VALIDATION OF A CEPHALAD FLUID SHIFT COUNTERMEASURE
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INTRODUCTION
This project will provide critical data required to objectively determine how an optimized thigh cuff could be incorporated into the NASA integrated physiological countermeasure suite. This project will determine if thigh cuffs used during simulated spaceflight impact intracranial pressure (ICP), ocular structure and function, and intraocular pressure (IOP) using state-of-the-art techniques. Additionally, some of the same methods, hardware, and protocols will be employed in the present investigation to enable direct comparisons to the International Space Station (ISS) “Fluid Shifts” experiment with Chibis-Lower Body Negative Pressure (LBNP). This study will determine the temporal physiological responses of thigh cuff application and removal on ocular and cerebral variables (including invasive ICP) in a microgravity analog. Furthermore, this proposed study will determine tissue pressure distribution applied by thigh cuffs in order to improve comfort, mobility, and efficacy of the countermeasure. Our specific aim is to determine the efficacy of a novel thigh cuff device to mitigate cephalad fluid shifts. We hypothesize that a thigh cuff countermeasure employed in a microgravity analog will temporarily reverse or attenuate ocular and cerebral-volume-pressure variables, approaching normal Earth-based seated posture, the most frequent posture assumed in daily life. In addition, we hypothesize that the magnitude of fluid and pressure redistribution using a thigh cuff countermeasure may require a longer exposure time than that of Chibis-LBNP (using ground-based data from our “Fluid Shifts” project). This project directly addresses Critical Path Roadmap Risks and Questions regarding “Risk of Spaceflight-Induced Intracranial Hypertension/Vision Alterations,” and IRP Gap VIIP13: We need to identify preventative and treatment countermeasures to mitigate changes in ocular structure and function and intracranial pressure during spaceflight.

METHODS
Noninvasive measures and tissue pressure distributions beneath thigh cuffs
The objectives of this study are to: 1) determine the distribution of skin surface pressures beneath the advanced thigh cuff in ten subjects, 2) calibrate the built-in pressure measurement system of the advanced thigh cuff using an industry standard device, and 3) collect subjective feedback and data on the new cuff design to allow for further adjustments prior to invasive studies. A Tekscan Industrial Sensing (I-Scan) system will measure the pressure distribution of the advanced thigh cuff against the skin. In addition, we will measure blood pooling in the thigh and record the circumference of the thigh using Hokanson strain gauge plethysmography. The advanced thigh cuff will be adjusted to obtain a skin contact pressure of 30-50 mmHg as visualized on the Tekscan system. The built-in advanced thigh cuff pressure monitor will be recorded simultaneously to allow direct comparison to the Tekscan measurements. The volunteer will then remove the thigh cuff and remain at rest for five minutes with no legging applied. The thigh cuff will be donned again and pressure measurements will be taken in the same manner for up to 10 repetitions to show reproducibility of pressure after donning. At the conclusion of the study, subjects will be asked to flex their knee, stand, walk, and sit with the thigh cuff activated. During each of these maneuvers the subject will rate their pain/comfort using a modified Borg scale.

Effect of thigh cuffs on ICP during simulated microgravity
Ommaya reservoir patients will be recruited from the John Wayne Cancer Institute. Ommaya reservoirs provide safe and direct access for the measurement of ICP. Subjects will be instrumented for continuous blood pressure, ECG, and invasive ICP measures. The subjects will be positioned in the upright sitting posture for a 10-minute stabilization period. After the 10-minute stabilization period, imaging measures [ICP, Optical Coherence Tomography, IOP, ocular and vascular ultrasound] will be performed. Following baseline seated measures, the subject will be positioned randomly in the supine, 15° head-down-tilt, and 15° head-down-tilt with thigh cuffs and measures repeated.

DISCUSSION
Tests to down-select thigh cuff designs will occur in early 2016. Invasive ICP and noninvasive eye imaging tests will begin in spring 2016. Supported by NSBRI through NASA NCC 9-58.