in under 20 minutes and has fragmented many stones in seconds. All work so far has been in water tanks or animals, not humans. The size fragments are controlled by the ultrasound frequency. The technique reduces peak pressure by 1/10th but increases pulse duration about five times and pulse repletion rate at least 20 times to deliver more energy more quickly and possibly without discomfort. AIM 2. Validate probes to visualize, reposition, and fragment kidney stones. Task 2.1. Validate capability to displace an obstructing stone. Task 2.2. Validate capability to displace a ureter stone. Task 2.3. Validate capability to comminute a stone. These tasks were completed. A small probe embedded centrally within the Burst Wave Lithotripsy (BWL) therapy probe connected to the Verasonics FUS system provides image guidance for BWL. We have targeted and fragmented human stones surgically placed in over 10 pigs. Preclinical test results have been submitted for publication. A clinical trial of the system is underway. AIM 3. Refine and validate imaging to guide therapy. Task 3.1. Refine and validate capability to measure the size of kidney stones. In a series of 3 papers, we demonstrated how ultrasound imaging can be optimized to accuracy similar to CT with user controls as well as software modifications. The imaging we have implemented on the Verasonics FUS appears to size stones more accurately than clinical imagers. Task 3.2. Refine capability to localize a stone. Task 3.3. Refine and validate capability to detect a ureter stone. We have developed enhanced B-mode, enhanced Doppler-based twinkling, and combined them into a stone specific imaging mode called S-mode. S-mode has been published. S-mode has been used to image stones in the kidneys and ureters in human subjects. In our most recent study of hundreds of imaging frames from 40 stones and 28 subjects, the signal to noise ratio of S-mode was ten times the grayscale SNR. This paper won Best Abstract at the Engineering and Urology meeting of the AUA in 2016.
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