Fiscal Year:	FY 2009	**Task Last Updated:**	FY 06/25/2009
PI Name:	Dulchavsky, Scott A. M.D., Ph.D.		
Project Title:	Ultrasound Fracture Diagnosis in Space		
Division Name:	Human Research		
Program/Discipline:	HUMAN RESEARCH		
Program/Discipline--Element/Subdiscipline:	HUMAN RESEARCH--Operational and clinical research		
Joint Agency Name:		**TechPort:**	Yes
Human Research Program Elements:	(1) **ExMC**:Exploration Medical Capabilities		
Human Research Program Risks:	(1) **Medical Conditions**: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 (2) **Renal Stone**: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:	48202-2608	**Congressional District:**	13
Comments:			
Project Type:	GROUND	**Solicitation / Funding Source:**	2007 Crew Health NNJ07ZSA002N
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No. of Post Docs:	0	**No. of PhD Degrees:**	0
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No. of Master's Candidates:	0	**No. of Bachelor's Degrees:**	0
No. of Bachelor's Candidates:	0	**Monitoring Center:**	NASA JSC
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Flight Program:			
Flight Assignment:			
Key Personnel Changes/Previous PI:	None		
COI Name (Institution):	Amponsah, David (Henry Ford Hospital) Hamilton, Douglas (Wyle) Knuth, Thomas (Henry Ford Hospital) Sargsyan, Ashot (Wyle)		
Grant/Contract No.:	NNX08AV74A		
Performance Goal No.:			
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Task Description:

Crew members on long duration space missions are at significant risk of decreased strength of bones despite counter-measures. The radiographic capabilities of future spacecraft are unknown, however, ultrasound is currently operational on the ISS. Preliminary investigations have shown that ultrasound can reliably diagnose long bone fractures. This proposal will evaluate the accuracy of ultrasound in the diagnosis of bony fractures and develop just in time, training methods to allow astronauts to perform and interpret skeletal ultrasound to answer the specific aims:
1. Evaluate the diagnostic accuracy of ultrasound for bony fractures and fracture healing in ground based studies.

2. Develop training programs to facilitate skeletal ultrasound to exclude fracture.

3. Develop pattern recognition algorithms to allow astronauts to autonomously diagnose skeletal fracture.

Methods:

Specific Aim 1: The accuracy of ultrasound will be evaluated against X-ray in a large cohort of acutely injured patients at the Level 1 trauma center at Henry Ford Hospital. Ultrasound examinations will be performed by experts in parallel with astronaut equivalents on patients with a history and exam consistent with bony fracture to assess sensitivity and specificity and optimize technique. The randomized trials will include patient groups with probable long bone, axial skeletal, and hand/foot fractures to allow statistical conclusions about exam accuracy to be determined.

Specific Aim 2: A computer based ultrasound training program will be developed for astronauts to allow skeletal ultrasound to be performed for axial and extremity fractures based on a successful Onboard Proficiency Enhancement (OPE) program.

Specific Aim 3: Autonomous ultrasound diagnostic capabilities will be developed for astronauts by combining cue card reference images, topographic ultrasound guides, and normal/anticipated pathologic images to allow pattern recognition diagnosis by the operators.

Significance to NASA: This proposal will develop training and techniques for autonomous/remote guidance of in-flight fracture diagnosis using crew performed skeletal ultrasound.

Rationale for HRP Directed Research:

Research Impact/Earth Benefits:

An interim analysis of the preliminary data to date in this research activity demonstrates that point of care ultrasound is a rapid, accurate, and reproducible test to diagnose acute injury to the musculoskeletal system. This technique can be used by non-experts to rapidly diagnose injuries to the upper and lower extremities, chest, and hands/feet to guide therapy. This technique can be expanded for use in the pre-hospital setting, in military conflicts, and in natural disasters to aid triage decisions.

FEASIBILTY REVIEW
Proposal Title: “Ultrasound Fracture Diagnosis in Space” ; Proposal Number: 07-HRP-2-0009 (from NASA Research Announcement NNJ07ZSA002N) ; PI: Scott Dulchavsky, Henry Ford Health System ; Co-I(s): Thomas Knuth, Henry Ford Hospital ; Douglas Hamilton, Wyle Integrated Science and Engineering ; Ashot Sargsyan, Wyle Integrated Science and Engineering ; Douglas Ebert, Wyle Integrated Science and Engineering ; David Amponsah, Henry Ford Hospital.

This ground-based proposal is accumulating high-level clinical evidence on the sensitivity and specificity of point of care ultrasound performed by expert and novice users for the rapid diagnosis of musculoskeletal injuries. This proposal is also developing and validating methodologies to provide just-in-time training of novice users by creating multi-media training tools and imaging procedures for Crew Medical Officers (CMOs), Ground Support Biomedical Engineering (BME) support, flight surgeons and local expert consultants. Expanded diagnostic use of ultrasound is being substantiated for the diagnosis of specific musculoskeletal injuries deemed possible in Low Earth Orbit (LEO) and future exploration-class missions. Successful completion of this proposal will provide an end-to-end mitigation strategy for crew health and performance risks associated with musculoskeletal trauma in human spaceflight, and will provide solid data to mission planners and system developers on important operational aspects of in-flight trauma management.

The schedule for this ground based proposal is shown below:

July 2008: Project Aim #1 Begins

January 2009: Interim Analysis Clinical Trials of Expert users

May 2009: Interim Analysis Clinical Trials of non-expert users

June 15, 2009: Feasibility Analysis report with statistics delivered to ExMC

July 21, 2009: Review at JSC of Feasibility report and plan for Aim #2

December 15, 2009: Midterm review at JSC of point-of-care training program

April 16, 2010 Final Data Analysis Report due and hand-off of training protocols (CMO, to Space Medicine.

June 30, 2010 Decision analysis for Addl funding for Comprehensive Space Medicine Integration Training Protocols (BME, Consultants, Flight Surgeons, Remote Medical Capabilities)

June 30, 2011: Publications completed; funding period ends.

This reporting period will focus on Specific Aim I in this cooperative agreement:

1. Evaluation of the diagnostic accuracy of ultrasound for bone fractures, associated muscle trauma and fracture healing in a ground-based study at an academic medical center.

PROGRESS REPORT SUMMARY:

Interim analysis, January 2009: Our preliminary data were reviewed by 2 musculoskeletal ultrasound experts (Marnix van Holsbeeck MD, and Antonio Bouffard MD) for training of operators, technical details, and data results. Our preliminary suggests that 2D ultrasound has appropriate sensitivity and specificity for the wide range of musculoskeletal

	injuries which may occur during LEO or exploration class spaceflight. Newer technologies such as volumetric or 3D ultrasound may provide additional precision for complex fractures or for operators without access to just in time training programs, however, these theoretic benefits have not been substantiated to date. Additional trials of 3D ultrasound in musculoskeletal trauma could be included in the subsequent funding year, however, this would impact the timeline and cost of this proposal. The interim analysis concluded that 2D ultrasound provides acceptable sensitivity and specificity for the diagnosis of musculoskeletal trauma and that 3D or volumetric ultrasound is not necessary at this time.
Task Progress:	PROGRESS: We have screened approximately 720 patients for enrollment into the Fracture Study in the emergency room at Henry Ford Hospital. Initial patient screening was done by Trauma Surgery or Emergency Medicine staff based on mechanism of injury, history, and presenting signs and symptoms suggestive of significant musculoskeletal injury. Informed consent was obtained and a localized ultrasound examination was completed prior to radiographic evaluation by MSK experts or minimally trained personnel using a 10.5 MHz linear probe. The ultrasound examination was initially done on the contra lateral, non-injured side to obtain a reference image and to optimize visualization and focal zone. The entire length of the bone was visualized with special attention to the injured area. A positive scan consisted of identification of cortical disruption or discontinuity. Secondary hematomas and muscular injury were also recorded. Routine radiographic imaging was then completed for comparison against the ultrasound examination. Demographic, anatomic, and radiographic information were collected for correlation to the ultrasonographic findings. A diagnostic scoring sheet with patient and exam specific data was filled out by the operator immediately following the examination. High fidelity ultrasound images/video loops were also archived for later blinded review. The sensitivity and specificity of the test was determined for the operator and the blinded reviewer. Statistical analysis of the examinations was determined for the operator and the blinded reviews and correlated with radiographic findings by Chi Square analysis with Kappa correction. The majority (76%) of the patients entered into the study were male with an average age of 38 (range 18-84). The majority of injuries involved falls (72%), followed by motor vehicle accidents (19%) and assaults (7%). This trial used a blend of expert and non-expert operators to scan the patients with musculoskeletal trauma. The non-expert users received a 1 hour targeted instruction in MSK ultrasound prior to scanning. There was no appreciable difference in examination quality or diagnostic accuracy between expert and novice users in this limited trial (Appendix). The overall sensitivity of ultrasound for the detection of fractures was 96% and the specificity was 99% in this targeted trial. Subgroup analysis shows that the sensitivity is less for fractures in the hand and foot (86%) which is most likely related to the complexity of the examination in this area. There were a limited number of examinations of the femur and hip making statistical analysis impractical, however, observations of this technique suggest that it could be reliable if appropriate attention is given to technical factors including probe selection and depth in larger patients. We have also evaluated fracture healing in a limited number of patients with hand and rib injuries. Fracture callus formation is readily apparent at 3-4 weeks and the maturation of the bony healing can be followed over a more prolonged period with specific ultrasound findings (Appendix). Conclusions: 2D ultrasound provides a sensitive and specific point of care examination for long bone MSK injury when performed by expert and non-expert operators. Additional information is necessary to determine the accuracy of the test for fractures in complex areas (wrist, foot) or the potential benefit of 3D ultrasound technologies. NEXT STEPS: This trial was done by experts and non-experts in a limited population of patients with MSK injury. We would like to continue to accrue patients in the subsets with small numbers to provide a more robust analysis and to begin work on Specific Aim II to develop a multi-media, point of care training program which would be suitable for NASA Space Medicine user groups and for Crew Medical Officers. SPECIFIC AIM 2: Develop robust, point-of-care training programs to facilitate the performance of skeletal ultrasound by non-physician CMOs to exclude fracture. NASA DELIVERABLES: • Computer based, CMO training program to perform skeletal ultrasound to diagnose skeletal injury • Cue card functionality to enhance rapid performance of skeletal ultrasound
Bibliography Type:	Description: (Last Updated: 02/23/2023)