

<b>Fiscal Year:</b>	FY 2012	<b>Task Last Updated:</b>	FY 01/11/2013
<b>PI Name:</b>	Crum, Lawrence A. Ph.D.		
<b>Project Title:</b>	Smart Therapeutic Ultrasound Device for Mission-Critical Medical Care		
<b>Division Name:</b>	Human Research		
<b>Program/Discipline:</b>	NSBRI		
<b>Program/Discipline--Element/Subdiscipline:</b>	NSBRI--Smart Medical Systems and Technology Team		
<b>Joint Agency Name:</b>	<b>TechPort:</b>	Yes	
<b>Human Research Program Elements:</b>	(1) <b>ExMC:</b> Exploration Medical Capabilities		
<b>Human Research Program Risks:</b>	(1) <b>Medical Conditions:</b> Risk of Adverse Health Outcomes and Decrements in Performance Due to Medical Conditions that occur in Mission, as well as Long Term Health Outcomes Due to Mission Exposures		
<b>Space Biology Element:</b>	None		
<b>Space Biology Cross-Element Discipline:</b>	None		
<b>Space Biology Special Category:</b>	None		
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<b>Zip Code:</b>	98105-6606	<b>Congressional District:</b>	7
<b>Comments:</b>			
<b>Project Type:</b>	GROUND	<b>Solicitation / Funding Source:</b>	2007 Crew Health NNJ07ZSA002N
<b>Start Date:</b>	08/01/2008	<b>End Date:</b>	09/30/2012
<b>No. of Post Docs:</b>	3	<b>No. of PhD Degrees:</b>	1
<b>No. of PhD Candidates:</b>	1	<b>No. of Master' Degrees:</b>	0
<b>No. of Master's Candidates:</b>	1	<b>No. of Bachelor's Degrees:</b>	0
<b>No. of Bachelor's Candidates:</b>	3	<b>Monitoring Center:</b>	NSBRI
<b>Contact Monitor:</b>	<b>Contact Phone:</b>		
<b>Contact Email:</b>			
<b>Flight Program:</b>			
<b>Flight Assignment:</b>	NOTE: End date should be 9/30/2012 (previously 7/31/2012) per NSBRI (Ed., 5/22/2012)		
<b>Key Personnel Changes/Previous PI:</b>			
<b>COI Name (Institution):</b>	Bailey, Michael ( University of Washington ) Carter, Stephen ( University of Washington ) Sapozhnikov, Oleg ( University of Washington )		
<b>Grant/Contract No.:</b>	NCC 9-58-SMST01601		
<b>Performance Goal No.:</b>			
<b>Performance Goal Text:</b>			

**Task Description:**

The major goal of this effort is to utilize existing ultrasound platforms and the concept of image-guided therapy to control traumatic bleeding, ablate benign and malignant tumors, and to diagnose and reposition kidney stones. We address (1) Lack of advanced therapeutic capability, (2) lack of capability to treat renal stones, and (3) lack of non-invasive diagnostic imaging capabilities. The original specific aims (SAs) are 1) Support ongoing leveraged efforts in Acoustic Hemostasis and High-intensity Focused Ultrasound (HIFU) Tumor Ablation by addressing fundamental scientific issues as well as to ensure National Space Biomedical Research Institute (NSBRI) relevance. 2) Develop methods and technologies that would enable detection of renal stones with ultrasound. 3) Develop technology and perform in vitro studies of stone comminution. 4) Utilizing technology and protocols developed in SAs 2 and 3, perform in vivo studies in a porcine model. The main findings and associated research productivity for year 4 are:

- We have continued to advance ultrasound technology to detect and reposition kidney stones. The imaging technology provides an alternative to imaging techniques that expose the patient to ionizing radiation on Earth and provides a user-friendly technique to detect even small stones in space. The repositioning technology provides an adjunctive treatment to surgery by which to facilitate the passage of residual fragments that may regrow to new stones, and provides a way to prophylactically remove small stones before they require surgery. The technology is also used to move a large obstructing stone to a non-obstructing location to delay the need for surgery. This year our major accomplishments were entering into the Food and Drug Administration (FDA) approval process for a human feasibility study and starting a company. In pigs we also moved a stone growing de novo, moved an obstructing stone, and moved a stone in the ureter.

- We contributed to the solicitation for a Flexible Ultrasound System (FUS), both as leaders in the platform and inventors of a required clinical capability (detecting and repositioning kidney stones), and an award for delivery of an FUS has now been granted.

- Developed a method and device to characterize the acoustic output of high intensity focused ultrasound (HIFU) devices. The University of Washington (UW) Center for Commercialization (C4C) has filed a provisional patent. The technique was added to the IEC TC87 62256 60601-2-62 standards document. The technology has now been demonstrated on several clinical HIFU systems. NIH (National Institute of Health) funding was obtained.

- Developed a method to accelerate and control tissue ablation with transcutaneous ultrasound. In particular, tissue was mechanically emulsified by millisecond bursts of HIFU at output levels that produce shock waves. C4C has filed a U.S. patent application. The Philips machine was modified to produce these outputs. Our method has several potential advantages over technique used in competitor's \$11 million start-up. This year we discovered and published the mechanism by which tissue is fractionated and joined University of Washington (UW) Urology in a proposal to develop urology cancer treatments.

- We published an explanation of the mechanism of the twinkling artifact (TA) that frequently occurs during Doppler ultrasound imaging of kidney stones. These findings lead to the conclusion that bubbles cause the twinkling artifact and as such we have developed and patented several algorithms to exploit this mechanism to better detect kidney stones. Because twinkling is seen on other calcifications in the body, the result also implies bubbles may be present throughout the body, which has significant implications for decompression sickness.

- Due to cost and concerns for repeated ionizing radiation exposure from CT (computed tomography) scans on Earth, ultrasound is often used for the initial evaluation and monitoring of kidney stone patients. In space ultrasound is the only option and size of the stone is critical in treatment planning. We published work, submitted a patent application, and began preliminary work to measure the inaccuracy of ultrasound in sizing stones and develop improvements.

- Obtained funding from U.S. Army to investigate the application of shocked ultrasound to slow bone loss in a murine paralysis model. Bone loss with our best but still not optimized exposure was less than 15% which was statistically significantly lower than the over 30% loss in the control.

- We published results in a porcine model to stop bleeding in a partial nephrectomy. We secured commercialization funding and contracted a vendor to build a refined system. We obtained NIH funding to develop the technology to clinical implementation. This is the same technology we developed with the military to stop bleeding on the battlefield and provides an avenue to develop an commercial off-the-shelf (COTS) device for NASA.

Proposed plan for the next year. We have developed extensive plans to continue forward and have submitted many proposals to continue funding. The efforts are on three fronts. One is to conduct a human feasibility study. The second is to start the company. The third is to secure NSBRI funding to develop the same capabilities for the FUS and to refine and test the system for NASA's unique applications. We were subcontract on one proposal to develop the FUS but did not receive that award. The NSBRI proposal aims are to refine and validate probes to detect, reposition, and fragment kidney stones.

Tasks are 1. Implement capability to image and reposition stones on the selected FUS manufacturer's state-of-the-art kidney imaging probe. 2. Integrate a clinical mechanically scanned 4D imaging probe with the FUS and refine and validate stone imaging and repositioning. 3. Develop and integrate a prototype 2D array probe to reposition and fragment stones. 4. Refine and validate capability to displace a large blocking stone, to detect a ureter stone, to displace a ureter stone, to expel a stone attached to tissue, and to measure the size of kidney stones.

**Rationale for HRP Directed Research:**

We have been encouraged by our interactions with the urology, ultrasound, and business communities that our technology to detect and reposition stones could significantly alter the way kidney stones are treated in clinical medicine. We have won awards in the six poster or business plan competitions we have entered. Most stones are small enough to pass naturally and thus patients are encouraged, through hydration, to try to pass the stone without intervention. This natural process might take 6-8 weeks and result in considerable discomfort to the patient over this interval. With our innovative technology, a stone could potentially be cleared in the first office visit. Many stones do not clear with hydration, and thus more aggressive approaches are required. More invasive procedures are often necessary if the stone is in the lower pole because even if fragmented, the pieces are unlikely to pass from this location. Our technological approach would keep the least invasive option open for these patients. In most existing procedures, there is a significant chance stone pieces will remain behind as seeds for future stones and further surgery. Our technology could help these pieces pass. In addition, stones are often recurrent; recurring-stone patients are often monitored, so that new

<b>Research Impact/Earth Benefits:</b>	<p>stones can be detected early—this monitoring could be done with our precise stone imaging approach. Our technology could also move these stones to the kidney exit before they are symptomatic. This technology reduces risk of surgery, complications of surgery for the patient, and the cost of surgery to the insurance companies; furthermore, the technology does not preclude any surgical options. Lastly, the algorithms to detect kidney stones alone stand to spare many patients the ionizing radiation of a CT scan, or to provide options to pregnant women or children with stones who are unlikely to receive CT. NSBRI quickly recognized the value of this technology and helped us initiate our commercialization effort that now has the full support of the UW, the Washington Research Foundation, and a commercial hardware provider, as well as the interest of several venture capitalists and ultrasound companies.</p> <p>The applications of our technology to the control of bleeding and for tumor ablation are at least as profound. Specifically, this year we have worked with the latest clinical HIFU machine—one developed by Philips Medical. This machine is intended for many clinical applications. We have used some of our effort to characterize the output of the machine and assess its potential bio-effects. Our work provides the clinicians, who intend to use this machine, the ability to select a treatment dose. At UW alone, it helps train the clinicians and establish the specificity of what size targets are treated. With our contribution, the clinicians are then likely to pursue their own clinical studies, and regulatory approval for various tumor treatments. Before our involvement, the machine sat dormant for a year. We are also exploring the effects of HIFU on the immune system and have proposed clinical trials to combine HIFU with chemical therapeutic agents. We believe that our efforts to carefully describe outputs and bio-effects will help the U.S. catch up with the rest of the world where over 400,000 patients have been treated by HIFU. In addition, our intimate knowledge of these details enables us to consider ways in which a similar, much reduced-in-size system could be developed for NASA to reduce some critical risks to astronauts during long duration space travel.</p>
<b>Task Progress:</b>	<p>Task 1A. Perform studies of bleeding detection in a flow-phantom model: Successfully detected and treated sites in a phantom developed with Defense Advanced Research Projects Agency (DARPA) and FDA in a blind test with an automated system.</p> <p>Task 1B. Perform studies to determine pressure and temperature in ex vivo tissue exposed to HIFU: Published several papers, which led to invitation to join IEC (International Electrotechnical Commission) working group on HIFU standards and the AIUM (American Institute of Ultrasound in Medicine) sub-committee on Transiently Increased Outputs, and to measure acoustic output of Philips clinical HIFU machine. Also, discovered and submitted patent application for a method to emulsify tissue with ultrasound.</p> <p>Task 2A. Develop new stone detection techniques based on radiation force and reverberation responsible for twinkling artifact: As part of our graduate student's dissertation, discovered that bubbles are responsible for the twinkling artifact. We have developed, implemented, tested, and patented new software to better detect stones.</p> <p>Task 2B. Test stone sizing technology in tissue: Published paper, filed U.S. and international utility patent applications, and are negotiating licensing. We have initiated human clinical studies to test ultrasound stone sizing versus CT.</p> <p>Task 3A. We utilized the YUANDE HIFU tumor ablation device as a test platform: Performed a number of studies.</p> <p>Task 3B. Engineer and optimize an image-guided, two-frequency HIFU system for renal stone comminution: We will work with Exploration Medical Capabilities (ExMC) Human Research Program Element to implement on the FUS system capability to detect, reposition, and comminute stones. All are implemented in a prototype for which we are pursuing an investigational device exemption (IDE) with the FDA. We have developed a concept of expelling small stones from a kidney before they require comminution or surgery. A system to detect and reposition stones based on an OEM diagnostic ultrasound platform has been built and demonstrated to be safe and effective in studies in a porcine model. Commercialization efforts are well underway. Our technology was called a "game changer" in the plenary session of the American Urological Association (AUA) Annual meeting in May 2012.</p> <p>Task 4A. Perform in vivo tests of the imaging protocols developed in Task 2: our paper is in press comparing twinkling to standard B-mode for stone detection in patients. New algorithm for stone detection implemented on clinical machine and tests of the algorithm initiated on human subjects. Data from 15 subjects has been collected.</p> <p>Task 4B. Performed studies to determine the potential for HIFU-induced stone comminution as well as any associated tissue injury. We used our stone repositioning system to fragment stones in an excised porcine kidney in which they were grown. In vivo tests scheduled for Oct 22, 2012. In vivo studies of our stone clearance system have been shown to be safe and effective. Several studies of safety in pigs have been complete and are in press. These data have been presented to the FDA as part of our application for investigational device exemption for a human feasibility study.</p>
<b>Bibliography Type:</b>	Description: (Last Updated: 03/22/2019)
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<b>Abstracts for Journals and Proceedings</b>	<p>Kucewicz J, Dunmire B, Bailey MR. "Improved Detection of Kidney Stone Twinkling Using Autoregressive Signal Processing Method." American Urological Association (AUA) 2012, Atlanta, GA, May 19-23, 2012.</p> <p>AUA 2012, Atlanta, GA, May 19-23, 2012. Abstract 1709. , May-2012</p>
<b>Abstracts for Journals and Proceedings</b>	<p>Harper JD, Sorensen MD, Hsi R, Cunitz B, Simon J, Wang YN, Paun M, Starr F, Lu W, Evan A, Liggit D, McAteer J, Bailey M. "Preclinical Efficacy and Safety of Ultrasonic Propulsion of Kidney Stones." 88th Annual Meeting, Western Section of the American Urological Association, Waikoloa, Hawaii, October 7-12, 2012.</p> <p>88th Annual Meeting, Western Section of the American Urological Association, Waikoloa, Hawaii, October 7-12, 2012. , Oct-2012</p>
<b>Abstracts for Journals and Proceedings</b>	<p>Harper JD, Sorensen MD, Hsi R, Cunitz B, Simon J, Wang YN, Paun M, Starr F, Lu W, Evan A, Bailey M. "Preclinical testing of ultrasonic propulsion of kidney stones." 2012 IEEE International Ultrasonics Symposium (IUS), Dresden Germany, October 7-10, 2012.</p> <p>2012 IEEE International Ultrasonics Symposium (IUS), Dresden Germany, October 7-10, 2012. , Oct-2012</p>

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Articles in Peer-reviewed Journals	Simon JC, Sapozhnikov OA, Khokhlova VA, Wang YN, Crum LA, Bailey MR. "Ultrasonic atomization of tissue and its role in tissue fractionation by high intensity focused ultrasound." Physics in Medicine and Biology. 2012 Dec 7;57(23):8061-78. Epub 2012 Nov 16. <a href="http://dx.doi.org/10.1088/0031-9155/57/23/8061">http://dx.doi.org/10.1088/0031-9155/57/23/8061</a> ; PubMed <a href="#">PMID: 23159812</a> , Dec-2012

Articles in Peer-reviewed Journals	Khokhlova TD, Canney MS, Khokhlova VA, Sapozhnikov OA, Crum LA, Bailey MR. "Controlled tissue emulsification produced by high intensity focused ultrasound shock waves and millisecond boiling." J Acoust Soc Am. 2011 Nov;130(5):3498-510. PubMed <a href="#">PMID: 22088025</a> ; Nov-2011
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Articles in Peer-reviewed Journals	Kreider W, Crum LA, Bailey MR, Sapozhnikov OA. "Observations of the collapses and rebounds of millimeter-sized lithotripsy bubbles." J Acoust Soc Am. 2011 Nov;130(5):3531-40. <a href="http://dx.doi.org/10.1121/1.3626157">http://dx.doi.org/10.1121/1.3626157</a> ; PubMed <a href="#">PMID: 22088027</a> ; Nov-2011
Articles in Peer-reviewed Journals	Sorensen MD, Bailey MR, Shah AR, Hsi RS, Paun M, Harper JD. "Quantitative assessment of shockwave lithotripsy accuracy and the effect of respiratory motion." J Endourol. 2012 Aug;26(8):1070-4. Epub 2012 Jun 13. <a href="http://dx.doi.org/10.1089/end.2012.0042">http://dx.doi.org/10.1089/end.2012.0042</a> ; PubMed <a href="#">PMID: 22471349</a> ; Aug-2012
Articles in Peer-reviewed Journals	Sorensen MD, Harper JD, Hsi RS, Shah AR, Dighe MK, Carter SJ, Moshiri M, Paun M, Lu W, Bailey MR. "B-mode ultrasound versus color Doppler twinkling artifact in detecting kidney stones." J Endourol. 2013 Feb;27(2):149-53. Epub 2012 Oct 15. <a href="http://dx.doi.org/10.1089/end.2012.0430">http://dx.doi.org/10.1089/end.2012.0430</a> ; PubMed <a href="#">PMID: 23067207</a> ; PubMed Central <a href="#">PMCID: PMC3573723</a> ; Feb-2013
Articles in Peer-reviewed Journals	Shah A, Harper JD, Cunitz BW, Wang YN, Paun M, Simon JC, Lu W, Kaczowski PJ, Bailey MR. "Focused ultrasound to expel calculi from the kidney." J Urol. 2012 Feb;187(2):739-43. Epub 2011 Dec 16. <a href="http://dx.doi.org/10.1016/j.juro.2011.09.144">http://dx.doi.org/10.1016/j.juro.2011.09.144</a> ; PubMed <a href="#">PMID: 22177202</a> ; Feb-2012
Awards	Simon J. "Runner-up, UW Student Entrepreneurial and Business Association business plan competition, September 2011." Sep-2011
Awards	Simon J. "University of Washington College of Engineering Dean's Fellowship, August 2012." Aug-2012
Awards	Simon J. "UW (University of Washington) Invents Graduate Student Award, February 2012." Feb-2012
Awards	Crum L. "Awarded the Acoustical Society of America's Gold Medal, June 2013." Jun-2013
Awards	Crum L, Bailey M, Simon J. "Best Poster, Society for Engineering and Urology, Annual meeting, May 2012." May-2012
Awards	Bailey M. "Appointed to Membership Committee of the Acoustical Society of America, October 2012." Oct-2012
Awards	Bailey M. "Awarded UW Applied Physics Laboratory Science and Technology Award, December 2011." Dec-2011
Awards	Bailey M. "Member of Transiently Increased Output (TIO) subcommittee of the American Institute of Ultrasound in Medicine, April 2012." Apr-2012
Awards	Khokhlova V. "Elected to Acoustical Society of America Executive Council, May 2012." May-2012
Awards	Khokhlova V. "Elected to Board of the International Society for Therapeutic Ultrasound, April 2012." Apr-2012
Awards	Lu W. "UW Invents Graduate Student Award. UW decided to give 2 awards instead of the usual 1 award; the other award was to student Julianna Simon. February 2012." Feb-2012
Awards	Sorensen MD, Harper JD, Hsi R, Cunitz B, Simon J, Wang YN, Paun M, Starr F, Lu W, Evan A, Bailey M. "2012 Best Poster and Invited Talk for 'Preclinical Efficacy and Safety of Ultrasonic Propulsion of Kidney Stones,' Society of Engineering and Urology, 27th Annual meeting, Atlanta, GA, May 19, 2012." May-2012
Dissertations and Theses	Lu W. "Ultrasonic Detection and Expulsion of Kidney Stones." Dissertation, University of Washington, August 2012. , Aug-2012
Papers from Meeting Proceedings	Simon JC, Sapozhnikov OA, Khokhlova VA, Wang YN, Crum LA, Bailey MR. "Tissue Atomization by High Intensity Focused Ultrasound." 2012 IEEE International Ultrasonics Symposium (IUS), Dresden Germany, October 7-10, 2012. 2012 IEEE International Ultrasonics Symposium (IUS), Dresden Germany, October 7-10, 2012. , Oct-2012
Significant Media Coverage	Ostrovsky G. "Finding, pushing kidney stones using ultrasound. Article about PI's research and finding kidney stones." MedGadget weblog. Feb 1, 2012. <a href="http://medgadget.com/2012/02/finding-pushing-kidney-stones-using-ultrasound.html">http://medgadget.com/2012/02/finding-pushing-kidney-stones-using-ultrasound.html</a> ; accessed 2/5/2015., Feb-2012
Significant Media Coverage	Williams M. "NSBRI, BCM Center for Space Medicine dedicated at BRC. Article on Rice University's BioScience Research Collaborative (BRC) and dedication of the new home for the NSBRI on March 19, 2012, including awarding its fourth annual Pioneer Award to Sen. Kay Bailey Hutchison." Rice University News and Media.. March 20, 2012. <a href="http://news.rice.edu/2012/03/20/nsbri-bcm-center-for-space-medicine-dedicated-at-brc/">http://news.rice.edu/2012/03/20/nsbri-bcm-center-for-space-medicine-dedicated-at-brc/</a> ; accessed 2/5/2015., Mar-2012
Significant Media Coverage	Garner J. "Open for Business: Start-up takes aim at kidney stones. Article about PI's research and the start-up company the researchers are forming." Columns. UW Alumni Magazine. June 2012., Jun-2012
Significant Media Coverage	Luiggi C. "Space Rocks. Orbiting ultrasound machines are being used to diagnose and treat astronauts' kidney stones. Article describing PI's research." The Scientist. June 1, 2012, p. 22. <a href="https://the-scientist.com/notebook/space-rocks-40934">https://the-scientist.com/notebook/space-rocks-40934</a> ; Jun-2012