

Fiscal Year:	FY 2014	Task Last Updated:	FY 05/07/2014
PI Name:	Dentinger, Aaron Ph.D.		
Project Title:	Non-Invasive Monitoring of Intracranial Pressure (ICP) with Volumetric Ophthalmic Ultrasound		
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) HHC :Human Health Countermeasures		
Human Research Program Risks:	(1) ExMC :Risk of Unacceptable Health and Mission Outcomes Due to Limitations of In-flight Medical Capabilities (IRP Rev E) (2) VIIIP :Risk of Spaceflight-Induced Intracranial Hypertension/Vision Alterations (IRP Rev E)		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
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City:	Niskayuna	State:	NY
Zip Code:	12309-1027	Congressional District:	21
Comments:			
Project Type:	GROUND	Solicitation:	2011 Crew Health NNJ11ZSA002NA
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No. of Post Docs:	0	No. of PhD Degrees:	0
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No. of Bachelor's Candidates:	0	Monitoring Center:	NSBRI
Contact Monitor:	Contact Phone:		
Contact Email:			
Flight Program:			
Flight Assignment:	NOTE: End date changed to 3/31/2016 per NSBRI report submission (Ed., 5/8/14) NOTE: Risk/Gap changes per IRP Rev E (Ed., 3/18/14)		
Key Personnel Changes/Previous PI:			
COI Name (Institution):	Jagannathan, Srinivasan (GE Global Research) Sargsyan, Ashot (Wyle Laboratories, Inc.) Patwardhan, Kedar (GE Global Research) Ebert, Douglas (Wyle Laboratories, Inc.) Melton, Shannon (Wyle Laboratories, Inc.) Garcia, Kathleen (Wyle Integrated Sciences and Engineering Group) Mills, David (GE Global Research)		
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Task Description:	<p>Further research is needed to understand the role elevated intracranial pressure (ICP) plays in visual impairment observed during and following space missions. This project will lead to the development of tools to non-invasively monitor changes in ICP and the body's ability to compensate for increases in ICP. A simplified ocular scan and new ocular metrics will provide the ability to track the short-term and long-term time course of ICP with minimal burden on the crew, to determine the correlation of ICP with visual acuity changes in response to microgravity, and to investigate effectiveness of potential treatments. In addition to in-flight monitoring of crew health during space missions, these techniques are applicable to many clinical applications where ICP plays a key role, such as monitoring patients with head trauma. The objective of this research is to non-invasively monitor ICP using 3-D ultrasound imaging by detecting changes in ocular structures and functioning of the eye that are correlated with elevated ICP. The new volumetric ultrasound imaging capability will provide user independent views of the entire ocular anatomy in a single scan with minimal crew time and ground guidance during image capture. Volumetric ultrasound data taken pre-flight, post-flight, and in-flight will be aligned with pre-flight and post-flight magnetic resonance scans allowing in-flight changes in the ocular anatomy to be tracked over time.</p> <p>In the first year of the grant, a prototype mechanical 3-D ultrasound probe for ophthalmic scanning through a closed eyelid has been integrated with the current portable, high-resolution medical ultrasound scanner on the International Space Station (ISS) (GE Vivid q). An external motor control unit has been designed and developed to enable 3-D imaging on the current ISS ultrasound scanner with minimal changes to the Vivid q ultrasound system. First in vitro images of an ultrasound imaging phantom were acquired with the prototype probes and Vivid q ultrasound system. Electrical safety tests and acoustical output measurements for ophthalmic use were completed on the prototype probe and Vivid q ultrasound system, and a protocol submitted to NASA's Institutional Review Board (IRB) for human subject scanning starting in year 2.</p> <p>The proposed research plan for upcoming year focuses on transitioning the technology development to in vivo evaluation of the volumetric prototype probe on human subjects. Sonographs of the optic nerve and globe will be extracted from the volumetric ultrasound data, and new 3-D measurement techniques for the size and shape of these structures will be developed to serve as indirect measures of ICP. The new ultrasound hardware and measurement techniques will be tested during ground-based in vivo human subject in collaboration with flight surgeon, sonographer, and technical team from Wyle Integrated Science and Engineering in Houston. Initial in vivo imaging will be performed to optimize the image quality for ocular structure with the prototype probe and the Vivid q ultrasound system. The first phase of the in vivo human subject evaluation includes MR (magnetic resonance) and volumetric ultrasound scans on 5 subjects to develop algorithms and evaluate the accuracy of multimodality registration and repeatability of 3-D ocular structure measurements. The second phase of the in vivo human subject evaluation includes volumetric ultrasound scans on 10 subjects during head-down tilt experiments to quantify the sensitivity of 3-D ocular metrics to mild changes in intracranial pressure. Additionally, discussions will continue with NASA Glenn Research Center on compatibility of the design with the next generation flexible ultrasound system, as well as with other mechanical 3-D ultrasound probes.</p>
Rationale for HRP Directed Research:	
Research Impact/Earth Benefits:	<p>The primary Earth-based clinical application of the technology is non-invasive ICP monitoring of traumatic brain injury patients. Portable ultrasound provides the opportunity for frequent non-invasive monitoring directly at the point of care without the need to transport patients to an imaging suite. Further research is required to translate the technology into the clinical setting, including automating and testing the reliability of the ultrasound-based 3-D measurement on clinical populations. Clinical validation of the technology will require partnering with a clinical collaborator to secure external funding, such as through an NIH grant.</p>
Task Progress:	<p>During the last funding year, progress on the grant focused on the task of developing volumetric ophthalmic imaging capability on the GE Vivid q portable, high-resolution ultrasound scanner toward achieving the first specific aim of the grant. The task progressed from design and hardware development to integration with the Vivid q and initial in vitro imaging to safety testing and submission of a protocol to NASA's IRB. Details of the progress are outlined below.</p> <p>Design - Computer simulation studies of acoustic array designs for ophthalmic imaging applications were conducted to guide selection of two prototype volumetric ultrasound probes for in vivo evaluation. Several options for implementing the volumetric imaging functionality on the Vivid q system were explored and a hardware design implemented that requires minimal modifications to the ultrasound system.</p> <p>Hardware - New hardware was developed and fabricated enabling volumetric imaging by interfacing to the Vivid q ultrasound system and controlling the stepper motor in the volumetric ultrasound probe. This motor control unit consists of a commercially available field-programmable gate array (FPGA) processor evaluation board, USB interface board, and two custom printed circuit boards to route the probe control signals. Additional connections between the motor control unit and the Vivid q through the USB and ECG ports were implemented. Firmware was written for the FPGA processor to generate the signal for controlling the stepper motor in the volumetric probe, responding to user inputs, and generating timing waveforms required for the reconstruction of the volume data.</p> <p>Integration - The properties of the prototype volumetric probes were characterized and the relevant parameters entered into probe specification tables on the Vivid q. The prototype probes were integrated with the acoustic model on the Vivid q enabling real-time display of acoustic output levels. Imaging applications were created on the Vivid q for the prototype probes specifying acquisition parameters for the ultrasound imaging modes that will be used in the in vivo evaluation. The Vivid q's acoustic output levels were set to the lower FDA limits for ophthalmic use for all imaging modes with the prototype probes (B-mode, M-Mode, Spectral Doppler, and Color Flow). Once integrated, the acoustic output of the prototype volumetric probes and Vivid q software were measured at an outside laboratory to verify the acoustic output levels were below the ophthalmic limits for the high acoustic output settings in each imaging modes.</p> <p>Evaluation - First images of an ultrasound imaging phantom were acquired with the prototype probes and Vivid q. Initial MR data collected on the same ultrasound imaging phantom allowed the initial development of the volumetric visualization and registration algorithms. The electrical and acoustic safety tests were completed and a protocol submitted the NASA's IRB for human subject scanning starting in year 2.</p>
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