Fiscal Year:	FY 2016	**Task Last Updated:**	FY 06/10/2016
PI Name:	Strangman, Gary E Ph.D.		
Project Title:	Testing Mechanical Countermeasures for Cephalad Fluid Shifts		
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) **SANS**:Risk of Spaceflight Associated Neuro-ocular Syndrome (IRP Rev I)		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
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Zip Code:	02129-2020	**Congressional District:**	7
Comments:			
Project Type:	GROUND	**Solicitation:**	2014-15 HERO NNJ14ZSA001N-Crew Health (FLAGSHIP & NSBRI)
Start Date:	06/01/2015	**End Date:**	05/31/2017
No. of Post Docs:	1	**No. of PhD Degrees:**	0
No. of PhD Candidates:	0	**No. of Master' Degrees:**	0
No. of Master's Candidates:	0	**No. of Bachelor's Degrees:**	0
No. of Bachelor's Candidates:	0	**Monitoring Center:**	NSBRI
Contact Monitor:		**Contact Phone:**	
Contact Email:			
Flight Program:			
Flight Assignment:			
Key Personnel Changes/Previous PI:			
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Task Description:	Current evidence suggests that NASA's visual impairment and intracranial pressure (VIIP) risk is related to an elevation in intracranial pressure (ICP) during spaceflight, either consequent to or aggravated by cephalad fluid shifts in microgravity. From recent data, VIIP occurs in >50% of astronauts, to varying degrees, and can lead to long term visual changes. Although its cause is unknown, its importance is high enough to motivate studies of potential countermeasures. The key objectives of this project are therefore: (1) to test and help validate two commercial devices as mechanical countermeasures for cephalad fluid shifts to potentially treat elevated ICP, (2) identify any potential adverse consequences during use or following release of such countermeasures, and (3) optimize deployment procedures for such countermeasures. The Russians currently use Braslet, an elastic thigh band, to help sequester blood in the legs and alleviate symptoms resulting from cephalad fluid shifts. While promising, this device has not been tested as a VIIP countermeasure. Lower body negative pressure (LBNP) is an alternative approach, which draws fluid into the legs using vacuum mechanism. Both have drawbacks, however. Braslet devices are custom-built, difficult to obtain and have limited calibration options. LBNP is bulky and hence only one such device would be available in-flight at a time, limiting the number of astronauts who could use it, or the duration of use, each day. As an alternative to Braslet, we will test the Kaatsu thigh cuff system. This commercially available system is designed for enhanced muscle training on Earth. Instead of the LBNP alternative, we will investigate use of a LymphaPress compression garment configured to provide a vascular resistance for fluid return (as opposed to enhanced fluid return) from the lower body. In Experiment 1, we will conduct tests using both potential countermeasures in healthy subjects undergoing head-down tilt (HDT) to elevate ICP by +10 mmHg, and in neurointensive care unit (NeuroICU) patients with invasive ICP devices implanted to monitor and treat elevated ICP. We will establish the ICP, cerebral blood flow, intraocular pressure, structural eye parameters, and cerebral vascular parameter changes associated with application, maintenance, and release of each countermeasure. This will also enable calibration of our non-invasive versus invasive cerebral measurements. In Experiment 2, we will examine more gradual discontinuation of device use versus more abrupt discontinuation. In Experiment 3, we will seek to quantify the relationship between exposure time to the countermeasure and cerebral responses during exposure as well as post-release. Together, these studies will help identify whether either countermeasure is a promising treatment for, or mitigator of, cephalad fluid shifts and elevated ICP. This project will increase the technology readiness level of mechanical countermeasures for VIIP from Countermeasure Readiness Level (CRL) 4 to CRL 6-7.
Rationale for HRP Directed Research:	
Research Impact/Earth Benefits:	Impact: Successful completion of this project will provide the first tests of commercial, user-friendly, and safety-tested devices as countermeasures (CMs) potentially suitable for VIIP. Results will include: (1) an assessment of both thigh cuffs and a compression garment as a VIIP countermeasure, (2) assessment of the influence of these devices on invasively measured ICP, (3) calibration of numerous non-invasive measures against the invasive measures of cerebral physiology, (4) parameterization of CM deployment and rebound effects on a wide range of physiological variables and, perhaps most importantly, (5) identification of the optimal countermeasure to use, CM release rate, and CM exposure time. Earth Benefits: Currently, there are few treatment methods for elevated intracranial pressure, which affects patients with traumatic brain injury, stroke, hydrocephalus, and cancer patients. None of the current methods involve non-invasive mechanical devices—instead focusing on surgical procedures or medications. This work therefore has the potential to identify one or more countermeasures and/or protocols--within a novel class of countermeasures--that could be used to help manage intracranial fluids. Since these approaches do not require drugs, they avoid the potential side effects, drug-drug interactions, or longer-lasting effects that often come from medication use.
Task Progress:	Current evidence suggests that NASA's visual impairment and intracranial pressure (VIIP) risk is related to an elevation in intracranial pressure (ICP) during spaceflight, either consequent to or aggravated by cephalad fluid shifts in microgravity. The key objectives of this project are therefore: (1) to test and assess two commercial devices as mechanical countermeasures for cephalad fluid shifts to potentially treat elevated ICP, (2) identify any potential adverse consequences during use or following release of such countermeasures, and (3) optimize deployment procedures for such countermeasures. Specifically, this work will test the following two commercial devices for their effect on cerebral and ocular parameters: the Kaatsu thigh cuff muscle training system, as an alternative to Braslet, and a reconfigured LymphaPress system designed for fluid management in edema patients. In year 1 of the project we: (1) obtained the commercial devices and learned in detail how they function, (2) adapted either the physical device or (when possible) normal-use protocols for our target ICP-related application, (3) conducted pilot studies to fine-tune suitable protocols for deployment, (4) worked closely with the clinical teams at both MGH (Massachusetts General Hospital) and Baylor College of Medicine to work out deployment requirements in clinical settings, and (5) finalized the device deployment protocols. Instead of using a standard Kaatsu protocol on the legs, which involves restriction of arterial inflow to the extremeties, we will use a lower pressure to restrict only venous outflow. Instead of the standard LymphaPress configuration of compressing fluids from the lower body to the abdomen, we will compress the abdomen area only to increase vascular resistance, enhance distal vascular dilation, and generate fluid sequestration in the lower body. Having completed device training, initial adaptation, protocol development phase, and pilot studies, we are about to initiate subject recruitment for the primary studies.
Bibliography Type:	Description: (Last Updated: 10/23/2019)