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Surgical Capabilities for Exploration and Colonization Space Flight – An Exploratory Symposium

December 2015

National Space Biomedical Research Institute
Houston, TX

Charles R. Doarn, MBA
George Pantalos, PhD
Gary Strangman, PhD
Timothy J. Broderick, MD

National Aeronautics and
Space Administration

Johnson Space Center
Houston, Texas 77058

November 2016

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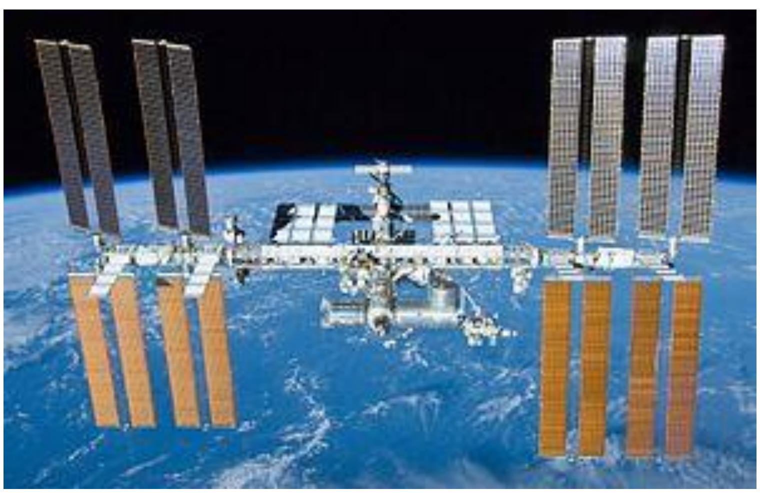

Executive Summary

Surgical capabilities in human space flight, whether on a space-based platform in low Earth orbit or on a long duration planetary exploration mission, will be challenging to conduct for a variety of reasons, some of which will be ameliorated by training, technology, and pre-flight planning. Nevertheless, inherent risks and challenges remain. Early space missions did not have any surgical capability. It was not until NASA's Skylab mission that serious consideration was given to this fundamental medical care capability. Over the past 30 years, subject matter experts have been brought together for discussion on the myriad of challenges and opportunities in this endeavor. The last such meeting was held in 2005 at the NASA Johnson Space Center. As we continue to move forward with human space flight activities for the International Space Station and beyond, the capabilities of information technology, robotics, sensors and imaging have rapidly changed since the last gathering of expertise. In December 2015, through sponsorship of the National Space Biomedical Research Institute (NSBRI), a diverse group of individuals from government, academia, and industry representing three countries gathered at the NSBRI Space 4 Biomedicine facility in Houston, TX. This two day symposia included comprehensive sessions that addressed the challenges that we all face in developing, deploying, and utilizing surgical care capabilities in all human space missions, regardless of mission duration or profile. The symposium benefited from the knowledge and experience of three seasoned NASA physician astronauts, Drs. Jay Buckey, Thomas Marshburn, and Lee Morin. At the end of the first day, the assembled group heard from the crew members about their experiences and their ideas. It is clear that the discussion of surgical capabilities is part of the larger discussion of consideration of advanced healthcare, including critical care, on exploration space missions.

This report represents the culmination of the symposium, capturing knowledge, experience, conceptual dialogue, and a narrative that can be used in supporting the development of future programs and potential policy. Each of the presentations that were provided by the guest speakers is included in the appendices. Those presentations that are not included were due to sensitivity of the material or at the request of the speaker. In addition, each speaker was offered an opportunity to provide comments in a 'lightning round' format. All of these comments and speaker abstracts also appear in the appendices.

At the conclusion of the second day, a discussion was held that reviewed the priorities that perhaps add value to decision makers. These are also summarized.

This report will serve as the final product of this symposium. Additional material may be produced for the peer-reviewed literature.

Acknowledgements

This exploratory symposium was developed and co-chaired by the individuals listed below.

Timothy J. Broderick, MD, FACS
Professor and Associate Dean for Research Affairs
Boonshoft School of Medicine Wright State University
Department of Surgery
Chief Scientist, Wright State Research Institute
Wright State Research Institute
Wright State University
Dayton, OH

Charles R. Doarn, MBA
Research Professor, Department of Family and Community Medicine
College of Medicine
University of Cincinnati
Cincinnati, OH
Special Assistant to the Chief Health and Medical Officer
NASA Headquarters
Washington, DC

George Pantalos, PhD, FAIMBE
Professor, Department of Cardiovascular and Thoracic Surgery and Department of Bioengineering
Cardiovascular Innovation Institute
University of Louisville
Louisville, KY

Gary Strangman, PhD
Smart Medical Systems Lead, NSBRI
Associate Professor, Department of Psychiatry
Harvard Medical School
Director, Neural Systems Group
Massachusetts General Hospital
Boston, MA

Administrative Support

Debra Shniderson
Senior Conference Coordinator
National Space Biomedical Research Institute
Houston, Texas

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Symposium Overview

G. Pantalos, C. Doarn, T. Broderick and G. Strangman

In preparation for this symposium and in order to capture previous efforts, Dr. George Pantalos reached out to discuss the concepts with Professor Charles Doarn at the University of Cincinnati and Dr. Timothy Broderick from Wright State University. Doarn and Broderick were responsible for the Surgical Care in Space Flight Symposium in 2005 and were involved in the 12th NASA Extreme Environment Mission Operations (NEEMO) mission. Dr. Pantalos has extensive experience with parabolic flight research and currently conducts NASA-sponsored research to develop surgical capabilities for space flight. Dr. Broderick, a surgeon, was also involved in both NEEMO 7 and NEEMO 9. Dr. Pantalos also worked closely with Dr. Gary Strangman from the Massachusetts General Hospital and Harvard University. Dr. Strangman serves as the National Space Biomedical Research Institute (NSBRI) lead for Smart Medical Systems. These four individuals served as the symposium co-chairs.

Once the planning was complete, the meeting was held at the NSBRI Space 4 Biomedicine / Baylor College of Medicine Center for Space Medicine facility located in the prestigious Texas Medical Center in Houston. The meeting was designed to cover a plethora of material over one and half days. Each of seven sessions were organized with subject matter expertise that included astronauts, surgeons, surgical systems specialists, NASA flight surgeons, medical device developers, an FDA representative, researchers, and others. The invitation-only symposium was designed to be small in order to maximize discussion and generate useful dialog. A few individuals intermittently participated via phone. All attendees, speaker abstracts, speaker presentations, and the agenda appear in the appendices of this report. The appendices also include a list of acronyms as well.

The sessions were devised to elicit thought and promote dialogue. The sessions were as follows (1) Planning for Low Earth Orbit, Lunar Colony, and Deep Space Exploration Missions; (2) Critical Care and Surgery in Extreme Environments; (3) Surgery in Reduced Gravity; (4) Smart Medical Technology; (5) Crew Composition, Training for Flight, The Effect of Transmission Latency; (6) Management of the Perioperative Environment; and (7) Technical Support for Surgery. Each session had a chair that functioned as a moderator. Each panel had several speakers that shared their experiences with the attendees.

In addition to the main topic areas, NSBRI leadership welcomed the participants and the co-chairs (Doarn and Pantalos) set the framework for symposium. Professor Doarn provided an in-depth summary of previous work, including meetings and research efforts, some of which was funded by the Telemedicine and Advanced Technology Research Center (TATRC) through support of the U.S. Army Medical Research and Materiel Command. Dr. Pantalos reviewed the objectives of the symposium. He also discussed the correlation of previous work and what NSBRI and the Human Research Project (HRP) are reviewing in support of the research and the ‘smart medical’ systems for exploration missions.

Key influences for the consideration of surgical capabilities for space flight were:

a) NASA Space Technology Roadmap, Area TA06, Section 2.3 (Human Health and Performance) with calls for medical assisted robotics for laparoscopic surgery and a surgical suite with sterile, closed loop fluid and ventilation systems for trauma and other surgeries (with development efforts to begin in 2015).[1]

b) National Research Council Report (2014): 4.2.6.1.9 Crew Health calls for highly capable diagnostic and treatment equipment, including surgical facilities designed for operation in space and on the surface.[2]
c) NASA Human Research Program, Exploration Medical Capabilities, List of Medical Conditions that includes skin lacerations and surgical treatment.[3]

With this background, the four objectives for the symposium were:

1) Review current planning for healthcare delivery for Lunar colonization and Martian expeditions.
2) Review previous and current efforts to develop surgical capabilities and related technologies for human space flight.
3) Given current capabilities and mission planning, propose reasonable scenarios and methods for delivery of surgical treatment.
4) Identify short term and long-term basic and applied science research initiatives as well as engineering and medical product development needed to answer existing challenges for surgical capabilities in space flight.

The following pages of this report summaries key points made during presentations and associated discussion at the symposium or in follow- up correspondence shortly after the symposium.

Mr. Doarn gave a short introduction presentation 'Summary of Previous Work: Surgery in Extreme Environments'. This presentation also included a comprehensive list of NASA reports, U.S. Military initiatives, and peer-reviewed literature covering a wide variety of materials related the symposium.

In the late 1980s and early 1990s, NASA contracted with Dr. Bruce Houtchens to serve as a surgical consultant for the Surgical Subsystem for Space Station Freedoms's Health Maintenance System for the Crew Health Care Systems. In 1990, NASA held the 'Space Station Freedom Clinical Experts Seminar' in which surgical care was discussed. The resulted in a report "Proceedings of the Space Station Freedom Clinical Experts Seminar, NASA 10069 by Billica RC, Lloyd CW and Doarn CR. Houtchens and others designed and conduct ground-based tests and parabolic flight tests on NASA's KC-135 aircraft. Soon after this conference, NASA brought in Dr. Mark Campbell to serve as the surgical consultant. He and many others conducted a variety of experiments both animate and inanimate on the ground and on the KC-135.

In 2005, Mr. Doarn secured several grants with the U.S. Army's TATRC to conduct a discipline-specific symposium "Surgery in Extreme Environments: Meeting Space Exploration Needs". This symposium brought together U.S. and Russian expertise in system design, flight experience

[1]http://www.nasa.gov/sites/default/files/500436main_TA06-ID_rev6a_NRC_wTASR.pdf p TA06-15

[2]National Research Council. Pathways to Exploration: Rationales and Approaches for a U.S. Program of Human Space Exploration. Washington, DC: The National Academies Press, Section 4.2.6.1.9 Crew Health, 2014.

[3]https://humanresearchwiki.jsc.nasa.gov/index.php?title=Category:Medical_Conditions

(Neurolab crew members), operational personnel, surgeons, and flight surgeon with knowledge and experience in extreme environments. The outcome of this effort was to produce a written report and perhaps the foundation for a monograph.

Mr. Doarn highlighted several research initiatives that were funded by TATRC. These include NEEMO 12, High Altitude Platforms for Mobile Robotic Surgery, Robotic Surgery in Flight – C-9 and other Microgravity Simulations, and the Advanced Center for Telemedicine and Surgical Innovation at the University of Cincinnati. The reports and peer-reviewed journal articles that were produced from this research are listed in the Reference section of this report.

See Presentations 1.1 and 1.2 in Appendix E.

Welcome and Introductions
Jeffrey P. Sutton, MD, PhD

Dr. Sutton, NSBRI director, welcomed the group to the NSBRI facility and indicated the Institute's keen interest in the subject. He also indicated that whatever resources, including previous written reports, etc. would be made available. In addition, he indicated that NSBRI would host all the materials on their servers and make it available as appropriate.

Planning for Low Earth Orbit, Lunar Colony, and Deep Space Exploration Missions
Panel Chair – Mark Shelhamer, ScD

Panelists:

LEO, Lunar Colony and Deep Space Exploration Plans including Healthcare
John Charles, PhD

Dr. Charles provided a very thought provoking presentation that covered a wide array of subjects. These included International Space Station (ISS) operations, access to ISS and space in the absence of the Space Shuttle, new transportation concepts and models and what pathways in exploration lie ahead after the ISS Program. He discussed the National Research Council (NRC) report on Rationales and Approaches for a U.S. Program of Human Exploration, including the Moon, asteroids and Mars. The presentation also touched on in situ threats (location, gravity, duration, radiation, etc.) to the crew, challenges in communications delay between the Earth and Mars, environmental hazards (dust, etc.), surface architecture, and transit requirements (nutrition, exercise, psychosocial support, etc.). Each of these provides challenges to crew health and safety. Dr. Charles discussed risks in human space flight and the kinds of clinical problems that might be expected and how an autonomous clinical care system would support diagnosis and treatment. He closed his remarks with a discussion on risk associated with space flight, including project rates of illness or injury.

See Dr. Charles' presentation summary, 2.1 in Appendix E.

Exploration Medical Capability
NASA Human Research Program
Erik Antonsen MD, PhD, MS

Dr. Antonsen described his group's effort (Exploration Medical Capability [ExMC]) as a link between Space Medicine Operations and the Human Research Program. The focus is to (1) develop a medical system that will support healthy crew members and enable the completion of mission objectives – both health/prevention and catastrophic events and (2) minimize mission medical risk through medical system design and integration into the overall mission and vehicle design. He discussed the challenges of supporting crew health both in LEO and on exploration class missions. ExMC charter is to reduce risk and its focus is on the design reference mission of a Mars mission of 1,000 days. ExMC is guided by NASA-STD-3001, Vol 1 Rev A, which delineates requirements. See Chart below.

Level of Care	Mission	Capability
I	LEO < 8 days	Space Motion Sickness, Basic Life Support, First Aid, Private Audio, Anaphylaxis Response
II	LEO < 30 day	Level I + Clinical Diagnostics, Ambulatory Care, Private Video, Private Telemedicine
III	Beyond LEO < 30 day	Level II + Limited Advanced Life Support, Trauma Care, Limited Dental Care
IV	Lunar > 30 day	Level III + Medical Imaging, Sustainable Advanced Life Support, Limited Surgical, Dental Care
V	Mars Expedition	Level IV + Autonomous Advanced Life Support and Ambulatory Care, Basic Surgical Care

In these five levels of care, trauma (Level III) and surgical care (Levels IV and V) are highlighted. At this time, there are no surgical care system requirements. The requirement 4.1.1.6.3 states "The training and caliber of the caregiver shall be at the physician level, due to the exclusively autonomous nature of the mission" and 4.1.1.6.4 states "The scope of medical care available shall be limited or triaged due to availability of supplies, consumables, or mission risk."

Dr. Antonsen also discussed some of the variables that may impact surgical care in space, including resource management, level of crew medical officer training, skills, recovery, tools/instruments, etc. Prior to requirements being developed there are several questions such as (1) Will surgery be needed?; (2) What kind of surgery will be needed?; (3) What type of skill sets must be provided?; and (4) How do you provide for skills retention or training if needed?; that need to be answered.

He also discussed the Integrated Medical Model (IMM), which list 100 potential medical conditions and the Medical Optimization Network for Space Telemedicine Resources (MONSTR) as efforts to understand risk.

He closed with comments regarding the EcMC's effort with HRP in understanding risk, looking at innovative approaches to supporting surgical care in space.

See Dr. Antonsen's presentation 2.2 in Appendix E.

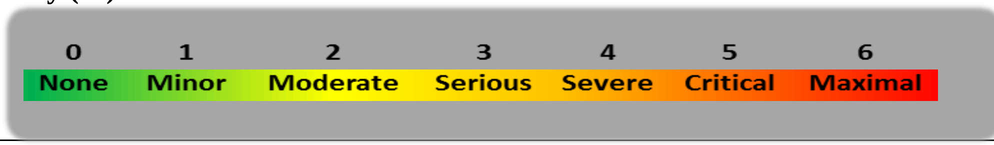
Medical and Surgical Capabilities required to Support Exploration Missions - Space Medicine-Opportunities and Constraints
Jeffrey Jones, MD, MS

Dr. Jones provided an in-depth review of human space exploration covering a wide variety of subjects including exploration initiatives and U.S. leadership commitments in the 21st century, elements of space exploration, space system architectures, and destinations. He also discussed the space flight environment with respect to air, water, noise, radiation, and the various mishaps such as the fire on Mir. Dr. Jones discussed the different kinds of medical events and the countermeasure that are used to minimize the impact of the space environment on human physiology.

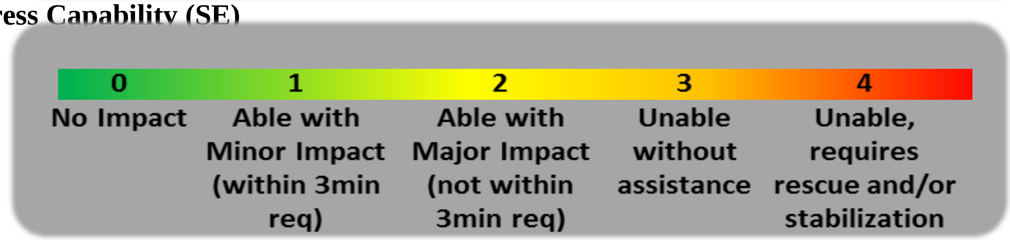
The Keep It Simple ~~Stupid~~ Smart was used as an illustration for Medical Operations concepts of medical systems to support exploration missions, which included different kinds of problems that have occurred on previous NASA missions and might occur in future missions. He used a similar table to Dr. Charles' (see Dr. Charles' presentation) to illustrate and discuss the level of medical care for various kinds of missions (moon, Mars, etc.). He addressed some of the challenges of weight and volume of both medical systems/supplies, environmental monitoring equipment, and exercise equipment. Dr. Jones also talked about suit trauma and extravehicular activities with particular concern for the potential threat caused by exposure to Lunar and Martian dust.

He closed his presentation with comments on enhanced medical care systems and the need to support ill or injured crew. The table below on 'Operationally-Relevant Injury Scale (ORIS)' was used to illustrate the scale in injury related to egress, return to flight and the severity of the injury. Dr. Jones also commented on the value of analogs as environments for learning, testing, training and engaging. The analogs he reviewed include the DC-9, NEEMO, and Haughton Crater.

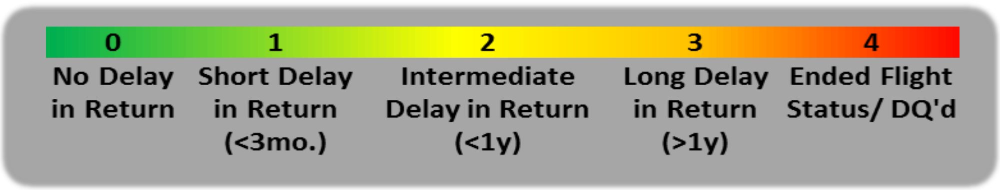
Injury Severity (IS)



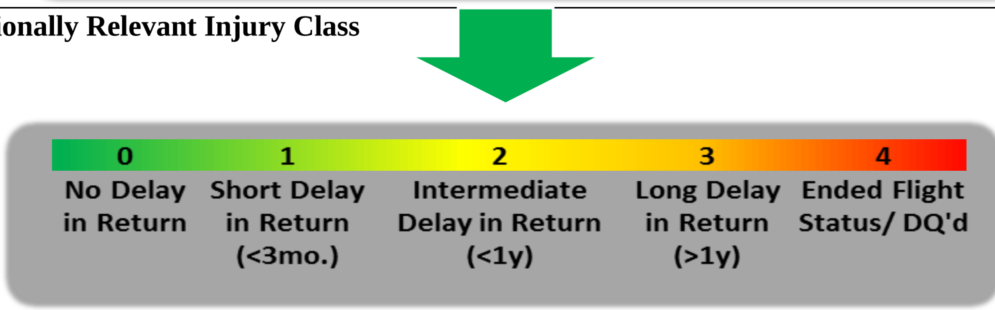
Self-Egress Capability (SE)



Return to Flight Status Estimate (FS)



Operationally Relevant Injury Class



At the conclusion of his remarks, Dr. Jones answered some questions regarding the FDA and its processes. Dr. Broderick commented on the FDA's 'Innovative Pathway' that can be used to fast-tracks certain products and applications. This of course must be tempered with NASA's Flight Readiness Process. The U.S. Military has similar challenges for its processes as well.

See Dr. Jones' presentation 2.3 in Appendix E.

Critical Care and Surgery in Extreme Environments
Panel Chair – Jon Clark, MD, MPH

Panelists:

U.S. Naval Experience on Submarines
Brett Sortor, MD

Dr. Sortor, Medical Officer for the Submarine Force, U.S. Pacific Fleet, provided a summary of the U.S. Navy's medical support for submarines. He described two levels medical care, including the Undersea Medical Officer (UMO) and the submarine Independent Duty Corpsman (IDC). The UMO is akin to a technician and the IDC is like a medic. The ICD does most of the medical care on submarines when they are at sea. These individuals receive training in preparation for their deployment. They mostly serve as the 'occupation health' officer. Submarines are deployed without medical doctors on board. He described the environment of a submarine, including crew size and the 24-hr communication delay. Deployed submarines cannot just surface to remove an ill or injured crew member without significant planning. A medivac is a dangerous activity. Medical events must be addressed in situ.

Dr. Sortor described the kinds of illness experienced on submarines. Common diagnoses include closed head injuries, fractures, mental health issues (situational depression) and abdominal and flank pain. Data on medical management of acute appendicitis has historically been ~85% successful in submariner experience with a few cases annually of sailors being transported from submarines for surgical treatment. Closed head trauma, mental health issues, abdominal and flank pain/kidney stones, or threatening dental conditions were other situations requiring evacuation.

Several examples were used to discuss health issues.

1) About 10 years ago, a mass casualty event after listing on a sea mount near San Francisco resulting in one death.
2) About 5 years ago while the USS Nebraska was in dry dock, an individual had a crushed pelvis. The patient acutely bled during ladder extrication out of the hatch. Patient was found to have severed femoral artery and vein.
3) Norovirus outbreaks occurs 3-5 times per year.

In addition, Dr. Sortor addressed several ethical issues, including prophylactic surgeries (which the U.S. Navy is not pursuing) and the inclusion of women on board submarines. His final observations were that extensive, pre-deployment screening did not eliminate the occurrence of medical incidents at sea and that it would be desirable to have more than one healthcare provider on a crew, especially when there is a situation of multiple, simultaneous events, requiring care such as a viral outbreak.

Surgery in Extreme Environments - NEEMO and Parabolic Flight
Timothy Broderick, MD

Dr. Broderick provide an in depth review of his research in NASA's analog environments of the NEEMO on the Aquarius undersea research station and the NASA KC-135/DC-9 parabolic flight laboratories. Each of these research efforts was focused on surgical care in extreme environments.

He discussed how 20 participants, including astronauts, surgeons, physicians and non-medical personnel conducted the experiments on the KC-135, 'Computer-based VR Surgical Simulation in Microgravity'. A series of tasks (clipping, cutting, grasping, and suturing) were conducted on a virtual reality simulator by a variety of skilled individuals during parabolic flight. The same tests were also conducted on the ground. The simulator emulated minimally invasive surgical steps. Key observations from his parabolic flight experience compared ground performance to flight performance, which was degraded as indicated by more force was being exerted, more time was needed, and more errors occurred when performing surgical tasks in reduced gravity.

Dr. Broderick reviewed robotic and telerobotic surgery and provided definitions on the variety of terms used in this discipline. This included a short summary of both Operation Lindbergh by Drs. Marescaux and Anvari's work in Canada as well as the daVinci work at the University of Cincinnati.

Dr. Broderick participated in several NEEMO missions, of which NEEMO-9 was one of the longest (17 days). He provided a summary of the robotic telesurgery work on NEEMO 9 (April 2006) and the telesurgery work on NEEMO-12 (May 2007, 11 days). During these missions, prototype surgical robots (tele-manipulation systems) were evaluated in the underwater habitat through a wireless communication link to locations on shore.

In September 2007, Dr. Broderick led a group of researchers in conducting robotic surgery on the DC-9 parabolic flight aircraft. He provided a summary of the objectives of each of these research tasks, highlighting challenges and the results, all of which have been published (see References). He also commented that manual suturing was still relevant for space flight.

As a former DARPA program manager, Dr. Broderick also highlighted some of the development of technology for society, including the Internet, GPS, the da Vinci robot, and prosthetics.

See the Reference section for the publications that were a result of this work.

See Dr. Broderick's presentation 3.1 in Appendix E.

Lumbar Puncture in Space: a primary aim of "Zero G and ICP: Invasive and Noninvasive ICP Monitoring of Astronauts on the ISS
Eric Bershad, MD

Dr. Bershad discussed a research project on the measurement of cerebrospinal fluid pressure (CSFP) as a surrogate for intracranial pressure (ICP) in astronauts pre-, in-, and post-flight to determine if this impacts Visual Impairment/Intracranial Pressure (VIIP) in long duration fliers. Current measurement techniques are invasive and noninvasive methods and they are not yet considered reliable. The main objective of this proposed research is to determine if abnormal ICP is present in the VIIP syndrome. This will be accomplished by performing a lumbar puncture to measure CSFP. A review of the flight experiment steps was presented as well as a discussion on monitoring paradigms and the risks associated with these methods.

The procedures discussed would require crew participation in conducting a lumbar puncture in space. Dr. Bershad also discussed crew training and various simulations that could be of educational value to the crew members. Challenges and contingency planning for adverse outcomes were also discussed.

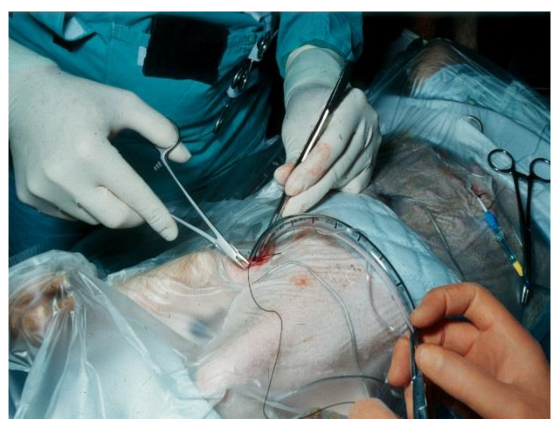
See Dr. Bershad's presentation 3.2 in Appendix E.

Surgery in Reduced Gravity
Panel Chair – Charles Doarn, MBA

Panelists:

Initial Parabolic Flight Research in Space flight Surgical Issues
Mark Campbell, MD

Dr. Campbell provided a thorough review of surgical care and research on surgery in space dating back to the Space Station Freedom program (1984 – 1993). He discussed the various components of the initial medical facility, the Health Maintenance Facility. This include various systems capabilities and a surgical restraint system.



Over the course of several years, Dr. Campbell was instrumental in developing a variety of surgical experiments on the KC-135 specifically on porcine models. The presentation was focused on the many lessons learned. During his presentation, he discussed systems to hold surgical instruments, restrain surgeon and patient, manage the surgical field, control blood flow (arterial and venous flow), and manage medical disposal.

Dr. Campbell concluded his remarks by summarizing the following:

1. Patient restraint can be accomplished by simple methods for patient and crew medical officer (CMO).
2. Instrument restraint is important and needs to be planned for in the system.

3. Bleeding can be controlled so that it does get into the cabin environment.
4. Advanced Trauma Life Support (ATLS) procedures can be performed.
5. Complex surgical procedures can be performed. Not more difficult, but require increased time to perform.
6. Fluids behave differently than in 1g.

See the Reference section for the publications that were a result of this work.

See Dr. Campbell's presentation 4.1 in Appendix E.

Surgery in Reduced Gravity: Initial Efforts in Low Earth Orbit
Jay Buckey, MD

As a physician astronaut, Dr. Buckey provided firsthand experience on surgical efforts during several Space Shuttle flights, including SLS-1, SLS-2, and Neurolab. During each of these flights, astronauts evaluated various medical systems that would be included in any surgical system. This included the flight on SLS-1 of the Bruce Houtchens' designed surgical restraint table.

The majority of Dr. Buckey's comments were on his participation as a crew member on Neurolab, which flew in 1998 on STS-90. He reviewed the kinds of surgical procedures that have been done in space to date. These include:

1. Tail vein cannulation
2. Timed dissection of temporal bone
3. Timed laminectomy
4. Various dissection procedures
5. Perfusion fixation
6. Survival surgery (anesthesia, visualization of soleus in neonatal rat, injection with tracer, wound closure, recovery)

In order to do these kinds of surgical tasks, the crew trained prior to the mission on the same systems on the Space Shuttle. This included the General Purpose Work Station, which had an air flow system). See inset photo of Dr. Buckey and Dr. Dave Williams performing surgical experiments using the work station. Dr. Buckey indicated that dexterity, fine motor control and control of instruments were not appreciably different between ground and space flight. He also commented on the need to wear surgical loupes but these interfere with getting close to the tissues.

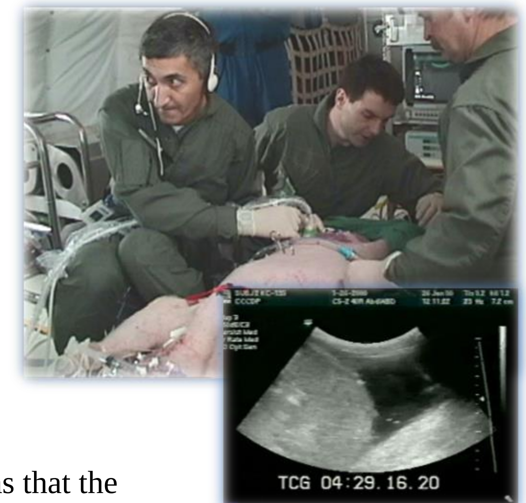
Dr. Buckey summarized his remarks by stating that surgical techniques were successfully demonstrated in rats during space flight. This included general anesthesia, wound closure, wound healing, hemostasis, control of surgical fluids, operator restraint, and control of surgical instruments. The Neurolab mission was the first space mission to conduct delicate surgical procedures successfully and with the first survival surgery.

Much of the research conducted on Neurolab has been published in the book ‘The Neurolab Space Mission: Neuroscience Research in Space’, which was edited by Drs. Jay Buckey and Jerry Homick. The book summarizes the results of the research conducted during the mission.

See Dr. Buckey’s presentation 4.2 in Appendix E.

The University of Calgary Surgery in Space Research Program
Andy Kirkpatrick, MD, MHSc

Dr. Kirkpatrick provided an overview of his medical center - Foothills Medical Centre in Calgary, Alberta, Canada and the various kind of research his group has been involved in with NASA and the Canadian Space Agency.



He commented on some of the historical work that had been done by Bruce Houtchens in the early 1980s as well as several research efforts in the extreme environments of Northern Canada. Much of Dr. Kirkpatrick’s work was focused on trauma support and the use of ultrasound during flight as well as laparoscopic surgical technique. Over the course of the last two decades, a number of experiments with numerous collaborators have taken place both in Canada and the U.S. using parabolic flight. The research also focused on gas insufflation and methods for supporting laparotomies.

A key observation shared from parabolic flight experience was that the abdominal tended to circularize in 0g, making visualization better for laparoscopic surgery. He suggested that some insufflation was still needed and that even with the better visualization, no insufflation would be dangerous. Abdominal bleeding was his biggest concern.

See the Reference section for the publications that were a result of this work.

See Dr. Kirkpatrick’s presentation 4.3 in Appendix E.

Smart Medical Technology
Panel Chair – Jimmy Wu, BS

Panelists:

Diagnostic Equipment
Gary Strangman, MD

Dr. Strangman, a lead scientist for NSBRI’s Smart Medical Systems team, discussed biomedical monitoring needs of space flight. This includes the ability to monitor the health of the crew, monitor the environment (space craft, EVA suit, etc.) and he described an example of an integrated research platform to coordinate data streams from multiple sources. He also presented NASA publication 65722 (March 2012) - Space Medicine Exploration Medical Condition List.

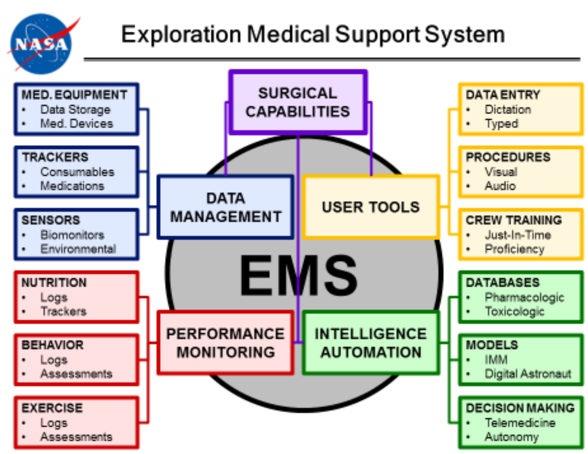
This document addresses 86 conditions and highlights areas which might require surgical intervention. These include abdominal injury, burns, chest injury, obstructed airway, compartment syndrome, and lacerations.

He provided a review of the current biomedical equipment on ISS from both the U.S. and from Russia. This equipment include medical monitoring, environmental monitoring and exercise equipment. Much of the challenges and constraints included the limitation on weight, volume, mass, power, time, money, and risk. Dr. Strangman discussed novel diagnostic approaches. The inset image is an example of medical diagnostic kits. He closed his comments by illustrating a ‘SpaceMED System’, which included data acquisition, data storage and utilization or decision making, and communication modalities.

See Dr. Strangman’s presentation 5.1 in Appendix E.

HRP Exploration Medical Capabilities Exploration Medical System Prototype
David Rubin, MS

Mr. Rubin discussed medical capabilities for exploration class missions, which will be characterized by (1) limited communications, (2) a harsher environment, (3) limited resources, (4) limited resupply, and (5) increase in the skills and proficiency of the crew. The implication is increased crew autonomy.



Using a variety of diagrams (see inset), Mr. Rubin presented how the Exploration Medical Support System might be configured in an integrated fashion. While some technologies are mature and could be integrated, automated intelligence and decision support software/systems are not mature. A significant challenge will be connecting and controlling all of the different pieces of equipment involved with medical information systems.

See Mr. Rubin’s presentation 5.2 in Appendix E.

NASA Robonaut as a Surgical Avatar – Recent Experiments
Ron Diftler, PhD

Dr. Diftler presented the work to date on Robonaut as a surgical avatar. He used a number of videos to illustrate the work that has been done and what the capabilities are for such a system on board a space-based platform.

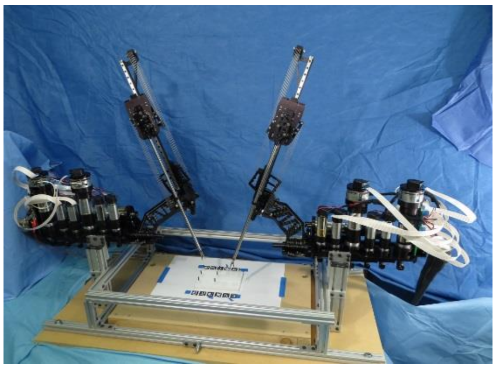
1) Robonaut Performs Taskboard Tethering - https://www.youtube.com/watch?v=P1uhTlnGZM0&list=PLTXQuaxXBKKyUXfL6Kt9ksfosresu2cpA&index=4
2) Robonaut Demonstrating Hand Rail Cleanings and Task Board Demonstration – https://www.youtube.com/watch?v=l_-NyvV96zY&index=8&list=PLTXQuaxXBKKyUXfL6Kt9ksfosresu2cpA
3) Robonaut Supports Telemedicine Advances- https://www.youtube.com/watch?v=9gbfL590Fgg
4) Robonaut Medical Training - http://pumpsandpipes2.hendrikmvp.com/Media/VideoPlayer/3231

To date, medical experiments have included (1) intubation, (2) laparoscopic assist, (3) ultrasound, and (4) Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) training that have demonstrated good digital manipulation. Development continues both for medical applications as well as assistance to astronauts in maintenance and construction type tasks.

See Dr. Diftler's presentation 5.3 in Appendix E.

RAVEN^{TM} and the Surgical Cockpit^{TM} - *Teleoperation Systems for Space Applications*
John Raiti, PhD

Dr. Raiti provided a history of the development of the Raven teleoperation system, including work involving Broderick and Doarn during NEEMO and the High Altitude Platforms for Mobile Tele-Robotic Surgery in the high desert (see References). The surgical system (see inset) has two components; the robotic systems and a control cockpit.



AppliedDexterity's goal is to modify the systems so that it can fit in the Microgravity Science Glovebox and conduct rodent research on the ISS. A concept of operations would include: (1) positioning – retrieve, stow, clamp, and pin, (2) grasping, (3) cutting – soft tissue and bone, (4) fluid handling – fixative, blood, and vacuum, and (5) open/close containers – vials, tissue bag, ziplock backs, and trash.

Dr. Raiti closed his remarks by indicating that this platform was ideal for incorporation into a broader smart medical system, it is ready for use now, and that it represents a pragmatic approach for extending research into the microgravity environment. Challenges for current

Raven development include optimizing the bandwidth needed for reliable operation and determining an acceptable latency period (0.5 to 3.0 seconds).

See Dr. Raiti's presentation 5.4 in Appendix E.

Multi-use dexterous robots for mission surgical capability
Marsha Morien, MSBA

Ms. Morien provided a summary of the research efforts at the University of Nebraska's Center for Advanced Surgical Technology. She discussed the evolution of surgery from open to laparoscopic to small robotic systems. These small systems are miniature *in vivo* robots, which are easy-to-use and reusable. Such a system (see inset) could be inserted into the body and could be operated using a laptop. A single incision is made and then the system is deployed with natural movements of the ands in synchrony with the instruments. (Note: Shortly after the symposium, the First in human clinical procedures of the robot they developed were conducted by their corporate partner, Virtual Incision, Corp).

Ms. Morien reviewed some the experiments conducted during parabolic flight to evaluate perception of the surgical field and ability to successfully operate controls.

See Mr. Morein's presentation 5.5 in Appendix E.

Robots for Telemedicine
Fuji Lai, MS, SM

Ms. Lai provided a great summary of robots currently in use for telemedicine applications. She talked briefly about Computer Motion's Zeus platform and Operation Lindbergh. She also discussed the current problems in healthcare, including shortages and maldistribution of specialists. This gap is where telemedicine and telepresence capabilities can be integrated to enable access and usher in a paradigm shift in healthcare.

Remote presence telemedicine solution, cleared by the FDA, provides useful model for healthcare. Using remote presence devices (see inset photo), physicians can interact with patients synchronously when they are separated by some distance. This device is the Virtual & Independent Telemedicine Assistant (VITA).

Ms. Lai also described surgical telementoring applications that enable mentoring and collaborating in the traditional isolated operating room. She highlighted the fact that human-robot collaboration for decision making and action are no longer on the horizon but in development of full integration.

See Ms. Lai’s presentation 5.6 in Appendix E.

Crew Composition, Training for Flight, the Effect of Transmission Latency
Panel Chair – Gary Strangman PhD

Panelists:

Who Should be on the Crew?
Richard George, MD

Dr. George discussed the type of trained person who should serve on board as the CMO. Specifically, prior medical training, obtaining and maintaining skill level. What makes an ideal clinician? He posed a number of questions about the kind of trained personnel we have, the kinds of tools or new tool development, and a number of “what ifs?”. He suggested the use of the Medical Judgement Pathway Metric, which has been pilot tested. While not definitive in addressing exploration needs, it provided a foundation for future discussion and consideration.

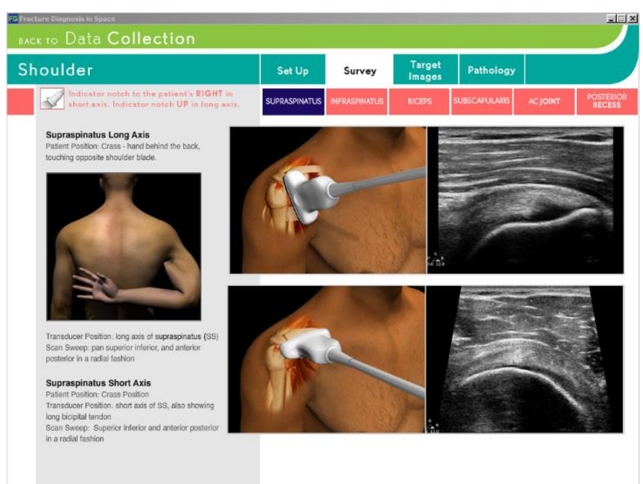
See Dr. George’s presentation 6.1 in Appendix E.

Factors Affecting Successful Performance of Medical Tasks
Doug Ebert, MD

Dr. Ebert discussed factors that affect the performance of medical tasks during flight. These include: (1) resources, (2) the environment, (3) the procedure or task, (4) experience of the operator, (5) autonomy, and (6) training. He used three cases: (1) Fracture Diagnosis in Space: Guide Evaluation, (2) Smart Ultrasound Remote Guidance Experiment (SURGE), and (3) Clinical Outcome Metrics for Optimization of Robust Training (COMfORT) as examples to illustrate the challenges. Each case included the project summary, approach, evaluation methods, imagery analysis and conclusions. The three examples included ultrasound of fractures, kidney/urinary imaging, and several common medical tasks. Research questions included whether physicians perform better than non-physicians and does training expire and need to be refreshed.

This research had four specific aims:

1. Develop clinical outcome metrics (immediate term) to discriminate between physician and non-physician CMO analogs.
2. Develop long-term clinical outcome metrics through modeling of mission impacts due to lack of complete clinical procedure success.
3. Develop advanced training products that increase retention and reduce errors during the performance of medical procedures.



4. Promote public understanding of human research and human activity in space environments through formal and informal education opportunities.

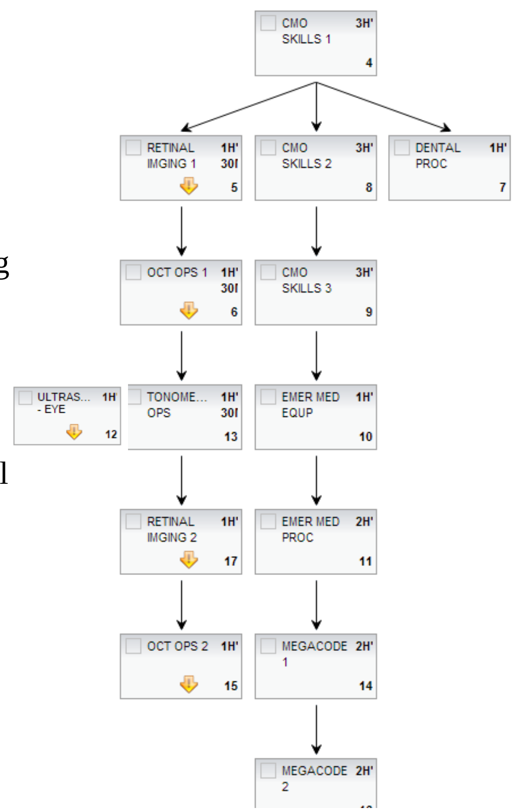
The following research products are expected:

1. Data that quantifies differences in medical outcomes when physician and non-physician CMO analogs are compared in procedure simulations (immediate term outcomes) and by IMM analysis (mission impacts).
2. Refined clinical outcome metrics for medical training and testing.
3. Innovative medical training products and solutions to maximize CMO performance.
4. Enhanced IMM capability through the development of algorithms that account for incorrect diagnoses and incomplete treatment.
5. Validation of the methods and products used by this experiment for operational use in the planning, execution, and quality assurance of the exploration mission CMO training process.

See Dr. Ebert’s presentation 6.2 in Appendix E

ISS Crew Medical Officer Training
Melinda Hailey, RN

Ms. Hailey provided a summary of the training program for preparing crew members who serve as CMO during ISS missions. Her presentation covered pre-flight and in-flight as well as future development challenges. Training prior to assignment is mandatory for CPR and DCS. Optional pre-assignment training allows the student (crew member) to observe and/or perform medical skills using human subjects. This training provides a unique opportunity for learning how flight hardware works, the ‘do not harm’ philosophy and variability in human anatomy. In addition, she covered both emergent and non-emergent conditions. Crew training include 7 hours of ALS with both classroom and mockup simulations. Specialist training is 26 hours in duration. In addition, there is training in VIIP as well.



Ms. Hailey covered the CMO work flow using the flowchart (see insert). In addition, there is a 45 minute drill 4-6 week prior to arrival and computer-based training every 30 days. This training is 25 minutes in duration and is for U.S. and international partners only (sans Russian crew).

The training timeline is 18 months before the flight with repetition training at the following intervals before flight 12 months, 9 months, and 6 months.

See Ms. Hailey’s presentation 6.3 in Appendix E

The View from the Crew
Panel Chair – Mark Campbell, MD

Physician Astronaut Panelists: Tom Marshburn, MD, Jay Buckey, MD, Lee Morin, MD, PhD

This symposium provided an outstanding opportunity for three crew members to discuss their flight experiences as physician astronauts. The panel consisted of Jay Buckey (Payload Specialist on STS-90 - Neurolab), Tom Marshburn (former NASA flight surgeon, STS-127 and Exp 34/35 on ISS – Soyuz TMA-07M) and Lee Morin (Mission Specialist STS-110). Dr. Mark Campbell, served as the panel chair facilitated a discussion with 'open ended questions' with each panel member providing responses based on their experiences during all phases of flight (pre-, in-, and post-flight).

Key concerns expressed by the panel related to maintaining skills proficiency, lacerations (particularly of the head), the CMO needs to fit in well with the crew and have "real-world" healthcare experience, and the minimum allotment for medical equipment on a space craft. The observation was made that it was possible to do surgery in reduced gravity with adequate resources and training.

Data Blitz
Chair – George Pantalos, PhD

At the conclusion of the first day, Dr. Pantalos introduced a 'lightening round' or 'data blitz' format, which provide invited speakers or attendees to make comments or very short yet informative presentations. Each speaker was limited to two slides and less than 5 minutes. The purpose of this format was to illicit additional comments and challenges that are faced in moving surgical care in space flight forward.

Speakers included the following individuals:

1) Comments from Mr. Drajeske of Applied Dexterity regarding the advantages and limitations of the Raven and Surgical Cockpit. In particular, he commented that teleoperation of a surgical robot may improve performance, but you also have to deal

with the consequence of signal delays and loss of signal (LOS) during space flight. (See presentation 7.1 in Appendix E).

2) Dr. Ebert comments regarding 'factors affecting successful performance of medical tasks' specifically aligned with imaging and the capability of the individual reading the images. (See Dr. Ebert's presentation 7.2 in Appendix E).
3) Ms. Allison Kumar provided an excellent presentation of the FDA's 'Fostering Medical Innovations' including the expedited pathway for medical countermeasures for disasters. (See Ms. Kumar's presentation 7.3 in Appendix E).
4) Ms. Morien – discussed the Multi-use Dextrous Robots for Mission Surgical Capability. This is a portable, single incision, minimally invasive system. (See Ms. Morien's presentation 7.4 in Appendix E).
5) Dr. James Cushman discussed medical training methods, degree of complexity, the training objectives and the time allowance for training in support of exploration missions. In particular, he recommended some medical training of the entire crew so they could act as a team in response to an urgent need. (See Dr. Cushman's presentation 7.5 in Appendix E).
6) Mr. Doarn provided a summary of the challenges of surgical care in space. He commented on surgical care systems NASA's report from IOM, the Medical Policy Board, historical efforts and NASA-wide strategic initiatives. (See Mr. Doarn's presentation 7.6 in Appendix E).

Dinner Presentations

History of Surgical Care in Space Symposiums
Mark Campbell, MD

Dr. Campbell has been involved in the development of surgical care of space, dating back to the Space Station Freedom (SSF) days. As a consulting surgeon to NASA and eventually as a NASA flight surgeon, Dr. Campbell, along with a number of other individuals conducted a wide variety or ground-based and parabolic flight activities. His presentation covered a myriad of materials related to surgical care in space. This included a review of symposia and discipline specific gathering of subject matter experts dating from 1983. The original SSF program (1984 – 1993) was discussed, including the Health Maintenance Facility (HMF) that included a significant surgical capability. Dr. Campbell discussed analog environments, including submarines and the Antarctic, specifically appendicitis. In addition, he discussed the Clinical Capabilities Development Project and other symposia held by others over the past several decades.

See Full presentation in Appendix E.

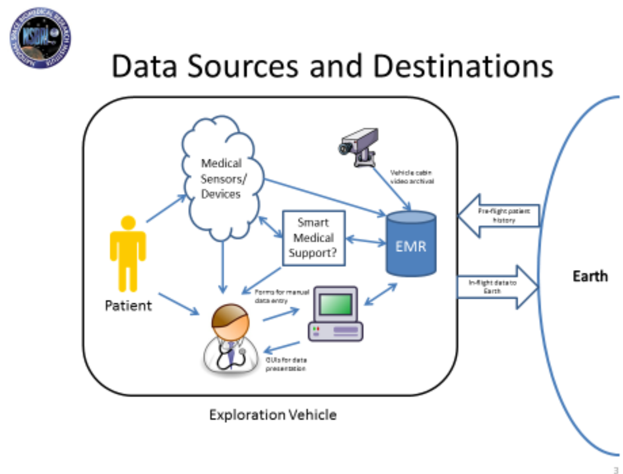
3D Printing of Surgical Instruments for Long-Duration Space Missions
Julielynn Wong

Dr. Wong gave a very interesting and thought provoking presentation on 3D printing, including a demonstration using a small printer. The capability of printing surgical and medical instruments along with building structures using the natural resources of the Martian surface of the Moon was also discussed. (See references 108 and 109 in the Reference section)

Management of the Perioperative Environment
Panel Chair – Timothy Broderick, MD

Panelists:

Data Management
Jimmy Wu, MD



Dr. Wu provided an interesting presentation on data and some of the challenges that will be faced in how it is stored and accessed, especially with communications delays on exploration class missions. Using the diagram (see inset), Dr. Wu discussed data sources and destinations. Areas of concern include how much patient history should be sent with the mission and will the CMO have access to all crew member's medical history? How will data be backed up? Will the data entry forms be customized based on CMO skillset? How will data integrity and security be ensured? Will non-human autonomy have a role? These questions provide the foundation for developing medical and surgical care systems for exploration class missions.

See Dr. Wu's presentation 8.1 in Appendix E

Anesthesia for Colonization and Exploration of Mars and the Moon
Hal Doerr, MD

Surgical care in space will require anesthesia. However, it is not clear at this time what kind of drugs or induction methods will be required. Vaporized anesthetics and high oxygen concentration cannot be used and fluid management of IV drugs and solutions is yet to be fully defined. Dr. Doerr discussed induction sequences: (1) Propofol, Lidocaine, Rocuronium Br, Fentanyl, and Versed (midazolam) and b) Ketamine + Precedex. Delivering these drugs in a closed environment requires thought as well as training and risk assessment. In addition, how the drugs are administered – spinal/epidural, regional, TIVA, general, or sedation with local infiltration – needs to be carefully considered.

See Dr. Doerr's presentation 8.2 in Appendix E

Parabolic Flight Evaluation of a Hermetic Surgical System (HESS) for Reduced Gravity 49-P
George Pantalos, PhD

Dr. Pantalos presented his research group's work on NASA's DC-9. The goals of experiment 49-P was to develop a medical device that can contain and control the surgical field while permitting surgical tasks in a reduce gravity environment. A containment system, the Aqueous Immersion Surgical System was built and tested in parabolic flight (see inset photo). The system is a dome shaped with access ports. Dr. Pantalos's team studied pressure and leak tests as well different kinds of adhesive materials. The ability to perform surgical tasks inside the containment dome (suturing, knot-tying, stapling, and cutting) in 0-G and Lunar-G have been successfully demonstrated. Newly developed leak-free ports (trocars) permit passage of endoscopic surgical instruments while maintaining fluid pressure inside the dome. In 2017, his team will conduct experiments on Virgin Galactic's suborbital experiment platform.

See Dr. Pantalos's presentation 8.3 in Appendix E

Post-operative Care, Rehabilitation, and Return to Crew Activity
Joe Dervay, MD

Dr. Dervay made general comments regarding the flight surgeons role in operations. He discussed a variety of medical issues and how the flight surgeons support the crew in all phases of flight. He also mentioned the consideration of a guide device, such as Google Glasses, to provide assistance during procedures.

Although Dr. Dervay used presentation material, it was not available for this report.

Overview of IVGEN
John McQuillen (replaced Jerry Myer)

Mr. McQuillen described a research and development project from the NASA's Glenn Research Center. He described the on orbit need for IV fluids. While there are challenges to launching IV fluids sufficient to address a medical emergency, the general consensus is to develop a system that could generate the IV fluids in orbit. A system, the IVGEN, was developed and field tested on the ISS.

The goal of the system is to develop sterile water for injection from potable water generated by the water recovery system (WRS) on the ISS. Mr. McQuillen provided a detailed description of the hardware and its evaluation on ISS in 2010 in the Microgravity Science Glovebox (see inset photo). The system produced 2 bags of saline and 4 bags of purified water. The flight experiment was successful. However additional work is required in selection of bag materials to limit total organic carbon contamination and validation of irradiation of salt crystals as a method of sterilization.

See Mr. McQuillen’s presentation 8.4 in Appendix E

Technical Support for Surgery
Panel Chair – Steve Parnis, BS

Panelists:

Hemostasis Capabilities for Exploration and Colonization Space Flight
Kenton Gregory, MD

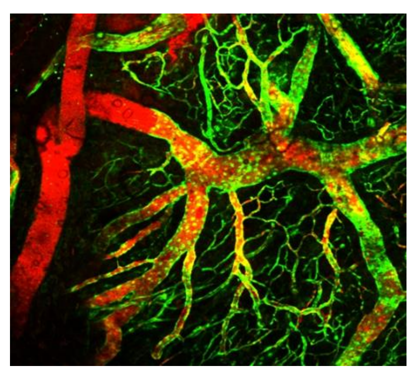
Dr. Gregory discussed hemostasis and wound healing using products like XStat™ and X Gauze. Space flight causes changes in blood volume, red cell mass and thrombocytopenia. Should a crew member become injured where hemorrhage must be controlled, a quick system must be deployed. Systems can include a variety of compression techniques, clotting materials, sealants, drugs, instruments, etc.

Dr. Gregory referenced military needs/requirements for treating hemorrhage, the leading cause of battlefield death, as quickly as possible. One such technology that shows promise are compression sponges that absorb and rapidly expand. He used a video of a porcine model where the subclavian artery in injured and the XStat material is applied in the immediate aftermath of the injury (see inset photo). Dr. Gregory discussed XStat™ as an internal compression sponges and stated that they generate 1mmHg pressure per sponge. The product was recently approved by the FDA in December 2015. “The FDA representative at the Symposium reminded everyone that the sponges used with XStat need to be removed after use; they have Xray markers imbedded to facilitate complete removal.”

See Dr. Gregroy’s presentation 9.1 in Appendix E

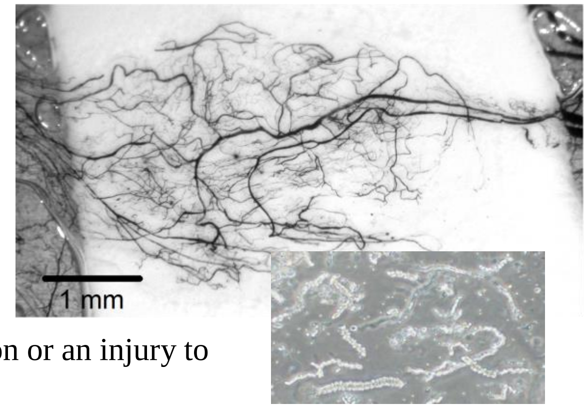
3-D Bioprinting in Space Bioinks
Stuart Williams, PhD

Dr. William’s presentation was focused on the ability to create organs, vascular structures, and other biomaterials via 3-D printing techniques. He discussed the components of bioprinting, including the various steps and systems required to accomplish the task of printing a new product from human cells accompanied with synthetic and natural occurring gels to create ‘bioinks’. He explained how you can print a 3-D microcirculation matrix.



See Dr. William’s presentation 9.2 in Appendix E

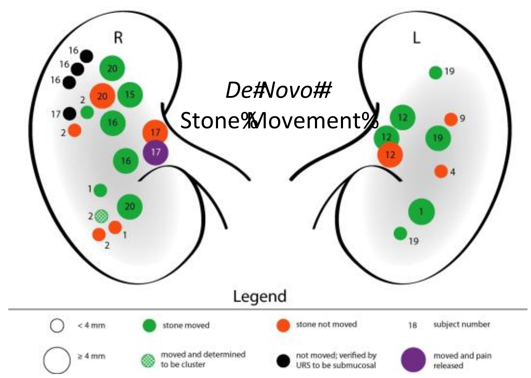
3-D Bioprinting for Wound Healing Applications
Gene Boland, PhD



Dr. Boland described 3-D Printing, including (1) electrospinning, (2) thermoplastic 3-D printing, and (3) hydrogel 3-D printing. Printing fibers allows for the creation of a scaffold as a foundation for tissue development. He also described a biomanufacturing system. Such system was used to create a microvascular construction. Such 3-D printed biomaterials could be used to treat a primary laceration or an injury to the cornea.

See Dr. Boland's presentation 9.3 in Appendix E

Therapeutic Ultrasound Techniques to Augment Surgical Capabilities in Space
George Schade, MD



Dr. Schade presented the University of Washington Urology Department's work in in the use of Therapeutic Ultrasound and High frequency ultrasound for hemostasis. Thus use of ultrasound propulsion can alleviate obstruction, facilitate treatment, and facilitate spontaneous passage. He discussed a clinical trial of how they used this technology to move renal calculi (top figure at right). In addition, he discussed burst wave lithotripsy, acoustic coagulation, and histotripsy. The burst wave lithotripsy can non-invasively grind stones to dust (see lower photos of a struvite stone). High intensity focused ultrasound has also been shown to seal ruptures in blood vessels via coagulation without closing off flow through the vessel.

See Dr. Schade's presentation 9.4 in Appendix E

Prioritized Opportunities to Establish Surgical Capabilities
Discussion Leaders – John Charles, PhD and Jon Clark, MD, MPH

At the conclusion of the presentations, the consensus opinion was that it was possible to perform surgical tasks in reduced gravity and the limited environment of an exploration space craft and a colonization module. The challenge remains how to move forward with exploration and colonization mission planning to incorporate the crew skills and training with space craft resources to make the option of surgical treatment possible. Drs. John Charles and Jon Clark led a discussion that summarized the symposia to stimulate consideration of a list prioritizing opportunities. Dr. Mark Campbell commented that an earlier conference by Drs. Sam Pool and Norm McSwain in 2002 would be of value to this group. Both Drs. Campbell and Sutton commented on the importance of reviewing their findings. Although this effort was in 2002, key questions remain relevant, including: (1) Who would be the CMO and what would be their qualifications?, (2) What would a CMO be expected to do in Exploratory Class missions?, and (3) What are optimal mission profiles and autonomous care capabilities for exploration class missions.

Symposium participants discussed how to move this topic forward at future AsMA meetings. Dr. Campbell pointed out that since October 1 is the deadline for submissions for the annual meeting, presentations or panels could be developed for the Denver AsMA meeting in 2017. He challenged the members of the symposium to submit the effort for program committee consideration. Dr. Campbell recommended concomitant review of past symposia such as the 2002 McSwain et al. Surgery Conference. He stated he would advocate for panels focused on surgical capabilities for space exploration.

In a lively exchange of ideas, thoughts, observations, and speculations, many topics were discussed. Current state of surgical capabilities and research were defined. Most importantly, symposium participants considered challenges that limit as well as research opportunities that could advance surgical capabilities for space exploration. Items discussed included:

1. Focus on “less is more”.
2. Minimally Invasive Surgery (MIS) is best for many surgical illnesses, if we can provide skills and resources to accomplish.
3. Traumatic injury is more likely than surgical illness. Trauma is not elective and not readily addressed by MIS. Trauma may be part of a “bad day” in space and resource limitations may preclude more than comfort care.
4. What is the minimal set of surgical equipment and supplies needed?
5. Communication latency during exploration class missions necessitate highly autonomous crew function and medical care. What has been done?
6. CMO(s) are the “tip of the spear”. What is the minimal repertoire of skills needed? Selection and training should consider expeditionary medical care as well as other individual and team attributes critical for mission success.
7. How do we implement “just-in-time” training?
8. How can we minimize preparatory time during a surgical emergency?
9. What is the best training plan for CMOs?
10. How can we leverage Dr. Sam Pool’s Space Surgeon Course Working Groups from the late 1990’s as well as Dr. Norm McSwain-led Space Surgery Conference in 2002?
11. Personnel selection is critical. The experience and success of physician astronauts was reviewed.
12. Should we select or design specialized training for astronauts to ensure relevant post-graduate level knowledge and skills? For example, do we select an astronaut who has completed aerospace medicine, emergency medicine, and/or surgery residency versus selecting a physician before residency and include a space surgery fellowship as part of their training?

13. Role of the flight surgeon moving forward? Do we need to update the curriculum to reflect potential service as crew on expeditionary missions?
14. Do physician astronauts have time to maintain clinical proficiency?
15. How do you maximize and optimize training opportunities while in the transit to Mars?
16. Triage and the need to potentially stop providing care are important for mission success.
17. How do we make cutting-edge dual use technology available to all (e.g., autonomous robotic systems and 3-D printing could support both medical care and research activities in the spacecraft)?
18. Could surgical technology being developed for use in third-world countries and the military be used during space explorations? Is there an opportunity to synergize technology development?
19. What are the surgical personnel, equipment, skills and training required for space exploration?
20. Are there unique needs and opportunities for wound healing in space flight? What do we know and what do we still need to know about wound healing in microgravity?
21. What are our short and long term surgical research priorities? A blend of exploratory and advanced technology development could address the needs of exploration space flight.
22. Previous symposia identified similar issues. Some of these issues have been addressed and some issues persist. What is the optimal schedule for assessment of surgical capabilities, revision of technology development plan, and funding allocation? Continuous funding of exploration-enabled surgical research is necessary.
23. How do we increase awareness that surgical capabilities are critical in future exploration class missions?
24. What role does "surgery in space" play in inspirational STEM education and workforce development?
25. What is the best approach to biomedical technology watch, community building and cultivation? Recent advances in big data analytics and the Microsoft Hololens were cited as technologies that could be of value.
26. Survey stakeholders and related groups on research needs and prioritize.
27. Consider lessons learned from other austere environments – not just space flight. For example, the Navy experience suggests it is valuable to have a physician on board. Appendicitis may be treatable by antibiotics, but the experience in submarines suggests there is a probability of appendicitis requiring treatment beyond antibiotics.
28. How can we foster collaboration between symposium participants (eg, NSBRI sharepoint site)? A standing working group is not probably necessary.
29. What is the highest impact method to archive and publish this information as well as information from other past meetings?

Opportunities

1) **Healthcare Provider Selection**: Ideally, there should be two healthcare providers on each exploration/colonization mission crew; a CMO and a Deputy Crew Medical Officer (DCMO) who will have the primary responsibility for healthcare delivery and health maintenance on a mission, but will also have other responsibilities in support of the overall mission. On these remote missions with limited crew size, in case the CMO becomes incapacitated, it will be necessary to have someone with some level of healthcare proficiency (the DCMO) to step in and provide care for the CMO and other crew members until the CMO has recovered. Since a situation on an exploration mission that requires advanced medical care, even surgery, will probably involve a traumatic injury, is preferable that the CMO be an experienced trauma surgeon or an experience emergency medical physician with sufficient training in surgery. The DCMO could be based in another scientific or engineering discipline, but with intensive training in first response (e.g. paramedic) healthcare. This CMO+DCMO approach to crew composition will maximize the healthcare capability while also contributing to the overall mission success.

2) **Healthcare training**: For an exploration/colonization mission, all crew members should receive a *in situ* pre-mission orientation to all medical supplies and equipment associated with the mission so that they can provide competent, secondary assistance for a procedure as well as have a working knowledge of the medical records system to help track their personal health assessment and assist others if needed. The CMO and DCMO would receive more extensive training, including situation simulations, to learn and develop plans to work through plausible scenarios that may occur during a mission. At some point pre-mission, the entire crew will participate in a more involved simulation scenario so that they can understand at a fully integrated level how the cooperation and involvement of each crew member may be needed and establish a pattern for crew communication in such a scenario. This is a critical part of the crew training when they reach a point in the mission where they will need to respond autonomously.

   Once the mission has started, periodic refresher training for the CMO and DCMO will be scheduled on a regular basis. The best schedule and method to implement the refresher training (e.g. onboard videos, real-time sessions with mission control when latency is not prohibitive, practice flight physicals on other crew members) needs to be determined. On a lesser frequency, simulations that involve the entire crew is needed.

3) **Establish a Controlled Healthcare Procedures Zone (HPZ)**: Room available on an exploration space craft will be limited, so it may not be possible to have a module dedicated to healthcare delivery. Consequently, space craft designers will need to identify a zone in a module nominally used for other purposes that can be designated and easily reconfigured for a healthcare procedure. This may be possible by screening off an area to minimize undesirable flow-through of objects or other crew members. This would also be located in an area with a high concentration of supplies and equipment used for healthcare with planned methods for healthcare provider, patient, supply and equipment restraint. Deploying and stowing equipment and materials needed for the HPZ should be included in pre-mission and during mission training and scenario sessions.

4) **Wound Healing**: Identify current gaps in the understanding of wound healing in reduced gravity and pursue promising approaches to eliminate the gaps and development appropriate treatment plans.

5) **Develop On-Board Fabrication Capabilities**: Rapid fabrication capabilities for all aspects of maintaining the health of the crew members and the space craft need to be further developed so that medical instruments and other items needed to support the on-going mission can be created. Optimal ways for rapid fabrication (e.g. 3-D printing) with materials that are flight acceptable (e.g. no-outgassing, easy to make and assemble, re-cycled materials) need to be developed and validated.

6) **Multi-tasking of On-board Equipment**: In the interest of conserving space and mass on a space craft, determine methods to use on-board equipment for more than one purpose. For example, an appropriately configured laptop computer could also be used for a patient monitor, a monitor screen for an ultrasonic imaging unit that can plug into a laptop, and a medium for skill maintenance training. An ultrasonic imaging device could also be used to create therapeutic ultrasound.

7) **Identify New Healthcare Equipment, Devices, and Supplies Needed**: Equipment, devices and supplies either new or in new configurations more compatible with exploration space flight need to be identified through an expert panel mechanism that would include astronaut/physicians, medical device developers, medical science researchers, mission planners, space craft designers, and medical regulators. The results of this panel would be used to specify targeted research and development efforts.

8) **Increase Resources for Space Healthcare Device and Supply Development**: With an identification of the technology and materials needed, there will need to be an increase in resources needed to fund the research and development effort. Industry is less likely to consider taking this on themselves unless a large, Earth-based market for the needed product is identified. Consequently, NASA should expand funding opportunities such as SBIR/STTRs for new device and supply development sufficient to appeal to small business developers. In addition, new partnerships should be created and existing partnerships should be expanded. For example, easily transportable, small, lightweight, and inexpensive medical devices for use in the remote areas of developing countries, by the military, or other austere environments may also be useful for spaceflight. NASA-facilitated partnerships with government, public, and private development agencies could help to expand the level of research and development resources available while creating new products that are needed.

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Appendices

Appendix A: Participant List

Appendix B: Agenda

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Appendix E Presentation Materials

Appendix A: Participants List

Erik Antonsen, MD, PhD, MS
Element Scientist Exploration Medical Capabilities
NASA JSC

Eric Bershad, MD
Neurology-Vascular Critical Care
Baylor College of Medicine

Nathan Bills, PhD, MBA
Research Coordinator
Center for Advanced Surgical Technology, University of Nebraska Medical Center

Eugene Boland, PhD
Chief Scientist
Techshot, Inc

Timothy Broderick, MD
Chief Scientist / Dean of Research Affairs
Wright State Research Institute / Wright State Boonshoft School of Medicine

Jay Buckey, MD
Astronaut (Ret)
Professor of Medicine
Geisel School of Medicine at Dartmouth

Mark Campbell, MD
Former NASA Flight Surgeon
General Surgery
Paris Regional Medical Center

John Charles, PhD
HRP Assoc. Mgr. for International Science
NASA Human Research Program

Jonathan Clark, MD, MPH
Former NASA Flight Surgeon
Associate Professor
Baylor College of Medicine

Morgan Crigger, BS
4th Year Medical Student
University of Louisville

James Cushman, MD
Associate Professor of Surgery
University of California San Francisco - East Bay

Marc Dean, MD
Chairman and Medical Director Vitruvio Institute of Medical Advancement

Joseph Dervay, MD
Lead, Medical Operations Group
NASA, JSC

Ron Diftler, PhD
Robonaut Project Manager
NASA, JSC

Charles R. Doarn, MBA
Research Professor, Family and Community Medicine
University of Cincinnati
Special Assistant to the Chief Health and Medical Officer
NASA Headquarters

Hal Doerr, MD
Director of Simulation, Asst Professor of Anesthesia
UT Medical School Houston

David Drajeske, MS
President & CEO
Applied Dexterity

Doug Ebert, PhD
Senior Scientist
Wyle Labs – NASA

Kenton Gregory, MD
Director
Oregon Health & Science University Center for Regenerative Medicine

Melinda Hailey, RN
Crew Training
Wyle

Shea Harrison, MS
Medical Student
University of Tennessee Health Science Center

Jeff Jones, MD, MS
Professor
BCM-Center for Space Medicine

Andrew Kirkpatrick, MD, MHSc
Professor
University of Calgary

Allison Kumarn, BA
Sr Program Manager
FDA / CDRH

Fuji Lai, MS, SM
Founder
Patient-Centered Engineering

Rick Linnehan, DVM
Astronaut/Mission Specialist
NASA/JSC

Karina Marshall-Bowman, MS, PhD(c)
German Aerospace Center (DLR)

John McQuillen, MS
Aerospace Engineer
NASA Glenn Research Center

Catherine Moreno
Administrative Coordinator
NSBRI

Marsha Morien, MSBA
Chief Administrative Officer
University of Nebraska Medical Center

Lee Morin, MD, PhD, MPH
Astronaut
NASA JSC

Dmitry Oleynikov, MD
Professor of Surgery
University of Nebraska Medical Center

George Pantalos, PhD
Professor, Cardiovascular and Thoracic Surgery
University of Louisville

Steven Parnis, BS
President
MPAT

John Raiti, PhD
Senior Research Engineer
Applied Dexterity

David Rubin, MS
Project Manager
Wyle

George Schade, MD
Assistant Professor of Urology
University of Washington

Victor Schneider, MD
Senior Medical Advisor/OCHMO
NASA Headquarters

Ronak Shah, MBA, DO
Deputy Element Scientist, Exploration Medical Capability
NASA JSC

Debra Shniderson
Senior Event Coordinator
NSBRI

Brett Sortor, MD
Submarine Force, U.S. Pacific Fleet Surgeon
U.S. Navy

Gary Strangman, PhD
Associate Professor
Harvard Medical School

Jeff Sutton, MD, PhD
NSBRI

Chethan Venkatasubba Rao MD
Assistant Professor
Program Director, Neurocritical Care Fellowship
Baylor College of Medicine

Stuart Williams, PhD
Director, Bioficial Organs
University of Louisville

Jimmy Wu, BS
Chief Engineer
NSBRI

Dor Yoeli, BA
Baylor College of Medicine

Appendix B: Agenda

The National Space Biomedical Research Institute

Surgical Capabilities for Exploration and Colonization Space Flight – An Exploratory Symposium

December 9-10, 2015

NSBRI Headquarters: BRC Room 280
BioScience Research Collaborative
6500 Main Street, Suite 910
Houston, TX 77030-1402
Phone: 713-798-7412
www.nsbri.org

Co-Chairs

George Pantalos, PhD	University of Louisville/Cardiovascular Innovation Institute
Gary Strangman, PhD	Massachusetts General Hospital / Harvard Medical School
Charles Doarn, MBA	University of Cincinnati, Department of Family and Community Medicine, College of Medicine
Timothy Broderick, MD	Wright State University, Wright State Research Institute

Symposium Agenda

Wednesday, December 9

8:00 – 8:30	**Breakfast and Registration at NSBRI HQ**
8:30 – 8:35	***Welcome and Introduction to NSBRI*** Jeffrey P. Sutton, MD, PhD Chief Executive Officer, President and Institute Director, NSBRI
8:35 - 8:45	***Brief Introductions of Invitees and Participants*** Gary Strangman, PhD Massachusetts General Hospital Harvard Medical School Smart Medical Systems Team Leader, NSBRI

8:45 - 9:00	***Workshop goals:*** George Pantalos, PhD Charles Doarn, MBA Timothy Broderick, MD Gary Strangman, PhD 1. Develop an understanding of the current planning for Lunar colonization and Martian expeditions including healthcare 2. Review previous and current efforts to develop surgical capabilities for space flight 3. Given current capabilities and mission planning, propose reasonable scenarios and methods for delivery of surgical treatment 4. Identify short term and long-term basic and applied science research needed to answer existing challenges for surgical capabilities in space flight
9:00 – 10:00	**Planning for Low Earth Orbit, Lunar Colony, and Deep Space Exploration Missions** Chair: Mark Shelhamer, ScD Panelists: John Charles PhD: Low Earth Orbit (LEO), Lunar Colony and Deep Space Exploration Plans including Healthcare Erik Antonsen, MD, PhD, MS: NASA/HPR Perspectives on healthcare for exploration and colonization space flight Jeff Jones, MD MS: Planned Medical Capabilities for the Constellation Program Discussion
10:00 – 10:15	**Break**
10:15 – 11:45	**Critical Care and Surgery in Extreme Environments** Chair: Jon Clark, MD, MPH Panelists: Brett Sortor – Submarine (No lecture material provided) Tim Broderick – NASA Extreme Environment Mission Operations (NEEMO) and Parabolic Flight Eric Bershad, MD – Measuring Inter Cranial Pressure (ICP) on the International Space Station (ISS) Discussion
11:45 – 12:30	**Lunch at NSBRI**

12:30 – 1:30	**Surgery in Reduced Gravity** Chair: Charles Doarn, MBA Panelists: Mark Campbell, MD – Initial Efforts in Parabolic Flight Jay Buckey, MD – Initial Efforts in Low Earth Orbit Andy Kirkpatrick, MD, MHSc – Recent Efforts in Parabolic Flight Discussion
1:30 – 2:45	**Smart Medical Technology** Chair: Jimmy Wu, BS Panelists: Gary Strangman, PhD – Diagnostic Equipment David Rubin, MS – EMSD Ron Diftler, PhD – Humanoid Assistance Robots John Raiti, PhD – External Surgical Robots Marsha Morien, MS – Internal Surgical Robots Fuji Lai, MS, SM – Robots for Telemedicine Discussion
2:45 – 3:00	**Break**
3:00 – 4:00	**Crew Composition, Training for Flight, The Effect of Transmission Latency** Chair: Gary Strangman, PhD Panelists: Richard George, MD – Who Should be on the Crew? Doug Ebert, PhD– Factors Influencing Crew Selection Melinda Hailey, RN – Training for Flight and Maintaining Proficiency Before and During Flight Discussion
4:00 – 4:30	**The View from the Crew** Chair: Mark Campbell, MD Panelists: Tom Marshburn, MD Lee Morin, MD, PhD, MPH Jay Buckey, MD
4:30 – 6:00	**Data Blitz** (2 slides per presenter)
6:00	**Adjourn for Dinner**

6:30	**Dinner with Guest Speaker at Conference Hotel (Hilton Houston Plaza)** Juleilynn Wong, MD, MPH – 3-D Printing of Surgical Instruments for Space Fligth Mark Campbell, MD - History of Surgical Capabilities for Space Flight

Thursday, December 10, 2015

8:00 - 8:30	**Breakfast at NSBRI HQ**
8:30 – 9:45	**Management of the Perioperative Environment**
	Chair: Timothy Broderick, MD Panelists: Jimmy Wu, BS – Data Management/Medical Records Hal Doerr, MD – Anesthesia, Fluids, and Drug Management George Pantalos, MD – Containing and Controlling the Surgical Field Joe Dervay, MD – Post-operative Care, Rehabilitation, and Return to Crew Activity John McQuillen, MS - Recovery of Surgical Waste Fluid Bill Tarver (invited) – Palliative Care/End of Life/Ethical Considerations (not present) Discussion
9:45 – 10:45	**Technical Support for Surgery**
	Chair: Steve Parnis, BDS Panelists: Kenton Gregory, MD, FACC – Hemostasis and Wound Care Stu Williams, PhD – Biomaterials for 3-D printing Gene Boland, PhD – 3-D Printing of Biomaterials in Reduced Gravity George Schade, MD – 3-D Printing of Medical Tools Discussion
10:45-11:00	**Break**
11:00 – 12:30	**DISCUSSION PERIOD: Prioritized Recommendations to Establish Surgical Capabilities** Discussion Leaders: John Charles, PhD Jon Clark, MD, MPH 1. Developing/ranking research and development topics 2. Identification of Topics not yet discussed 3. Discussion of products (requirements definition, proposed research initiatives, publications, etc.)

	4. Future Actions
12:30	**Adjourn – Grab & Go Box Lunch Provided**

Appendix C: Acronym List

3-D	three dimensional
ALS	Advanced Life Support
AsMA	Aerospace Medical Association
ATLS	Advance Trauma Life Support
CMO	Crew Medical Officer
COMfORT	Clinical Outcome Metrics for Optimization of Robust Training
CPR	Cardiopulmonary Resuscitation
CSFP	Cerebral Spinal Fluid Pressure
DARPA	Defense Advanced Research Projects Agency
DCMO	Deputy Crew Medical Officer
DCS	Damage Control Surgery
ER	Emergency Room
EVA	Extravehicular Activity
ExMC	Exploration Medical Capability
FDA	Food and Drug Administration
GPS	Global Positioning System
HMF	Health Maintenance Facility
HFUS	High Frequency Ultrasound
HPZ	Healthcare Procedures Zone
HRP	Human Research Program
ICP	Intracranial Pressure
IDC	Independent Duty Corpsman
IMM	Integrated Medical Model
IOM	Institute of Medicine
ISS	International Space Station
IVGEN	Intravenous Fluid Generator
LEO	Low Earth Orbit
LOS	loss of signal
MIS	Minimally Invasive Surgery
MONSTR	Medical Optimization Network for Space Telemedicine Resources
NASA	National Aeronautics and Space Administration
NEEMO	NASA Extreme Environment Mission Operations

NRC	National Research Council
NSBRI	National Space Biomedical Research Institute
ORIS	Operationally-Relevant Injury Scale
SBIR	Small Business Innovation Research
SLS	Space Launch System
SAGES	Society of American Gastrointestinal and Endoscopic Surgeons
STD	Standard
SURGE	Smart Ultrasound Remote Guidance Experiment
SSF	Space Station Freedom
STTR	Small Business Technology Transfer
TATRC	Telemedicine and Advanced Technology Research Center
TIVA	Total Intra Venous Anesthesia
TM	Transfer Module
TOC	Total Organic Carbon
TUS	Therapeutic Ultrasound
UMO	Undersea Medical Officer
VIIP	Visual Impairment/Intracranial Pressure
VITA	Virtual & Independent Telemedicine Assistant
WRS	Water Recovery System

Appendix D: Abstracts

The following is a collection of the abstract that were submitted by presenters.

Erik Bershad

I am an Assistant Professor of Neurology and Space Medicine, and Principal or Co-investigator on several NSBRI or NASA projects studying the VIIP syndrome. The VIIP syndrome is currently considered a critical risk for spaceflight, but the invasive intracranial pressure has not yet been measured in microgravity. Our project "Zero G and ICP (Michael Williams, PI)" was selected by NASA in order to develop an approach to invasive and non-invasive ICP measurement in astronauts before, during and after spaceflight. Non-invasive ICP modalities are not yet validated, and likely could not be used alone to determine the ICP accurately. Several invasive methods exist which we are considering, but each carries a unique set of risks which would have to be anticipated. The possibilities for ICP monitoring include: pre-flight implantation of telemetric ICP probe, Ommaya reservoir, or in-flight lumbar puncture or lumbar drain. The potential risks of ICP monitoring include pain, infection, intracranial hemorrhage, CSF hypotension (post-LP or lumbar drain) and seizures. Of the invasive ICP options, lumbar puncture is considered the safest, yet post-LP headache is a common occurrence. A process for managing this complication should be developed. Logistics for safely and efficiently performing LP in space should be carefully planning. Some specific questions include: (1) Optimal timing of LP and how many astronauts, (2) Training requirements for procedure pre-flight, (3) Remote supervision needed, (4) Equipment required, (5) Peri-procedural antibiotics, (6) Method for measuring ICP. (7) Management of post-LP headache, and (8) Any additional monitoring for unexpected complications.

James Cushman

INTEREST: My interest in America's space program began with Project Apollo and a coalescence of awareness of collective national achievement in geology, human biology and space exploration. Following completion of my training in General Surgery in 1991 has been a 24 year career in surgery, specializing in trauma, surgical critical care, education of medical students and training of residents and fellows in specialties including Surgery, Emergency Medicine and Anesthesia. One of the key periods of my career came during a recent 7-year appointment to The Shock Trauma Center in Baltimore, MD which happened to include participation of medical providers from the United States Air Force performing pre-deployment training; Their "C-STARS" model has been a highly effective way at improving skills and sustainability in surgical combat readiness.

INVOLVEMENT: 1991-present: Academic Surgeon in urban trauma centers (*except 2011-2013) 2007: Aerospace Medical Association, Membership 2010: Aerospace Medicine Clerkship, NASA and Wyle Life Sciences (Josef Schmidt, MD Advisor).

Space Medicine Association (Lifetime member)

Invited speaker at UTMB-Galveston "Short Course" on Surgery in Space 2011-13: *Residency in Aerospace Medicine, UTMB-Galveston

MPH Thesis: "On Being a NASA Flight Surgeon"

Invited speaker at 83rd, 84th and 85th Annual AsMA meetings and International Association for the Advancement of Space Safety (IAASS), presenter, Montreal, CA.

2014: "Identification of Medical Training Methods for Exploration Missions", NASA/TM-2014-1734, Co-author.

CONCERNS: Based on my experience as a trauma surgeon working in large, public hospitals in often resource-poor conditions I have come to appreciate that proper training can often ameliorate austere conditions and provide conditions necessary for optimal outcomes. During my two year involvement with the aerospace community and to some degree the flight surgeon community at Johnson Space Center between 2011-2013, it was clear to me that similar priorities are given to this concept of medical training. Pre-mission or pre-event training and repetitive experience and/or simulation may be a key program element for the contemporary development of surgical capabilities for exploration and colonization in spaceflight. The two slides that I would like to present during the data blitz and my comments given with them will emphasize this.

Ron Diftler

Utilization of the NASA Robonaut as a Surgical Avatar in Telemedicine
Marc Dean, MD, Vitruvio Institute for Medical Advancement
Myron Diftler, PhD, NASA Johnson Space Center

Background: The concept of teleoperated robotic surgery is not new; however, most of the work to date has utilized specialized robots designed for specific set of surgeries. This activity explores the use of a humanoid robot to perform surgical procedures using the same hand held instruments that a human surgeon employs. For this effort, the tele-operated Robonaut (R2) was selected due to its dexterity, its ability to perform a wide range of tasks, and its adaptability to changing environments. To evaluate this concept, a series of challenges was designed with the goal of assessing the feasibility of utilizing Robonaut as a telemedicine based surgical avatar. **Method:** NASA's Robonaut was temporarily installed at the Houston Methodist Institute for Technology, Innovation & Education (MITIE) and evaluated by two robotic certified surgeons while performing multiple medical and surgical tasks via teleoperation, specifically: intubation, assisting during simulated laparoscopic surgery, preforming ultra sound guided procedures and executing a SAGES[i] training exercise. **Results:** Robonaut was able to complete all the tasks listed above; however, there was a significant learning curve in utilizing the robot for these procedures. A post evaluation analysis was performed and three areas were identified in need of significant improvement to enable advancement in the performance of medical procedures. These areas are: the tele-operator interface, the configuration of the "soft flesh" on the robot's hands that impacts grip positions, and the adjustability of the tool point to achieve better endpoint mobility and accuracy conducive to surgical applications. **Conclusion:** Robonaut was found to have significant potential as a tele-robotic surgical avatar; however, there are several capabilities that need to be addressed before it can realize this potential in a clinical setting. The teleoperator interface needs to be more intuitive and include, in a non-intrusive fashion, additional information to improve situational awareness. The control system requires an upgrade to easily allow the surgeon to control rotation of surgical tools not only around the grip location, but also arbitrary points along the tool, including the tip. The hand was originally designed to manipulate gross mechanical tools similar to a mechanics; however, do to the unique grips required in surgery and the refined nature of the instruments, the soft body of Robonaut's hands/palms as well as the grip/finger control need to be modified to be more conducive for medical and surgical procedures. With these improvements, Robonaut will be able to perform the above procedures more efficiently and also increase the number of procedures it can complete. Looking further out, it will be important to consider the ramification of time delay and loss of signal as part of the avatar control strategy.

Charles Doarn

Surgical Care in Human Space Flight – Exploration Missions

Providing surgical care during space flight is dependent upon a number criteria and challenges. These are listed below:

Location of the space craft – LEO or transit missions to a distant location (Mars, etc). This may also include the moon. However, the moon in in close proximity

Communications – In LEO, the crew and ground will be in synchronous communications. The farther from Earth, the longer the delay in communications – therefore any communication will have to be asynchronous.

Training of the crew medical officer (CMO) – the person should be an MD but most likely will not be. It is currently not a requirement. Therefore there must be pre-flight training on systems, procedures, etc. This training will also be part of the in-flight training as well through simulations, etc. Other crew members who might support the CMO must also be trained.

Personnel – See training above. A surgeon is not likely to be on all flights to Mars. Therefore, the selection of the CMO and support personnel is critical.

Risk – The current risk matrix and future predictions of need must be reviewed and updated as appropriate. The risk must be carefully reviewed.

Surgical Care Systems

- Robotics and robotic assist devices
- Sensors
- Consumables / packaging
- Systems
- Communications
- Gases
- Sterility
- Trash management
- Decision Support Systems
- Anesthesia
- Per-operative system
- Monitoring devices
- Wound management
- Power
- Pharmaceutical (packaging and shelf life)
- Blood supply and other fluids
- Imaging
- Surgical field issues
- Containment

Challenges

- Anatomical changes
- Common terms
- Culture
- Resupply

Historical Perspective of Surgery in Space

Previous efforts/Reports

<u>Flight experience</u>

- 1970s – Skylab –limited surgical capabilities
- 1980s-2011 – Space Shuttle – limited surgical capabilities
- 1998 – Present – ISS – limited surgical capabilities (Neurolab)

<u>Seminars/Subject Matter Experts</u>

- Proceedings of SSF Medical Experts Seminar – NASA Conference Report 10069 – April 1991
- Strategic Considerations for Support of Humans in Space and Moon/Mars Exploration Missions – NAC Aerospace Medicine Advisory Committee report – 1992
- Dr. Samuel Pool / Dr. Norman McSwain Working Group
- Subject matter experts (Drs. Bruce Houtchens, Mark Campbell, Smith Johnston)
- Ground-based research
- Parabolic flight experiments
- Surgery in Extreme Environments – Meeting Space Exploration Needs (USAMRMC-TATRC Contract W81XWH-05-1-0414 – PI - C. Doarn. Symposium held Dec 2005.

Kenton Gregory

Dr. Gregory is a cardiologist and Professor of Biomedical Engineering at Oregon Health Sciences University who has long term research interests in battlefield and space medicine. Hemorrhage control, wound healing, human extracellular matrix protein based biomaterials and the use of autologous stem cells for tissue regeneration are specific research areas for addressing battlefield injuries that may have particularly important implications for space travel.

The development of devices to treat non-compressible hemorrhage on the battlefield may have unique benefits in treating hemorrhage from wounds or surgery in microgravity. The ability of an astronaut medical provider to use compressive force on a wound to stop bleeding could be problematic in microgravity. The recently FDA approved X Stat cellulose mini-sponges are light weight, compact that can be easily placed into a wound that then rapidly absorb blood, expand and exert and maintain hemostatic pressure stops severe bleeding in seconds. Blood activated and regulated expansive force released within the wound by these mini-sponges should not be affected by micro-gravity.

Wound healing from injuries have been reported to heal poorly in microgravity. Long and complex missions in space may result in injuries or surgeries where poor healing could compromise mission objectives and astronaut health or viability. The majority of human healing is achieved by resident tissue, circulating and bone marrow stem and progenitor cells. In STS 93 Dr Gregory studied cell migration as a potential cause of poor wound healing in microgravity. Stem cell migration has been observed to be a principle determinant of stem cell functionality and can predict favorable regenerative response, or not, after catastrophic injuries. Dr Gregory, the founding Director of the OHSU Center for Regenerative Medicine is developing technologies that could be used to understand stem cell mediated healing in microgravity which may become of critical importance in long term space travel or Mars missions.

Andy Kirkpatrick

Surgery in Space Research Activities at the University of Calgary
AW Kirkpatrick MD MHSc FRCSC FACS

The University of Calgary (UofC) Space Medicine research group has carried out a number of research campaigns with Professor AW Kirkpatrick as the Principal Investigator. These campaigns have primarily focused on; A) ultrasound in weightlessness; B) Terrestrial applications of tele-ultrasound as a space medicine spinoff; C) laparoscopic surgery in weightlessness using anesthetized swine; D) Open Damage Control surgery in weightlessness using a Hyper-realistic surgical phantom. In all cases, the analogue weightless environment utilized was parabolic flight, and the goals of each Campaign has been to either advance the knowledge of performing interventions in weightlessness or to potentially spinoff space medicine techniques for terrestrial benefit.

In 2000, the research group addressed whether abdominal trauma ultrasound was feasible in weightlessness[1-3], and with the guidance of Scott Dulchavsky also performed the first studies using ultrasound in weightlessness to infer the presence of pneumothoraces.[4,5] These studies catalyzed many follow-up studies introducing the ultrasound diagnosis of pneumothoraces to the main-stream terrestrial trauma care.[6-10] Continuing work concerning Minimally Invasive Surgical (MIS) techniques with Dr Campbell were also conducted on anesthetized swine.[11]

Subsequently, Drs Dulchavsky, Hamiltion, and Sargsyan proceeded to essentially create the new discipline of telementored remote ultrasound, guiding novice astronauts onboard the ISS to obtain diagnostic quality images remotely guided from earth.[12-17] In a parallel process the UofC group examined the potential terrestrial benefits of spinning off this space medicine technology in terrestrial trauma settings; including real-time remote trauma resuscitation[18,19]; using hand-held technologies20-24; using just-in-time training of novice users[25-27]; and creating virtual global networks of mentoring experts.[28,29]

In 2006, the UofC group conducted the first anesthetized animal surgery in weightlessness in Canada using the Falcon 20 Parabolic flight research aircraft from the National Research Council of Canada in a Campaign investigating the potential of using gasless laparoscopy for emergency MIS surgery in space.[30,31] While these investigations concluded the gasless MIS surgery was not feasible[32], they offered insights into the potential for safe reduced pressure MIS interventions, provided physiologic data for understanding thoraco-abdominal polycompartment interactions in weightlessness, and constituted the longest critical care/anesthetic trial of life support in weightlessness.[33-35]

The latest UofC Campaign, conducted in 2015 has involved an evaluation of the potential benefits of a technological marriage of hyperrealistic surgical training phantoms (“Cut-suit”) with active and measurable blood loss and the techniques of remote technical mentoring for invasive procedural performance.[36] In these studies the actual procedure has constituted the completion of a “Damage-control laparotomy” (DCLs) with liver packing to arrest exsanguinating hemorrhage. In addition to studying performance characteristics of novice Military Medics with and without mentoring[37], the investigators also conducted comparative studies of trained surgeons performing such DCLs in 1 compared to 0g onboard the Falcon 20. Such work is expected to inform planners as to the minimum requirements required to potentially address exsanguinating hemmorhage onboard an Exploration Class Mission.

References (see the Reference Section)

Fuji Lai

Fuji Lai believes surgical and medical capabilities for exploration and colonization of space flight will involve designing solutions that merge the best of human and computer strengths. Robot-human collaboration, human-centered design, and information fusion for the optimal level of autonomy and task sharing will enable the expansion of human and space frontiers.

Fuji Lai is passionate about revolutionizing the patient and human experience through augmenting human capabilities, improving healthcare access and enhancing quality of care. Fuji leverages her unique interdisciplinary background in biomedical engineering, robotics, human factors design and healthcare consulting to create new insights, to collaborate across diverse stakeholders, to translate research into commercially-viable results, to transform glimmers of futuristic ideas/moonshots into tangible deployed products embraced by users/market, to impact and solve complex human challenges.

Her experience driving innovation spans medical/surgical robotics, telemedicine, mobile health, connected health, human-robot teams, human-machine interfaces, simulation, VR and other emerging, disruptive intelligent technologies that drive the smart healthcare system of the future with the patient as integrated member of the continuum of care team and ranges from building startups to strategic partnerships with Fortune 500 companies and federal agencies.

Fuji has served as a medical robotics startup leadership member at InTouch Health where her role involved innovating a vision and strategy for an acute care healthcare delivery telemedicine platform and leading the design and development of Remote Presence (RP) telepresence robots including the RPVITA (with iRobot), the world's first FDA-Class-II-cleared telemedicine robot with one-touch "go there" autonomous navigation enabling new care delivery models and a 2014 Medical Design Excellence Award Finalist. Results include creating several new markets, developing a suite of Remote Presence Robots tailored for specific clinical environments (partners for the OR versions included Intuitive Surgical and Karl Storz) and FDA-cleared as Class II medical devices, shipping 8 new products in 5 years, and establishing virtual healthcare delivery networks now in 1300 hospitals globally from the ICU, OR, ED, clinic to ambulance. In particular she enjoyed leading the creation of the RP-VITA, a truly unprecedented product, and was responsible for driving the RP-VITA from a glimmer of a moonshot idea, to crystallization of behaviors, to shipped FDA-cleared product, to clinical deployment, to real social impact. This was a unique opportunity for her to envision a groundbreaking innovation to transform patient care and "bring to life" a robot with the behaviors and the social smarts to collaborate seamlessly with clinical teams to save patient lives.

She also founded a new medical human factors offering designing mission-critical medical devices and healthcare environments to enhance user experience, safety, performance, capturing $4M new business with DoD/NASA/NIH and premier hospitals to build a 20-project program portfolio, and as PI led R&D efforts around the Hospital of the Future and more specifically the OR of the Future. This included DoD-funded work on a vision and development blueprint for surgical robots to disrupt and redefine the OR of the Future using information augmentation, human-robot task sharing and semi-autonomy, as well as development of an OR Wall of Knowledge integrated information dashboard. She also has a biomedical engineering and robotics background, built surgical robotics, haptics, human-machine interfaces to enhance safety and efficiency in robotic surgery including virtual fixtures for collaborative control in teleoperated soft tissue surgery, and was development team member on the first FDA-cleared surgical robot at Computer Motion (now Intuitive Surgical).

Fuji is author of 30+ peer-reviewed publications/presentations, inventor on 15+ patents, and earned SM Biomedical Engineering (Harvard), MS Mechanical Engineering (UC Berkeley), BS Biomedical Engineering (Duke), BS Electrical Engineering (Duke). She was also a Google Award recipient selected to participate at Singularity University, an innovation think tank and accelerator program at NASA Ames which brings together global impact leaders to solve humanity's grand challenges and positively impact the lives of a billion people within ten years.

Marsha Morien

Multi-use dexterous robots for mission surgical capability
Bills, N., Cubrich, L., Morien, M., Farritor, S., & Oleynikov, D.

Background: The Center for Advanced Surgical Technology (CAST) at the University of Nebraska consists of a collaborative team of surgeons, experts in surgical training, engineers, and computer scientists that have an extensive history of NASA-funded research in space medicine with a flagship grant "Supporting Surgical Options in Space" that was just completed. In addition to this funding, there have been multiple projects funded through Nebraska EPSCoR and NASA Nebraska mini space grants. These include studies on non-invasive intracranial pressure measurement, gastrointestinal sensor implants, and training models for skills learning and retention in telemedicine.

As mission length and distance from Earth increase, any on-board medical system should include surgical capability in order to ensure crew safety. The National Research Council congressionally-mandated report issued June 4, 2014, "Pathways to Exploration—Rationales and Approaches for a U.S. Program of Human Space Exploration," in section 4.2.6.1.9 "Crew Health" states, "... Highly capable diagnostic and treatment equipment, including *surgical facilities* designed for operation in-space and on the surface, would reduce the threats posed by injuries and illnesses..."

The Human Research Roadmap Exploration Medical Capability (ExMC), "Risk of Unacceptable Health and Mission Outcomes Due to Limitation of In-Flight Medical Capabilities" includes gaps that are only addressable by including surgical capability in long-term missions.

Challenges: Challenges include the need to enable and train non-surgeon medical personnel to perform surgical tasks. To prepare for the eventuality of an emergency surgery during space flight, it is essential that technology be developed appropriate to these tasks. Design considerations include ease-of-use, reusability and minimum mass. Mini-surgical robots provide a novel solution to the challenges of surgery in space. We have extensively tested our mini-surgical robots in bench top, animal and cadaver terrestrial experiments, as well as on one parabolic flight. Our mini-robot mirrors the hand motions of the operator, making emergency surgery for minimally-trained flight surgeons significantly easier and more feasible than surgery with traditional laparoscopic tools.

Future Directions: These mini-robots, which operate similar to other astronaut equipment through manipulation of remote arms, will reduce the skill level and time required for training and retention of basic surgical skills. Since the miniature robots are operated through an electronic buffer, surgeons will be able to operate in microgravity while securely strapped to a surgical console and maintain the dexterity necessary to perform surgery. A library of simulated subtasks and complete surgical procedures will enable skill acquisition and retention to be scheduled during long-duration missions and provide a virtual assistant for emergent surgeries. Built-in haptic capability will allow robot end-effectors to be used for palpation and diagnostics using smart diagnostic systems.

The development and validation of the performance of robotic surgical systems will aid in the understanding of surgical procedure feasibility for long-duration exploration missions and these small robots could be an important component of a medical system used in future planetary missions. The long-term goal would be to use image-guided *in vivo* mini-robots to enable many surgeries to be converted to a less-invasive approach that is feasible for use during long-term spaceflight. Multiple mini-robots could be placed through a single natural orifice or other single-incision site to improve capabilities. The proposed project aligns directly with NASA's vision to enable long-term space flight and future colonization of the moon or Mars.

As an added benefit, and in order to maximize payload utility, these robots, which possess dexterous multiple degrees of freedom end effectors, would also be able to function as multipurpose tools for intra- or extra-vehicular tasks in small spaces where precise manipulation is required.

Concerns: Of special concern to us is that, even though surgical capability is not currently at the highest echelon of NASA priorities, critical momentum developed under ours and others research on space surgical capability may be lost without prioritization and continued support.

George Pantalos

Parabolic Flight Evaluation of an Aqueous Immersion Surgical System for Reduced Gravity
NASA Flight Opportunities Program: Payload 49-P
George Pantalos, Morgan Crigger, Troy L. Kennedy, Elvis Joseph, Ishita Jain Elif Ayvali, Alyssa Meyer, Cecelia Morales, Tyson Montidoro, James E. Burgess, James F. Antaki University of Louisville and Carnegie Mellon University

Introduction: The ability to surgically treat trauma and other disorders in reduced gravity requires reliable wound containment. Parabolic flight testing of an aqueous immersion surgical system (AISS) to achieve this goal is reported. The AISS is a clear chamber with leak-free instrument ports that is filled with an immersion fluid (e.g. saline) to control bleeding, cleanse the wound, and maintain a clear visual field. **Methods:** During reduced gravity parabolic flight (0-G and Lunar-G), attachment of the AISS dome to simulated skin using surgical drape and surgical glue was evaluated. Attachment of the AISS dome with surgical drape to a human torso was also evaluated. Automated filling and emptying of convex, concave, and conical AISS dome geometries without air trapping was examined. Pressure regulation of the immersion fluid and the ability insert and withdraw endoscopic instruments across a range of pressures was evaluated. Staunching of bleeding with pressure elevation and purging of blood from the dome was tested. Bleeding flow patterns in air and saline were investigated. The ability to suture, tie knots, cut, and staple using endoscopic instruments inside the AISS dome was evaluated. **Results:** Successful attachment of the AISS dome flange to simulated skin with surgical drape creating a leak-free interface up to 78 mm Hg was accomplished. Surgical glue application onto the flange was inconsistent, resulting in a leaky interface. The dome could be successfully attached to a human torso using surgical drape with a leak-free interface up to 35 mm Hg. Different sized endoscopic instruments could be inserted and withdrawn from the AISS dome without leakage up to 100 mmHg of dome pressurization. AISS dome geometries reliably filled in reduced gravity without air trapping. Tight immersion fluid pressure regulation was achieved up to 100 mmHg during suction and pressure perturbation challenges. Bleeding into the cabin atmosphere showed a random distribution of blood droplets with large droplet adherence to the bleeding location whereas bleeding into saline created a defined envelope easily removed by suction. Bleeding could be staunched by transient elevation of the pressure inside the AISS with purging of the dome able to clear the view of the surgical field. Suturing, knot tying, cutting, and stapling were all possible in 0-G with stapling being much easier and quicker to perform than suturing and knot tying. **Discussion:** Several key performance features of the AISS showed incremental progress toward the demonstration of surgical capability in reduced gravity. Reduced gravity filling of the AISS dome requires a balance among angular momentum, viscous interaction, and surface tension influenced by AISS geometry and immersion fluid inflow rate that will be optimized in future efforts. Integration of AISS subsystem components is anticipated with automated control of the AISS system to maximize the functionality of the AISS approach to surgical treatment.

John Raiti

AppliedDexterity

Surgical Robotics for Space Applications

John Raiti, PhD and David Drajeske

Applied Dexterity produces, sells, and supports the RAVEN surgical robot as a research platform and rapid prototyping environment for advances in robotically assisted surgery. RAVEN was originally developed between 2002 and 2007 at the University of Washington with funding from the Department of Defense. While robotically assisted surgery was making commercial inroads, the systems were large and dominated an operating room. Existing systems did not fulfill the military's vision of a surgical robot that could be deployed in the field. The DoD's requirements for a compact, rugged, surgical robot are consistent with many of the requirements of a surgical robot for space applications.

In the US Army sponsored HAPs/MRT demonstration (High Altitude Platform/Mobile Telesurgery, 2005), RAVEN was set up in a tent in the desert (Simi Valley, CA) powered by a gasoline generator. A surgeon performed simulated surgery by teleoperation from a distant tent. Control signals were relayed via an autonomous drone circling above the surgical site. To accommodate limited communication bandwidth, the frequency of sending position updates from the controller to the robot was reduced and the video signal was highly compressed, but surgical performance was not hampered.

In a separate test, as part of NASA's NEEMO-12 mission , sections of RAVEN were transported in dive bags to the Aquarius underwater habitat. Following two days of training on system assembly, startup, and disassembly tasks, NASA aquanauts successfully assembled and commissioned RAVEN in the habitat. The system was then teleoperated from Seattle, 3000 miles away, to perform a variety of surgical skills tasks. These tasks were successfully completed while experiencing communication delays of about one second.

We are currently working with NASA to pursue installation of a modified RAVEN on the ISS to facilitate ongoing rodent research. The system, teleoperated from the ground, will be used to perform rodent dissections that are currently performed by flight crew. In addition to buying back crew time, the installation will provide dramatic demonstration of long distance surgical teleoperation to enable a range of complex procedures.

Our areas of interest include:

- Surgical robot design for space facilities
- Long distance teleoperation
  - Methods to mitigate limited bandwidth, time delay, and periods of loss of signal (LOS)
- Human/Robot Interaction
  - Methods to achieve complex tasks through integrated efforts of robotics/automation, flight crew, and remote subject matter experts.

Brett Sortor

Submarine Medical Considerations Applied to Space Flight

I have been associated with Undersea Medicine in the U.S Navy for 17 years. For the last year, I have served as the Medical Officer for the Commander Submarine Force, U.S. Pacific Fleet. My primary role is to serve as a special advisor to the Commander, but I also ensure the standard of care provided onboard submarines is essentially equivalent to what would be provided in a Navy clinic.

The U.S. Navy does not perform surgery on submarines. In fact, medical officers have not been required by the U.S. Navy to be aboard on deploying boats since the end of the Vietnam War. Instead, the crew is carefully screened so that approximately 140 healthy men and women are able to deploy. The Independent Duty Corpsman (IDC), having spent 58 weeks in medical and occupational health training, is the only medical provider on board. The IDC trains a small team to assist him and to serve as stretcher bearers, but he relies upon history, physical exam, and basic laboratory equipment to make diagnoses.

Submarine medical treatment protocols attempt to delay or prevent the need for surgery because it may take 5-10 days before a MEDEVAC can occur. Acute abdominal pain is a complicated condition for which the submarine force pioneered a treatment protocol with conservative management (bowel rest, ivf, antibiotics) and close monitoring. This protocol has been expanded to treat abdominal and pelvic pain in female submariners now. IDCs communicate with Undersea Medical Officers (UMOs) for advice and treatment recommendations, but are taught when to implement these protocols while waiting for a response from the UMOs. These responses may take up to 24 hours to be received.

The most common conditions requiring MEDEVAC from submarines are trauma/injuries, mental health issues, abdominal pain, renal colic, musculoskeletal conditions, and dental problems such as broken teeth or lost fillings. Lacerations are frequently repaired and seem to take a little longer to heal, which may be a result of the mildly hypoxic atmosphere.

Experience on a submarine indicates that everything is possible. A dining space can be transformed into an OR and instruments can be jury-rigged as occurred on USS Seadragon when a pharmacists mate performed an (unapproved) appendectomy in 1942. Space crew members can undergo prophylactic appendectomies and cholecystectomies, yet these procedures and rigid screenings will never remove all medical risks. On a submarine, the only single point of failure is the IDC; there is redundancy for every other system. When the IDC becomes the patient, everything is more difficult. Is it worth having two crew members with medical expertise?

Julielynn Wong

3D4MD Research Activities
Julielynn Wong, MD, MPH

The 3D4MD program has carried out a number of research projects with Dr. Julielynn Wong as the Principal Investigator. These projects have focused on; (i) 3D printing surgical instruments to support autonomous, crew-administered healthcare during long-duration space missions[1-2], (ii) designing and 3D printing a lower cost dental instrument on demand for long-duration space missions[3], (iii) solar-powered 3D printing of surgical supplies at a Mars analog research station[4], (iv) terrestrial applications of solar-powered, ultra-portable "suitcase" 3D printers as a space medicine spin-off[4], (v) 3D printing custom mallet splints at the point of use[5], (vi) crowd-sourcing 3D designs of medical equipment for the International Space Station (vii) creating Challenger Center mission activities on 3D printing for students and teachers.

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2. Wong JY, Pfahnl AC. Evaluation of 3D printed surgical instruments by Mars analog crew members [Abstract]. International Congress of Aviation and Space Medicine, Mexico City, Mexico, October 13, 2014.

3. Wong JY. Evaluating the functionality and cost benefits of a 3D printed thermoplastic dental instrument for long-duration space missions [Abstract]. Aerosp Med Hum Perform 2015;86(3):219.

4. Wong JY. Ultra-Portable Solar-Powered 3D Printers for Onsite Manufacturing of Medical Resources. Aerosp Med Hum Perform 2015;86(9):830-4.

5. Wong JY. On-Site 3D Printing of Functional Custom Mallet Splints for Mars Analogue Crewmembers. Aerosp Med Hum Perform 2015;86(10):911-4.

Appendix E: Presentation Materials

This appendix contains the presentations provided during the symposium.

Day 1

1.0 <u>Workshop Goals</u>

1.1 Summary of Previous Work Surgery in Extreme Environments – *C. Doarn*

1.2 CONSIDERATION OF SURGICAL CAPABILITIES FOR EXPLORATION SPACE MISSIONS – *G. Pantalos*

2.0 <u>Planning for Low Earth Orbit, Lunar Colony, and Deep Space Exploration Missions</u>

2.1 LEO, Lunar Colony and Deep Space Exploration Plans including Healthcare – *J. Charles*

2.2 Exploration Medical Capability NASA Human Research Program – *E. Antonsen*

2.3 Medical and Surgical Capabilities required to Support Exploration Missions Space Medicine-Opportunities and Constraints – *J. Jones*

3.0 <u>Critical Care and Surgery in Extreme Environments</u>

3.1 Surgery in Extreme Environments NEEMO and Parabolic Flight – *T. Broderick*

3.2 Lumbar Puncture in Space: a primary aim of "Zero G and ICP: Invasive and Noninvasive ICP Monitoring of Astronauts on the ISS – *E. Bershad*

4.0 <u>Surgery in Reduced Gravity</u>

4.1 Initial Parabolic Flight Research in Spaceflight Surgical Issues – *M. Campbell*

4.2 4.2 Initial Efforts in Low Earth Orbit – *J. Buckey*

4.3 The University of Calgary Surgery in Space Research Program – *A. Kirkpatrick*

5.0 <u>Smart Medical Technology</u>

5.1 Diagnostic Equipment – *G. Strangman*

5.2 HRP Exploration Medical Capabilities Exploration Medical System Prototype – *D Rubin*

5.3 NASA Robonaut as a Surgical Avatar – Recent Experiments – *R. Diftler*

5.4 RAVEN™ and the Surgical Cockpit™ - Teleoperation Systems for Space Applications – *J. Raiti*

5.5 Multi-use dexterous robots for mission surgical capability – *M. Morien*

5.6 Robots in Telemedicine – *F. Lai*

6.0 <u>Crew Composition, Training for Flight, the Effect of Transmission Latency</u>

6.1 Who Should be on the Crew? – *R. George*

6.2 Factors Affecting Successful Performance of Medical Tasks – *D. Ebert*

6.3 ISS Crew Medical Officer Training – *M. Hailey*

7.0 <u>Data Blitz</u>

7.1 Drajeske - Applied Dexterity

7.2 Ebert – Surgical Capabilities and Factors

7.3 Kumar – FDA 'Fostering Medical Innovations'

7.4 Morien –Multi-use Dextrous Robots for Mission Surgical Capability

7.5 Cushman – Identification of Medical Training Methods for Exploration Missions

7.6 Doarn – Challenges and Historical Context

Dinner Presentations

History of Surgical Care in Space Symposiums – *M. Campbell*

3D Printing of Surgical Instruments for Long-Duration Space Missions – *S. Wong*

8.0 Management of the Perioperative Environment

8.1 Data Management – *J. Wu*

8.2 Anesthesia for Colonization and Exploration of Mars and the Moon– *H. Doerr*

8.3 Parabolic Flight Evaluation of a Hermetic Surgical System (HESS) for Reduce Gravity 49-P – *G. Pantalos*

8.4 Overview of the IVGEN Experiment – *J. McQuillen*

8.5 Recovery of Surgical Waste Fluid – *J. Myer*

9.0 Technical Support for Surgery

9.1 Hemostasis Capabilities for Exploration and Colonization Space Flight – *K. Gregory*

9.2 3-D Bioprinting in Space Bioinks – *S. Williams*

9.3 3D BioPrinting for Wound Healing Applications – *G Boland*

9.4 Therapeutic Ultrasound Techniques to Augment Surgical Capabilities in Space – *G Schade*

1.0 Workshop Goals

Summary of Previous Work
Surgery in Extreme Environments

NSBRI – Surgical Capabilities for Exploration and Colonization Space Flight – An Exploratory Symposium
December 9-10, 2015

Charles R. Doarn
Research Professor
Department of Family and Community Medicine

Special Assistant to the Chief Health and Medical Officer
Office of the Chief Health and Medical Officer
NASA Headquarters

My thoughts

Background
Charles R. Doarn, MBA, FATA
Education –
BS – The Ohio State University, 1980
MBA – The University of Dayton, 1988

Faculty –
Research Professor of Family and Community Medicine, University of Cincinnati*
(*Appointments in Environmental Health and Political Science)
(Faculty appointments at George Washington University, Wright State, Yale University, Virginia Commonwealth University – Medical College of Virginia, International Space University)

Other Activities –
Special Assistant to the Chief Health and Medical Officer, NASA Headquarters, Washington, DC (NASA – Funded)
Co-Chair – Federal Telemedicine 'FedTel' working group
Team Lead – Governance Committee – NATO, Romania/Russia Multinational Telemedicine System for Emergencies
Fulbright Specialist - US Department of State's Bureau of Education and Cultural Affairs (BECA) and Council for International Exchange of Scholars - Macedonia
Editor – Space Physiology and Medicine – Evidence and Practice, 4th Edition, Springer
Editor – Space Medicine Pioneers: In Their Own Words (NLM-Funded)
Editor-in-Chief, Telemedicine and e-Health Journal
Medical Technology Editor – World Health and Medical Policy Journal
Editorial Board / Reviewer for numerous international journals
Travel to conduct research, teach or implement healthcare systems (telemedicine) in numerous countries

Contact Information
Phone (513) 558-6148
E-mail: charles.doarn@uc.edu or charles.r.doarn@nasa.gov

Previous Efforts

1. NASA–funded workshops
2. USAMRMC – TATRC-funded efforts
3. Reports
4. Literature

Previous Efforts

NASA–funded Workshops

- 1990 Proceedings of the Space Station Freedom Clinical Experts Seminar
- Bruce Houtchens

Billica RD, Lloyd CW, Doarn CR. Proceedings of Space Station Freedom Medical Experts Seminar, *NASA Conference Report 10069*, April 1991.

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Previous Efforts

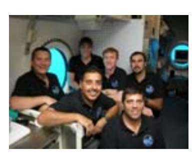
USAMRMC – TATRC-funded Efforts *(Outcome – MS and Tech Reports)*

- NEEMO 12
  - W81XWH-07-2-0039 (PI – C Doarn)
  - Collaborative Accelerated Medical Technology Development
- Advanced Center for Telemedicine and Surgical Innovation
  - W81XWH-07-02-0035 (PI – T Broderick)
  - Robotic Surgery in Flight
  - Telesurgery: A Technology Report – Where is it and Where is it Going
  - Sea Orbiter
- High Altitude Platforms for Mobile Robotic Telesurgery (PI – T Broderick)
  - W81 XWH-05-2-0080
- Surgery in Extreme Environments: Meeting Space Exploration Needs (PI – C Doarn)
  - W81XWH-5-01-0414
- Robotic Surgery in Flight. C-9 and Other Microgravity Simulations (PI-T Broderick)
  - *NASA/TM-2008-214765*

Previous Efforts

USAMRMC – TATRC-funded efforts

- NEEMO 12
  - W81XWH-07-2-0039 (PI – C Doarn)
  - Collaborative Accelerated Medical Technology Development
  - Evaluate different robotic systems
  - Conducted wireless demonstrations



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USAMRMC – TATRC-funded efforts

- Advanced Center for Telemedicine and Surgical Innovation
  - W81XWH-07-02-0035 (PI – T Broderick)
  - Robotic Surgery in Flight
  - Sea Orbiter

Telesurgery
A Technology Report
Where is it and Where is it Going?

September 1, 2009

Authors

Charles R. Doarn, MBA
Timothy J. Broderick, MD, FACS

Advanced Center for Telemedicine and Surgical Innovation
Department of Surgery
University of Cincinnati
Cincinnati, Ohio

USAMRMC Grant W18XWH-07-2-0035

Previous Efforts

USAMRMC – TATRC-funded efforts

- High Altitude Platforms for Mobile Robotic Telesurgery (PI – T Broderick)
  - W81 XWH-05-2-0080

Harnett BM, Doarn CR, Rosen J, Hannaford B, Broderick TJ. Evaluation of Unmanned Airborne Vehicles and Mobile Robotic Telesurgery in an Extreme Environment. *Telemed J E Health* 2008; 14(6):539-44

Previous Efforts

USAMRMC – TATRC-funded efforts

- Surgery in Extreme Environments: Meeting Space Exploration Needs (PI – C Doarn)
  - W81XWH-5-01-0414
  - Formal report written

REPORT DOCUMENTATION PAGE

Surgery in Extreme Environments: Meeting Space Exploration Needs

Charles R. Doarn, MBA

University of Cincinnati

Previous Efforts

USAMRMC – TATRC-funded efforts

- Robotic Surgery in Flight. C-9 and Other Microgravity Simulations (PI-T Broderick)
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- Key Literature (See also Reference List)

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University of Cincinnati

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Technical Reports

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CONSIDERATION OF SURGICAL CAPABILITIES
FOR EXPLORATION SPACE MISSIONS

George Pantalos and a Constellation of Collaborators
University of Louisville

Houtchens (1988): Conclusion

"With appropriate equipment and protocols, it should be possible to perform emergency medical procedures and transport in micro-G with minimum departure from techniques used in one-G. This is fortunate, because it is in one-G that most of the practice for spaceflight medical care will occur."

The details are in the "appropriate" equipment and protocols – and everything else!

The Need: On the NASA Space Technology Roadmap, Section TA06 is the statement of the NASA Human Health, Life Support and Habitation Systems. The Technology Area Strategic Road Map, Area 6, Section 2.3 (Human Health and Performance) calls for medical assist robotics for laparoscopic surgery and a surgical suite with sterile, closed-loop fluid and ventilation systems for trauma and other surgeries.

- NRC Report 2014: 4.2.6.1.9 Crew Health

"Apart from the effects of weightlessness, crew physiology would be threatened by other factors, such as space radiation, illness, and injuries. . . . . Highly capable diagnostic and treatment equipment, including surgical facilities designed for operation in-space and on the surface, would reduce the threats posed by injuries and illnesses, but this is a difficult challenge given that (1) the types of injuries and illnesses that might be experienced cannot all be anticipated, and (2) the mass and volume of medical facilities on spacecraft and in ground habitats will be limited."

NASA HPR
Exploration Medical Capabilities

LIST OF MEDICAL CONDITIONS

Skin Laceration

Surgical Treatment

GOING FORWARD?

- Over three decades of effort have gone into investigating how to provide surgical capabilities in reduced gravity
- The microgravity environment presents unique challenges related to controlling and containing the surgical field and fluid management
- It takes the commitment of substantial resources to develop clinically qualified medical devices
- NASA will need to make a decision as to what healthcare capabilities are going to be available on exploration class missions and determine the source for the R & D resources needed to support the required innovation as the "develop for commercialization" model may be insufficient due to the unique requirements of μ-gravity.

Symposium Goals

- Develop an understanding of the current planning for Lunar Colonization and Martian expeditions including healthcare

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- Review previous and current efforts to develop surgical capabilities for space flight
- Given current capabilities and mission planning, propose reasonable scenarios and methods for delivery of surgical treatment
- Identify short-term and long-term basic and applied science research needed to answer existing challenges for surgical capabilities in space flight

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- Develop an understanding of the current planning for Lunar Colonization and Martian expeditions including healthcare
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- Given current capabilities and mission planning, propose reasonable scenarios and methods for delivery of surgical treatment
- Identify short-term and long-term basic and applied science research needed to answer existing challenges for surgical capabilities in space flight (gaps between the gaps)
- Document the proceedings on the NSBRI website and in a review article for future reference

A Hypothesis

H1: It is possible to conduct safe and effective surgical procedures in reduced gravity

ACCEPT OR REJECT?

THE DILEMMA

If it is possible to perform safe and effective surgical procedures in reduced gravity, do we choose to include that capability in mission planning, what is the scope of that capability, and how is it implemented?

THE DILEMMA

If it is possible to perform safe and effective surgical procedures in reduced gravity, do we choose to include that capability in mission planning, what is the scope of that capability, and how is it implemented?

What is the risk of doing surgery and what is the risk of not doing surgery?

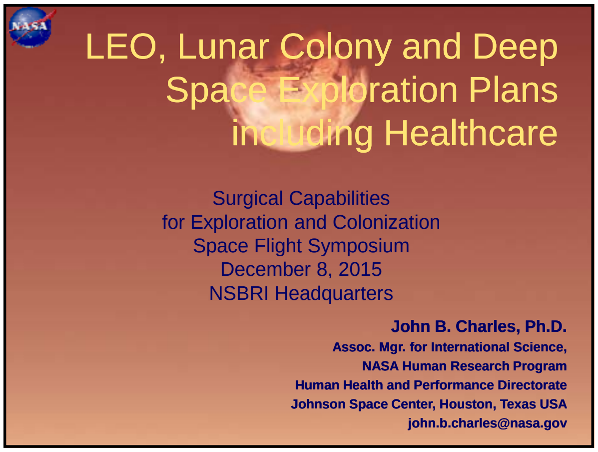
Welcome!

Welcome!

Many thanks for making the effort to attend and actively participate

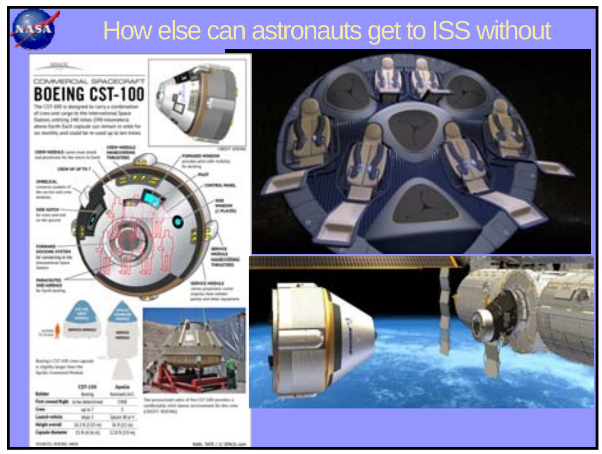

Welcome!
Many thanks for making the effort to attend and actively participate
Let’s get to work and enjoy the symposium

2.0 Planning for Low Earth Orbit, Lunar Colony, and Deep Space Exploration Missions


LEO, Lunar Colony and Deep Space Exploration Plans including Healthcare
Surgical Capabilities
for Exploration and Colonization
Space Flight Symposium
December 8, 2015
NSBRI Headquarters
John B. Charles, Ph.D.
Assoc. Mgr. for International Science,
NASA Human Research Program
Human Health and Performance Directorate
Johnson Space Center, Houston, Texas USA
john.b.charles@nasa.gov


International Space Station


How do astronauts get to ISS without Shuttle?
Energiya)
✓First test flight : 1966
✓>111 have launched manned since 1967
✓>29 have gone to ISS since 2000
Lifetime in orbit
• 180 days nominally
• + 30 days reserve
SOYUZ ROCKET


How else can astronauts get to ISS without
COMMERCIAL SPACECRAFT
BOEING CST-100


How else can astronauts get to ISS without Shuttle?
Dragon-Falcon 9 (SpaceX)
✓First test flight : 2010
✓First ISS cargo flight : 2012
❑First ISS astronaut flight : 2017?
Falcon 9 Rocket & Dragon Spacecraft


If not ISS (after 2024), then where else is there to go?
Tiangong & Shenzhou (China) 2011-2017
2020…
Bigelow (USA) Genesis1 (2006) Genesis 2 (2007)
Bigelow BA-330 (USA) Was 2014, now…?

After ISS, Where Next?

Augustine report delivered to NASA in October 2009
- Provided context but not commitments

The Flexible Path

➢ **ALL options require ISS**

National Research Council, 2014

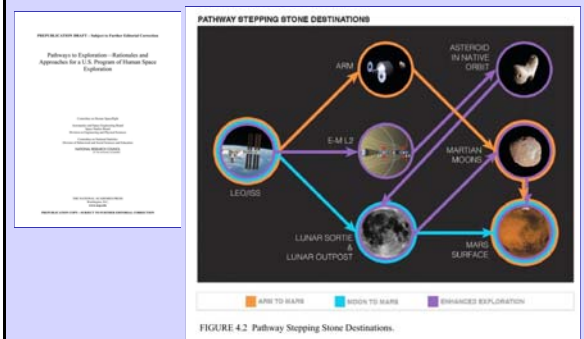
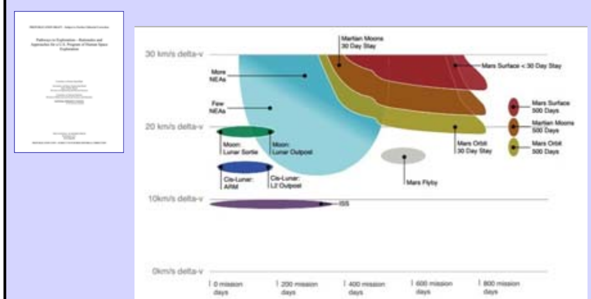


FIGURE 4.2 Pathway Stepping Stone Destinations.

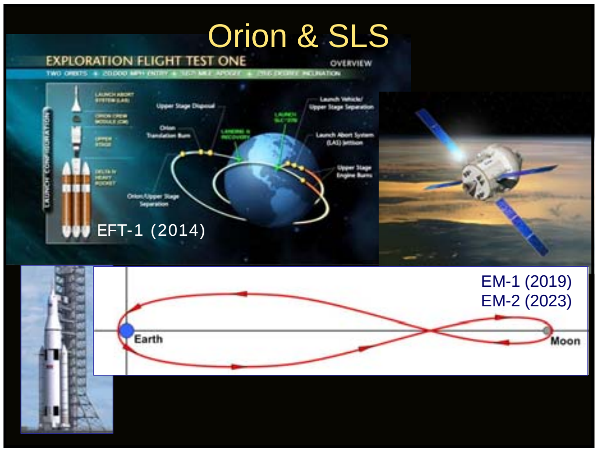
National Research Council, 2014

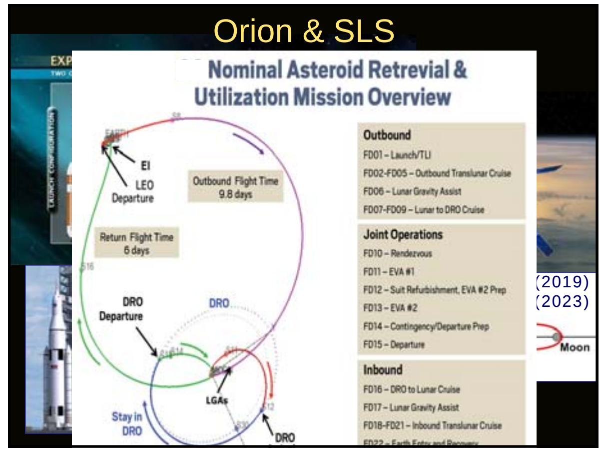


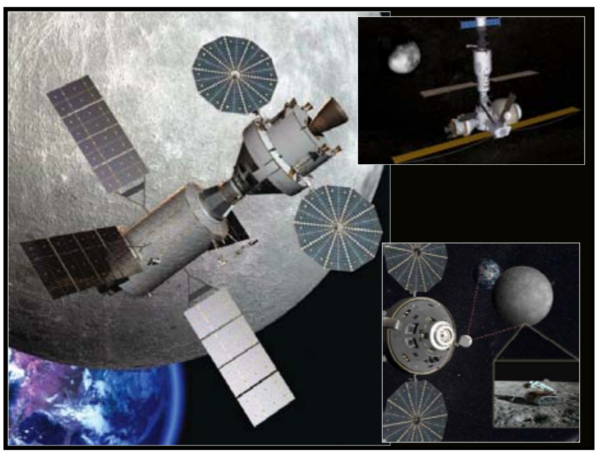
Human space exploration missions under study

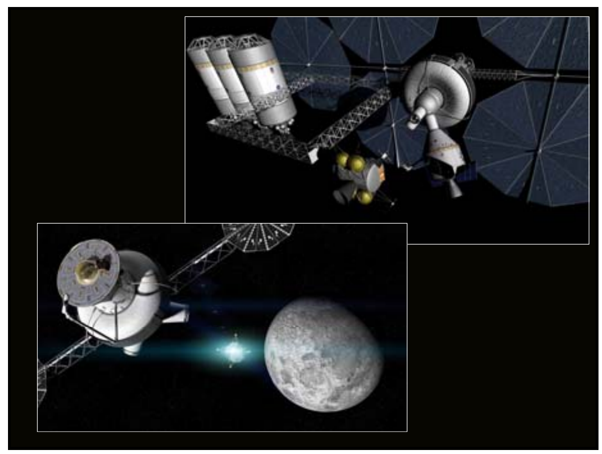
Destination	Location	Duration						Crew size
		Total	Outbound	At destination		Inbound		
International Space Station (exploration-enabling)	Low Earth orbit	6 months	2 days or 6 hours	6 months	0 g	3.3 hours		6
		1 year		1 year				2/4+4
Moon	Surface outpost	6 months	3-4 days	6 months	1/6 g	3-4 days		4
	Earth-Moon L2	1-6 months	11 days	1-6 months	0 g	11 days		4
Near-Earth Asteroid	Solar orbit	3 months – 1 year	1 -5 months	1 month	0 g	1-6 months		2-4
	Distant retrograde lunar orbit	22 days	10 days	6 days		6 days		4
Mars	Flyby	1.4 years	7½ months	Less than 1 day	0 g	9 months		2
	Phobos, Deimos	2½ years	6 months	1½ years		6 months		6
	Surface				1/3 g			

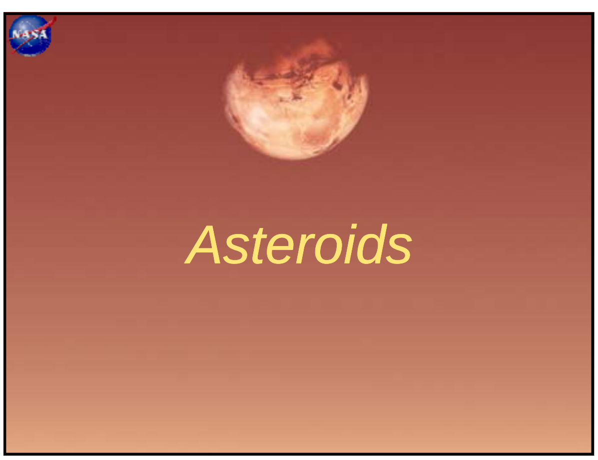
The Moon

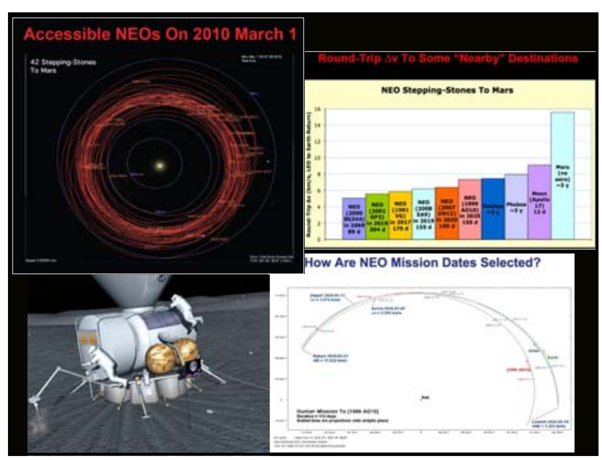

Orion & SLS
EXPLORATION FLIGHT TEST ONE
EFT-1 (2014)
EM-1 (2019)
EM-2 (2023)
Earth
Moon

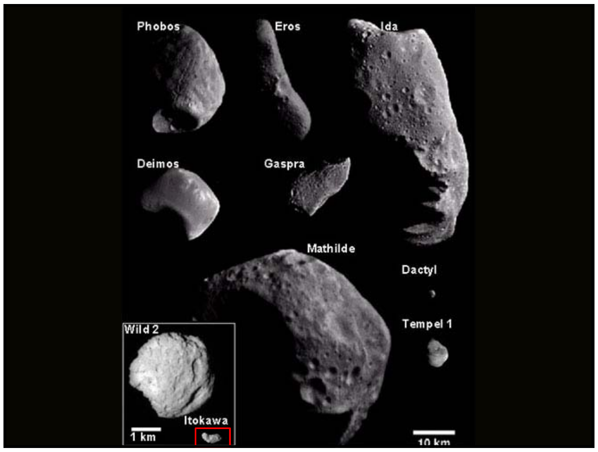

Orion & SLS
Nominal Asteroid Retrieval & Utilization Mission Overview
Outbound
FD01 – Launch/TLI
FD02-FD05 – Outbound Translunar Cruise
FD06 – Lunar Gravity Assist
FD07-FD09 – Lunar to DRO Cruise
Joint Operations
FD10 – Rendezvous
FD11 – EVA #1
FD12 – Suit Refurbishment, EVA #2 Prep
FD13 – EVA #2
FD14 – Contingency/Departure Prep
FD15 – Departure
Inbound
FD16 – DRO to Lunar Cruise
FD17 – Lunar Gravity Assist
FD18-FD21 – Inbound Translunar Cruise
Outbound Flight Time
9.8 days
Return Flight Time
6 days
EI
LEO
Departure
DRO
Departure
DRO
Stay in
DRO
LGAs
DRO

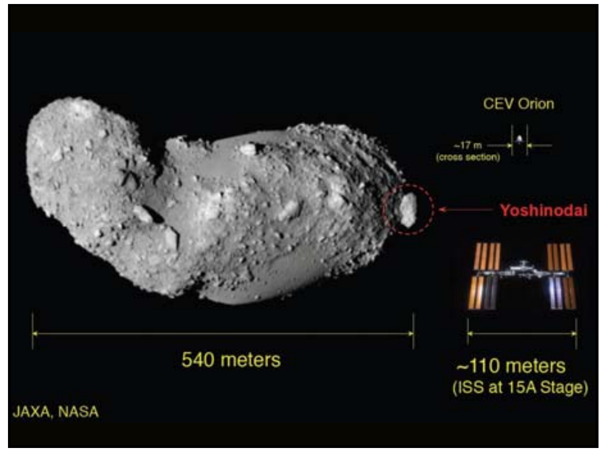


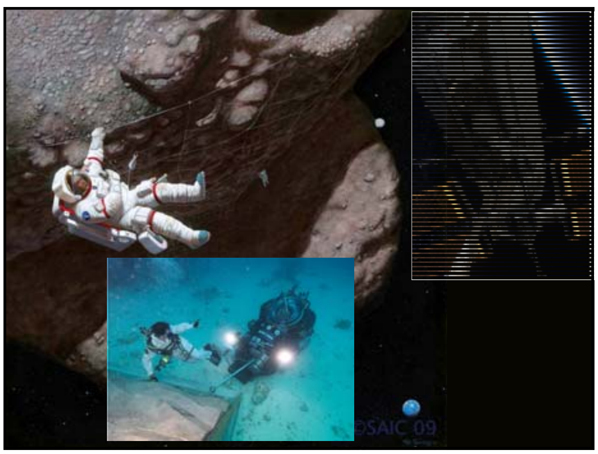


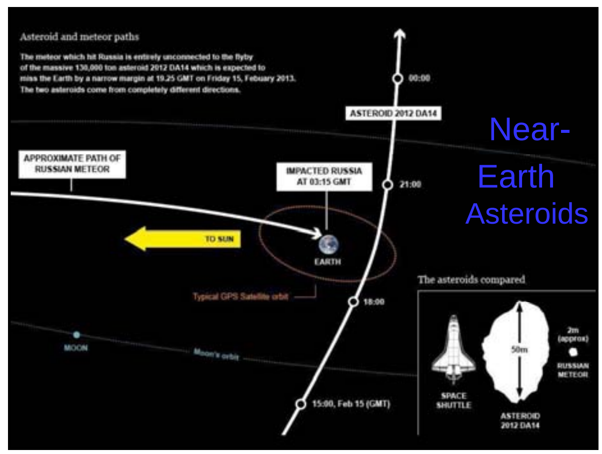

Asteroids

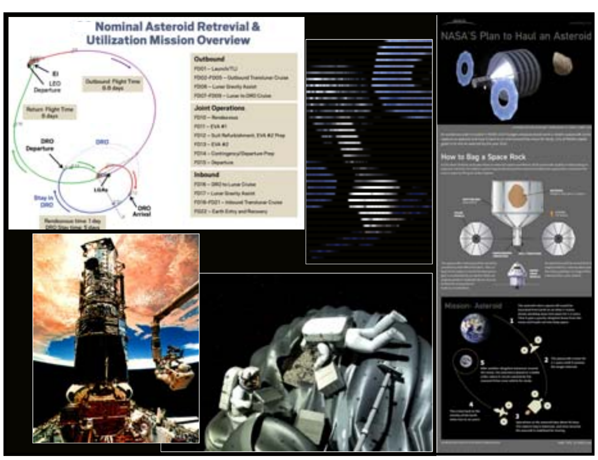

Accessible NEOs On 2010 March 1
Round-Trip Δv To Some "Nearby" Destinations
NEO Stepping-Stones To Mars
How Are NEO Mission Dates Selected?

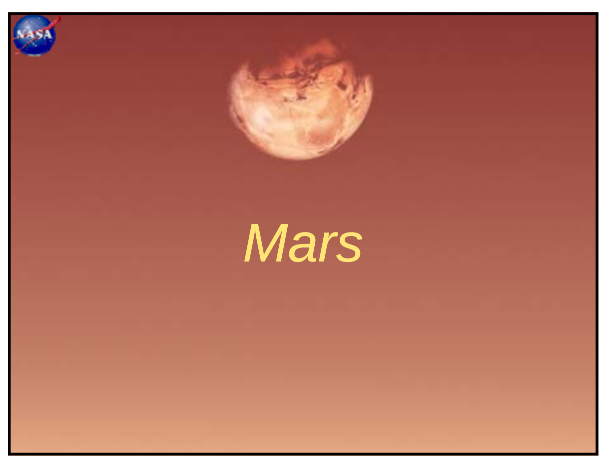

Phobos
Eros
Ida
Deimos
Gaspra
Mathilde
Dactyl
Tempel 1
Wild 2
Itokawa
1 km
10 km

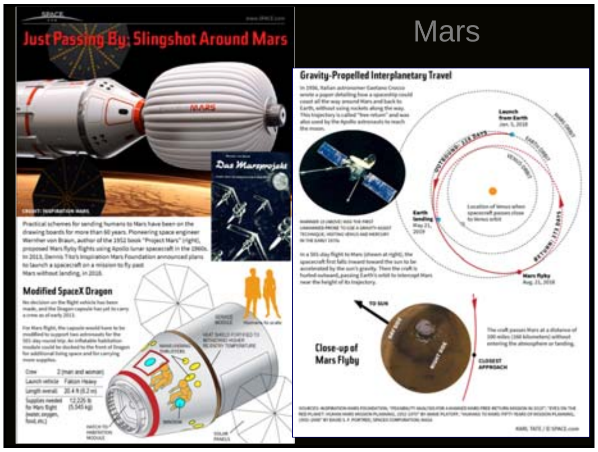

CEV Orion
~17 m
(cross section)
Yoshinodai
540 meters
~110 meters
(ISS at 15A Stage)
JAXA, NASA


SAIC 09

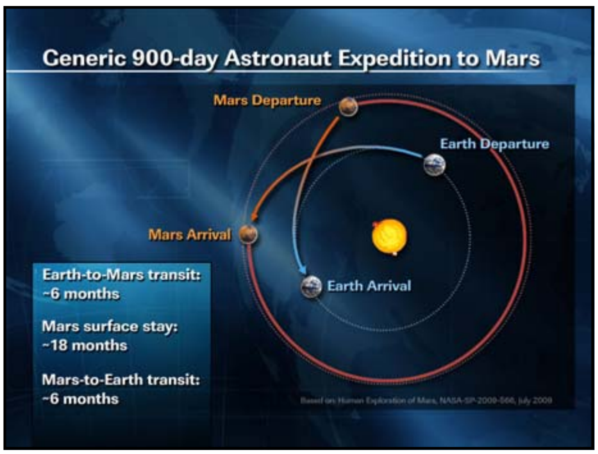

Asteroid and meteor paths
The meteor which hit Russia is entirely unconnected to the flyby of the massive 130,000 ton asteroid 2012 DA14 which is expected to miss the Earth by a narrow margin at 19.25 GMT on Friday 15, Febuary 2013. The two asteroids come from completely different directions.
ASTEROID 2012 DA14
APPROXIMATE PATH OF RUSSIAN METEOR
IMPACTED RUSSIA AT 03:15 GMT
00:00
21:00
TO SUN
EARTH
Typical GPS Satellite orbit
18:00
MOON
Moon's orbit
15:00, Feb 15 (GMT)
The asteroids compared
SPACE SHUTTLE
50m
ASTEROID 2012 DA14
2m (approx)
RUSSIAN METEOR
Near-
Earth
Asteroids

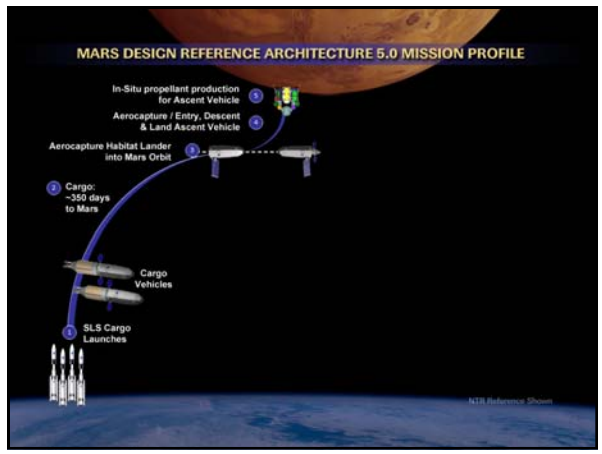

Nominal Asteroid Retrevial &
Utilization Mission Overview
NASA'S Plan to Haul an Asteroid
How to Bag a Space Rock

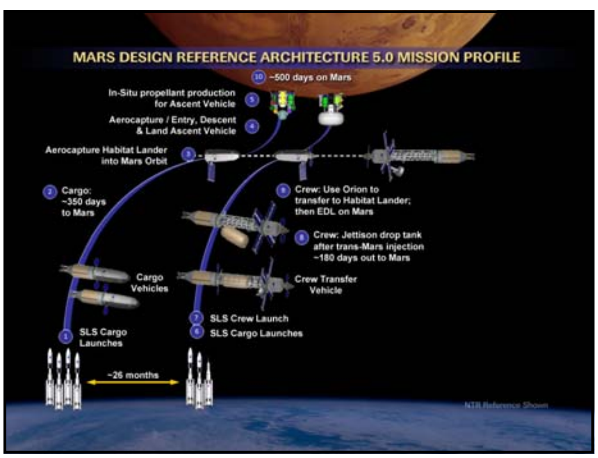

NASA
Mars

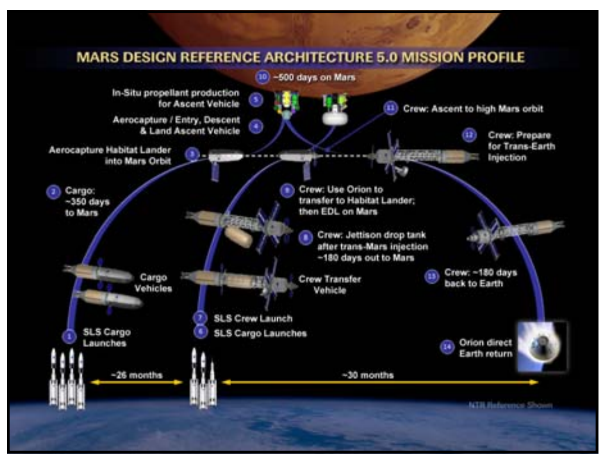

Mars
Just Passing By: Slingshot Around Mars
Das Marsprojekt
Gravity-Propelled Interplanetary Travel
Modified SpaceX Dragon
Close-up of Mars Flyby

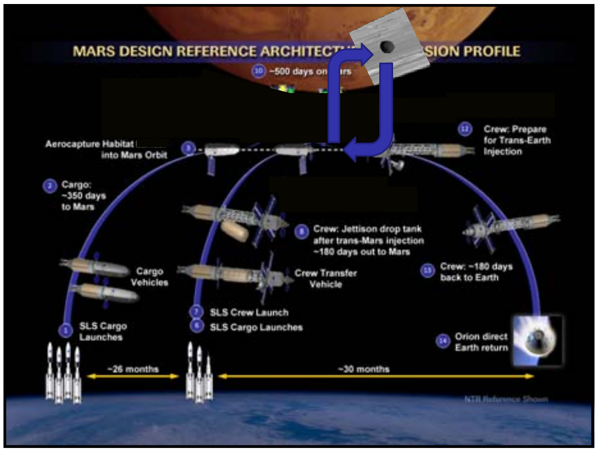

Human Exploration of Mars
Design Reference Architecture 5.0
July 2009


Generic 900-day Astronaut Expedition to Mars
Mars Departure
Earth Departure
Mars Arrival
Earth Arrival
Earth-to-Mars transit: ~6 months
Mars surface stay: ~18 months
Mars-to-Earth transit: ~6 months


MARS DESIGN REFERENCE ARCHITECTURE 5.0 MISSION PROFILE
In-Situ propellant production for Ascent Vehicle
Aerocapture / Entry, Descent & Land Ascent Vehicle
Aerocapture Habitat Lander into Mars Orbit
Cargo: ~350 days to Mars
Cargo Vehicles
SLS Cargo Launches

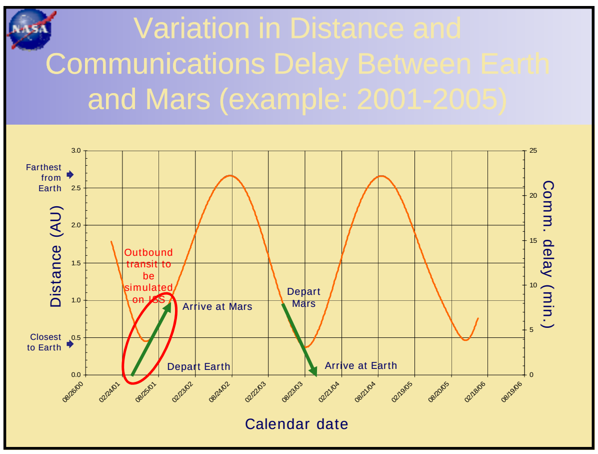

MARS DESIGN REFERENCE ARCHITECTURE 5.0 MISSION PROFILE
~500 days on Mars
In-Situ propellant production for Ascent Vehicle
Aerocapture / Entry, Descent & Land Ascent Vehicle
Aerocapture Habitat Lander into Mars Orbit
Cargo: ~350 days to Mars
Crew: Use Orion to transfer to Habitat Lander; then EDL on Mars
Crew: Jettison drop tank after trans-Mars injection ~180 days out to Mars
Cargo Vehicles
Crew Transfer Vehicle
SLS Crew Launch
SLS Cargo Launches
SLS Cargo Launches
~26 months

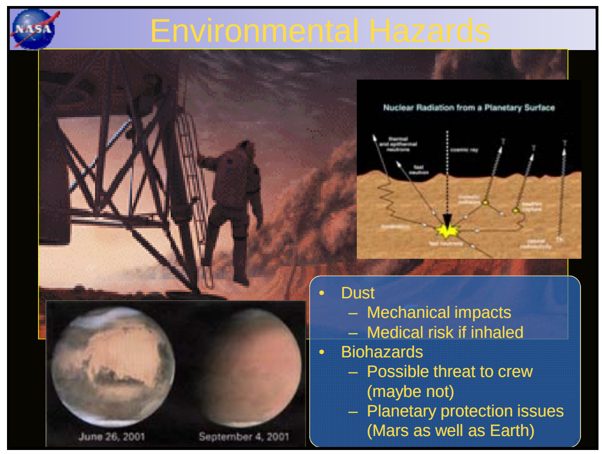

MARS DESIGN REFERENCE ARCHITECTURE 5.0 MISSION PROFILE
~500 days on Mars
In-Situ propellant production for Ascent Vehicle
Aerocapture / Entry, Descent & Land Ascent Vehicle
Crew: Ascent to high Mars orbit
Crew: Prepare for Trans-Earth Injection
Aerocapture Habitat Lander into Mars Orbit
Cargo: ~350 days to Mars
Crew: Use Orion to transfer to Habitat Lander; then EDL on Mars
Crew: Jettison drop tank after trans-Mars injection ~180 days out to Mars
Cargo Vehicles
Crew Transfer Vehicle
Crew: ~180 days back to Earth
SLS Crew Launch
SLS Cargo Launches
SLS Cargo Launches
Orion direct Earth return
~26 months
~30 months

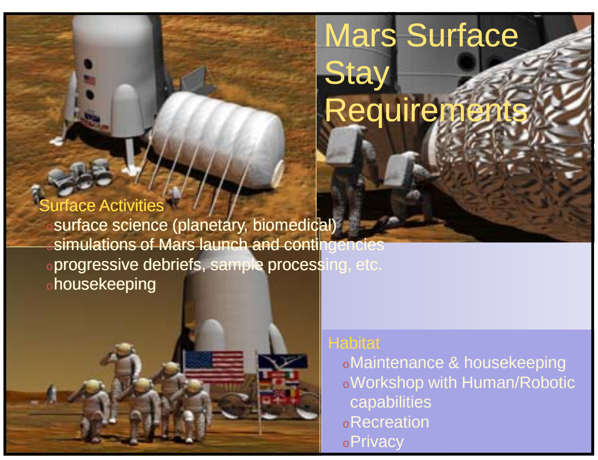


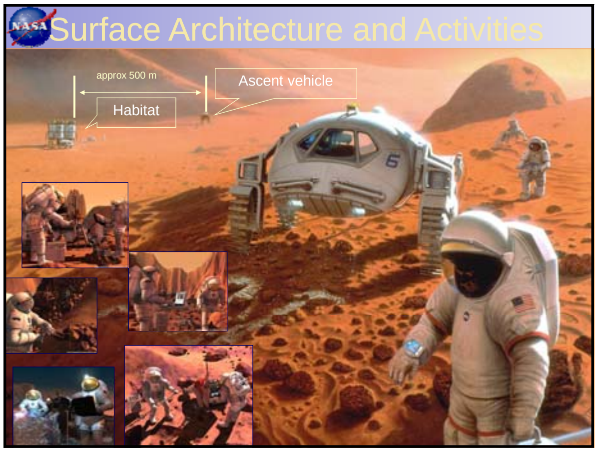
Human *in situ* space exploration threats

Destination	Location	Total Duration	Gravity	Radiation	Confined	Isolation & autonomy	Crew size	Injury
International Space Station (exploration-enabling)	Low Earth orbit	6 months	0 g	√	√	√	6	√
		1 year					2/4+4	
Moon	Surface outpost	6 months	Almost all @ 1/6 g	√√	√	√	4	√√
	Earth-Moon L2	1-6 months	0 g	√√√	√√	√	4	√
Near-Earth Asteroid	Solar orbit	3 months – 1 year	0 g	√√√	√√√	√√	2-4	√
	Distant retrograde lunar orbit	22 days		√√√	√√√	√	4	√
Mars	Flyby	1.4 years	0 g	√√√	√ √	√√√	2	√
	Phobos, Deimos	2½ years		√√√	√√√	√√√	6	√
	Surface		1 year @ 0 g 1½ year @ 1/3 g	√√	√	√√√		√√

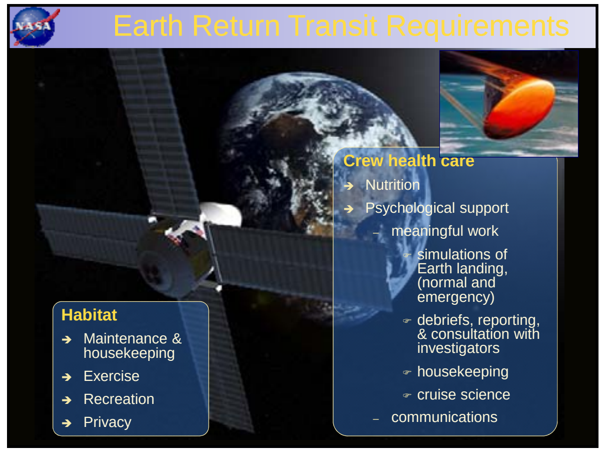








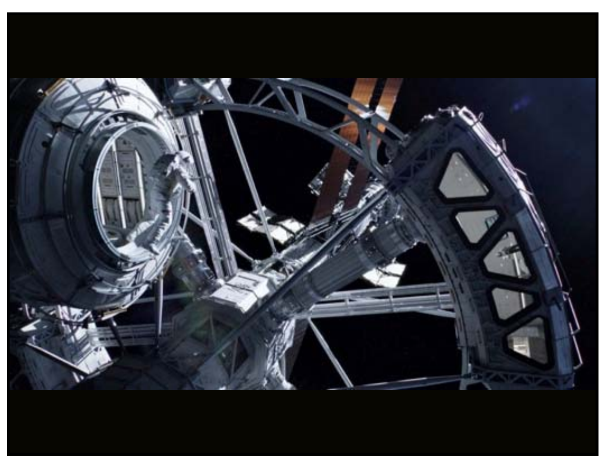
Surface Architecture and Activities
approx 500 m
Ascent vehicle
Habitat



Earth Return Transit Requirements
Crew health care
Nutrition
Psychological support
meaningful work
simulations of Earth landing, (normal and emergency)
debriefs, reporting, & consultation with investigators
housekeeping
cruise science
communications
Habitat
Maintenance & housekeeping
Exercise
Recreation
Privacy

Clinical Problems
Autonomous Clinical Care
non-invasive diagnostic capabilities for medical/surgical care
•"smart" systems
•non-invasive imaging systems
definitive surgical therapy including robotic surgical assist devices and surgical simulators
blood replacement therapy
laboratory support
• Expected illnesses and problems
– Orthopedic and musculoskeletal problems (esp. in hypogravity)
– Infectious, hematological, and immune-related diseases
– Dermatological, ophthalmologic, and ENT problems
• Acute medical emergencies
– Wounds, lacerations, and burns
– Toxic exposure and acute anaphylaxis
– Acute radiation illness
– Development and treatment of decompression sickness
– Dental, ophthalmologic, and psychiatric
• Chronic diseases
– Radiation-induced problems
– Responses to dust exposure
– Presentation or acute manifestation of nascent illness

Exploration Brings Risks…



Projected Rates of Illness or Injury

Past Experience

0.06 person/year

Based on U.S. and Russian space flight data, U.S. astronaut longitudinal data, and submarine, Antarctic winter-over, and military aviation experience:

- Incidence of *significant* illness or injury is
  - **0.06 per person-year**
    - as defined by U.S. standards
    - requiring emergency room (ER) visit or hospital admission
- Subset requiring intensive care (ICU) support is
  - **0.02 per person-year**

Mars DRM

0.90 person/mission

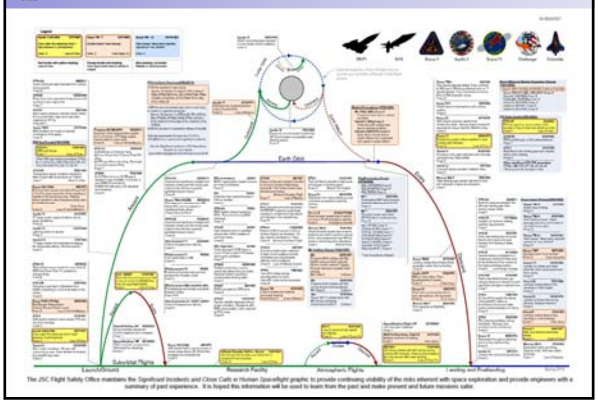
For DRM of 6 crewmembers on a 2½ year mission, expect:

- **0.9 persons per mission,** or ~one person per mission, to require ER capability
- **0.3 persons per mission,** or ~once per three missions, to require ICU capability
  - ~80% require intensive care only 4-5 days
  - ~20% do not.

Note: Decreased productivity, increased risk while crew reduced by 1-2 (including care-giver)

Data from R. Billica, January 1998, and D. Hamilton, June 1998

Risks of Human Spaceflight



Thank you!

Questions?

National Research Council, 2014

Destination	Public Engagement	Science	Human Research	Exploration Preparation
Lunar Flyby/Orbit	Return to Moon, "any time we want"	Demo of human robotic operation	10 days beyond radiation belts	Beyond LEO shakedown
Earth Moon L1	"On-ramp to the inter-planetary highway"	Ability to service Earth Sun L2 spacecraft at Earth Moon L1	21 days beyond the belts	Operations at potential fuel depot
Earth Sun L2	First human in "deep space" or "Earth escape"	Ability to service Earth Sun L2 spacecraft at Earth Sun L2	32 days beyond the belts	Potential servicing, test airlock
Earth Sun L1	First human "in the solar wind"	Potential for Earth/Sun science	90 days beyond the belts	Potential servicing, test in-space habitation
NEO's	"Helping protect the planet"	Geophysics, Astrobiology, Sample return	150-220 day, similar to Mars transit	Encounters with small bodies, sample handling, resource utilization
Mars Flyby	First human "to Mars"	Human robotic operations, sample return?	440 days, similar to Mars out and return	Robotic operations, test of planetary cycler concepts
Mars Orbit	Humans "working at Mars and touching bits of Mars"	Mars surface sample return	780 days, full trip to Mars	Joint robotic/human exploration and surface operations, sample testing.
Mars Moons	Humans "landing on another moon"	Mars moons' sample return	780 days, full rehearsal Mars exploration	Joint robotic/human surface and small body exploration

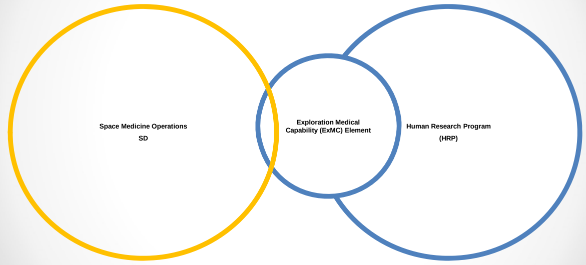
FIGURE 2.5 Benefits of various destinations along the Flexible Path. SOURCE: Review of U.S. Human Spaceflight Plans Committee (2009), *Seeking a Human Spaceflight Program Worthy of a Great Nation*, p. 41, http://www.nasa.gov/pdf/396093main_HSF_Cmte_FinalReport.pdf.

Exploration Medical Capability
NASA Human Research Program

Surgery in Space Symposium
Dec 9, 2015

Erik Antonsen MD, PhD
Element Scientist

Where we fit.



2

Our Mission

The medical system supports healthy crew to enable completion of mission objectives. We are concerned with health/prevention not just catastrophic events.

To minimize mission medical risk through medical system design and integration into the overall mission and vehicle design.

3

Considerations

- The current Medical Operations benefit from regular resupply of materials, real-time communications, and the potential for evacuation if serious medical concerns arise.
- This approach will need to evolve as exploration missions develop to encompass new challenges including crew autonomy.
- Medical care includes screening, prevention, diagnostic capability, treatment capability, follow up care, and prognosis.
- Exploration medical care can be decomposed to emergent, urgent, and health maintenance/wellness.

4

Mission Limitations

The LEO paradigm

ISS Current Operations:

- Private Medical Conferences in Real Time
- Procedural Guidance in Real Time
- Regular Resupply
- Evacuation Potential Exists

Exploration paradigm

Exploration missions are different:

- Delayed or Absent Communications
- Limited if any Resupply
- No Evacuation Potential
- Shrinking resources (mass, volume, power, etc.)
- The only resource growing is data handling capability (Moore's Law)

5

Risk Statement

Given that medical conditions will occur during human spaceflight missions, there is a possibility of adverse health outcomes and decrements in performance during these missions and for long term health.

- ExMC is chartered to reduce this risk.
- If we decrease medical risk to a crew member and end up increasing overall mission risk then we have failed.

6

ExMC Focus

- ExMC focuses on the Design Reference Missions provided by NASA for exploration spaceflight.
- The longest of these missions is a Human Mission to Mars estimated around 1000 days.
- Concept of colonization is not in our purview at this time.

7

Levels of Care

MEDICAL CARE CAPABILITIES

Level of Care	Mission	Capability
I	LEO < 8 days	Space Motion Sickness, Basic Life Support, First Aid, Private Audio, Anaphylaxis Response
II	LEO < 30 day	Level I + Clinical Diagnostics, Ambulatory Care, Private Video, Private Telemedicine
III	Beyond LEO < 30 day	Level II + Limited Advanced Life Support, Trauma Care, Limited Dental Care
IV	Lunar > 30 day	Level III + Medical Imaging, Sustainable Advanced Life Support, Limited Surgical, Dental Care
V	Mars Expedition	Level IV + Autonomous Advanced Life Support and Ambulatory Care, Basic Surgical Care

NASA-STD-3001 Vol 1, Rev A

8

NASA Standards 3001, Volume 1

- **4.1.1.6.3** The training and caliber of the caregiver shall be at the physician level, due to the exclusively autonomous nature of the mission.
- **4.1.1.6.4** The scope of medical care available shall be limited or triaged due to availability of supplies, consumables, or mission risk.
- No direction given on what "Trauma Care" or "Basic Surgical Care" encompass

9

Variables affecting Surgery in Space

- Terrestrially surgery is a resource intensive capability.
- Significant trades in medical capability are expected within the limited mass, power, and volume available in envisioned vehicles.
- Affects availability of fluids, medications, consumables, tool selection, and follow up care options.
- CMO will be at "the physician level" – however the required skill sets have not been defined. Assistant will be needed.
- In short: skill sets and training needs, personnel needs, equipment needs, resource limitations and challenges that the environment poses.
- Because of this, HRP and ExMC have not defined Surgical Capability as a Critical Exploration Medical Capability at this time.

10

Fundamental Questions

- Will surgery be needed?
- What kind of surgery will be needed?
- What type of skill sets must be provided?
- How do you provide for skills retention or training if needed?
- What tools should I send to support them?
- How do we provide the support personnel normally needed?
- How do we provide the needed supporting resources?
- Where do we draw the line in terms of planned care?

11

Risk Understanding Projects

- Integrated Medical Model (IMM)
  - Use the prior experiences in spaceflight to try to predict the likelihood of medical conditions occurring and the effect of the medical kit on outcome.
- Medical Optimization Network for Space Telemedicine Resources (MONSTR)
  - Use the terrestrial standard of care to determine what resources are needed to provide capability
  - Prioritize research investments to maximize capability to address all medical concerns
  - Provide objective measures of utility to support system trades

12

The IMM Medical Conditions**

1. Abdominal Injury
2. Abdominal Wall Hernia
3. Abnormal Uterine Bleeding
4. Acute Arthritis
5. Acute Cholecystitis / Biliary Colic
6. Acute Compartment Syndrome
7. Acute Diverticulitis
8. Acute Closed-Angle Glaucoma
9. Acute Pancreatitis
10. Acute Prostatitis
11. Acute Radiation Syndrome
12. Acute Sinusitis
13. Allergic Reaction (mild to moderate)
14. Altitude Sickness
15. Angina/ Myocardial Infarction
16. Anaphylaxis
17. Ankle Sprain/Strain
18. Anxiety
19. Appendicitis
20. Atrial Fibrillation/ Flutter
21. Back Sprain/Strain
22. Back Pain (SA)
23. Barotrauma (sinus block)
24. Behavioral Emergency
25. Burns secondary to Fire
26. Cardiogenic Shock secondary to Infarction
27. Chest Injury
28. Choking/Obstructed Airway
29. Constipation (SA)
30. Decompression Sickness Secondary to EVA
31. Dental : Exposed Pulp
32. Dental Caries
33. Dental: Abscess
34. Dental: Avulsion (Tooth Loss)
35. Dental: Crown Loss
36. Dental: Filling Loss
37. Dental: Toothache
38. Depression
39. Diarrhea
40. Elbow Dislocation
41. Elbow Sprain/Strain
42. Eye Irritation/Abrasion
43. Eye Chemical Burn
44. Eye Corneal Ulcer
45. Eye Infection
46. Eye Penetration (foreign body)
47. Finger Dislocation
48. Fingernail Delamination (2° EVA)
49. Gastroenteritis
50. Head Injury
51. Headache (CO2 induced)
52. Headache (Late)
53. Headache (SA)
54. Hearing Loss
55. Hemorrhoids
56. Herpes Zoster
57. Hip Sprain/Strain
58. Hip/Proximal Femur Fracture
59. Hypertension
60. Indigestion
61. Influenza
62. Insomnia (SA)
63. Knee Sprain/Strain
64. Late Insomnia
65. Lower Extremity Stress Fracture
66. Lumbar Spine Fracture
67. Medication Overdose / Reaction
68. Mouth Ulcer
69. Nasal Congestion (SA)
70. Nephrolithiasis
71. Neurogenic Shock
72. Nose bleed (SA)
73. Otitis Externa
74. Otitis Media
75. Paresthesias (2° EVA)
76. Pharyngitis
77. Respiratory Infection
78. Retinal Detachment
79. Seizures
80. Sepsis
81. Shoulder Dislocation
82. Shoulder Sprain/Strain
83. Skin Abrasion
84. Skin Infection
85. Skin Laceration
86. Skin Rash
87. Small Bowel Obstruction
88. Smoke Inhalation
89. Space Motion Sickness (SA)
90. Stroke (CVA)
91. Sudden Cardiac Arrest
92. Toxic Exposure: Ammonia
93. Traumatic Hypovolemic Shock
94. Urinary Incontinence (SA)
95. Urinary Retention (SA)
96. Urinary Tract Infection
97. Vaginal Yeast Infection
98. VIIIP – Visual Impairment/ Increased Intracranial Pressure (SA)
99. Wrist Fracture
100. Wrist Sprain/Strain

SA = Space Adaptation   **47 conditions have occurred inflight, 53 others considered possible

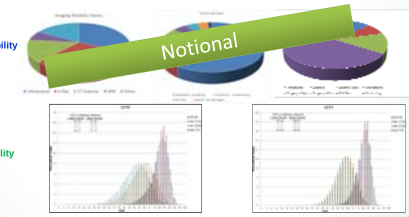
Trade Space Development

- Identify the terrestrial standard of care
- Capture the resources needed to provide that level of care
- Provide objective measures of capability to support system trades

Medical Optimization Network for Space Telemedicine Resources (MONSTR)

Medical Capability (MONSTR)

Event Probability (IMM)



Draft Data Only

Principles

- We are not going to Mars to do medicine (or surgery)
- Any investments we make have to decrease medical risk…
- …without increasing mission risk.
- Any medical/surgical capability we take has to be part of a larger system.

Conclusion

- HRP and ExMC need to define the risk, taking into account multiple variables characteristic of spaceflight, prior to engaging in active surgical research. This effort is underway.
- Innovative approaches are needed to decrease the resource burden that surgical capability poses.
- ExMC and HRP are interested in following the progress that is made in this domain, as innovative solutions are identified surgical capability may become a more attractive option to reducing the overall medical risk.

Medical and Surgical Capabilities required to Support Exploration Missions

Space Medicine- Opportunities and Constraints

Baylor College of Medicine

Dec 9, 2015

Jeffrey A. Jones, MD, MS, FACS, FACPM, FAsMA
Professor BCM-Center for Space Medicine
R. Scheuring, et al

Extracts from 2006- Lunar TIM with NSBRI

Our Destiny is to Explore!

- The goals of our future space flight program must be worthy of the expense, difficulty and risks which are inherent to it.
- We need to build beyond our current capability to ferry astronauts and cargo to low Earth orbit.
- Our steps should be evolutionary, incremental, and cumulative.
- To reach for Mars and beyond we must first reach for the moon.

A committed and long term lunar effort is needed, and we need to begin that investment now!

A Bold Vision for Space Exploration

- Complete the International Space Station
- Safely fly the Space Shuttle until 2010
- Develop and fly the Crew Exploration Vehicle no later than 2014 (goal of 2012)
- Return to the Moon no later than 2020
- Extend human presence across the solar system and beyond
- Implement a sustained and affordable human and robotic program
- Develop supporting innovative technologies, knowledge, and infrastructures
- Promote international and commercial participation in exploration

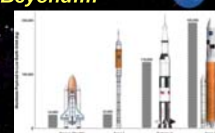
"It is time for America to take the next steps.

Today I announce a new plan to explore space and extend a human presence across our solar system. We will begin the effort quickly, using existing programs and personnel. We'll make steady progress – one mission, one voyage, one landing at a time"

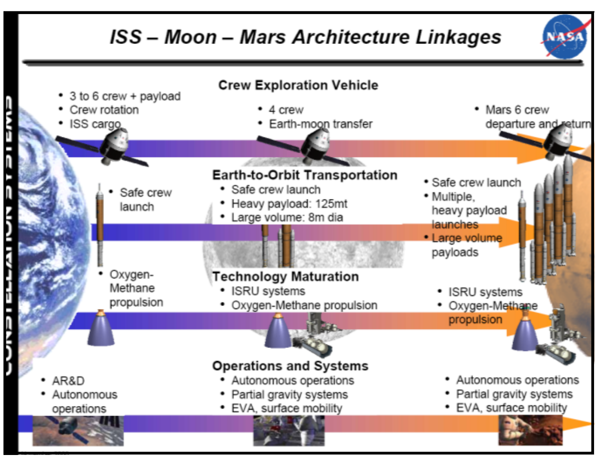
President George W. Bush – January 14, 2004

The Moon - the 1st Step to Mars and Beyond….

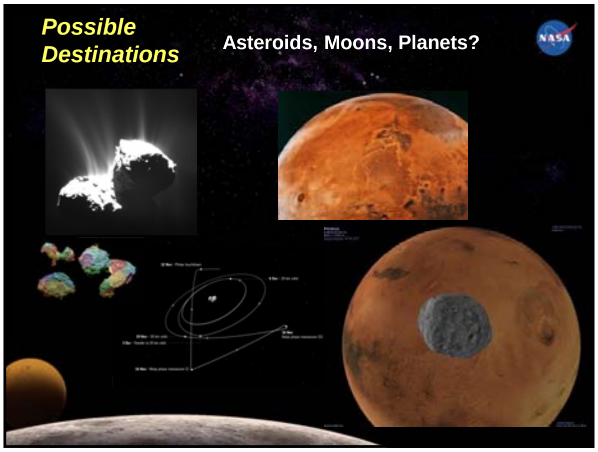
- Gaining significant experience in operating away from Earth's environment
  - Space will no longer be a destination visited briefly and tentatively
  - "Living off the land"
  - Human support systems
- Developing technologies needed for opening the space frontier
  - Crew and cargo launch vehicles (125 metric ton class)
  - Earth ascent/entry system – Crew Exploration Vehicle
  - Mars ascent and descent propulsion systems (liquid oxygen / liquid methane)
- Conduct fundamental science
  - Astronomy, physics, astrobiology, historical geology, exobiology



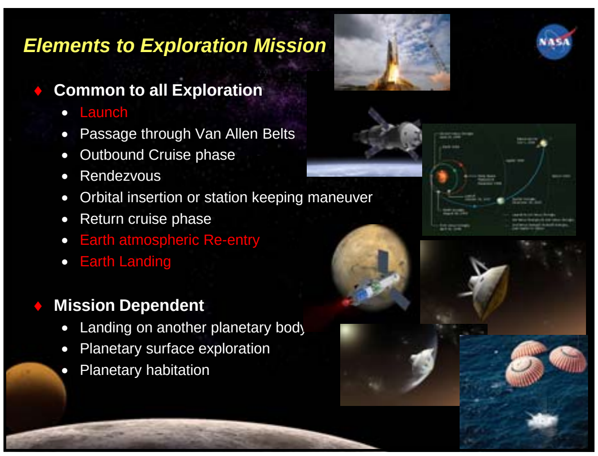
Next Step in Fulfilling Our Destiny As Explorers



Now the exploration mission is crystal clear…..?


Possible Destinations
Asteroids, Moons, Planets?


Elements to Exploration Mission
Common to all Exploration
Launch
Passage through Van Allen Belts
Outbound Cruise phase
Rendezvous
Orbital insertion or station keeping maneuver
Return cruise phase
Earth atmospheric Re-entry
Earth Landing
Mission Dependent
Landing on another planetary body
Planetary surface exploration
Planetary habitation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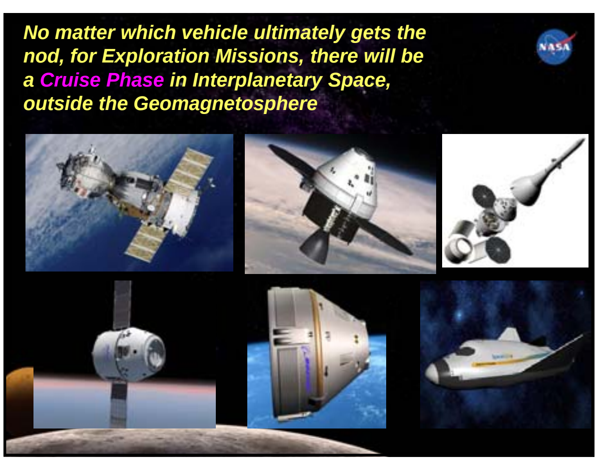
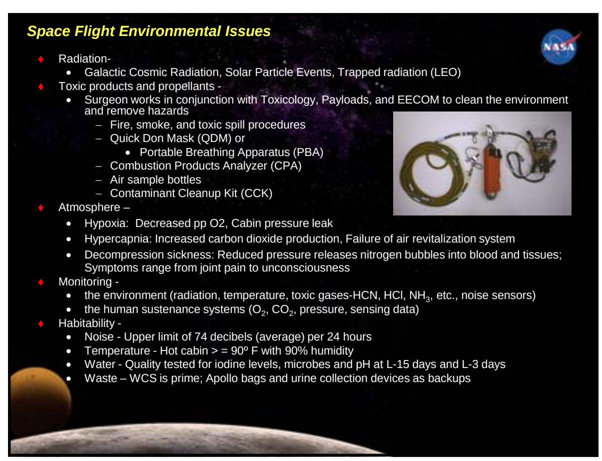
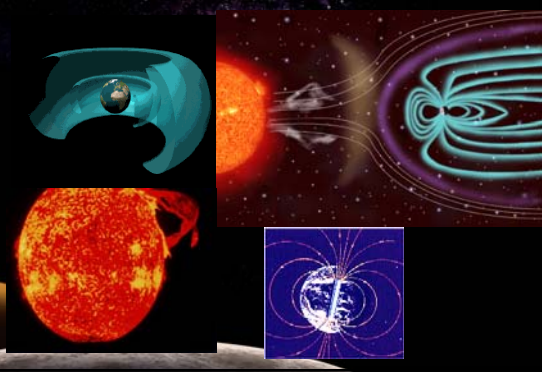
Planetary surface exploration
Planetary habitation


Leave Launch and Landing Medical Contingencies to Ground Forces to manage
Nominal Potential Landing Sites


No matter which vehicle ultimately gets the nod, for Exploration Missions, there will be a Cruise Phase in Interplanetary Space, outside the Geomagnetosphere

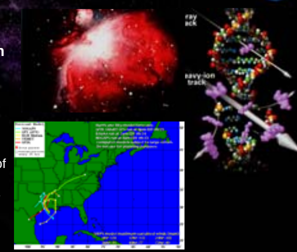

Space Flight Environmental Issues
Radiation-
Galactic Cosmic Radiation, Solar Particle Events, Trapped radiation (LEO)
Toxic products and propellants -
Surgeon works in conjunction with Toxicology, Payloads, and EECOM to clean the environment and remove hazards
Fire, smoke, and toxic spill procedures
Quick Don Mask (QDM) or
Portable Breathing Apparatus (PBA)
Combustion Products Analyzer (CPA)
Air sample bottles
Contaminant Cleanup Kit (CCK)
Atmosphere –
Hypoxia: Decreased pp O2, Cabin pressure leak
Hypercapnia: Increased carbon dioxide production, Failure of air revitalization system
Decompression sickness: Reduced pressure releases nitrogen bubbles into blood and tissues; Symptoms range from joint pain to unconsciousness
Monitoring -
the environment (radiation, temperature, toxic gases-HCN, HCl, NH_3, etc., noise sensors)
the human sustenance systems (O_2, CO_2, pressure, sensing data)
Habitability -
Noise - Upper limit of 74 decibels (average) per 24 hours
Temperature - Hot cabin > = 90º F with 90% humidity
Water - Quality tested for iodine levels, microbes and pH at L-15 days and L-3 days
Waste – WCS is prime; Apollo bags and urine collection devices as backups

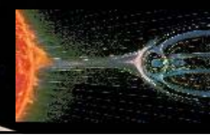
LEO: Radiation Exposure protection from the Earth's Geomagnetosphere GCR and SPE

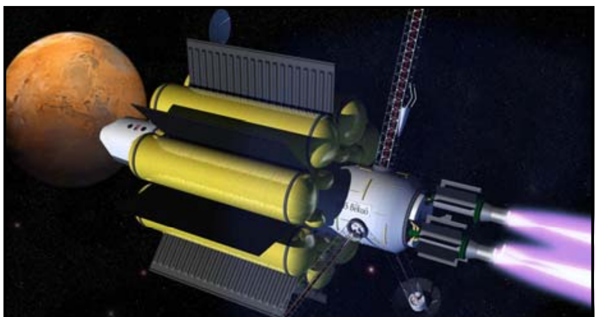


Radiation Safety and Protection

- Module dose monitors
- Small, lightweight detectors with EVA teams
  - Alarms integrated into suit CnW
  - Best on rover vs. PLSS of each suit?
- Early warning satellite network
  - Improved modeling for prediction of progressive events
  - Not all X-ray flares are followed by energetic protons
- Deployable shielding
  - On rover
  - ? Walkback portable shield
- Radioprotectants;
  Radiomodulators;
  Radiomitigants







VaSIMR (Variable Specific Impulse Magnetoplasma Rocket) engines do not use chemical reactions to produce rocket thrust. Instead the hydrogen is turned into plasma, a super hot gas at temperatures higher than the interior of the Sun. The plasma is created by electromagnetic waves in a magnetic chamber and expelled through a magnetic nozzle. Advanced superconducting magnets generate the strong fields required by the engine.

Getting there faster is the best countermeasure medical could hope for!!!!

Other Environmental Contingencies- medical response required

"Those that do not read and understand history are doomed to repeat it"
– President Harry S. Truman

- Apollo 1 fire
  - **100% oxygen**
  - **Lack of materials control**
- Apollo 13
  - **Critical consumables location**
  - **Multiple hardware developers**
    - **CO2 removal**
- **Shuttle, Shuttle/Mir, ISS experiences**

Air Quality Upsets During Shuttle, Mir & ISS Missions

Shuttle

- Teflon sleeve pyrolyzed by electrical short (STS-28)
- Wire burnt beneath humidifier (STS-6)
- LiOH dust escaped from CO2 removal canisters
- Brown dust released from waste management system
- Combustion products from electronics pyrolysis in 2 data display units (STS-35)
- Formaldehyde pollution from pyrolysis of motor housing in refrigerator (STS-40)
- Undersized capacitor overheated in laptop causing odor (STS-50)
- Microbial production of methyl sulfides from liquid waste (STS-55)
- Mir airlock adapter coating strongly off-gassed (STS-89)

Mir

- Frequent leaks of ethylene glycol from cooling loops into air
- Formaldehyde escaped containment on Mir-18
- Oxygen candle fire produced various thermal degradation products (Feb 97)
- Overheating BMP beds produced health threatening levels of CO (Feb 98)

ISS

- Crew sickened in FGB during poor ventilation, probably from rebreathe of exhaled air/CO2 (Flight 2A.1)
- Freon 218 leaks from SM air conditioner (Apr 01 to Mar 02)
- Extremely high methanol in a sample of FGB air; exact source never determined
- METOX canister regeneration caused noxious air-many pollutants in air (Feb 02)
- Formaldehyde levels periodically exceed long-term limits, especially when debris restricted ventilation (mid 02 to Feb 03)
- Strong solvent-like odor from Elektron oxygen generator after repair work (Mar 04)
- Potential acid preservative aerosol escape from Russian urinal problem (Exp 10/Feb 05)
- Electrical odor traced to lamp on Service Module (Exp 10/Mar 05)

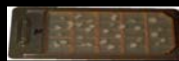
Combustion Events in Space

- Apollo 1 Fire- Lethal for 3 crew
- STS-6: arcing in Kapton-PFTE insulation=> noticeable odor
- STS-28: arcing in Kapton-PFTE insulation=> noticeable odor
- STS-35: overheating of electronic display unit
- STS-40: motor burn (refrigerator/freezer)
- Salyut 5 fire, mission abort from headache
- Mir (1994): Wire bundle caught fire
- Mir: (1997) Solid Fuel Oxygen Generator fire
- Mir: (1998) Catalytic Oxidizer overheat with Carbon Monoxide release

Water Quality Incidents on Shuttle, Mir & ISS

Shuttle
- High iodine & nickel for multiple flights
- Occasional high bacteria

Mir during Shuttle-Mir Program
- Ethylene glycol coolant leaks
- High levels of chloroform in ground-supplied water
- Oxygen candle fire halted condensate reclamation



ISS
- Elevated cadmium from dispenser valve
- Incidents of high silver in ground supplied water
- Persistent high bacteria in ground supplied water
- Persistent high turbidity in stored water
- Trace lead (Pb) in processed condensate; no breakthrough

Medical Events in Flight – Medical with Mission Impact

- Apollo 9 - EVA rescheduled due to motion sickness
- Apollo 11 – Type 1 DCS in command module pilot
- Apollo 13 – Urinary tract infection during mission
- Apollo 15 – Cardiac irregularity during lunar EVA
- Salyut- Kidney Stone- 1982
- Shuttle - 4 cases of urinary retention resulting in bladder catheterization
- ISS - Crewmember pulled from EVA due to cardiac abnormalities

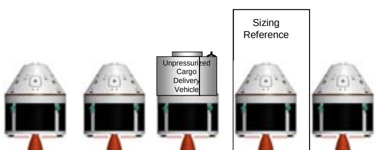
Medical Events in Flight – Medical Evacuation from Space

- Salyut 5 space station (1976) abandoned 49 days into 54 day mission for intractable headaches following probable combustion event
- Salyut 7 space station (1985) evacuation 56 days into 216 day mission for urinary tract infection
- Mir space station (1987) evacuation 6 months into 11 month mission for heart irregularity

Medical Events in Flight – Near Misses

- 1 cardiac ischemic event within 3 days of launch (crew changed out)
- 2 cardiac ischemic events inflight, followed by myocardial infarction (MI) postflight
  - Case 1: acute diaphoresis, fatigue and bigeminy on orbit, MI 2 years post flight
  - Case 2 event treated with ASA and beta blocker, MI 6 weeks post flight

CEV Block Mass Summaries

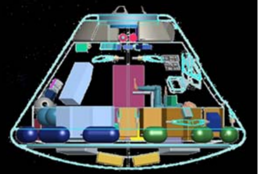


	Block 1A ISS Crew	Block 1B ISS Press Cargo	CDV ISS Unpress Cargo	Block 2 Lunar Crew	Block 3 Mars Crew
Crew Size	3/6	0	0	4	6
LAS Required	4,218	None	None	4,218	4,218
Cargo Capability (kg) [1]	400/0	3,500	6,000	Minimal	Minimal
Crew Module (kg)	9,342	11,381	12,200	9,506	TBD
Service Module (kg)	13,558	11,519	6,912	13,647	TBD
OMS Delta-V (m/s)	1,544 [2]	1,098 [2]	330	1,724	TBD
EOR-LOR 5.5m Total Mass (kg)	22,900	22,900	19,112	23,153	TBD

Note 1: Cargo capability is the total cargo capability of the vehicle including FSE and support structure.
A packaging factor of 1.29 was assumed for the pressurized cargo and 2.0 for unpressurized.
Note 2: Extra Block 1A and 1B OMS delta-V used for late ascent abort coverage

CEV Overview - Crew Module

Functions
- CM attitude control propulsion (GO2/Ethanol)
- Docking system (LIDS)
- Contingency EVA
- Crew Accommodations
- Avionics: DMS, C&T, GN&C, VHM
- Life Support and Thermal Control
- Earth Atmospheric Entry and Recovery



Habitability/ Crew Size (6 to ISS; 4 to Moon; ? to Mars)

Human/User Interfaces Requirements Scope

- Vehicle Interior Volume & Layout:
  - Overall crew cabin configuration
  - Net equipment and habitable volumes allocations
  - Equipment layout, size & shape effects on human/system functionality & habitability
- Subsystem Outfitting & Equipment:
  - Crew interfaces to subsystem hardware
  - Design of all interactions between crew and equipment interfaces
  - Commonality among vehicle interfaces
- Information Display & Design:
  - Cockpit software displays and other system displays
  - Systems that convey/ present data (such as labels, procedures, alarms)
  - Design of all human/system interactions with information systems
- Operational Integration:
  - Integration of crew with vehicle systems
  - Early inclusion of vehicle operational scenarios into human/system design solutions to provide resources needed to efficiently perform tasks
  - Crew time as a program resource
  - Limiting crew workarounds as "fixes" to poor design
  - Participation throughout lifecycle including operational lessons learned post-mission
  - Task Analysis- Veriifcation of Utility

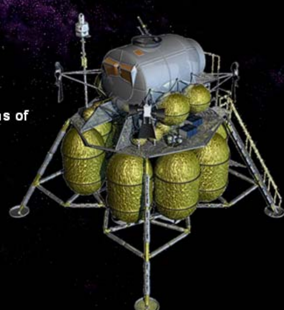
Grim realities of Early Lunar Exploration

- **Early Lunar transport vehicles will not be spacious!**

Lunar Lander and Ascent Stage (*LSAM- Lunar Surface Access Module*)

Upgrades from Apollo:

- **4 crew to and from the surface**
  - Seven days on the surface
  - Lunar outpost crew rotation
- **Global access capability**
- **Anytime return to Earth**
- **Capability to land 21 metric tons of dedicated cargo**
- **Airlock for surface activities**
- **Descent stage:**
  - Liquid oxygen / liquid hydrogen propulsion
- **Ascent stage:**
  - Liquid oxygen / liquid methane propulsion



Countermeasures- Exercise

Due to measured de-conditioning in even short duration space missions, an exercise device is felt to be needed by the ECP to protect/facilitate:

Cardiovascular fitness – to maintain overall fitness level, aid in ambulation during G-transitions, and to minimize fatigue

Muscle strength and endurance – to complete both nominal and contingency mission tasks (e.g., lunar rover failure requiring "walk back" of distances up to 10km; post landing egress)

Muscle recovery – from strenuous tasks or confined postures

Other possible system benefits – psycho/social, postural stability

A multifunctional exercise device to protect the maximum number of physiological systems?

Countermeasures- Exercise

When should it be available?

Transit return to prepare for piloting and egress

Transit outbound to maintain physical condition in preparation for surface operations

Lunar surface

½ Mid-deck locker (1 ft^3)

22 lbs (10 kg), including all accessories

No vehicle power or data interface

90 ft3 operational volume (volume is primarily subject volume, assumes 6.5 ft x 4.2 ft x 3.3 ft required for subject with margin)

Device	Weight (lbs)	Volume (cu ft)	# MLE (locker)
Lunar Sortie Device	*22*	*1.0*	*0.5*
TVIS	949	33.2	16.6
CEVIS	236	8.8	4.4
RED	410	16.5	8.3

Human Research Program

Exploration Medicine Capability

Medical Concept of Operations for Exploration

Our mandate:
Keep the mission going
Maintain a healthy/functional crew

Jeff Jones
Exploration Medical Operations Lead
JD Polk, Rick Scheuring, Jim Locke, Pete Bauer, Smith Johnston, Mike Chandler, Tara Volpe, David Baumann

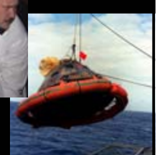
Basic Tenets of Exploration Medicine

- **Prevention, Prevention, Prevention!!!!!**
  - Strict selection criteria
  - Aggressive manage predisposing conditions
  - Maximally prepare crew prior to flight
  - Health maintenance strategy
    - Healthchecks
    - Countermeasures
    - Early Warning
- **Small medical h/w footprint**
- **Expand capability as mission demands**
  - Destination
  - Duration


Guiding Philosophy:
Prevention; Prevention; Prevention (with a little Prophylaxis mixed in)

- **Revised selection and mission medical standards**
- **Improved pre-flight medical readiness program**
  - Fitness
  - Optimization of health
  - Crew rest???
- **Better system design to reduce crew overhead**
  - Reduce fatigue
- **Emphasis on safety**
  - Vehicular components
  - Mission Planning, esp. EVA
  - Flight Rules
- **Maintenance of Performance**
  - EVA
  - Re-entry
  - Recovery

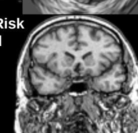
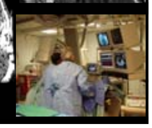




Changes to Medical Standards (from S. Johnston, et al)

- **Better Understanding of Disease and Aerospace Medical Physiology**
- **Improved Laboratory and Imaging Diagnostic Techniques**
- **Improved Treatment Modalities**
  - Endoscopic and Minimally Invasive Surgery
  - Image Guidance
  - New Biochemical Approaches and Pharmaceuticals
- **Neurological – Brain MRI**
- **EENT- Lens and Retinal Photos; Tympanograms**
- **Cardiovascular-EBCT; Framingham Risk**
- **Gastrointestinal- scoped from aft end**
- **Genitourinary- Abd and Pelvic U/S**
- **Laboratory Testing**
  - ? Genetic Susceptibility



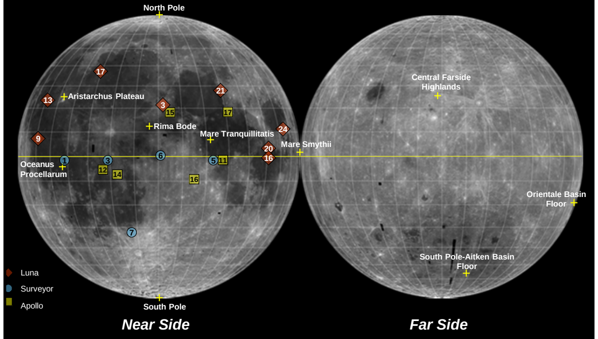




Operating Principle

- **As schedule constraints begin to rear their ugly head- ready to fly man-rated new vehicle by Sept. 2012, 3, 4, 5, 6, 7, ?**
- **Neutral NASA budget- no significant new funding for constellation program, carved from existing programmatic budgets**
- **Forcing a unifying principle of operations:**

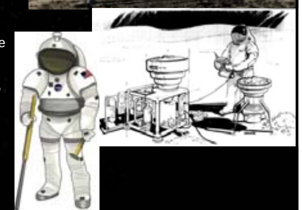
Keep
It
Simple
S~~tupid~~ mart

High Priority Lunar Exploration Sites



Lunar Sortie Crew Missions- Surface Operations Concept

- Sorties do not depend on pre-deployed assets and can land at any location on the Moon
- Four crew members lives out of landed spacecraft for up to 7 days
- EVAs can be conducted every day with all crewmembers
  - Crew can work as two separate teams simultaneously or alternate team days
- Unpressurized rovers for surface mobility (2 for simultaneous but separate EVA ops) gives crew approximately 15-20 km range from lander
- Sortie mission surface activities focus on three activities
  - Lunar science (geology, geophysics, low frequency radio astronomy, Earth observations, astrobiology)
  - Resource identification and utilization (Abundance, form and distribution of lunar hydrogen/water deposits near lunar poles; geotechnical characteristics of lunar regolith)
  - Mars-forward technology demonstrations and operational testing (autonomous operations, partial gravity systems, EVA, surface mobility)



Lunar Surface Activities

- **Initial demonstration of human exploration beyond Earth orbit**
  - Learning how to operate away from the Earth
- **Conduct scientific investigations**
  - Use the moon as a natural laboratory
    - Planetary formation/differentiation, impact cratering, volcanism
  - Understand the integrated effects of gravity, radiation, and the planetary environment on the human body
- **Conduct in-situ resource utilization (ISRU) demonstrations**
  - Learning to "live off the land"
  - Excavation, transportation and processing of lunar resources
- **Begin to establish an outpost - one mission at a time**
  - Enable longer term stays
- **Testing of operational techniques and demonstration of technologies needed for Mars and beyond…..**

Levels of Care from SHSD- Spaceflight Health Standards Document

Level of Care	Mission Ex.	Capability
One	CEV to ISS	SMS, BLS, First Aid
Two	STS, EDOMP	One + AmbCare, Clinical Diagnostics
Three	Lunar Sortie	Two + Limited ALS, Trauma, Telemedicine
Four	Lunar Outpost	Three + Sustainable ALS, Imaging
Five	Mars Mission	Four + Complete Autonomy, Basic Surgical

Medical Operational Concept

Lifecycle Phase: CEV to lunar orbit ; LSAM to surface

- Nominal:
  - Same as Block 1A but a larger set of equipment/supplies will be stowed in the Block 2 CEV.
  - A subset of this equipment will be taken with the crew in the LSAM to support surface operations.
  - A small exercise device (~0.5 MLE) will be stowed for onboard use.
  - The crew will perform exercise in the CEV and will require attach points for the exercise device. The details are TBR. (Portable Equipment/Medical I/F Whitepaper}. The operational envelope of the crew/exercise device is currently 90 ft3.
- Off-nominal:
  - Same as Block 1A but the advanced life support/trauma management equipment will be stowed in the LSAM to stabilize crewmembers experiencing lunar surface contingencies and brought into the CEV only in case of a need to transport and ill or injured crewmember.

Medical Operational Concept

Lifecycle Phase: Surface Operations – Lunar Sortie

- Nominal:
  - The crew will bring a subset of the CEV medical equipment and the exercise device (TBR) into the LSAM to support nominal surface operations
  - Advanced life support/trauma management equipment will be stowed in the LSAM.
  - The flight surgeons in MCC will monitor physiological parameters (i.e. heart rate/EKG, oxygen, carbon dioxide, temperature, etc.) will be monitored by the flight surgeon in MCC during surface EVAs via telemetry data down-linked to the ground.
  - Two-way private audio/video is required for performing Private Medical Conferences especially pre/post EVA. The two-way communication will also support Private Family Conferences (PFC) at least weekly between the crew and their family, and Private Psychological Conferences (PPC) as required.
- Off-nominal:
  - An EVA Contingency Response Kit will be stowed in the Airlock which will contain a Contamination Kit (brushes, bags, wipes), DCS treatment, fluids, and anti-inflammatory medication for the crew to use.
  - The medical equipment brought from the CEV and stowed in the LSAM will be used to treat ill/injured crewmembers per instructions from the flight surgeons. Data from the medical monitoring devices will be communicated to the ground for further diagnostic purposes. Power will be required for the medical equipment. Pressurized oxygen may be required for certain medical conditions for the ill/injured crewmember.
  - A significant illness or injury will be stabilized using LSAM-based medical equipment in preparation for ascent and transfer to CEV.
  - Two-way private audio/video is required for performing Private Medical Conferences with the flight surgeon in MCC to ensure optimization of medical care via the Crew Medical Officer.

Medical System Mass and Volume Allocation-GFE

- **CEV Lunar Sortie**
  - Med Kit
    - Volume- 0.016 M^3 (14.5 x 7 x 9.5 in.)
    - Mass 4.55 kg
  - Medical Interface
    - Volume- 0.002-0.003 M^3 (7 x 5 x 5 in.)
    - Mass 1.5-2.0 kg
  - Portable Breathing Apparati (4-PBAs)
    - Volume 0.047 M^3 (8 x 4 x 18 in. stowed each)
    - Mass <36.28 kg
  - Exercise Device- aerobic and resistive
    - Mass <10 kg.
    - Volume- ½ CTB: < 1 ft^3 (15 x 11 x 10 in.)
  - Crew Survival Kit for Post Landing: Volume 0.22 M^3

Medical System- Hardware Elements

Lunar Sortie- Lander:

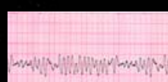
- Ambulatory Medical Kit (Routine symptom response: HA,
- Medical Contingency Kit (Trauma management; O2 concentrator, AED)
- Environmental Response Equipment
  - Airlock EVA Contingency Response (Contamination Clean-up, PPE and Contamination or Decompression Sickness Medical Kit)
  - Contingency Breathing Apparati (4-portable or umbilical-based devices)
  - Eyewash (system to flush contaminants from crew)




Medical Operational Concept

Lunar Sortie- Return transfer mission

- Nominal:
  - The crew will perform daily exercise in the CEV in preparation for return to 1g.
  - Private two-way audio/video communication will allow a Pre-entry PMC.
  - Leave LSAM medical kit on surface; use CEV med kit for return trip medical issues
- Off-nominal:
  - If illness or injury on the lunar surface occurs, the LSAM required hardware will be transported back with the crewmember to ensure a stabilized condition is maintained.
  - Two-way private audio/video is required for performing Private Medical Conferences with the flight surgeon in MCC to ensure optimization of medical care via the Crew Medical Officer.
  - PPE for off-nominal environmental issues


Medical System Mass and Volume Allocation - GFE H/W

- **LSAM**
  - Med Kit
    - Volume- 0.047 M^3 (26 x 14 x 8 in)
    - Mass 18.2 kg
  - Medical Trauma and Life Support
    - Volume- 0.10 M^3 (32 x 12 x 16 in.)
    - Mass 25 kg
  - Portable Breathing Apparati (4-PBAs)
    - Volume 0.047 M^3 (8 x 4 x 18 in. stowed each)
    - Mass 36.28 kg
  - Airlock EVA Contingency Response (Contamination Clean-up and Medical Kit)
    - Volume 0.010 M^3 (10 x 11 x 15 in.)
    - Mass 2.270 kg


Item ***for*** *Lunar Sortie-Lander*	Mass	Volume	Development Concept
Medical Kit	**10 [lbs]**	**0.243 ft^3 [10x7x6 in]**	**COTS**
Medical Contingency Kit	**30 [lbs]**	**3.531 ft^3 [32x12x16 in]**	**Modified COTS**
EVA Contingency Response Kit (with Contamination Clean-up)	**16 [lbs]**	**1.259 ft^3 [16x16x8.5 in]**	**Modified COTS**
Environmental Health Kit	**7.5 [lbs]**	**0.255 ft^3 [7x7x9 in]**	**Modified COTS**
Exercise Equipment	**5 [lbs]**	**0.104 ft^3 [6x6x5 in]**	**Technology Development Required**

Capability- *Sortie*: **Level III** Care as per Spaceflight Health Standards Document:
Routine ambulatory medical needs will be met with standard spaceflight **mini-medical** kit.
Advanced life support/trauma management equipment will be stowed in the medical contingency kit to stabilize crewmembers experiencing **lunar surface contingencies** and brought into the CEV only in case of a need to transport ill or injured crewmember.
An **EVA Contingency Response Kit** will be stowed in the Airlock which will contain a Contamination Kit (brushes, bags, wipes, personal protective equipment), DCS treatment, fluids, & anti-inflammatory medication.
The medical equipment in lander used to treat ill/injured crewmembers per instructions from flight surgeons. Data from medical monitoring devices communicated to the ground for further diagnostic purposes. Some medical equipment will need power interface, pressurized breathing gas, with or without oxygen concentration for certain medical conditions or for environmental contingencies- depressurization, fire, tox release. Crew will don **personal protective equipment (PPE)** during **toxic spill clean-up, or dust-ridden activities**. A significant illness or injury will be stabilized using LSAM-based medical equipment in preparation for ascent and transfer to CEV.
Two-way private audio/video is required for performing Private Medical Conferences with the flight surgeon in MCC to ensure optimization of medical care via the Crew Medical Officer.
A very **small exercise device** will be flown for sortie mission crew use during outbound and between EVA days

Outpost: **Level IV** Care as per the Spaceflight Health Standards Document (see next page)

Lunar Dust

Why are we concerned?

- **Dust particles levitated at the lunar terminator, perhaps due to polarity changes (Criswell '72). 0.16 G at lunar surface, where there is a layer of fine particles that are easily disturbed and placed into suspension. These particles cling to all surfaces and pose serious challenges for the utility of construction equipment, air locks, and all exposed surfaces (Slane '94)**
- **After lunar EVA the crewmen and the samples they had collected were covered with fine lunar material. Despite attempts at clean-up and packaging in the LM, transfer of crew and materials back to the CM resulted in contamination of the CM atmosphere (Brady et. al, 1975)**
- **Apollo astronauts were not in the lunar environment long enough to develop the clinically significant, dust-related symptoms. However, during upcoming missions, crews will be on the Moon for months at a time.**
- **Properties**
  - Size, shape, lack of weathering
  - Possible reactivity- volatiles, solar protons





Apollo Medical Operations Recommendations

In-Flight Illnesses

- Low back pain (>70%)
- Nasal congestion was experienced by most Symptoms related to lunar dust were described like allergies
- The **lunar dust is very difficult** to get off of your hands. Cabin fiberglass was also a problem. Both caused **Ocular irritation**
- Constipation
  - One CMP went entire 6 day mission without BM
- Space Motion Sickness (SMS)
- UTI (back pressure caused in UCD, dehydration)
- Arrhythmia experienced during lunar EVA (hypokalemia, dehydration; but actual underlying CAD was the cause)
- One lunar crewmember sustained a laceration on his right wrist "to the bone" from the EVA suit wrist ring
- Headaches (frequent- ? elevated cabin CO_2 levels)
- Skin irritation multiple sites, esp after lunar surface EVA
- Forearm soreness and fatigue during and after EVAs
- A physician crewmember: increase comfort level among crew, cross-trained to do other activities; Flight surgeon needs to protect crews from themselves

Apollo Medical Operations Recommendations

Medication/Medical Kits

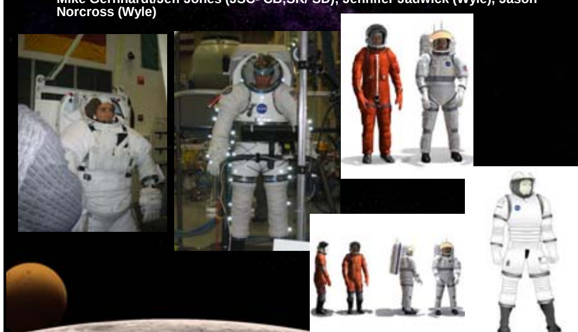
- Crew felt they did not want to report any medication usage or other problems because they did not want anyone to know about it
  - PMC was not available
- Confusion regarding drug t ½ and indications
  - One CDR remarked that he had forgotten how long Dexedrine lasted and suggested putting a card in the med kit to inform the crew of the medication duration, indication, and interaction with other meds
- Crew felt that the following medications should be taken by the crew when necessary and not require radio comm. with ground
  - Afrin
  - Lomotil
  - ASA
  - Dexedrine

Exploration EVA

- **EVA will be a critical capability of the NASA exploration program.**
- **Humans and Robots will need to work together but:**
  - " A human can do in 30 seconds what our rovers took 2 months to do" – JPL manager of Mars Rover Program
- **The Space Shuttle and Space Station were not optimized for doing EVA**
  - Current EVA is difficult , requires special skills and an inordinate amount of overhead just to get out the airlock
- **Apollo lacked an airlock on the LEM; and the suits had significant CG and mobility issues**
- **In the exploration program the concept of operations includes from two to five EVAs/week**
- **We need to make some big improvements!**

Biomedical and Crew Performance Aspects of the Exploration EVA system: EVA Physiology, Systems and Performance Project

Mike Gernhardt/Jeff Jones (JSC- CB;SK/ SD); Jennifer Jadwick (Wyle), Jason Norcross (Wyle)



Biomedical and Crew Performance Aspects of the Exploration EVA System

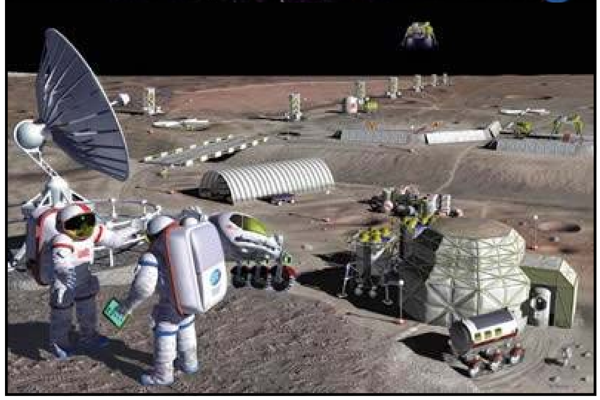
- **Goal to provide the biomedical data to drive suit design decisions that optimize human performance and minimize suit induced trauma**
- **Predictive models of metabolic costs and biomechanical parameters based on gravity levels, suit weight and mass, kinematics, pressure and center of gravity**
- **No overhead biomedical harness- built into thermal garment/LCVG**

Lunar Surface Rover- Reality, Planetary Mobile- Exploration Concepts under Testing and very cool Hollywood fantasy

Medical Issues to Manage for EVA-

- Space Medicine/Medical Operations – charged with Crew Health and Safety responsibility
  - **LSS: Oxygen/Carbon Dioxide**
  - **Thermal Loading**
  - **Metabolic Loading**
  - **Wear-ability/Comfort**
  - **Injury Prevention**
  - **Decompression Sickness**
  - **Dust Toxicity**
  - **Radiation Protection**
- **EVA Contingency Medical Kit**
  - Protective masks, gloves, etc. in case of contamination of suits with FORP, etc.
  - Initial Airlock DCS ancillary treatment
  - DCS impact risk reduction measures:
    - Lower LSAM pressure
    - Possible variable pressure suit with possible ability to return to LSAM pressure in-suit
  - Considering Rx of DCS first in-suit, then with Airlock pressure above ambient
    - Anti-inflammatory, 100%O2 via mask, IVFs, etc.

LSAM- Lunar descent, surface operations, and ascent



Medical/Exercise/Environmental Monitoring System Mass and Volume Allocation-GFE

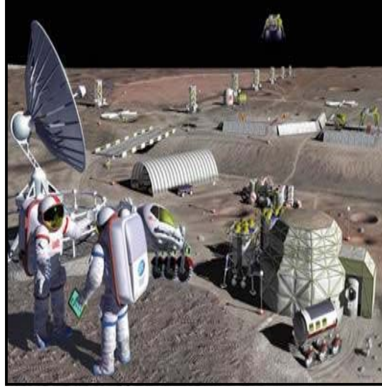
Lunar OutpostOutpost- Long duration Habitat:

Periodic Health Status via Telemedicine WS
Exercise/Fitness station
Improved autonomy for Contingency Response
Environmental Contingency Response

Medical h/w and supplies to outfit the HabiTank:

Telemedicine Workstation
Diagnostic Capability
Portable Imager (U/S)
Advanced Life Support/
Trauma stabilization kit
Medical procedure kit
Dental
Laceration repair
Acute Care pack
Size- Approx. ISS ISO Rack: 0.5-0.75 M2
Volume TBD 0.5-0.75 CTBE
Mass 10-20 kg

Lunar Outpost- Long duration Habitat: Medical

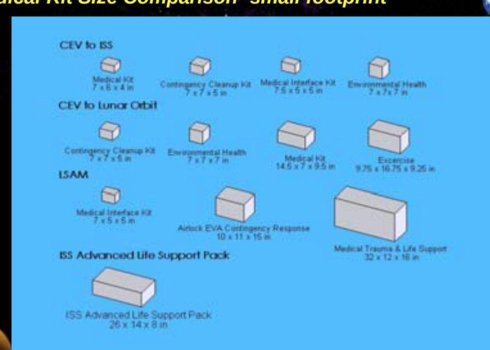


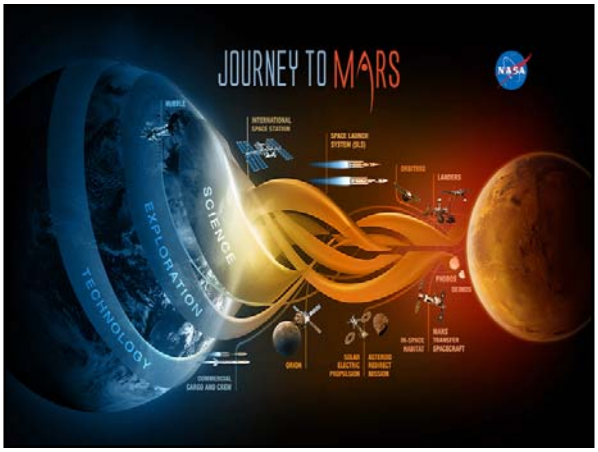
- **Concept: Medical h/w and supplies to launch in rack (must meet launch mass constraints) ALS/Trauma stabilization kit**
- **Portable Imager (U/S)**
- **Telemedicine Workstation**
- **Medical procedure kit**
  - Dental
  - Laceration repair
  - Acute Care pack
- **Once Stabilized, Transport back to Earth**

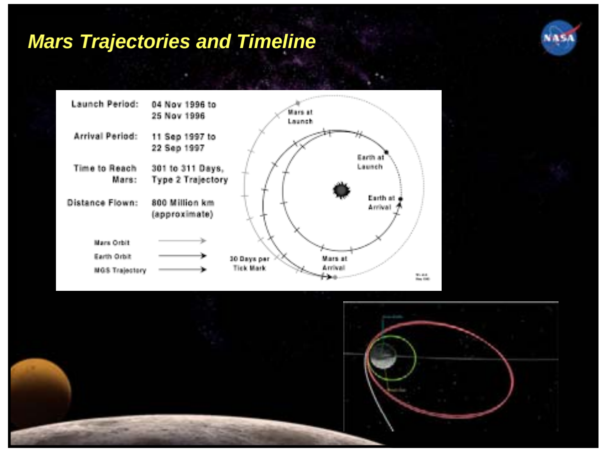
Medical Hardware and Stowage- Lunar Outpost

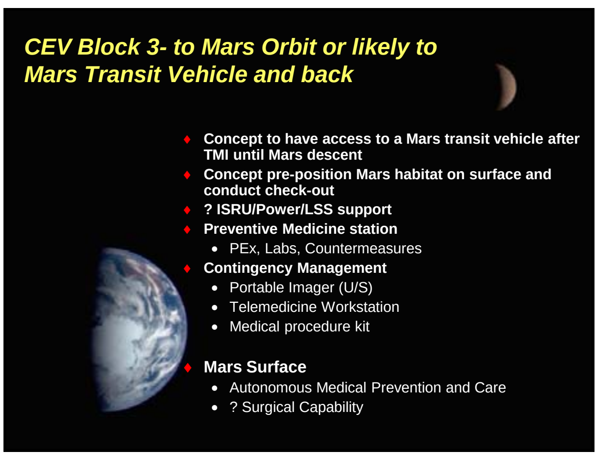
Item		Mass	Volume	Development Concept
MEDICAL System		300 lbs	53 ft³ (similar to ISS ISO rack)	Program Provided
	Telemedicine Workstation	50 lbs		Technology development
	Contaminant Clean-up Kit	10 lbs		COTS
	Portable Imager (Ultrasound)	15 lbs		COTS
	Advanced Life Support/Trauma Stabilization Kit	25 lbs		Modified COTS
	Medical Procedure Kit ---Dental ---Laceration repair ---Acute Care pack	20 lbs		COTS
	Environmental Hardware ---Total Organic Carbon Analyzer ---Volatile Organic Analyzer ---Radiation Detection System ---Compound Specific Analyzer ---Microbiology Analyzer ---Dust Monitor ---Acoustic Monitoring ---Hearing Protection Device	100 lbs		Based on ISS hardware, technology development will be necessary for miniaturization and better reliability.
	Contingency Breathing Apparati (Possibly portable)	20 lbs		Modified COTS
	Other: Biomedical Sensors, Assisted Procedure Device, Medical Grade Water Generation, Closed Loop Oxygen Concentrator/Delivery System			Technology Development
EXERCISE COUNTERMEASURES				
	Aerobic	75 lbs	111 ft³ [8 x 3.3 x 4.2 ft]	Tech. Dev't
	Resistive	125 lbs	200 ft³ [5.7 x 5 x 7 ft]	Tech. Dev't
DUST	Dust management: Suit Lock may reduce dust loading	?	?	Tech Dev't

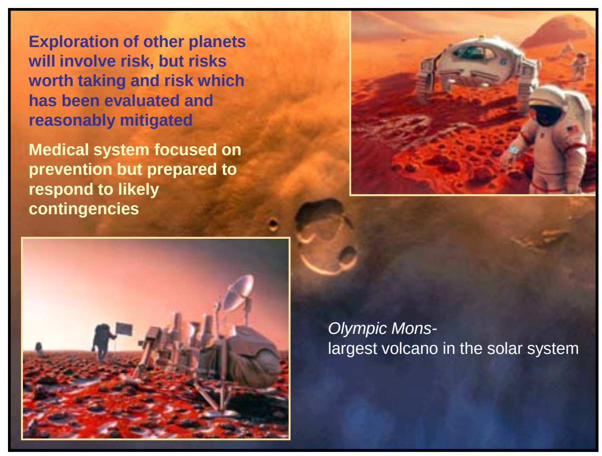
Medical Kit Size Comparison- small footprint

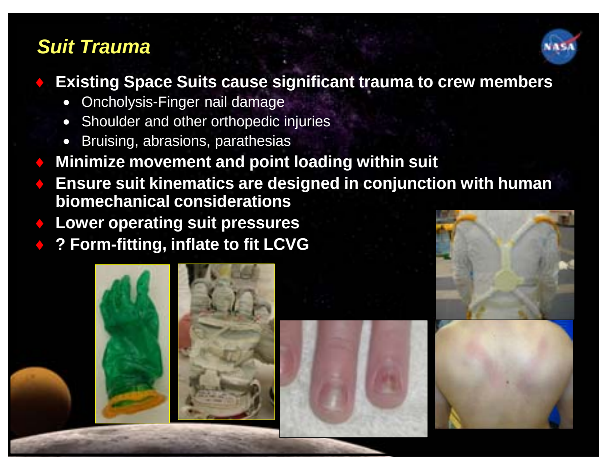



JOURNEY TO MARS
NASA
TECHNOLOGY
EXPLORATION
SCIENCE
HUBBLE
INTERNATIONAL SPACE STATION
SPACE LAUNCH SYSTEM (SLS)
ORBITERS
LANDERS
PHOBOS
DEIMOS
IN-SPACE HABITAT
MARS TRANSFER SPACECRAFT
SOLAR ELECTRIC PROPULSION
ASTEROID REDIRECT MISSION
ORION
COMMERCIAL CARGO AND CREW


Mars Trajectories and Timeline
Launch Period: 04 Nov 1996 to 25 Nov 1996
Arrival Period: 11 Sep 1997 to 22 Sep 1997
Time to Reach Mars: 301 to 311 Days, Type 2 Trajectory
Distance Flown: 800 Million km (approximate)
Mars Orbit
Earth Orbit
MGS Trajectory
30 Days per Tick Mark
Mars at Launch
Earth at Launch
Earth at Arrival
Mars at Arrival

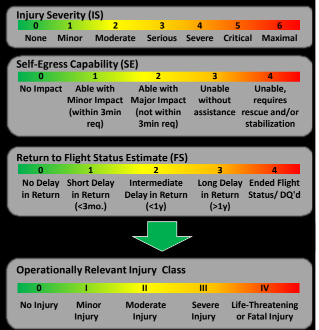

CEV Block 3- to Mars Orbit or likely to Mars Transit Vehicle and back
Concept to have access to a Mars transit vehicle after TMI until Mars descent
Concept pre-position Mars habitat on surface and conduct check-out
? ISRU/Power/LSS support
Preventive Medicine station
PEx, Labs, Countermeasures
Contingency Management
Portable Imager (U/S)
Telemedicine Workstation
Medical procedure kit
Mars Surface
Autonomous Medical Prevention and Care
? Surgical Capability


Exploration of other planets will involve risk, but risks worth taking and risk which has been evaluated and reasonably mitigated
Medical system focused on prevention but prepared to respond to likely contingencies
Olympic Mons-
largest volcano in the solar system


Suit Trauma
Existing Space Suits cause significant trauma to crew members
Oncholysis-Finger nail damage
Shoulder and other orthopedic injuries
Bruising, abrasions, parathesias
Minimize movement and point loading within suit
Ensure suit kinematics are designed in conjunction with human biomechanical considerations
Lower operating suit pressures
? Form-fitting, inflate to fit LCVG

Operationally-Relevant Injury Scale

- **Operationally-Relevant Injury Scale (ORIS) Development**
  - Developed Injury scale that considers not only severity, but also self-egress ability and flight status impact
  - AIS tells us severity with regard to survival, but not SIGNIFICANCE within a certain operational context
  - Uses a weighted algorithm to calculate a composite score indicating the appropriate injury level
  - Example: Clavicle Fracture is a minor injury by AIS standards, but could prevent a crewmember from self-egressing the vehicle immediate after landing



Injury Risk by Program

	Injuries Per Crash				Injuries Per Sortie			
Program	Class I	Class II	Class III	Class IV	Class I	Class II	Class III	Class IV
NASCAR	0.36%	0.58%	0.39%	0.04%	0.02%	0.03%	0.02%	0.00%
IRL	1.58%	2.28%	2.46%	0.35%	0.07%	0.09%	0.10%	0.01%
USAF Rotary Wing		100%		100%		0.087%		0.063%
USAF Fixed Wing	57.0%	5.6%	7.0%	8.5%	0.006%	0.001%	0.001%	0.001%
USN Rotary Wing	59.27%		17.16%	23.57%	0.054%		0.015%	0.021%
USN Fixed Wing	68.4%		12.3%	19.3%	0.09%		0.02%	0.03%
USA Rotary Wing	36%	40%	9%	16%	0.0027%	0.0029%	0.0007%	0.0012%
USA Fixed Wing	48%	35%	14%	3%	0.040%	0.030%	0.012%	0.002%
Passenger Vehicles				0.005%				0.0003%
Shuttle	0%	0%	0%	0%	3.14%	0%	0%	0.0%
Soyuz	15.9%	1.6%	0%	1.6%	4.1%	0.4%	0%	0.4%
Orion	5%	5%	5%	5%	0.5%	0.5%	0.5%	0.5%

- **Using data from other programs, a basis of risk can be established to allow Occupant Protection project to relate Orion risk**
- **The idea here is to help relate probability numbers to real risks that team members have experience with and understand (Shuttle, NASCAR, Rotary Wing, etc.)**

Mars Surface Operations scenarios: courtesy of "The Martian"

"The Martian"- continued

- **So why did they fly McGill ET tube forceps in the Mars surface medical kit??**

Short term- Technology needs

- Oxygen concentrator
- Non-contact Biomedical sensor system which also provides IVA biomedical h/w
- Lightweight, portable exercise device
- Trauma management kit h/w
- Improved MAG for both nominal EVA and contingency use
- PPE: Protective mask- for mucous membranes and respiratory system
- EVA compatible radiation dosimeter and alarm system
- Deployable radiation shielding for SPE

Longer term- Technology Needs

- IV fluid generation
- Health maintenance/ Diagnostic support software
- Non- or minimally invasive diagnostic/lab device
- Environmental atmospheric sensor for toxic contaminants

Long term- Technology Needs

- Autonomous Medical System
- Surgical capability

Space Medical Issues- Future

- **Expected illnesses and problems**
  - Orthopedic and musculoskeletal
  - Infectious, hematological, and immune- related diseases
  - Dermatological
  - Ophthalmologic
  - ENT problems
- **Acute medical emergencies**
  - Wounds, lacerations, and burns
  - Toxic exposure and acute anaphylaxis
  - Acute radiation illness
  - Dental, ophthalmologic, and psychiatric
- **Chronic diseases**
  - Radiation-induced problems
  - Responses to dust exposure
  - Presentation or acute manifestation of nascent illness

Medical Capabilities Envisioned to Support Exploratory Class Space Flight Implications for the Future

- **Small steps needed for diagnostic imaging upgrade/miniaturization**
- **Still need a giant leap for the autonomous medical system to support Lunar Colonies and Mars Exploration**
- **Plenty of work for all that are interested in Medical Technology Development**
- **Medical Suite in Habitat and Rover**
- **Remote/ Automated Diagnostics**
  - Vital Signs
  - Imaging
  - Laboratory
- **Non-Invasive monitors/sensors**
- **Telemedicine**
  - Enhanced TIP for consultation to Earth
  - Telerobotics
  - Computer-based diagnostic and treatment algorithms; virtual consultant

Analog Missions: Motivation

Learn	Advance Planetary Science & Define Exploration Systems Requirements via Experience, Observations, & Experiments on Earth
Test	Evaluate and/or Verify Performance of Specific Candidate Exploration Systems Test Systems of Systems/Components and Select Design Solutions
Train	Develop & Optimize Performance and Interfacing of Humans within Selected Exploration Systems Astronauts and Program Community-flight controllers, project managers require training; Human-Robotic systems interactions
Engage	Sustain Public Interest Support and Enhance Education Develop International Cooperation

Analog Exploration Environments

- **Backyard/Nearby**
  - Rockpile
  - Desert RATS
- **Remote/Extreme Environments**
  - Devon Island, Haughton Crater-HMP
  - NEEMO
  - Antarctica- Coastal and Polar Stations
  - HI-SEAS- Volcanic terrain sim
- **Flight**
  - Zero-g Aircraft
  - ISS

Docs are operational oriented and focused on developing experienced-based confidence in medical support system

Many are ex- or current military and/or have experience in expeditionary support

Endoscopic Surgery in μ-gravity for Planetary Transit Contingency developed on 0-g Aircraft Analog

References:
Jones, J, Johnston, S, Billica, R et al Urology 53(5); 1999, pp892-897

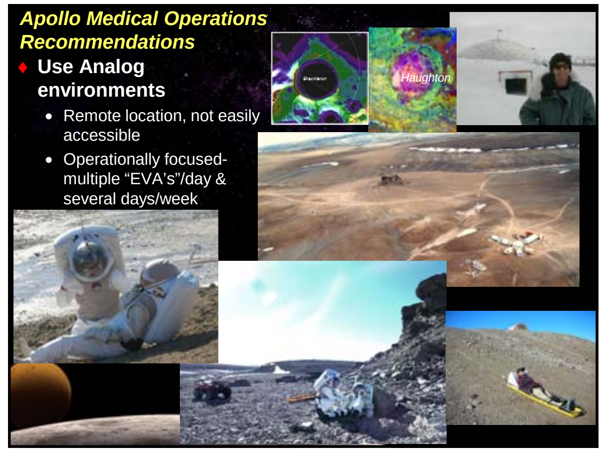
Rafiq, Jones, Broderick et al: Aviation, Space, Environ Med 76(4) April 2005;p.385-91

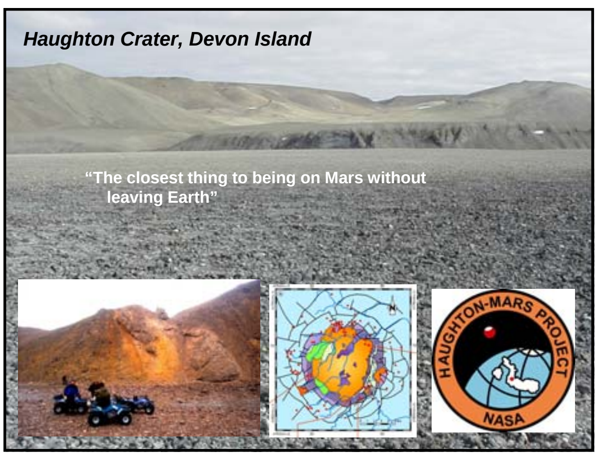
Surg Endosc (2001) 15: 1413–1418
Endoscopic surgery in weightlessnes The investigation of basic principles f surgery in space* M. R. Campbell, A. \ Kirkpatrick…S. A. Dulchavsky

Surgery on the Zero-G Aircraft: Window on the Future and Virtual Reality Skills Maintenance

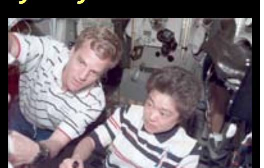
J Trauma Management & Outcomes

Severe traumatic injury during long duration spaceflight: Light years beyond ATLS
Andrew W Kirkpatrick*[1], Chad G Ball[1], Mark Campbell[2], David R Williams[3], Scott E Parazynski[3], Kenneth L Mattox[4] and Timothy J Broderick[5]





2035, a Space Odyssey?



- Whether our Beyond Earth Orbit long range goal is Mars, a NEO or the Moon, Medivac times will be much greater
- Astronaut Caregivers (Astronaut Physicians and b/u CMOs) & Flight Surgeons on console will take on different roles:
- Crew will have greater responsibility because of time latency: need for a broader medical and surgical skill set, and/or accept higher risks?
- More need to "treat in place," rather than returning to Earth
- Mass and volume limited: will be more constrained on med kit
- Longer missions result in lower proficiency: need for "Just In Time Training" and telementoring
- Flight Surgeons: will be crucial advisors to onboard Caregivers, but will be challenged to lead resuscitations or other major interventions due to time delays

AstroDocs of the Future

- What type of undergraduate and graduate medical training will be required in the future?
  - SP: broad training in science and engineering, coupled with a knowledge of aerospace and acute care med-surg is my best guess
- What type of Residency training program will be best suited?
  - SP: personal bias towards EM or general surgery for a hands-on clinical background, with broad exposure to aerospace medicine, anesthesia, IM/FP and industrial/environmental medicine
  - "Space Surgeon" was proposed in 2004: an amalgam of the above, focusing on the unique operational aspects of exploration class missions far from home
    - SP: great concept, but "limited market" --- primary care background with additional, focused Space Surgeon training once selected as an Astronaut or Flight Surgeon more likely than a specialize residency training program
    - Because of their autonomy (e.g. on Mars), they'll need a greater baseline depth of knowledge and technical skill than current program requirements

AstroDoc & CMO Training

- Level of training varies as a f(n) of:
  - Medical background of the individual astronaut
  - Medical capability of the spacecraft (ISS > Shuttle)
  - Ability to Medivac home (easier on Shuttle than ISS/Soyuz)
  - Known and perceived risks: common things occur commonly (!), plus radiation, DCS, dust inhalation, etc.

Inflight Medical Condition	Incidence in US Space Program
Space Motion Sickness	56.0 %
Space Adaptation Back Pain	53.0 %
Musculoskeletal Injuries	8.28 per person-year
Urinary Retention	1.67 %
Skin Rashes	3.29 per person-year
Headache	57.0 %
Eye Injury	2.58 per person-year
Early Insomnia	35.0 %

AstroDoc Training in the Future

- Once selected, how do they keep their proficiency preflight and during lengthy interplanetary missions?
  - Need to recognize that CMO duties will only be a minor role during their expedition: entire crew comprised of Jacks-of-all-trades (machinists, IT expertise, EVA/robotics operators, electricians, bottle washers…)
  - Will have limited time for medical proficiency training once selected, but suggest that a few days a month in appropriate hospital rotations is paramount (like maintaining flying proficiency, these are perishable skills)
  - Telepresence/telementoring technologies are in development testing at NEEMO, in parabolic flight and elsewhere: will be required ("Just In Time Training": refresher module for laparoscopic cholecystectomy?)

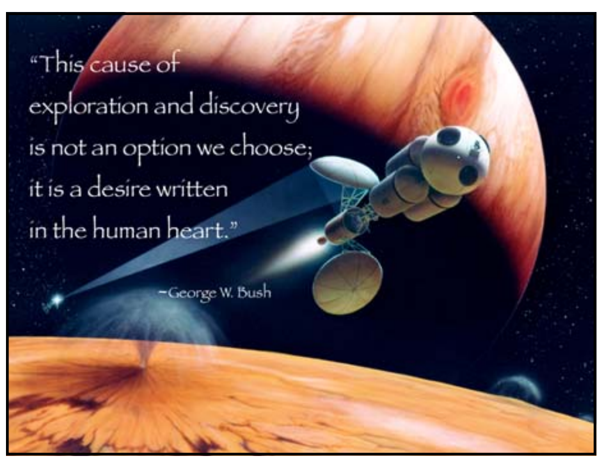
Astronaut Physician Inflight Activities

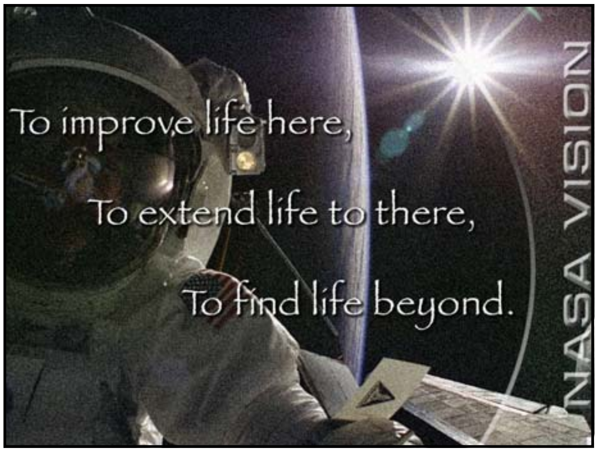
Recent Astronaut Physician Flight Experiences

Scott Parazynski	STS-120	2007
STS-100 (2001), STS-95 (1998), STS-86 (1997), STS-66 (1994)		
Mike Barratt	Soyuz TMA-14, ISS Exp 19, 20	2009
Robert Thirsk	Soyuz TMA-15, ISS Exp 20, 21	2009
Thomas Marshburn	STS-127	2009
David Wolf	STS-127	2009
STS-112 (2002), NASA-Mir 6 (1997-98), STS-58 (1993)		
Robert Satcher	STS-129	2009
Oleg Kotov	Soyuz TMA-16, ISS Exp 22, 23	2009-present
Soyuz TMA-10, ISS Exp 15 (2007)		

Why should humans go to Mars or anywhere outside LEO?

- **To increase knowledge of the universe**
  - To answer the questions:
    - Are we alone? Does life exist elsewhere in the universe?
- **To explore, man by his very nature longs to discover-no more earthy frontiers**
- **Advance science and engineering**
- **Generate new technologies for Earth**
  - 9:1 return on investment in the way of spin-offs
- **Enable the commercialization of space**
  - Limitless, untapped source which is feasible and 'profitable' (except Iridium and a few others)
- **So we don't destroy each other or the planet**
  - Cooperative peaceful endeavor to unite the peoples of the world (US/England has been at war (hot or cold) with 4 of I.P.'s in last century)
  - Scientific Findings- Impacts to Philosophy, Religion
- **There are many reasons to explore Mars and other bodies in our solar system, but the overriding reason is the human need to push the boundaries of our species or risk extinction**
  - Projections for severe energy and resource shortages by 2100




To improve life here,
To extend life to there,
To find life beyond.
NASA VISION


NASA

3.0 Critical Care and Surgery in Extreme Environments

Surgery in Extreme Environments
NEEMO and Parabolic Flight

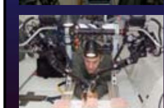
December 9, 2015

Timothy J Broderick, MD, FACS
Chief Science Officer, Wright State Research Institute
Associate Dean Research Affairs, School of Medicine
Professor of Surgery
Wright State University

Surgery in Space

Surgery in Extreme Environments



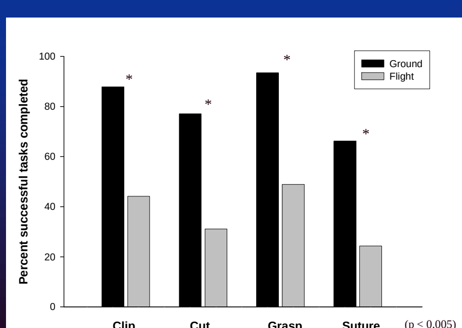


- More extreme -> increased risk and severity of injury
- Emergent as life, limb, and mission threatening
- Environmental and medical "skills" required for successful treatment of illness and injury
- Increased medical capabilities -> dual use technologies
  - Simulation
  - Robotics

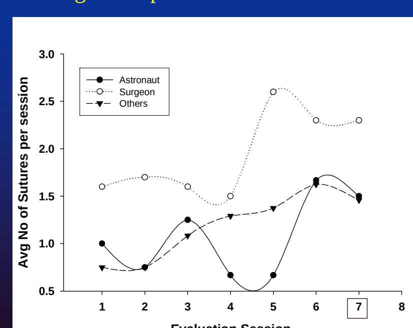
Computer-Based VR Surgical Simulation in Microgravity


- Simulators
  - Virtual Reality (1g & 0g) & Inanimate
- 20 participants
  - 3 astronauts
  - 1 flight surgeon
  - 5 surgeons
  - 6 physicians
  - 1 medical student
  - 4 engineers
- Protocol
  - 4 tasks (clip, cut, grasp, suture)
  - Training: 2.5 hours over 5 days
  - Evaluations sessions:
    - 25sec: 4 tasks on 2 simulators
    - 6 pre – 1 flight – 1 post

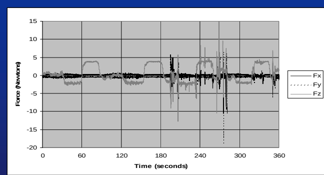
Surgical Performance Degradation in Microgravity

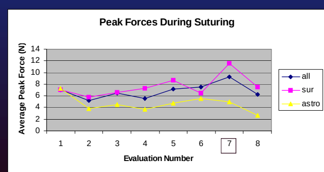


Surgical Experience and Performance

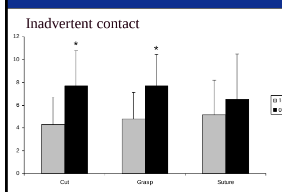


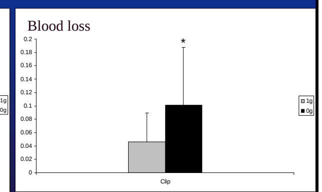
Microgravity Experience and Force Application





Virtual Tissue Damage and Bleeding





Surgery In Space

- Similar to flight, surgical simulation enables:
  - Effective training
  - Safe development of surgical capabilities for spaceflight
- Microgravity minimally invasive surgery is feasible, but:
  - Performance associated with more force, more time, more errors
  - If surgical capability is required, select and/or train surgeons
- Development of exploration medical systems and technologies require persistent focus and funding

NASA and DoD Robotic Surgery

Computer Motion Zeus

UNL *In Vivo*

SRI International M7

UW Raven

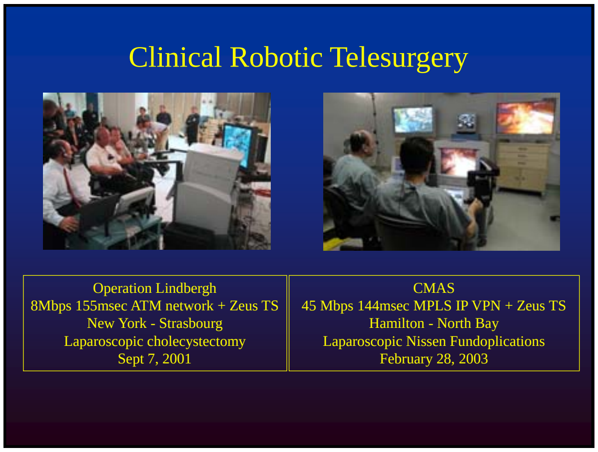
Intuitive daVinci

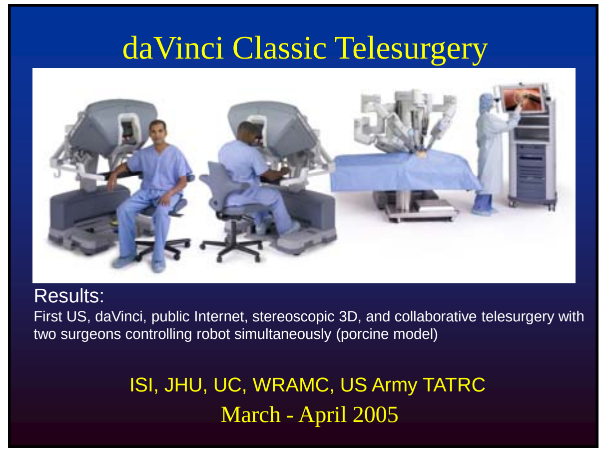
Definitions

- Telerobotic surgery: remotely performed surgery through combined use of telecommunications and a surgical "robot" (telemanipulator)
- Robot: a powered, computer-controlled manipulator with artificial sensing that can be programmed to move and position tools to carry out a wide range of tasks
- Automation: machines performing defined tasks traditionally performed by humans - predetermined responses within predictable environments and static missions
- Autonomy: capability and freedom to self-direct and achieve objectives in complex environments and dynamic missions
- Human Machine Teaming (HMT): Human and machines understanding mission context, sharing understanding and situation awareness, and adapting to the needs & capabilities of each other.

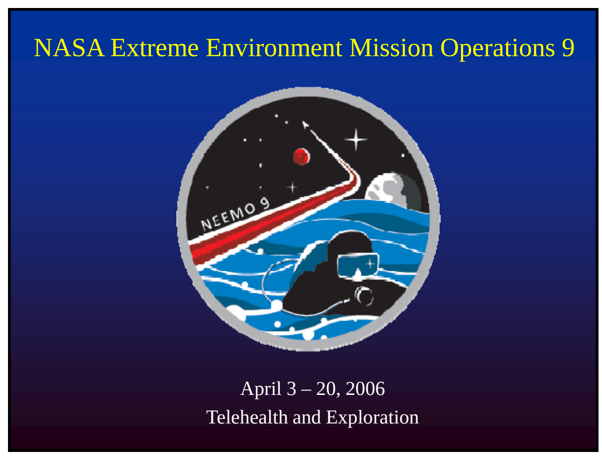
Projected Advances in Surgical Robotics

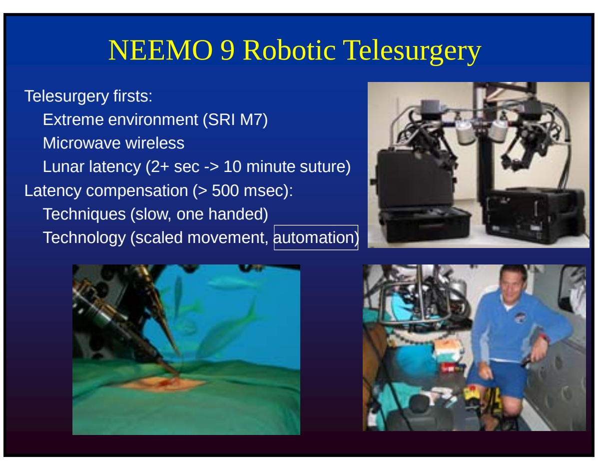
- Big data analytics augment training, operation, outcomes
- Distributed telesurgery – latency limits space application
- HMT: anthropomorphic -> supervised sliding autonomy
- Multi-modal sensing / directed energy therapy
- Enabling technologies increasingly used across applications such as surgery and astrobiology research


Clinical Robotic Telesurgery
Operation Lindbergh
8Mbps 155msec ATM network + Zeus TS
New York - Strasbourg
Laparoscopic cholecystectomy
Sept 7, 2001
CMAS
45 Mbps 144msec MPLS IP VPN + Zeus TS
Hamilton - North Bay
Laparoscopic Nissen Fundoplications
February 28, 2003


daVinci Classic Telesurgery
Results:
First US, daVinci, public Internet, stereoscopic 3D, and collaborative telesurgery with two surgeons controlling robot simultaneously (porcine model)
ISI, JHU, UC, WRAMC, US Army TATRC
March - April 2005


NASA Extreme Environment Mission Operations
NEEMO PROJECT
NASA UNDERSEA RESEARCH TEAM


NASA Extreme Environment Mission Operations 9
NEEMO 9
April 3 – 20, 2006
Telehealth and Exploration


NEEMO 9 Robotic Telesurgery
Telesurgery firsts:
Extreme environment (SRI M7)
Microwave wireless
Lunar latency (2+ sec -> 10 minute suture)
Latency compensation (> 500 msec):
Techniques (slow, one handed)
Technology (scaled movement, automation)


NASA Extreme Environment Mission Operations 12
Expanding the Frontiers of Medicine
NEEMO XII
May 7 – 18, 2007
Telehealth and Exploration

NEEMO 12 Robotic Telesurgery Summary

UW Raven:
- Time delay compensation
- Robotic SAGES FLS

SRI M7:
- Telesurgical US guided access vessel
- Autonomous US guided access vessel

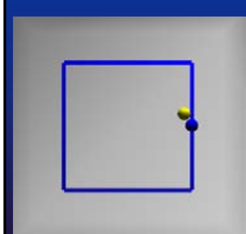
NEEMO 12 Semi-Autonomous Robotic Telesurgery

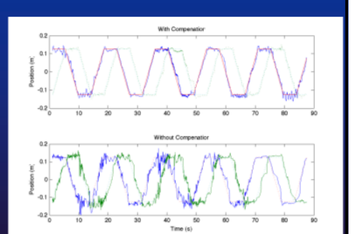
Robotic Surgery in Flight

- Robotic surgery in parabolic flight
  - DoD: CCAT
  - NASA: Spaceflight
- Upgraded SRI M7
  - Master
    - HMD stereo or HD video monitor
    - Force Dimension haptic controllers
  - 3-axis acceleration compensation
    - Variable (eg, turbulence) -> dampening
    - Constant (eg, Mars) -> neutralizing force
- Inanimate incision and suturing

September 2007

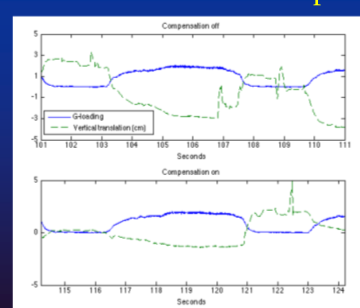
Variable Acceleration Dampening





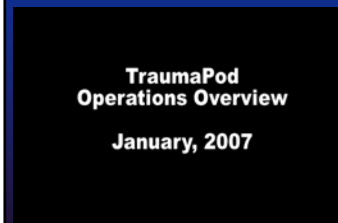
“Good surgery despite really bad driving”

Constant Acceleration Compensation



Improved Robot Use during Flight and Planetary Surface

DARPA Trauma Pod
Telesurgical, semi-autonomous casualty care



- Military trauma
  - On battlefield / during transport
- Damage control surgery
  - ATLS (Airway, CT, IV/IO)
  - Hemorrhage control
- Surgical specialty
  - Neurologic (TBI, SCI)
  - Orthopedic
  - Opthalmologic

January 2007

Game Changers

Technology to make and keep the fight unfair - Game Changers

DISTRIBUTION A: Approved for public release; distribution unlimited (88ABW-2014-5267)

4

Google Moves to the Operating Room in Robotics Deal With J&J

Wall Street Journal
March 27, 2015

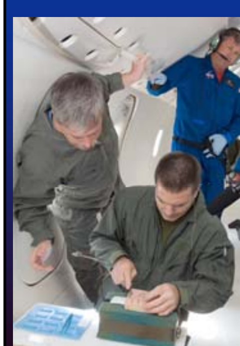
The surgical robotics effort aims to integrate Google's expertise in computer science, advanced imaging and sensors into tools that surgeons use to operate.

The partnership is with Ethicon, a part of J&J that focuses on surgical devices and technology.

Real-time image analysis could help surgeons see better and software could highlight blood vessels, nerves or the edges of tumors that are difficult to see with the naked eye, Google said.

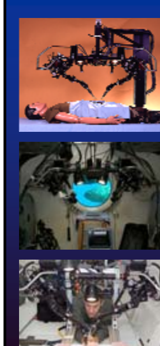
The focus is on so-called minimally-invasive surgery, which uses tools and other technology to reduce scarring, blood loss, pain and speed recovery times.

Simulated Microgravity and Lunar Surgery



- Robotic & manual inanimate suturing
- Robotic suturing - feasible
  - 3-axis acceleration compensation valuable
    - Variable (eg, turbulence) -> dampening
    - Constant (eg, Mars) -> neutralizing force
- Manual suturing – operationally relevant
  - Suture accuracy and wound coaptation
    - Earth (1g) = space (0g) = lunar (0.16 g)
  - Speed
    - Earth (1g) > lunar (0.16g) = space (0g)

Surgery in Extreme Environments



- More extreme -> increased risk and severity of injury
- Emergent as life, limb, and mission threatening
- Environmental and medical "skills" required for successful treatment of illness and injury
- Increased medical capabilities -> dual use technologies
  - Simulation
  - Robotics

Surgery in Space

- Surgical research in analog environments laid the foundation
- Small animal experiments during spaceflight validated feasibility
- Further ground and flight-based research are necessary to develop surgical care for space exploration

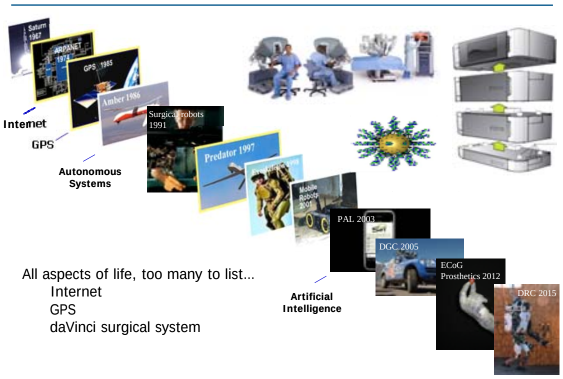
timothy.broderick@wright.edu

Microgravity Improves Visualization during Insufflation

Kirkpatrick CSA Falcon February 2007

Fluid Behavior in Microgravity

Snapshots of familiar DARPA technology



All aspects of life, too many to list…
- Internet
- GPS
- daVinci surgical system

35

Lumbar Puncture in Space: a primary aim of "Zero G and ICP: Invasive and Noninvasive ICP Monitoring of Astronauts on the ISS"

Presented by Eric Bershad, MD, Assistant Professor of Neurolog and Space Medicine, Baylor College of Medicine

M. A. Williams[1], E. M. Bershad[2], B. D. Levine[3], J. Clark[2], D. R. Hamilton[4], J. Malm[5], A. Eklund[6]

[1]University of Washington School of Medicine, Departments of Neurology and Neurological Surgery, Seattle, WA
[2]Baylor College of Medicine, Department of Neurology, Houston, TX
[3]Institute for Exercise and Environmental Medicine, U.T. Southwestern Medical Center, Dallas, TX
[4]University of Calgary Research and Innovation Centre, Calgary, AB, Canada
[5]Dept. of Clinical Neuroscience, Umeå University, Umeå, Sweden, [6]Dept. of Radiation Sciences, Umeå University, Umeå, Sweden

Objectives

- This research will result in the first-ever invasive measurements of intracranial pressure (ICP) in astronauts before, during, and after an ISS mission, providing direct physiologic evidence to demonstrate if VIIP is associated with alterations of ICP in long-duration spaceflight.

2

Specific Aims

- To determine whether ICP in space is elevated in comparison to baseline ICP on Earth, and to determine whether ICP after return to Earth differs from baseline values by directly measuring ICP in astronauts before, during, and after an ISS mission using NASA-approved invasive methods.
- To validate noninvasive ICP measurement methods and their correlation with invasive ICP methods before, during, and after spaceflight, and to quantify their error of measurement.
- To determine the correlation of ICP changes to other indicators of VIIP by collecting biomarkers of VIIP for correlation to ICP and hydrodynamic variables.

3

Our Team

- Michael Williams, MD – Expert in CSF circulation disorders, neurointensivist and bioethicist, Principal Investigator.
- Eric Bershad, MD – Neurointensivist and vascular neurologist, NASA/NSBRI-funded researcher, Co-I/Site-PI for Baylor
- Benjamin Levine, MD, PhD – Co-I, *Cardiologist* with >20 years of NASA and NSBRI funded research, expert in cardiovascular physiology
- Jonathan Clark, MD, MPH – Co-I, Neurologist, former NASA flight surgeon
- Douglas R. Hamilton, MD, PhD – Co-I, Internist, engineer, former NASA flight surgeon
- Jan Malm, MD, PhD – Neurologist with >20 years expertise in CSF disorders, PI on Swedish National Space Board companion study
- Anders Eklund, PhD – Co-I, Biomedical engineer with >20 years expertise in CSF disorders, and instrumentation and control systems for CSF infusion

4

Rationale for Invasive ICP in Space

- Noninvasive methods are not yet considered reliable to replace invasive ICP measurement.
- The selection of the invasive ICP method reflects a balance of potential risks and benefits.
- We recommend invasive ICP monitoring because it is the best and most accurate way to determine whether abnormal ICP is present in VIIP syndrome.

5

Flight Experiment Implementation Steps

1. Selection of ICP monitoring paradigm
2. Selection of invasive and noninvasive ICP methods
3. Measurement time points
4. Standardization of methods
5. Training of astronauts in ICP methods
6. Contingency planning for adverse outcomes on the ISS
7. Analysis and interpretation of data

6

Selection of ICP Monitoring Paradigms

- **Short-term ICP Monitoring**
  - Lumbar puncture with fluid-coupled transducer
  - 30 minutes is the minimum recommended
- **Long-term ICP Monitoring**
  - Needed because ICP elevation is not always seen in wakefulness.
  - If short-term ICP monitoring were to demonstrate no change from baseline, then long-term ICP monitoring (~3 hours) would be needed

7

Selection of Invasive and Noninvasive ICP Methods

- **Invasive ICP Methods**
- Techniques based on LP vs intracranial ICP methods
- Risk / Benefit analysis unequivocally favors LP
  - No surgery. No implant. Virtually zero risk of infection. Tiny risk of bleeding. No risk of seizures.
  - Procedure can be immediately stopped in case of emergency

8

Selection of Study Time Points

Proposed Study Time Points

PRE-FLIGHT		IN-FLIGHT		POST-FLIGHT	
L-270 to L-180	**L-45**	**FD 30**	**FD 170 to FD 180**	**R+14**	**R+90**
LP Noninvasive ICP Specimen Collection	Noninvasive ICP	LP Noninvasive ICP Specimen Collection	LP Noninvasive ICP Specimen Collection	LP Noninvasive ICP Specimen Collection	Noninvasive ICP

9

LP Procedure on the ISS

- 2-3 Astronauts to perform the LP
  - 2 Sterile: One to insert the needle and one to assist
  - 1 for situational awareness and oversight (could be done remotely)
- Method to secure the astronaut having the LP and the astronaut inserting the needle
- Transparent tent-like glovebox to maintain sterile environment and prevent equipment or CSF from floating away

A massage chair is used to stabilize a patient for spinal catheter insertion. This method can be adapted to secure an astronaut on the ISS.

10

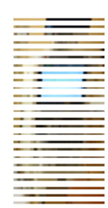
Short-term and Long-term ICP Monitoring

- On the ISS awake or asleep, the most likely position would be with arms out, legs slightly bent, and back slightly bent forward
- On Earth, an equivalent position would be supine with a wedge under the knees and a pillow beneath the head.
- A special fenestrated bed is available for this purpose on Earth, and has been used in Umeå for ICP research

11

Physiologic Monitoring

- 3-way stopcock attached to LP needle
  - Connected via tubing to pressure transducer
- Digital data collection system similar to ICU monitor
  - ICP
  - EKG
  - SaO2, Nasal ETCO2, respiratory trace
  - Noninvasive BP.



12

Training of Astronauts

- Ground-based education
  - Didactic review and hands-on training
  - Curriculum will be developed
  - Training with simulation mannequins on Earth <u>and</u> in parabolic flight

13

Other Spaceflight Considerations

- Different anatomy due to microgravity
- Sterile field
- Maintaining stability of operators, subject, and equipment
- CSF fluid collection
- Ultrasound guidance? Remote monitoring

14

Contingency Planning for Adverse Outcomes

- Known potential complications of LP on Earth
  - Epidural CSF leak with postural headache (common)
  - External CSF leakage (extremely rare)
  - Back pain (common), temporary
  - Vasovagal response (uncommon), temporary
  - Parasthesias (uncommon), temporary
  - Epidural bleeding (extremely rare)
  - Meningitis (extremely rare)

15

Contingency Planning for Adverse Outcomes - Solutions

- Stopping Criteria
  - Develop with input from astronauts, flight surgeons, and investigators
  - Inability to encounter CSF
  - Pain or discomfort
  - Adverse physiologic response (e.g., vasovagal)
  - Equipment malfunction

16

Summary

- Invasive ICP measurement is needed to determine whether the VIIP related changes are related to ICP.
- Non-invasive ICP may be useful for screening, but not to give an accurate ICP at this point.
- Lumbar puncture (lumbar CSF pressure) is probably the best choice for invasive ICP measurement during space-flight given a more favorable risk:benefit ratio compared to other invasive methods
- Technical challenges although numerous, can be addressed by proper planning including simulations, analog environments, and multidisciplinary input.

17

4.0 Surgery in Reduced Gravity

Initial Parabolic Flight Research in Spaceflight Surgical Issues

National Space Biomedical Research Institute

Surgical Capabilities for Exploration and Colonization Space Flight

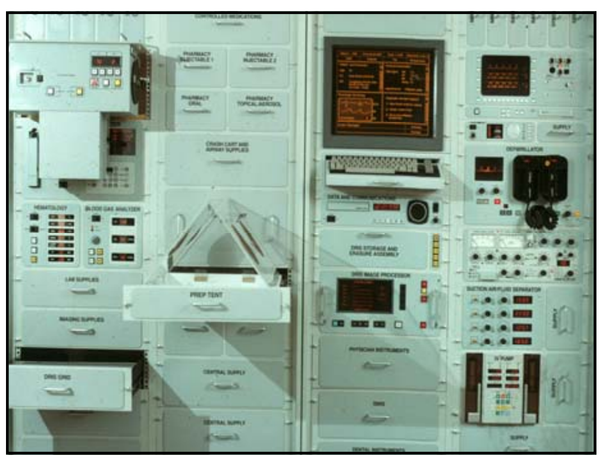
December 9-10, 2015

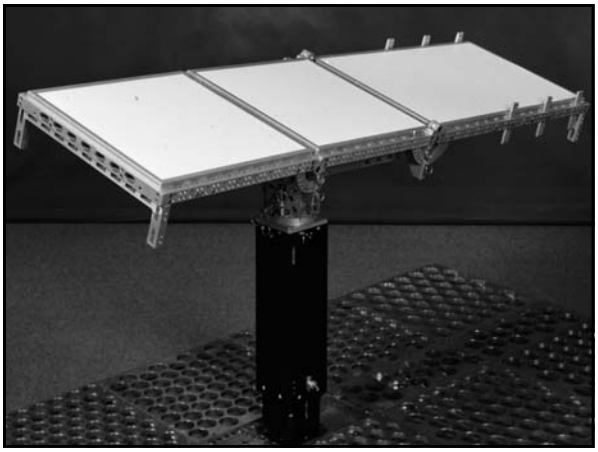
Space Station Freedom Health Maintenance Facility

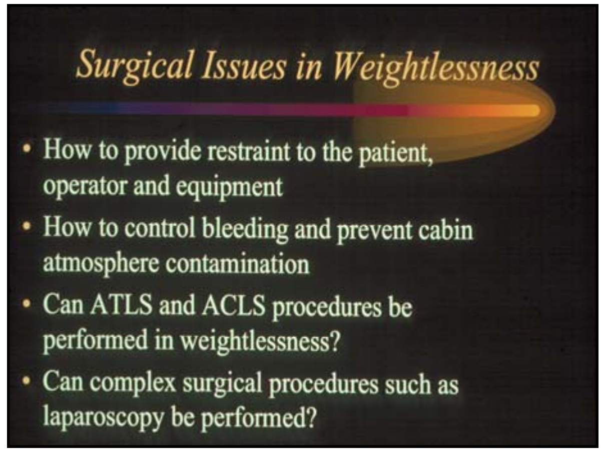
- Space Station Freedom - 1984-1993
  - No ACRV
  - Definitive medical care time of 45 days
  - CMO probably be an MD (some advocating a surgeon)
- Health Maintenance Facility – 1200 lbs, 2400 sq ft
  - Surgical workstation (waist level OR table)
  - Digital X-Rays (DRIS)
  - Task lighting
  - Surgical cautery
  - Ventilator, Defibrillator, IV pump
  - Waste Management System, including surgical suction
  - Medical computer
  - Telemedicine
  - Anesthesia (general)

Space Station Freedom Health Maintenance Facility

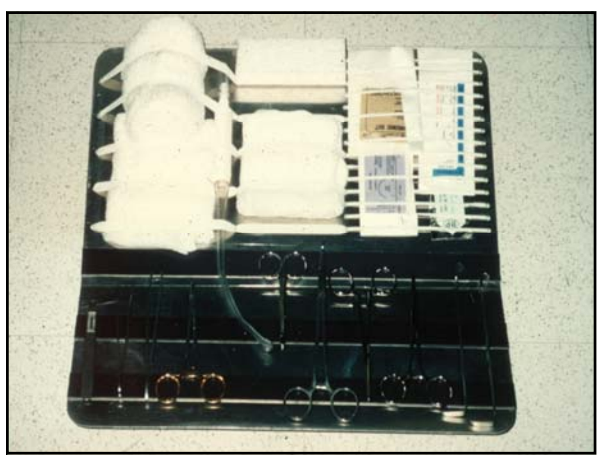
Procedures
- Complex wound closures
- Chest tube insertion
- Tendon repair
- Appendectomy
- Amputation
- Ortho – splints or ext fixation
- Open abdomen, thoracic, vascular, ortho?
- Burr holes for head trauma?

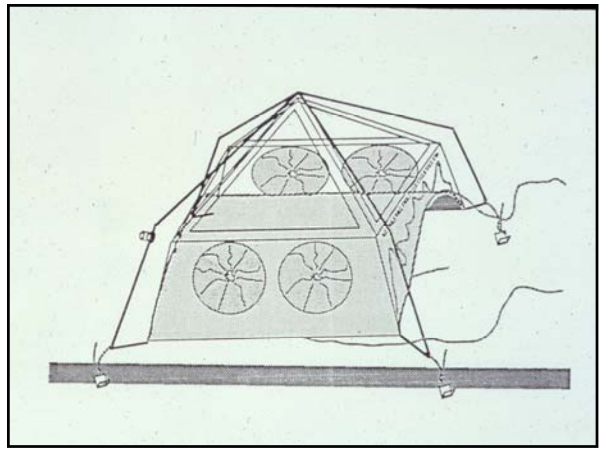


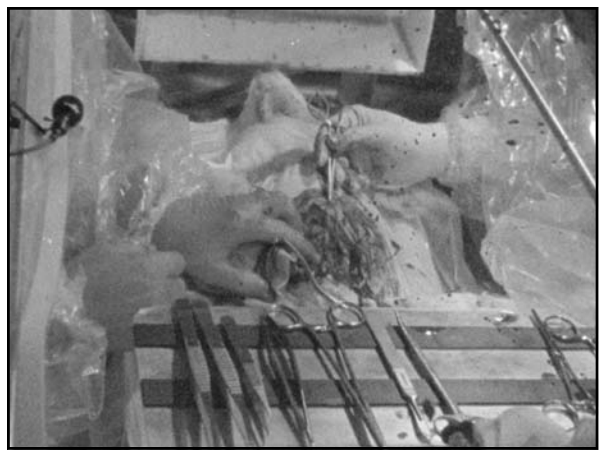


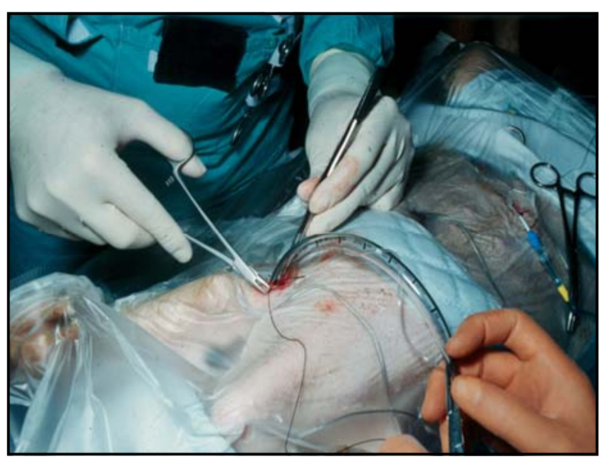

Surgical Issues in Weightlessness
• How to provide restraint to the patient, operator and equipment
• How to control bleeding and prevent cabin atmosphere contamination
• Can ATLS and ACLS procedures be performed in weightlessness?
• Can complex surgical procedures such as laparoscopy be performed?

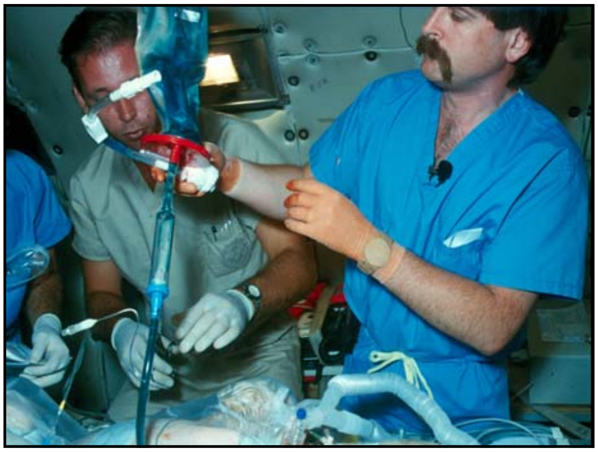

NASA

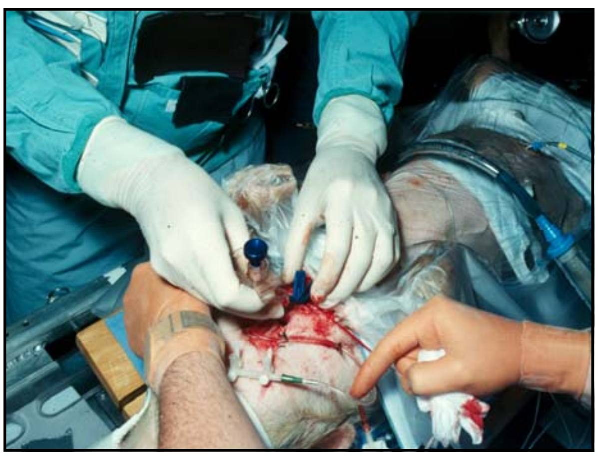


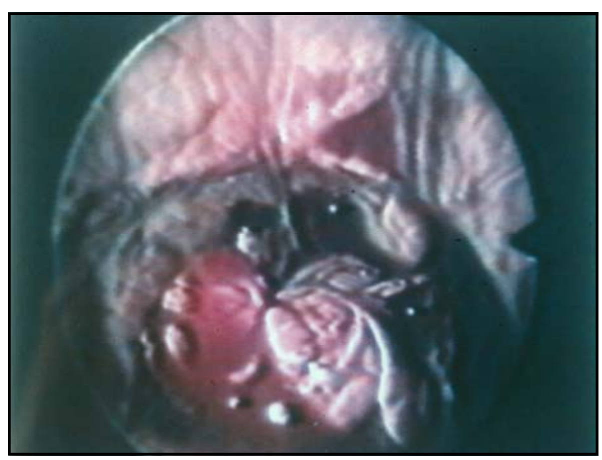












Parabolic Flight Conclusions

- Restraint can be accomplished by simple methods for patient and CMO
- Instrument restraint is important and needs to be planned for in the system
- Bleeding can be controlled
- ATLS procedures can be performed
- Complex surgical procedures can be performed. Not more difficult, but require increased time to perform.
- Fluids behave differently than in 1g.

Surgery in Reduced Gravity

Initial Efforts in Low Earth Orbit

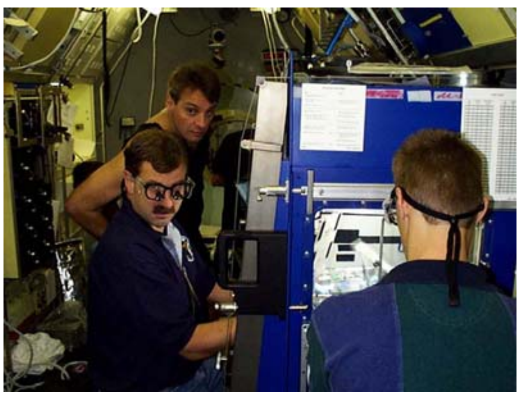
Jay C. Buckey, M.D.
Geisel School of Medicine at Dartmouth
STS-90, Neurolab

Spacelab program (SLS-1, SLS-2, Neurolab missions)

- Dedicated life sciences missions
- Various human and animal experiments
- Experiments with medical restraint tables, IV pumps, etc.
- Intensive animal dissection and surgical procedures

Surgical/Procedures in Space

- Tail vein cannulation
- Timed dissection of temporal bone
- Timed laminectomy
- Various dissection procedures
- Perfusion fixation
- Survival surgery (anesthesia, visualization of soleus in neonatal rat, injection with tracer, wound closure, recovery)



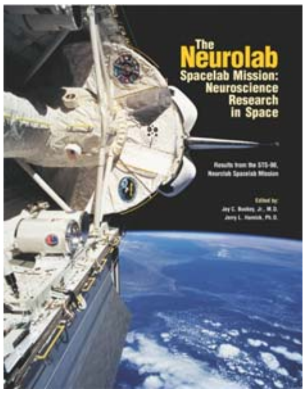
Questionnaire responses from three of the four payload crewmembers on Neurolab about their experiences with surgical techniques in space. Crewmembers were asked to respond to statements on a five-point scale from 1 (strongly agree) to 5 (strongly disagree):

•Overall, dexterity was not changed in spaceflight compared to my terrestrial experience (Dexterity question)

•My fine motor control was not changed in spaceflight compared to my terrestrial experience (Fine motor question)

•It was no more difficult to control instruments in spaceflight compared to my terrestrial experience (Instrument question).

Question	*Early inflight*	*Late inflight*
Dexterity	2.7	1.6
Fine motor	2.7	1.3
Instrument	3.0	3.6



Summary

- Surgical techniques successfully demonstrated in rats during space flight include general anesthesia, wound closure, wound healing, hemostasis, control of surgical fluids, operator restraint, and control of surgical instruments.
- Delicate surgical procedures performed successfully--first survival surgery.
- ACLS protocols and procedures worked out.

The University of Calgary Surgery in Space Research Program

Major AW Kirkpatrick CD MD MHSC FACS FRCSC
Professor of Surgery and Critical Care Medicine, Calgary, Alberta
Canadian Forces Medical Services

Disclosures

- I serve as a Reservist in the Canadian Forces Medical Services
- I consult for
  - Innovative Trauma Care
  - Acelity Corporation
- I have received travel compensation from all the above and
  - Cook Medical Corporation

Foothills Medical Centre

- Calgary, Alberta, Canada
- One of Canada's Largest Single Site Hospitals
- Busiest Trauma Service in Canada

Great Colleagues

- Doug Hamilton
- Chad Ball
- Paul McBeth
- Many others

Great Networks

- Canadian Forces
- Academia
- Canadian Space Agency
- NASA
- National Research Council of Canada
  - FRL
- Royal College of Physicians and Surgeons on Canada
- Industry
  - Strategic Operations
  - Innovative Trauma Care

The University of Calgary "Program"

Terrestrial spin-off studies in clinical and especially telementored resuscitative ultrasound 1999 - present

Review Papers, 97- present

Ultrasound studies In weightlessness (NASA $) 99-00

Canadian Space Agency sponsored studies into the physiology and techniques of MIS surgery in Weightlessness – (CSA $), 2006-2007

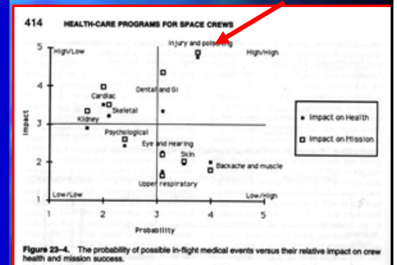
Telementored ultrasound studies onboard the ISS – (NASA $), 2001 - present

Canadian Forces sponsored studies in Damage Control Surgery in weightlessness - (CF-NRC $), 2015-present

Reviews of Surgery in Space

Risks of Trauma in Space

- Traumatic injury has been ranked at the highest level in terms of the "probable incidence versus impact on mission and health"



Billica , Space Physiology and Medicine, Williams and Wilkins, 1994

Requirement for Laparotomy

- 1983 Council of trauma surgeons, space physicians, biomedical engineers identified the ability to perform laparotomy as the minimum desirable surgical capability
- Thus Space Station Freedom mandated surgical capabilities of a level III hospital

Houtchens NASA Grant NASW-3744 1983

The medical penalty of geography

- Canadians living in isolated areas of Canada are grossly under-serviced
- Rural trauma victims have a greater than 50% increased risk of dying in a motor-vehicle crash than urban patients[1,2,4]
- If survive worse functional outcomes (OR = 1.5 worse)[3]

Thousands of kilometers Many hours or days away

[1]Mueller J Trauma 1988
[2]Grossman J Trauma 1997
[3]Sihler, J Trauma 2009
[4]Mitchell, Rural Remote Health 2010

Excluded from ready access to trauma centre

- Overall, 20% of the Canadian population, including 100% of the residents of the 3 territories, lives beyond 1 "Golden" hour by road from definitive trauma care

Hameed M et al., Access to trauma systems in Canada, *J Trauma.* 2010;69: 1350–1361

Space Medicine Spinoffs

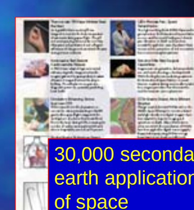
Telemetry

pacemakers

Surgical Robotics

Smoke-detectors

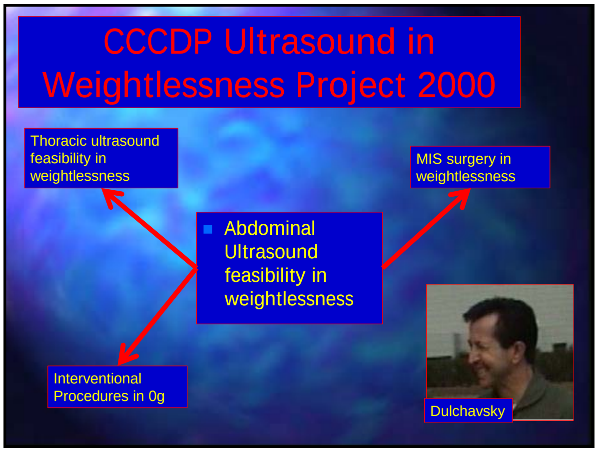
Flow-cytometers



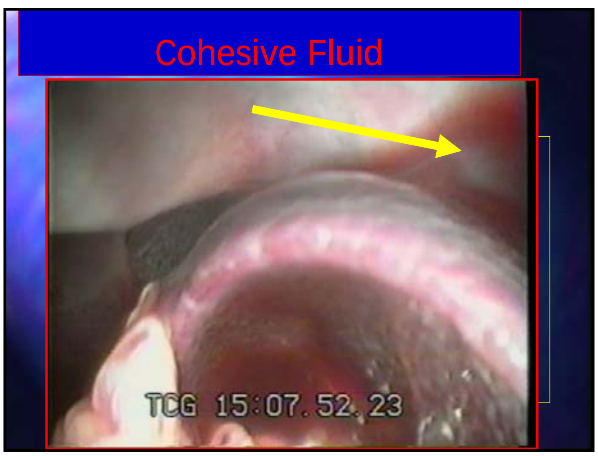
30,000 secondary earth applications of space technology

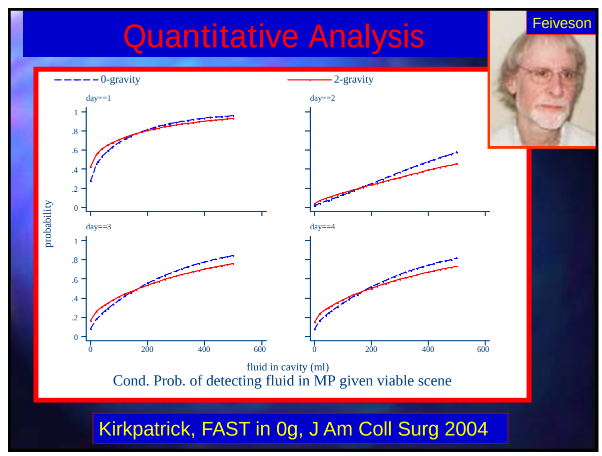
http://www.nasa.gov/pdf/363454main_medical_flyer.pdf

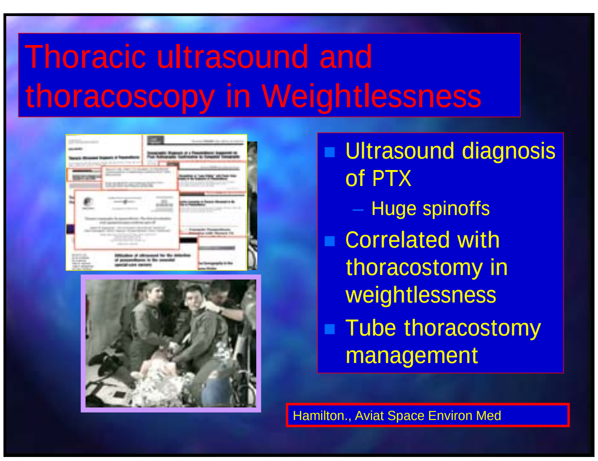
Thirsk et al., Spinoffs from space. CMAJ 2009;180:1324-1325

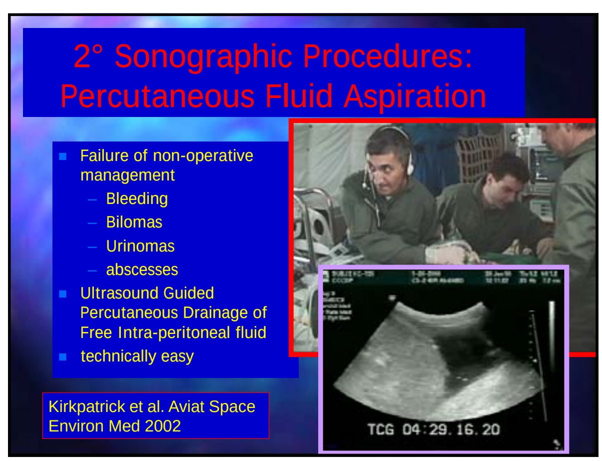

CCCDP Ultrasound in Weightlessness Project 2000
Thoracic ultrasound feasibility in weightlessness
MIS surgery in weightlessness
Abdominal Ultrasound feasibility in weightlessness
Interventional Procedures in 0g
Dulchavsky

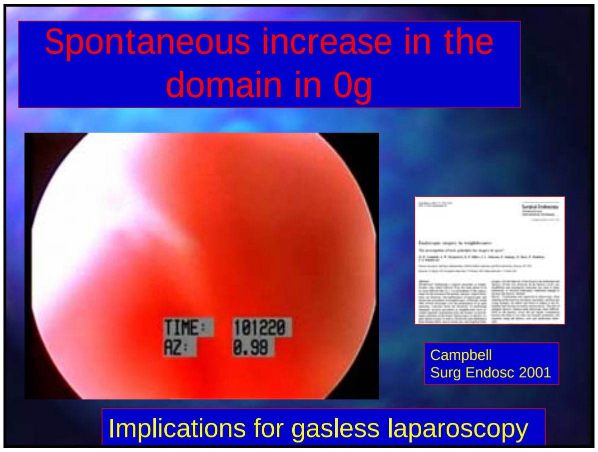

Abdominal ultrasound remains a feasible modality in weightlessness
Focused Assessment with Sonography for Trauma in Weightlessness: A Feasibility Study
J Am Coll Surg 2003

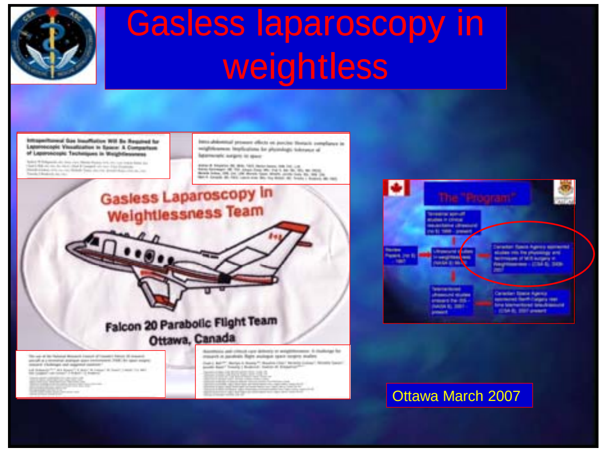

Cohesive Fluid
TCG 15:07.52.23


Quantitative Analysis
Feiveson
0-gravity
2-gravity
day==1
day==2
day==3
day==4
probability
fluid in cavity (ml)
Cond. Prob. of detecting fluid in MP given viable scene
Kirkpatrick, FAST in 0g, J Am Coll Surg 2004

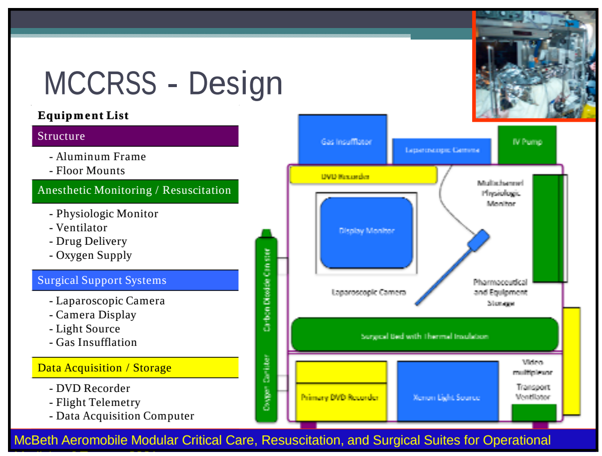

Thoracic ultrasound and thoracoscopy in Weightlessness
Ultrasound diagnosis of PTX
– Huge spinoffs
Correlated with thoracostomy in weightlessness
Tube thoracostomy management
Hamilton., Aviat Space Environ Med


2° Sonographic Procedures: Percutaneous Fluid Aspiration
Failure of non-operative management
– Bleeding
– Bilomas
– Urinomas
– abscesses
Ultrasound Guided Percutaneous Drainage of Free Intra-peritoneal fluid
technically easy
Kirkpatrick et al. Aviat Space Environ Med 2002
TCG 04:29.16.20

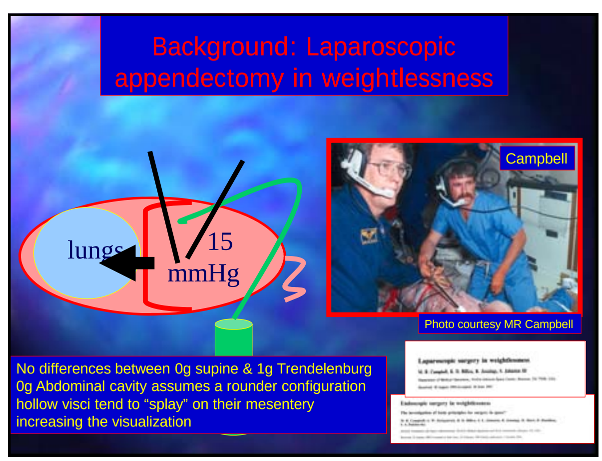

Spontaneous increase in the domain in 0g
TIME: 101220
AZ: 0.98
Campbell
Surg Endosc 2001
Implications for gasless laparoscopy


Gasless laparoscopy in weightless
Gasless Laparoscopy in Weightlessness Team
Falcon 20 Parabolic Flight Team
Ottawa, Canada
The "Program"
Ottawa March 2007

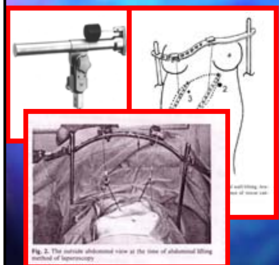

National Research Council of Canada's
Flight Research Laboratory
FLIGHT RESEARCH
NRC-CNRC
RECHERCHES EN VOL
Flight Research Laboratory, Uplands Airport, Ottawa


MCCRSS - Design
Equipment List
Structure
- Aluminum Frame
- Floor Mounts
Anesthetic Monitoring / Resuscitation
- Physiologic Monitor
- Ventilator
- Drug Delivery
- Oxygen Supply
Surgical Support Systems
- Laparoscopic Camera
- Camera Display
- Light Source
- Gas Insufflation
Data Acquisition / Storage
- DVD Recorder
- Flight Telemetry
- Data Acquisition Computer
McBeth Aeromobile Modular Critical Care, Resuscitation, and Surgical Suites for Operational


Anesthesia and critical care in weightlessness
Prolonged general anesthetics (mean 10.28 hrs/day)
Multiple transport and gravitational environments
Septic shock
Cardiac arrest
Hypothermic stresses
Planetary and Space Science
Anesthesia and critical care delivery in weightlessness: A challenge for research in parabolic flight analogue space surgery studies
Ball, Keaney, Chun et al.,
Planetary Space Sci 2010


Background: Laparoscopic appendectomy in weightlessness
lungs
15
mmHg
Campbell
Photo courtesy MR Campbell
No differences between 0g supine & 1g Trendelenburg
0g Abdominal cavity assumes a rounder configuration
hollow visci tend to "splay" on their mesentery
increasing the visualization
Laparoscopic surgery in weightlessness
Endoscopic surgery in weightlessness

Abdominal wall lift Laparoscopy

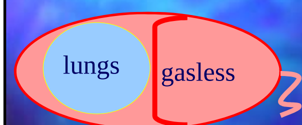


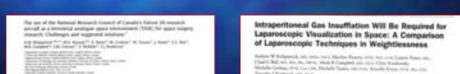
Holthausen, World J Surg 1999
Kirkpatrick ANZ J Surg 2005

- CO_2 pneumoperitoneum requires increased abdominal pressure
- potential adverse consequences
  - visceral perfusion
  - abdominal compartment syndrome
  - intra-cranial pressure
- in space
  - aerosol production
  - gaseous release

Mark Campbell and Tim Broderick

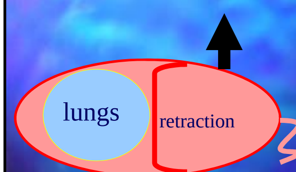
Gasless (Baseline)

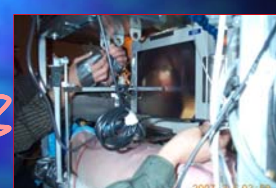



Intraperitoneal Gas Insufflation Will Be Required for Laparoscopic Visualization in Space: A Comparison of Laparoscopic Techniques in Weightlessness

Planet Space Sci 2010 | J Am Coll Surg 2009

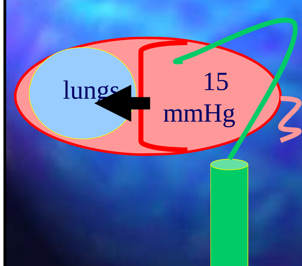
Abdominal Wall Retraction





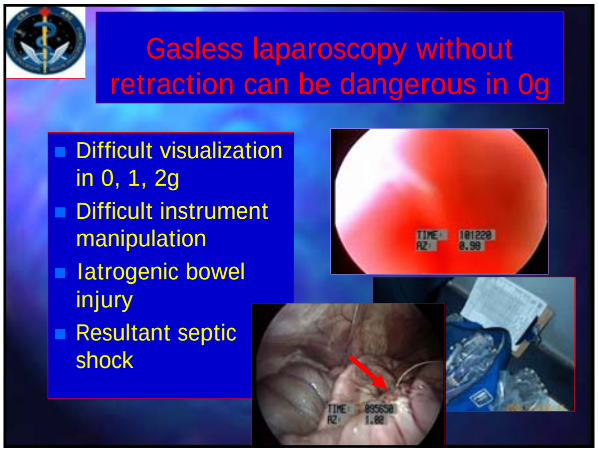

Intraperitoneal Gas Insufflation Will Be Required for Laparoscopic Visualization in Space: A Comparison of Laparoscopic Techniques in Weightlessness

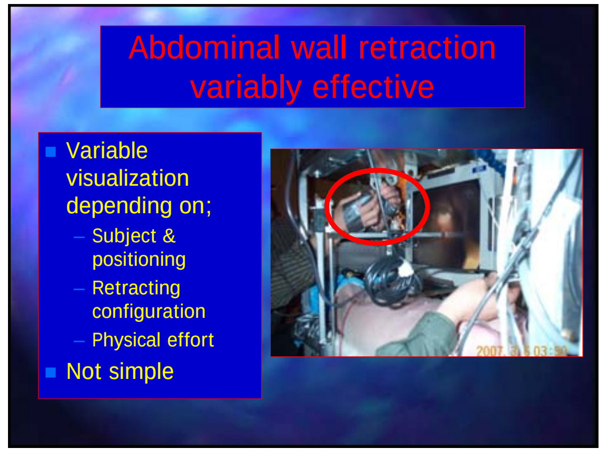
Standard Gas Insufflation

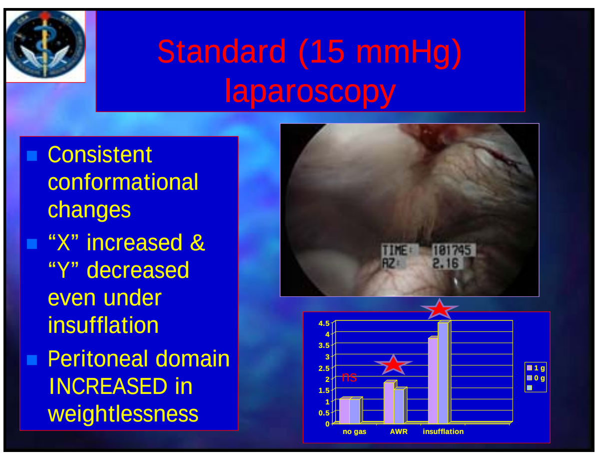


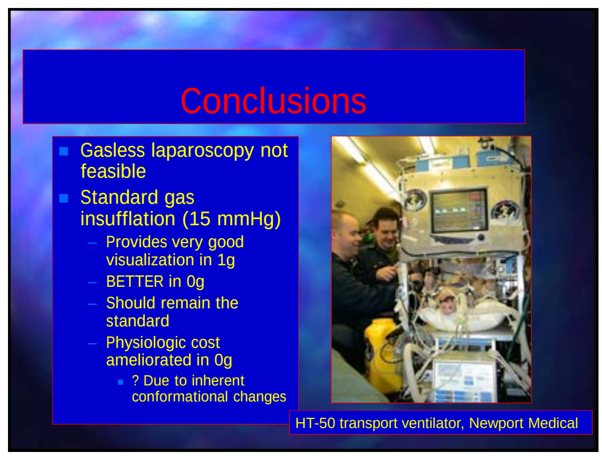
Grade I: IAP 12-15 mmHg,
Grade II: IAP 16-20 mmHg,
Grade III: IAP 21- 25 mmHg
Grade IV: IAP > 25 mmHg

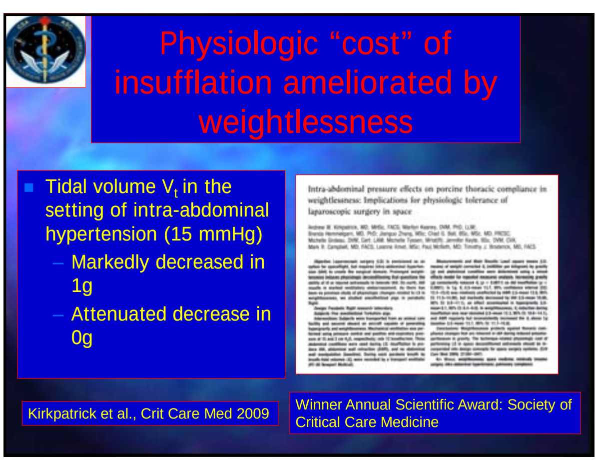
Chaotic study environment


Gasless laparoscopy without retraction can be dangerous in 0g
Difficult visualization in 0, 1, 2g
Difficult instrument manipulation
Iatrogenic bowel injury
Resultant septic shock

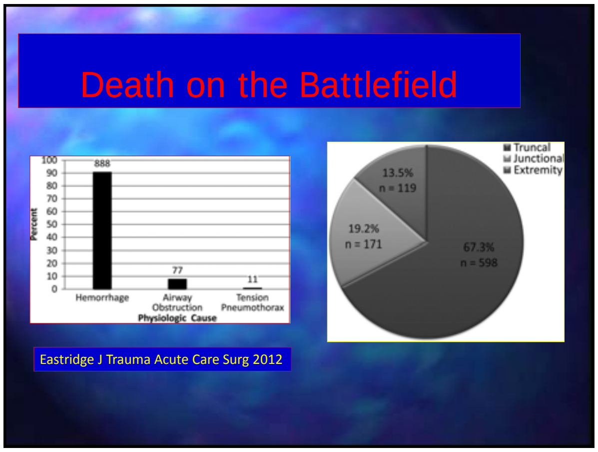

Abdominal wall retraction variably effective
Variable visualization depending on;
– Subject & positioning
– Retracting configuration
– Physical effort
Not simple

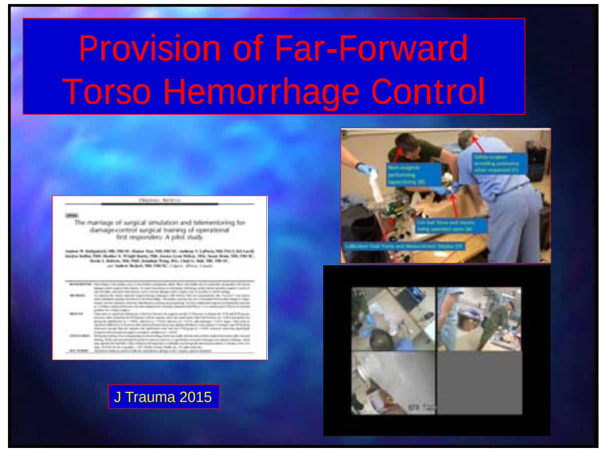

Standard (15 mmHg) laparoscopy
Consistent conformational changes
"X" increased & "Y" decreased even under insufflation
Peritoneal domain INCREASED in weightlessness
ns
no gas
AWR
insufflation
1 g
0 g

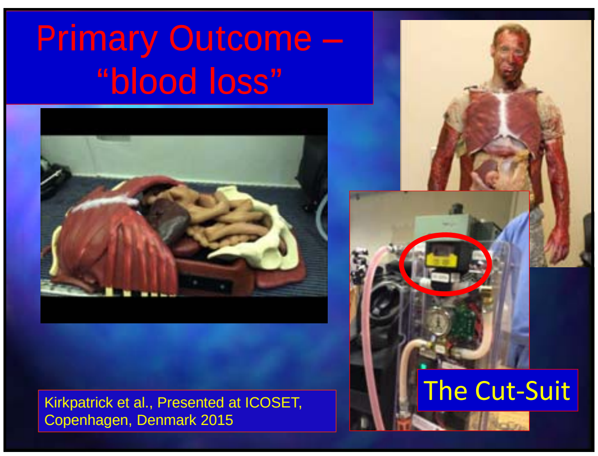

Conclusions
Gasless laparoscopy not feasible
Standard gas insufflation (15 mmHg)
– Provides very good visualization in 1g
– BETTER in 0g
– Should remain the standard
– Physiologic cost ameliorated in 0g
? Due to inherent conformational changes
HT-50 transport ventilator, Newport Medical


Physiologic "cost" of insufflation ameliorated by weightlessness
Tidal volume V_t in the setting of intra-abdominal hypertension (15 mmHg)
– Markedly decreased in 1g
– Attenuated decrease in 0g
Kirkpatrick et al., Crit Care Med 2009
Winner Annual Scientific Award: Society of Critical Care Medicine

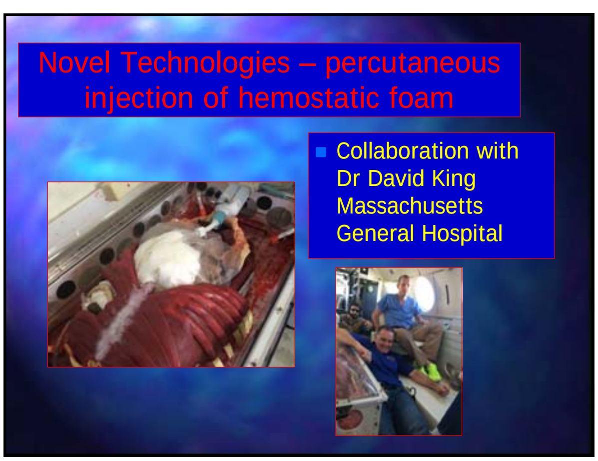

Damage Control Surgery in Weightlessness 2015
ROYAL COLLEGE
Surgery in weightlessness — it's possible!
Ottawa, June 2015

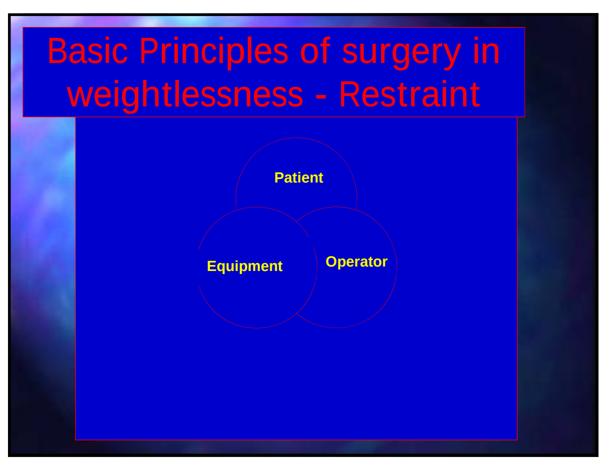

Death on the Battlefield
Percent
100
90
80
70
60
50
40
30
20
10
0
888
77
11
Hemorrhage
Airway Obstruction
Tension Pneumothorax
Physiologic Cause
Truncal
Junctional
Extremity
13.5%
n = 119
19.2%
n = 171
67.3%
n = 598
Eastridge J Trauma Acute Care Surg 2012


Provision of Far-Forward Torso Hemorrhage Control
J Trauma 2015


Primary Outcome – "blood loss"
Kirkpatrick et al., Presented at ICOSET, Copenhagen, Denmark 2015
The Cut-Suit


Controlled evaluation of Damage Control for Torso Hemorrhage Control in Weightlessness


Novel Technologies – percutaneous injection of hemostatic foam
Collaboration with Dr David King Massachusetts General Hospital


Basic Principles of surgery in weightlessness - Restraint
Patient
Equipment
Operator


Thank you
Andrew.kirkpatrick@albertahealthservices.ca

5.0 Smart Medical Technology

Diagnostic Equipment

Gary Strangman, PhD

Associate Professor of Psychology, Harvard Medical School
Director, Neural Systems Group, Massachusetts General Hospital
Team Lead, Smart Medical Systems & Technology, NSBRI

Spaceflight Biomedical Needs

Clinical / Operational

- Vital signs
  - BP, HR, RR, temperature
- EVA monitoring
  - ECG, RR, air/water supplies
- Radiation monitoring
- Detection/diagnosis/treatment
  - bone/muscle, kidney, retina, brain
  - sensory/behavioral assessment (auditory, visual, cognitive)

Research

- Cardiovascular
  - physiology
- Musculoskeletal
  - strength, density, functional capabilities
- Sensorimotor functioning
  - reaction time, accuracy
- Sleep
  - actigraphy, hormones
- (several more)

Environmental

- Air / Water / Surfaces
  - CO_2, volatile organics, water, bacteria, formaldehyde

Medical Device Constraints

- ❑ Mass
- ❑ Power
- ❑ Volume
- ❑ Time
- ❑ Money
- ❑ Risk

Not an option … (at least not yet)

Spaceflight Medical Conditions List

- 86 conditions
- Hemorrhoids to burns and toxic exposure
- Potential surgical issues
  - Abdominal injury
  - Burns
  - Chest injury
  - Obstructed airway
  - Compartment syndrome
  - Lacerations


Space Medicine Exploration Medical Condition List

ISS Biomedical Equipment

US Medical Items

Stethoscope, blood pressure cuff
Pulse oximetry (heart rate, SpO_2)
Electrocardiography (ECG)
Ultrasound imaging system
Optical coherence tomography (OCT)
Ocular tonometer
Medical & dental cameras
Portable clinical blood analyzer (PCBA)
Multiple radiation dosimeters (passive, CPDS, TEPC)
Environmental monitoring (CO2, volatile organics, total organic carbon, water microbiology, surface sampler)
Compound specific (combustion) analyzer
Advanced life support pack (ALSP)
Respiratory support pack (RSP)
Exercise: TVIS, IRED, ARED, CEVIS
Defibrillator
IV pump

Russian Medical Items

Beta-08 equipment (ECG, pneumogram, ear temp with real-time transmission)
Gamma-1M complex (BP, ECG, sphygmography, pulsography, kinetocardiography, rheography; downlinked via telemetry)
Tensoplus (arterial BP, pulse rate)
Urolux urinalysis (reflectance photometry)
Cardio recorder (ECG 24 hrs, cassette tape)
Reflotron-4 (blood analyzer)
Hematocrit set (centrifuge)
Ecosphere set (bacterial/fungal testing)
Dosimeters (personal, segments, etc)
Chibis suit (LBNP)
Cycle ergometer VB-3
Tonus-3 kit (electrical stim to muscles)
NC-1 force loader (exercise)

Data from: House NG, Samarin GI (2009). Biomedical research in spaceflight. In: U.S. and Russian Cooperation in Space Biology and Medicine. Eds CF Sawin, SI Hanson, NG House and ID Pestov. Reston, VA, American Institute of Aeronautics and Astronautics. V: 69-194.

Novel Diagnostic Approaches

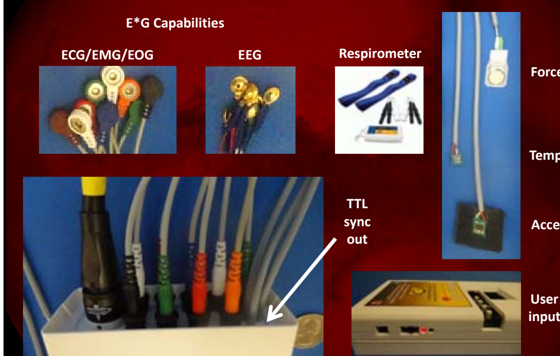
Device	Target Application	Alternative to …
Ultrasound speckle imaging (PI: Bailey)	Kidney stone detection	CT
Ultrasound bone density (PI: Y-X. Qin)	Bone loss due to detraining or osteoporosis	DEXA
Optic nerve & ocular ultrasound (PI: Dentinger)	Intracranial pressure (ICP)	Invasive sensor
Vittamed, DPOAE, TMD (Pis: Bershad, Williams)	ICP	Invasive sensor
Eye movement racking (PI: Ritlop)	Cognitive/ICP status	Invasive sensor
Near-infrared imaging (PI: Strangman)	Brain/muscle function assessment	fMRI

Medical Device Constraints

- ❑ Mass
- ❑ Power
- ❑ Volume
- ❑ Time
- ❑ Money
- ❑ Risk

NINscan-SE Multi-Use System

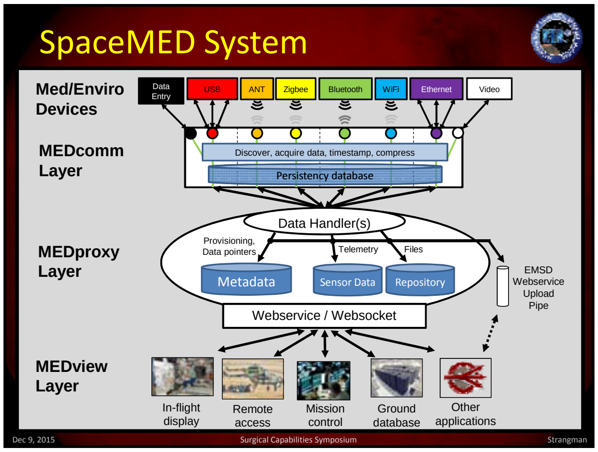
NINscan-SE Auxiliary Sensors



Medical Device Management

- Minimal automation
- Time and training burden for astronauts
- No insight into system health/performance
- Medial Equipment Computer can support only one type of data acquisition at a time
- Poor scalability/extensibility
- Limited in-flight access to data
- Minimal security

Medical Diagnostics “Kit”


SpaceMED System
Med/Enviro Devices
Data Entry
USB
ANT
Zigbee
Bluetooth
WiFi
Ethernet
Video
MEDcomm Layer
Discover, acquire data, timestamp, compress
Persistency database
MEDproxy Layer
Data Handler(s)
Provisioning, Data pointers
Telemetry
Files
Metadata
Sensor Data
Repository
EMSD Webservice Upload Pipe
Webservice / Websocket
MEDview Layer
In-flight display
Remote access
Mission control
Ground database
Other applications
Dec 9, 2015
Surgical Capabilities Symposium
Strangman


Exploration Medical Kit
?
NIKE
Dec 9, 2015
Surgical Capabilities Symposium
Strangman

National Aeronautics and Space Administration

NSBRI Symposium on Surgical Capabilities for Exploration and Colonization Space Flight

HRP Exploration Medical Capabilities
Exploration Medical System Prototype

December 9, 2015

Presented by:
David Rubin
Wyle Science, Technology & Engineering

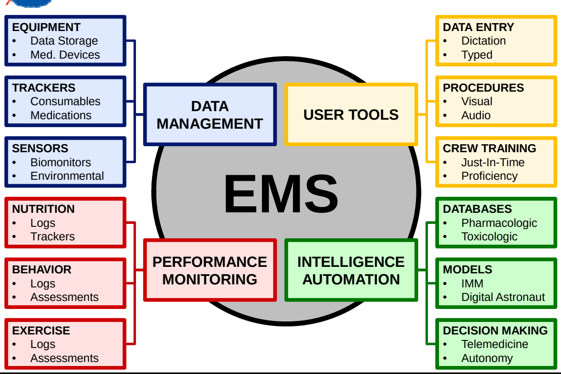
www.nasa.gov

Mission Constraints

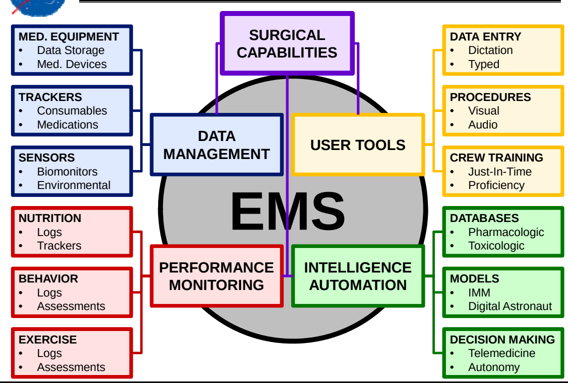
Communication → Restricted
Environment → Harsher
Resources → Limited
Resupply → Limited
Skills Needed → Increased

Increased Crew Autonomy ← Proficiency ← Resources

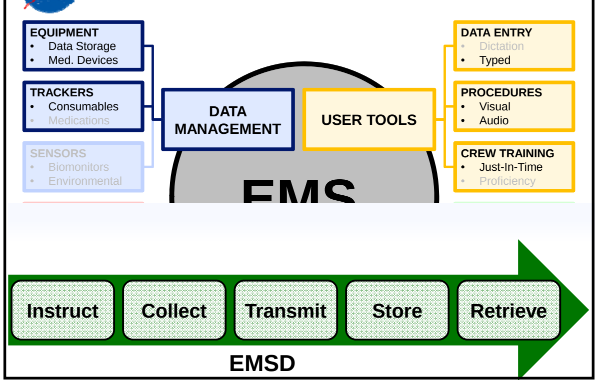
Exploration Medical System



Exploration Medical Support System



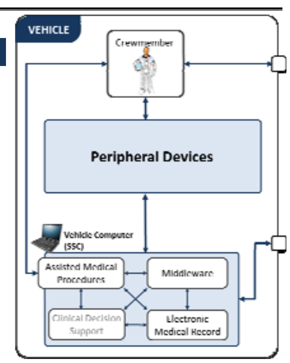
Exploration Medical System Project



EMSD Core Components

Store

- OpenEMR (Open Source)
- Repository for medical data, images, and reports
- Association with patient record
- Retrievable
- API-friendly



Questions:
- **What data will be produced?**
- **How will data be submitted?**
- **What data will be retrieved?**

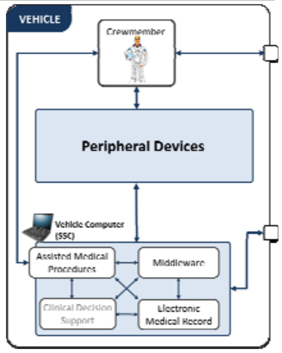
EMSD Core Components

Instruct & Retrieve

- Assisted Medical Procedures (AMP)
  - Based on WebPD & ePAT (NASA)
- System user interface
- Step-by-step instructions
- Basic procedure logic
- Reduces crew training load

Questions

- **What instructions are needed?**
- **What form will instructions take?**
- **Who will read the instructions?**



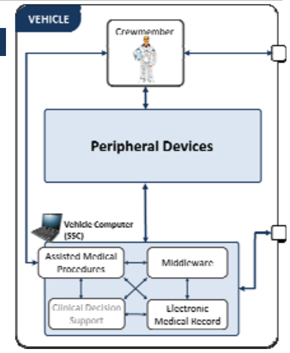
EMSD Core Components

Collect/Transmit

- OpenDDS (Open Source)
- API Development
- Standardized device connectivity and data communication interfaces
- Assists with automated transfer of data between devices and system

Questions

- **What requires integration?**
- **What data will be brokered?**
- **Sources and destinations?**



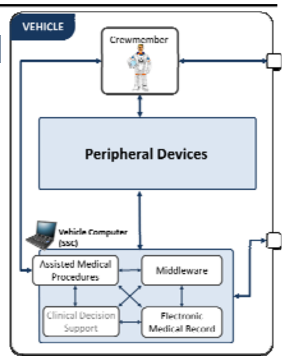
EMSD Core Components

Analyze

- Decision Support Software analyzes patient medical data and relevant data.
- Provide assistance in diagnosis or prediction of medical situations
- Augments physician knowledge & decision making

Questions

- **What information is required by the system?**
- **What assistance will the crew need?**



EMSD Peripheral Devices

Hardware

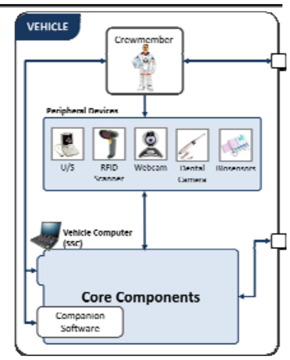
- Philips Ultrasound
- Cardiax ECG
- Acteon Dental Camera
- Webcam
- Surgical Hardware?

"Companion" Software

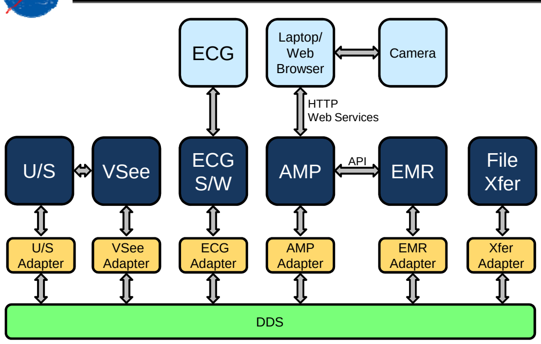
- Cardiax
- Surgical Software?

External Systems

- Medical Consumables Tracker
- Surgical Resources?



System Schematic



EMSD Bottom Line

The Conclusion

- An Exploration Medical System <u>can</u> be built
- Most individual technologies exist in relatively mature form
- An integrated system reduces manual operational overhead

The Challenges

- Interfacing all the disparate solutions into a fully integrated solution
- Providing an optimal, non-intrusive user interface
- Automated Intelligence & Decision Support software is not mature
- Integrating the medical system into the vehicle & habitat

NASA Robonaut as a Surgical Avatar – Recent Experiments

Ron Diftler, PhD
NASA/Johnson Space Center
Marc Dean, MD,
Vitruvio Institute for Medical Advancement

12/9/2015

Robonaut Motivation

Capable Tool for Crew
- Before, during and after activities

Share EVA Tools and Workspaces.
- Human Like Design

Increase IVA and EVA Efficiency
- Worksite Setup/Tear Down
- Robotic Assistant
- Contingency Roles

Surface Operations
- Near Earth Objects
- Moon/Mars

Interplanetary Vehicles
Telescopes

Astronaut Nancy Currie works with 2 Robonauts to build a truss structure during an experiment.

Robonaut 2 Introduction

https://www.youtube.com/watch?v=YTN-gHZNMX8&list=PLTXQuaxXBKKyUXfL6Kt9ksfosresu2cpA&index=43

EVA Task Development

https://www.youtube.com/watch?v=P1uhTInGZM0&list=PLTXQuaxXBKKyUXfL6Kt9ksfosresu2cpA&index=4

R2 First Humanoid Robot In Space

https://www.youtube.com/watch?v=I_-NyvV96zY&index=8&list=PLTXQuaxXBKKyUXfL6Kt9ksfosresu2cpA

Telemedicine - UltraSound

https://www.youtube.com/watch?v=9gbfL590Fgg

Medical Applications

http://pumpsandpipes2.hendrikmvp.com/Media/VideoPlayer/3231

Medical Experiments Results

Completed Tasks
- Intubation
- Laparoscopic assist
- Ultra Sound
- SAGES training

R2 Improvements Needed – Near Term
- Teleoperator Interface
- Distribution of "soft flesh" on hands
- Rotation control about arbitrary point
- Shared Control

Robonaut Improvements Needed – Long Term
- Advanced autonomy
- Next gen hands
- Size reduction

RAVEN™ and the Surgical Cockpit™

Teleoperation Systems for Space Applications

Dr. John Raiti

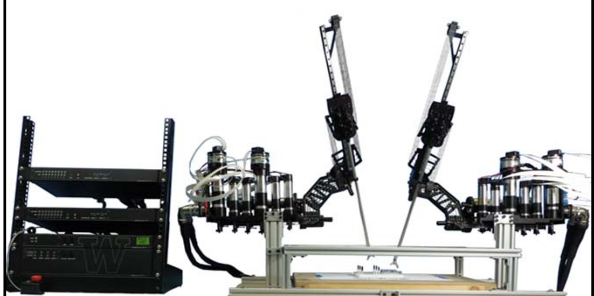
NSBRI Symposium
December 9, 2015

Outline

1. Product History
2. Technical Specifications
   a. RAVEN
   b. Cockpit
3. Space Applications
4. Conclusions

2

The RAVEN II



3

Harsh and Remote Environments

- *Top*: NEEMO mission
- *Bottom*: Panoramic view of the of the HAPs/MRT experimental setup deployed in Simi Valley CA

4

RAVEN Global Community

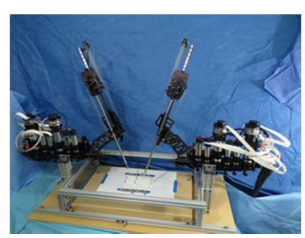
Johns Hopkins	Stanford	IC London
Harvard	U Central FL	KIST
U Nebraska	W Ontario	Ben Gurion
UC Berkeley	Montpellier	U S Denmark
UCLA		CIGIT
UC Santa Cruz		UIUC
U Washington		

- A common platform
  - Open Source software
  - Community support
  - Shared developments
  - Replication and extension of results

5

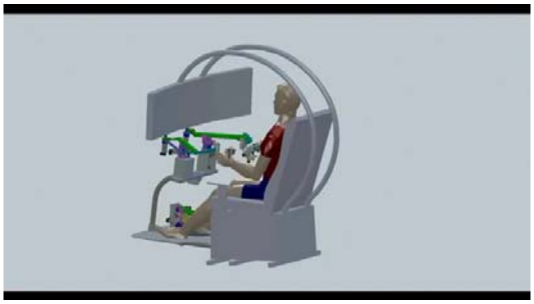
RAVEN Details

- Proven capabilities in long distance teleoperation
- Drives wide range of 7 DOF tools
  - 3 DOF position
  - 4 DOF on interchangeable tools
- Broad spectrum of ongoing research leading to future capability enhancements



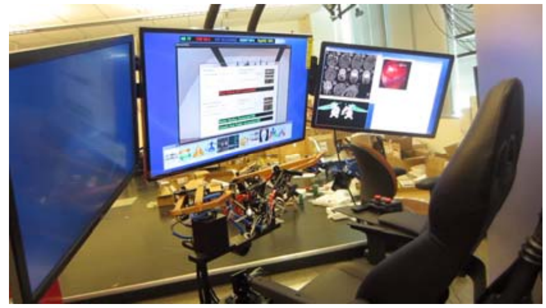
6

Surgical Cockpit



AppliedDexterity 7

Surgical Cockpit



AppliedDexterity 8

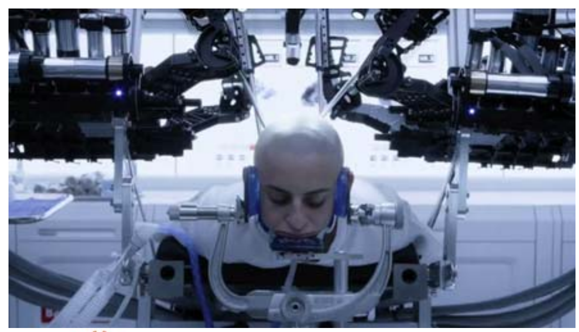
Surgical Cockpit details

- 24 Degrees of Freedom
  - Two 12-DOF hand + finger controls (9 haptic DOFs)
  - Suitable for rendering haptic palpation
  - 4 DOF Haptic foot pedal
- 3D primary monitor and HD peripheral displays

AppliedDexterity 9

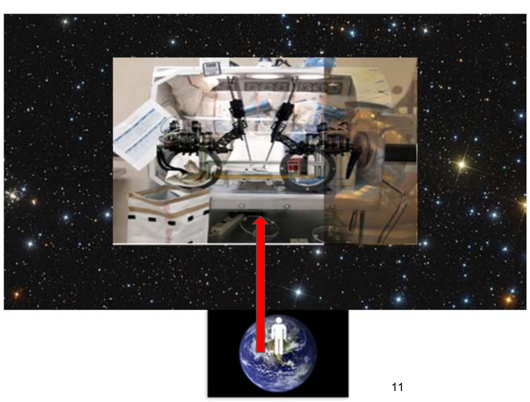
The Future of Teleoperation?

RAVEN in *Ender's Game*



AppliedDexterity 10

RAVEN on the ISS

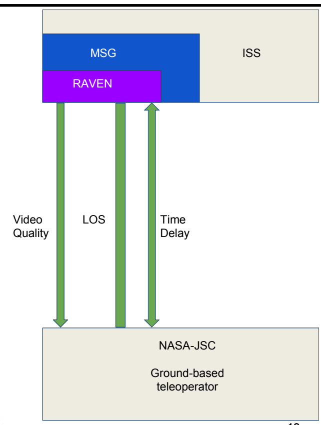


11

Project

- Modify RAVEN for installation in Microgravity Science Glovebox (MSG)
- Develop Concept of Operations (CONOP) for RAVEN assisted Rodent Research

AppliedDexterity 12



AppliedDexterity 13

Feasibility of Current Tasks

- Positioning/Immobilizing
  - Retrieve, stow, clamp, pin
- Grasping
- Cutting
  - Soft tissue, bone
- Fluid handling
  - Fixative, blood, vacuum
- Open/Close containers
  - Vials, tissue bag, ziplock bags, trash

AppliedDexterity 14

Model Surgical Tasks

Fundamentals of Laparoscopic Surgery (FLS) Block Transfer and Circle Cutting used to evaluate task performance under varying time delay.

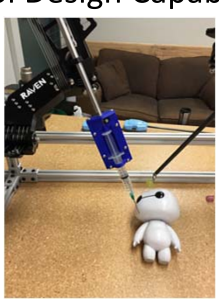
AppliedDexterity 15

Adapt Tasks/Equipment for RAVEN

- Robot manipulates objects designed for humans with current tool set
  - Can add adapters to COTS items to facilitate
- Design new ancillary equipment
- Design new robot tools

AppliedDexterity 16

Tool Design Capability

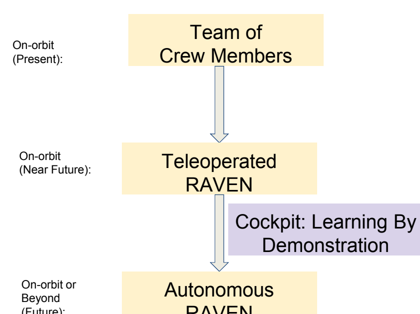


Syringe tool

Designed by Andrew Lewis (Applied Dexterity)

AppliedDexterity 17

Path Moving Forward



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Conclusions

1. Platform ideal for development of smart medical technologies
2. Ready to use now
3. Pragmatic approach for extending research and to achieving results in microgravity

AppliedDexterity 19

AppliedDexterity 20

Acknowledgments

- NASA
- DOD
- Charles Doarn, PhD
- Timothy Broderick, MD
- NSF
- AD team

AppliedDexterity 21

“Multi-use dexterous robots for mission surgical capability”

CAST - Center for Advanced Surgical Technology
University of Nebraska Medical Center, Omaha, NE

Nathan Bills, PhD, MBA
Lou Cubrich, B.S.
Marsha Morien, MSBA, FHFMA, FACHE
Shane Farritor, PhD
Dmitry Oleynikov, M.D., FACS
Joseph Ka-Chun Siu, PhD

University of Nebraska Medical Center

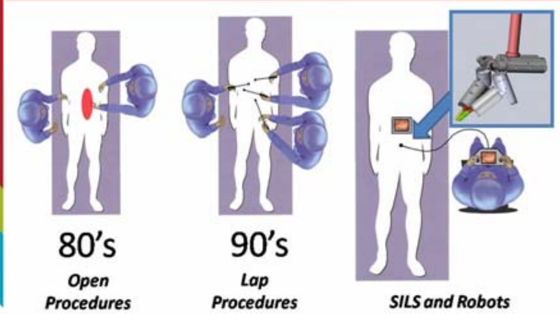
CAST–Center for Advanced Surgical Technology

Multi-campus, long-term (13+ year) collaboration among engineers, computer scientists and physicians at the University of Nebraska Medical Center; University of Nebraska, Lincoln; and University of Nebraska, Omaha

- PI’s
  - Dmitry Oleynikov, M.D. FACS, General Surgeon, Chief of Minimally Invasive Surgery, Director - CAST
  - Shane Farritor, Ph.D., Professor, Mechanical Engineering
- CAST members/Collaborators
  - Marsha Morien, MSBA, FACHE, Executive Director - CAST
  - Joseph Ka-Chun Siu, Ph.D., Physical Therapy
  - Jeff Hawks, Ph.D. , Mechanical Engineering
  - Carl Nelson, Ph.D., Mechanical Engineering
  - Ben Terry, Ph.D., Mechanical Engineering
  - Raj Dasgupta, Ph.D., Computer Science
  - Matt Goede, M.D., Trauma Surgeon
  - Vishal Kothari, M.D., General and Bariatric Surgery
  - Keely Buesing, M.D., Trauma Surgeon
  - William Thorell, M.D., Neurosurgery
  - James Gigantelli, M.D., Ophthalmology
  - Deepta Ghate, M.D., Ophthalmology
- 25+ Graduate and Undergraduate Students

Evolution of Surgical Procedures

Open -> Laprascopic -> SILS -> NOTES



Miniature *In Vivo* Robots

- Easy to use
- Re-usable
- Minimal Mass, Multipurpose
  - Surgery
  - Inter- and extra-vehicular tasks

Miniature *In Vivo* Robots

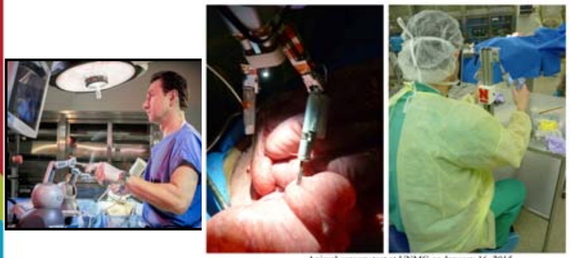
Portable system created to provide in-flight surgery capability controlled by a laptop station

- Single incision; minimally invasive
- Few local requirements
- Small, deployable, reusable
- Naturally align hands & instruments
- Faster patient recovery
- Over 75 animal surgeries
- 1st human use planned for early 2016

Miniature *In Vivo* Robots

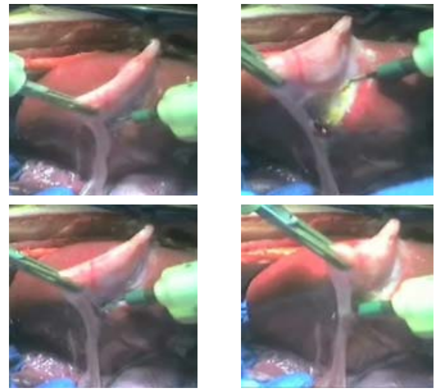
- Complete Suite of Capabilities:

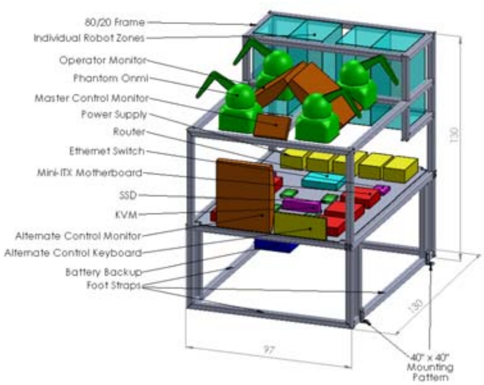
  Clamp, Cut, Cauterize, Coagulate, Suction



Animal surgery test at UNMC on January 16, 2015

Insertable Mini-Robot Cholecystectomy

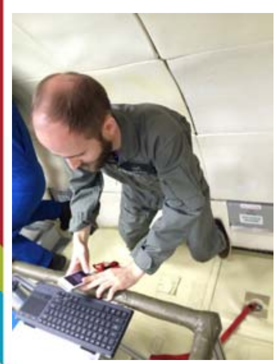




Payload 49-P flown on April 21, 2014

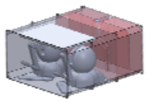
Payload 49-P flown on April 21, 2014 - lessons learned:

- **Weather unpredictable- had to fly two missions the same day with no time to retool/adjust between flights**
- **Solid state drives**
- **Diminished duration of reduced gravity periods indicates future flights should include:**
  - **More automated routines for robot**
  - **Seated, "strapped in" position for "flight surgeon" so ready to go**

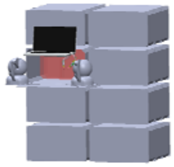


Students won't stop texting – even weightless!

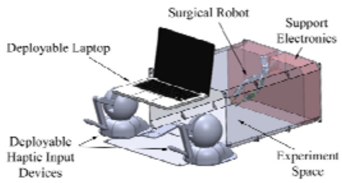
Flight Surgeon – Anton Simorov, M.D.



Robot Controller/Test Chamber Stowed for Launch

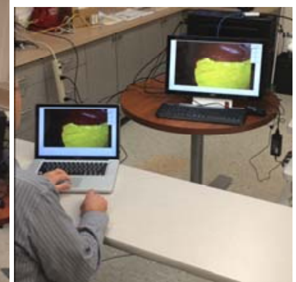


Robot and Controller in Express Dock



Deployed Robot in ISS

Telestration System for Remote Controlled Laparoscopic Robot



Tech Watch Visit – March 08, 2013

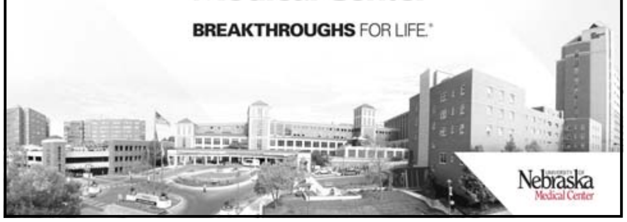
The Future of Space Surgery

Urgent need to maintain research and development momentum

- CAST continuously funded by NASA since 2008
- Engineering and clinical faculty collaborations need to be maintained and fostered
  - Develop more inter-campus, interstate, interagency collaborations to continue development to be ready in 10 years
  - Train next generation of clinicians and scientists for space surgery
- Congressionally-mandated report from the National Research Council, National Academy of Sciences – 2014
  - "Highly capable diagnostic and treatment equipment, including surgical facilities designed for operation in space and on the surface, would reduce threats posed by injuries and illnesses . . ."
- ExMC Roadmap
  - Identified gaps in surgical capabilities for long-term missions

University of Nebraska Medical Center

BREAKTHROUGHS FOR LIFE.



Nebraska Medical Center

The National Space Biomedical Research Institute

Surgical Capabilities for Exploration and Colonization Space Flight:

Robots for Telemedicine

December 9, 2015

Fuji Lai

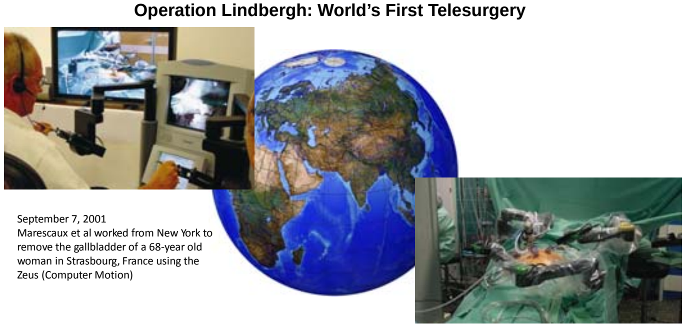
Why Robots for Telemedicine?

- Robots enhance human capabilities:
  - Make existing minimally-invasive surgery (MIS) simpler; makes difficult and new MIS possible
  - Enables computer-enhanced capability to average surgeon
  - Resulting in faster patient recovery and better outcomes

Zeus Surgical Robot (Computer Motion, Inc. now Intuitive Surgical, Inc.)

Robots extend reach of surgical care

Operation Lindbergh: World's First Telesurgery



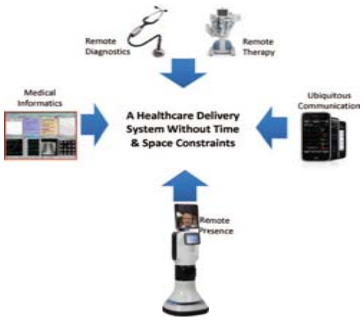
September 7, 2001
Marescaux et al worked from New York to remove the gallbladder of a 68-year old woman in Strasbourg, France using the Zeus (Computer Motion)

The Problem

- Delivering quality health care for patients with acute conditions in a timely, affordable fashion is a major challenge
- Shortage and unequal geographic distribution of specialists
  - e.g. < 500 Neuro-interventional and endovascular specialists
  - e.g. Intensivists: large gap between supply & demand in non-metro areas
  - Problem compounded by increasing specialization
- Need for new healthcare delivery models

The Solution

- Convergence of enabling technologies is unprecedented
- Remotely-enabled care is:
  - Transforming the reach & quality of patient care
  - New paradigm for healthcare delivery



"Paging Dr. Robot: Telemedicine a game changer," NBC Nightly News

Weblink: https://wwwyoutube.com/watch?v=0xm-sdR6RNE

Virtual & Independent Telemedicine Assistant (VITA)

First FDA-Class-II Cleared Telemedicine Robot with Autonomous Navigation

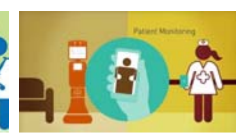
2014 Medical Design Excellence Award Finalist




Smart Robots:
Semi-Autonomous Scripted Activities

- Team-Based Care
- Patient-Family Experience
- Assisting Care Delivery





The Future:

Human-Robot Collaboration for Decisionmaking & Action

Thank You!

Fuji Lai
fuji@post.harvard.edu

6.0 Crew Composition, Training for Flight, the Effect of Transmission Latency

NSBRI Surgical Capabilities for Exploration and Colonisation Space Flight

An Exploratory Symposium
9-10 December, 2015

Who Should be on the Crew?

Richard L. George, MD, MSPH

No Disclosures

Who should be on the crew?

- To be clear, our focus has been on the question of the CMO
- More specifically, what is the impact on prior medical training for the CMO

Similarities to Current Medical Education Challenges

- Assessing adequacy of current training modalities - the rules have changed
- Obtaining/Maintaining skills for low frequency, high risk situations
- Time constraints

What makes up your ideal clinician?

- Minimum standard for knowledge base (typically assessed with standardised written/computer exams)
- Minimum standard for skills (typically assessed throughout residency and, for some, oral boards)
  - Collect data (History & Physical Exam)
  - Develop differential diagnoses list
  - Efficient use of diagnostics
  - Interpret results to resolve a diagnosis
  - Implement plan of care in a timely fashion/demonstrate procedural skills

How are we doing?

- Various constraints
  - Increasing size of knowledge base
  - Changes in the students - Generation __
  - Reduced hours/balancing service for education/protected time (therefore, in an educational environment, not a clinical environment)
  - Increasingly, services are staffing with more APPs (Advanced Practice Providers: PA, CNP, CNS, etc.)

How are we doing?

- We continue to look for other ways to consistently measure those we educate as our standard tools may no longer be relevant as the education paradigms change

- We all know that 'book smarts' don't necessarily translate into being a good clinician
- All too often, we find out late in his/her educational career ... too late
- We need a new tool

What could the ideal tool look like?

- Objective
- High-fidelity
- Immersive
- Reflective of real clinical scenarios with all the depth and complexities we actually face

What could the ideal tool look like?

- A virtual reality scenario with tactile feedback
- Believable, actual patient complexities (for surgeons, throw in a couple of anatomic variants!)
- Envision the very best video game: not constrained to 4 or 8 directions; responsive to the impact of the same information being given early vs. late in the same scenario; responsive to different student styles of 'play'; incorporating all of the various input/outputs for all the relevant organ systems for a given patient condition - simultaneously; identifying the 'blind squirrel' finding ...

What could the ideal tool look like?

- If you try to map out a case with sufficient 'what if' branch points, it is a monumental task for the most mundane of scenarios
- If poorly done, as soon as a student hits 'you can't do that,' he/she may interpret that as guidance ... if the door won't open in a video game, the player will factor that into subsequent decisions

Where are we now?

- We don't have a video game, but partner with medical simulation
- We have developed a Medical Judgment Pathway Metric (MJPM)
- Used in concert with a high fidelity simulation case and a critical action checklist
- A content expert runs the simulation to provide the depth and responsiveness of the sim case

Where are we now?

- We have completed a pilot study with the initial version
- Finalising our data analysis with apparent favourable results
- Revising the MJPM tool
- Study version 2.0

Questions?

How would I choose my clinical provider for a long, resource limited journey?

- Use the Exploration Medical Conditions List and the IMM to determine the conditions that most pose risk
  - Ensure a current assessment of health risk for the cohort (as new risk assessment tools are developed, e.g. for cancer, dementia, etc)
  - Ensure that the effect of reduced health screening is incorporated into the model
- Build representative High Fidelity simulation cases, MJPMs, and critical action checklists

How would I choose my clinical provider for a long, resource limited journey?

- Use the conditions to determine the clinical areas from which to recruit
- Determine a minimum years of experience
- Keep candidates clinically active (or, regular clinical simulation assessments) throughout pre-deployment training

Factors Affecting Successful Performance of Medical Tasks

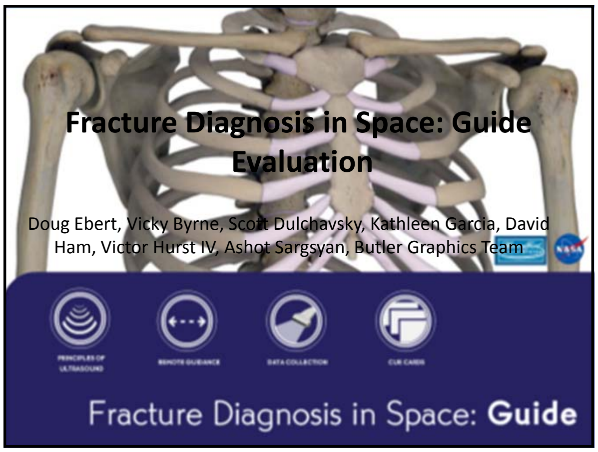
Surgical Capabilities for Exploration and Colonization Space Flight Symposium

December 9, 2015

Doug Ebert

Factors

- Resources
  - Equipment
  - Supplies
- Environment
  - Sterility
  - Stress
  - Ergonomics (restraints, stability, immediate availability of supplies/equipment)
- Which procedure/task?
- Experience of the operator
- Autonomy (availability of guidance or guidance materials)
- Training (including recall of training)

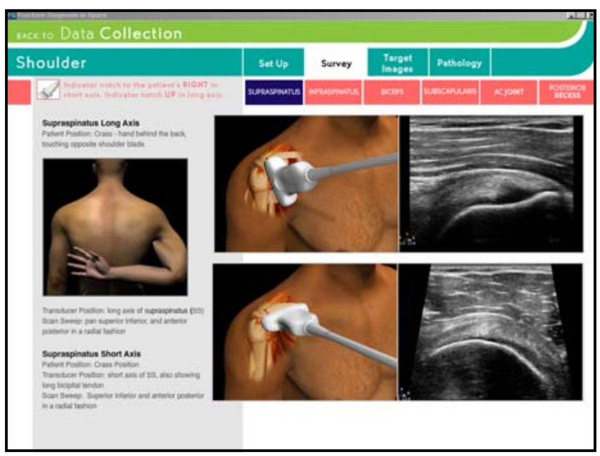


Fracture Project Summary

- Primary purpose: software evaluation
- Factors addressed
  - Experience of the operator
  - Which procedure/task?
- Factors not addressed (constants)
  - Autonomy
  - Training

Evaluation Methods

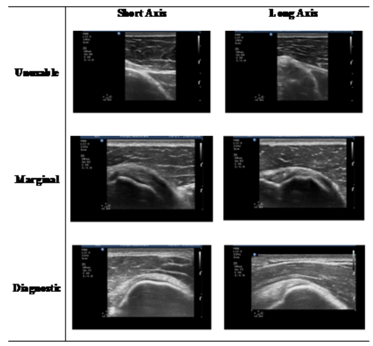
- Subjects autonomously collected ultrasound images for target musculoskeletal locations with the aid of *Fracture Diagnosis in Space: Guide* software
- 2 hour session per subject
  - 10 min: overview and consent
  - 20-25 min: general ultrasound training
  - 30-45 min: 7 autonomous views, (2 phantom, 5 live)
  - 20 min: questionnaire & debrief
- No training on software use



Imagery Analysis

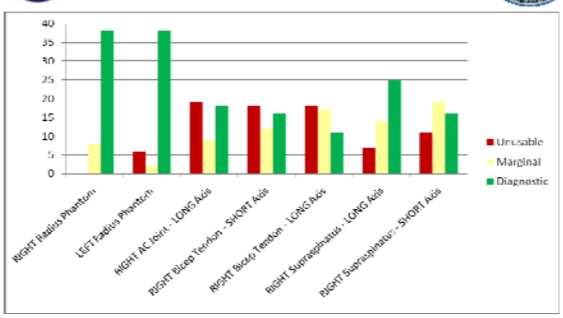
- Imagery
  - Phantom forearms:
    - 1A Right Radius Phantom
    - 1B Left Radius Phantom
  - Human Shoulder:
    - 2A Right AC Joint Long Axis
    - 3A Right Bicep Tendon Short Axis
    - 3B Right Bicep Tendon Long Axis
    - 3C Right Supraspinatus Long Axis
    - 3D Right Supraspinatus Short Axis
- All images evaluated by 2 independent sonographers
  - 0=unusable
  - 1=marginal
  - 2=diagnostic

Results



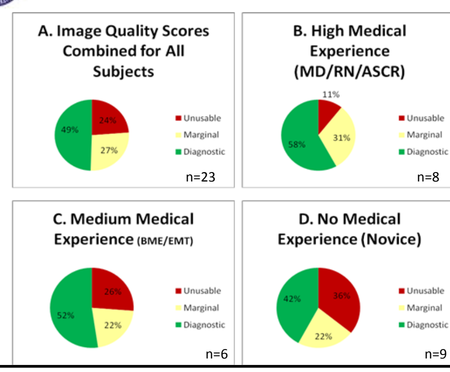
Examples of Supraspinatus Images scored Unusable, Marginal *and* Diagnostic

Results



Frequency of unusable, marginal, and diagnostic image quality scores by physical target as rated for all subjects (n = 23) x 2 expert raters (46=100%)

Results



Fracture Conclusions

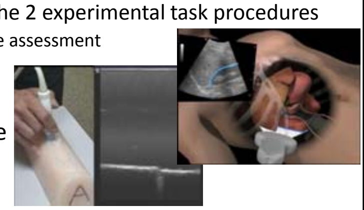
- Medical experience translated into higher image quality
- All subjects performed well on the more simple, phantom imaging task
- Success rates were much lower with complex tasks on human subjects

SURGE Project Summary

- Purpose: determine optimal combination of support for medical imaging tasks
- Factors addressed
  - Autonomy
  - Experience of the operator
  - Which procedure/task?
- Factors not addressed (constants)
  - Training

Guidance Tools

- Onboard Proficiency Enhancer Lite (OPE-L)
  - Menu driven just-in-time training software
  - Derived from the original OPE used on ISS for the ADUM experiment
  - Contained only the 2 experimental task procedures
    - Forearm fracture assessment
    - FAST exam
- Cue Cards
- Remote Guidance



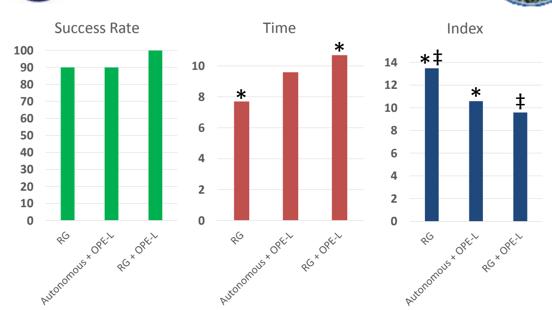
Evaluation Methods

- Subjects (n=30) divided into 3 groups
  A. Remote Guidance (RG) + cue cards
  B. Autonomous + OPE-L + cue cards
  C. RG + OPE-L + cue cards
- ~1 hour session per subject
  - 10 min task explanation, basic ultrasound training, and OPE-L and cue card orientation
  - Image acquisition
  - Questionnaire & debrief
- 5 second communication delay (lunar) for RG

Imagery Analysis

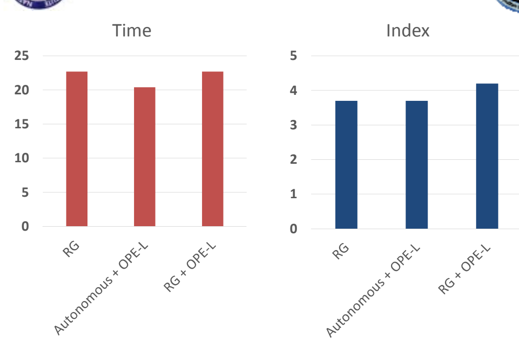
- Imagery
  - Phantom forearms:
    - Right Radius Phantom (longitudinal and transverse)
    - Left Radius Phantom (longitudinal and transverse)
  - Human FAST:
    - Hepatorenal interface
    - Splenorenal interface
    - Suprapubic
    - Sub-xyphoid
- Images evaluated by an Emergency Medicine Physician
  - Each task's image average expressed as 1-4 scale
  - "Fracture index" or "FAST index" = quality adjusted for completion time

Results – Fracture



*, ‡ statistically significant differences between group means, as identified by Tukey post hoc comparisons (p<0.01)

Results – FAST



Results – Medical Training

- Significant difference in FAST image exams when subjects with > 2 years of medical school were compared to other subjects:

FAST quality mean difference
0.7 [0.2-1.3], p=0.01

FAST index mean difference
1.8 [0.5-3.0], p=0.01

SURGE Conclusions

- Successful RG with 5 second delay
- Autonomous performance compared well with RG
- Medical training resulted in better performance

Clinical Outcome Metrics for Optimization of Robust Training

COMfORT

NSBRI Smart Medical Systems and Technology Team
grant # SMST03801

Doug Ebert, Vicky Byrne, Richard Cole, Scott Dulchavsky, Kathleen Garcia, Robert Gibson, David Ham, Victor Hurst IV, Eric Kerstman, Kerry McGuire, Ashot Sargsyan, Millennia Young, and the Butler Graphics team

COMfORT Project Summary

- Purpose: quantify the differences in performance of physician vs. non-physician crew medical officer (CMO) analogs during medical simulations
- Factors addressed
  - Experience of the operator
  - Which procedure/task?
- Factors not addressed (constants)
  - Autonomy
  - Training (consistent)

Conditions and Assumptions

- Crew Medical Officer (CMO) analogs are operating autonomously (store and forward mode)
- Hands-on tasks are experimentally separated from diagnostic tasks
- Medically trained non-physicians excluded from the study (nurses, emergency medical technicians, etc.)

Map to the Human Research Program Integrated Research Plan

- Primary: Exploration Medical Capability (ExMC) “Risk of Unacceptable Health and Mission Outcomes Due to Limitations of In-flight Medical Capabilities”
  - *ExMC 2.02: We do not know how the inclusion of a physician crew medical officer quantitatively impacts medical risk during exploration missions.*
- Secondary: Space Human Factors and Habitability Element (SHFE) “Risk of Performance Errors Due to Training Deficiencies”.
  - *SHFE-TRAIN-01: How can we develop objective training measures to determine operator proficiency during and after ground training?*
  - *SHFE-TRAIN-02: How do we develop training methods and tools for space medical application if time is minimal?*
  - *SHFE-TRAIN-03: How can onboard training systems be designed to address Just-in-Time (JIT) and recurrent training needs for nominal and off nominal scenarios?*

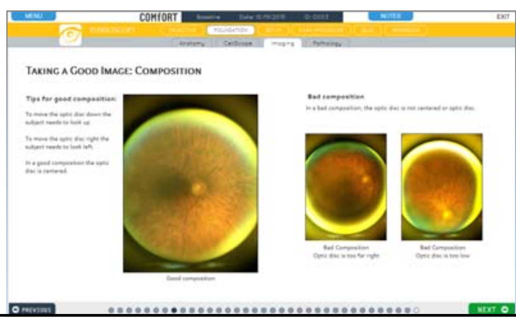
Specific Aims

1. Develop clinical outcome metrics (immediate term) to discriminate between physician and non-physician CMO analogs.
2. Develop long-term clinical outcome metrics through modeling of mission impacts due to lack of complete clinical procedure success (Integrated Medical Model).
3. Develop advanced training products that increase retention and reduce errors during the performance of medical procedures.

Experimental Design

Training/Testing Modules

Fundoscopy (diagnostic) with human volunteer "patient"

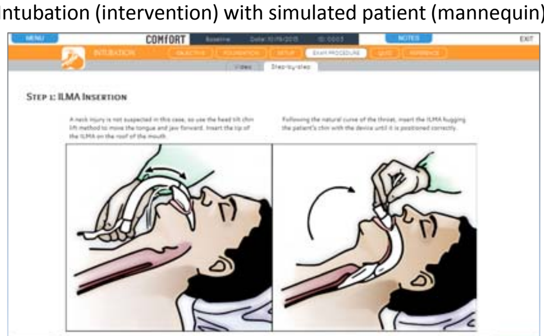


Training/Testing Modules

Kidney/urinary ultrasound (diagnostic) with human volunteer "patient"

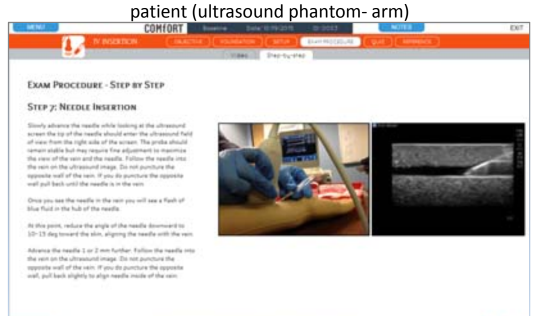
Training/Testing Modules

Intubation (intervention) with simulated patient (mannequin)



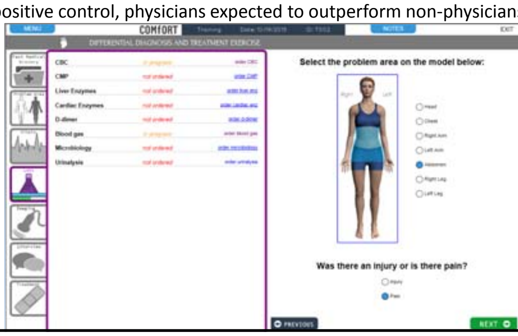
Training/Testing Modules

Ultrasound guided intravenous access (intervention) with simulated patient (ultrasound phantom- arm)



Training/Testing Modules

Differential diagnosis and treatment exercise (software-based, diagnostic positive control, physicians expected to outperform non-physicians)



Testing Procedures

- **Training**
  - Didactic and hands-on
  - Software tool used for content as well as familiarization
- **Test and re-test**
  - Autonomous
  - Access to software tool and other required resources
  - Timed
  - Live observation and metric recording
  - Software tool “click tracking”
  - Quad screen synchronized video recording

Expected Outcomes

- **Do physicians perform as well as non-physicians?**
- **Which procedures are do physicians/non-physicians perform better?**
- **When does training “expire”?**
  - **Does it differ physician vs. non-physician?**

QUESTIONS/DISCUSSION

BACK UP CHARTS

Specific Aim 1

- **Specific Aim 1:**
  - Develop clinical outcome metrics (immediate term) to discriminate between physician and non-physician CMO analogs.
- **Research questions:**
  - What are the performance differences between physician and non-physician CMOs?
  - Do the types of errors change over time since initial training?
  - What are the best refresher training intervals for specified medical procedures?
- **Method:**
  - Evaluate physician and non-physician performance at baseline post training session, and at one retention interval (3, 6 or 12 months from their initial medical training/baseline simulation)

Specific Aim 2

- **Specific Aim 2:**
  - Develop long-term clinical outcome metrics through modeling of mission impacts due to lack of complete clinical procedure success.
- **Research question:**
  - When mission-long impacts are considered in cases where diagnoses or interventions are not 100% correct, are the individual and mission outcomes different than when only immediate-term outcomes are considered?
- **Method:**
  - Incorporate physician and non-physician performance data into the NASA IMM to determine predicted clinical outcomes, and resource and mission impacts for specified conditions.

Specific Aim 3 and Aim 4

- **Specific Aim 3:**
  - Develop advanced training products that increase retention and reduce errors during the performance of medical procedures.
- **Specific Aim 4:**
  - Promote public understanding of human research and human activity in space environments through formal and informal education opportunities.

Research Products

- This research will yield the following products:
  - Data that quantifies differences in medical outcomes when physician and non-physician CMO analogs are compared in procedure simulations (immediate term outcomes) and by IMM analysis (mission impacts)
  - Refined clinical outcome metrics for medical training and testing
  - Innovative medical training products and solutions to maximize CMO performance
  - Enhanced IMM capability through the development of algorithms that account for incorrect diagnoses and incomplete treatment
  - Validation of the methods and products used by this experiment for operational use in the planning, execution, and quality assurance of the exploration mission CMO training process

ISS Crew Medical Officer Training

Melinda Hailey BSN, RN, CEN
281-244-6841 (office)
281-928-4720 (cell)

Overview

- Big picture of training : pre / post assignment
- Pre Flight Training
- In Flight Training
- Future Development Challenges

CMO Training

Pre Assignment: 2-42 hours

____

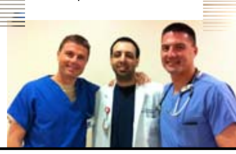
Post Assignment:
Operators – 7
Specialists - 26 hours

CMO Training
Mandatory Pre - Assignment

- CPR
- DCS

CMO Training
Optional - Pre Assignment

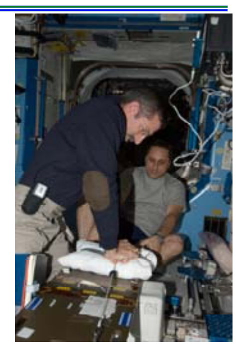
Field Medical Training:
Provide students with the opportunity to observe and / or perform medical skills using human subjects
- ✓ Operation and use of flight similar hardware
- ✓ 'Do no harm' philosophy as r/t each task
- ✓ Familiarize with human anatomic variability as r/t task performance



In-Flight Medical Events Con Ops

Non emergent conditions
- Dehydration requiring IV catheterization
- Urinary retention requiring bladder cath
- Dental event

Emergency conditions
- Choking
- Cardiac Arrest
- Early anaphylaxis



CMO Specialist Training
Flight Assigned

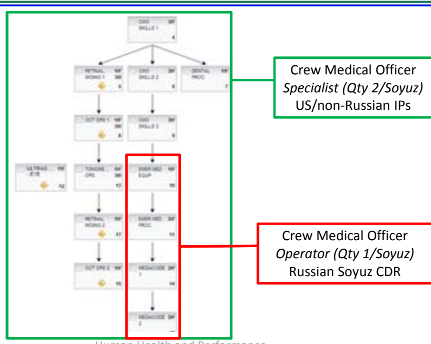
2 Crew Medical officers (CMO) per Soyuz flight
- ~ 19 hours task trainer centric training in CMO responsibilities, plus:

CMO Specialist & Operator Training
Flight Assigned

~7 hours of Advanced Life Support training
(classroom + mockup simulation)

Human Health and Performance
Exploring Space | Enhancing Life

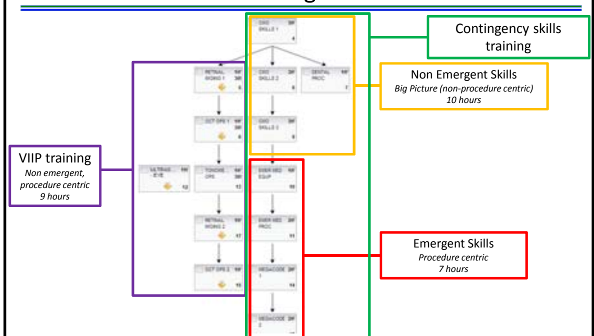
CMO Class Flow
Who



Human Health and Performance
Exploring Space | Enhancing Life

Note: CPR & DCS are pre-req to CMO Flow

CMO Class Flow
What – Big Picture

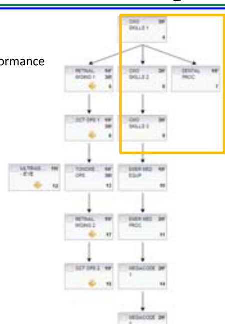


Human Health and Performance
Exploring Space | Enhancing Life

Note: CPR & DCS are pre-req to CMO Flow

CMO Class Flow
What – Non Emergent Contingency

Delivery:
Lecture
Demonstration / Performance



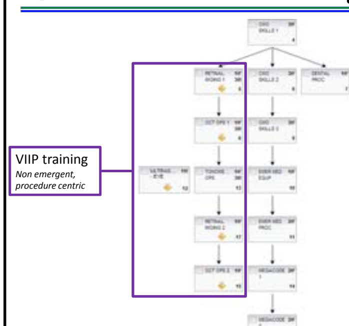
Non Emergent Skills
Big Picture (non-procedure centric)
10 hours

Objectives:
- Introduction to system/hardware
- General orientation and practice
  - Physical Exam skills
  - Non emergent skills
    - ✓ Injections
    - ✓ IV Catheterization
    - ✓ Wound Repair
    - ✓ Bladder Catheterization
    - ✓ Replace crown
    - ✓ Temporary Tooth filling
    - ✓ Local nerve block (dental, wound)

Human Health and Performance
Exploring Space | Enhancing Life

Note: CPR & DCS are pre-req to CMO Flow

CMO Class Flow
What – Non Emergent VIIP



Delivery:
Lecture
Demonstration / Performance

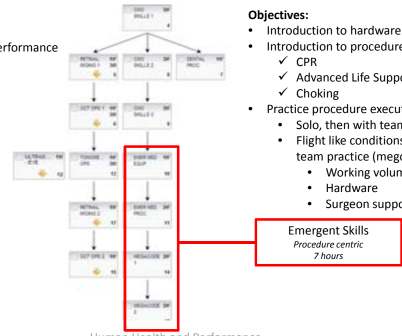
Objectives:
- Introduction to hardware
- Introduction to remote guidance
- Practice exam
  - Active coaching from remote guider
  - Utilizes test subjects
  - Flight like conditions (where possible)
    - Hardware
    - Software
    - Environment
    - Comm
    - Medications to facilitate exam
- Tasks deemed as more challenging are repeated (OCT, Retinal Imaging)

Human Health and Performance
Exploring Space | Enhancing Life

Note: CPR & DCS are pre-req to CMO Flow

CMO Class Flow What-Emergent

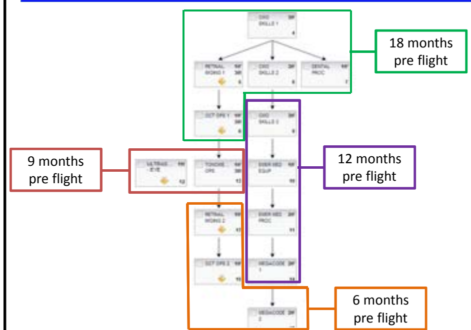
Delivery:
Lecture
Demonstration / Performance



Objectives:
- Introduction to hardware
- Introduction to procedure
  - ✓ CPR
  - ✓ Advanced Life Support
  - ✓ Choking
- Practice procedure execution
  - Solo, then with team
  - Flight like conditions with team practice (megcodes)
    - Working volume
    - Hardware
    - Surgeon support

Note: CPR & DCS are pre-req to CMO Flow

CMO Class Flow When



Note: CPR & DCS are pre-req to CMO Flow

In-Flight Training

Emergency Drill - Within 4-6 weeks of arrival
- 45 min duration, all three arriving Soyuz crew together
- Practice CPR positioning
- Review medical emergency procedures and hardware

Computer Based Training – every 30 days
- 25 mins, US and IP crew only (no Russians) self study
- Review electronic media on designated topic

Future Development Challenges

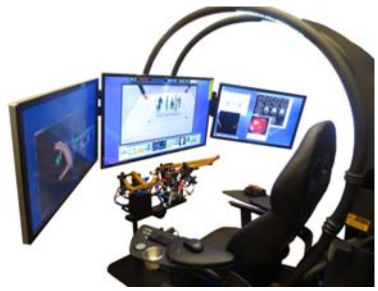
- **Time** (never enough)
  - ✓ Constantly competing with other orgs that also have valid need for crew face time – often with high profile tasks
- **Competition**
  - ✓ student has competing priorities for task mastery, often changing gears several times a day/week
- **Training Fidelity**
  - ✓ If all of your training is on a pretty pink task trainer, how will you learn real world application
  - ✓ Students need exposure to real medical events, but are limited by time, distance from training and concerns regarding liability
- **Untested training –**
  - ✓ 66% of tasks trained are never used in flight, so there is no validation that what / how we train is going to result in inflight success
  - ✓ Students are not required to prove proficiency beyond instructor subjective assessment
  - ✓ When medical events occur in space that require use of ground training, privacy / regulations limit what we can learn

Questions?

Melinda Hailey BSN, RN, CEN
281-244-6841 (office)
281-928-4720 (cell)

7.0 Data Blitz

AppliedDexterity



RAVEN™ and the Surgical Cockpit™

1

Key Areas of Interest

- Surgical robot design for space facilities
- Long distance teleoperation
  - Methods to mitigate limited bandwidth, time delay, and LOS
- Human/Robot Interaction
  - Integrated efforts of robots/automation, flight crew, and remote experts

AppliedDexterity

2

Factors Affecting Successful Performance of Medical Tasks

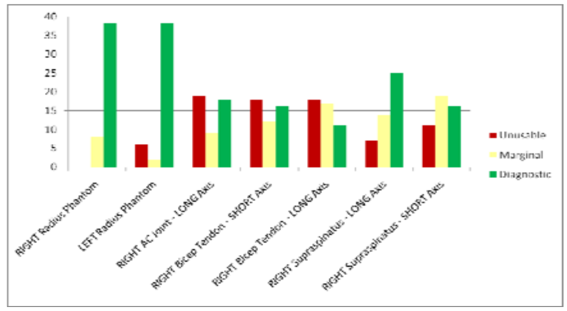
DATA BLITZ!

Surgical Capabilities for Exploration and Colonization Space Flight Symposium

December 9, 2015

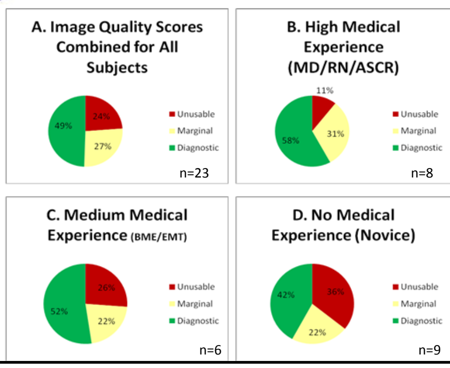
Doug Ebert

Results – Fracture Evaluation



Frequency of unusable, marginal, and diagnostic image quality scores by physical target as rated for all subjects (n = 23) x 2 expert raters (46=100%)

Results- Fracture Evaluation



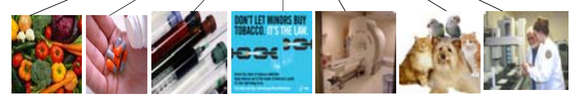
Fostering Medical Innovations

Allison Kumar
Sr. Program Manager

Supporting activities that will boost CDRH knowledge, build inter-governmental partnerships, and expedite medical device innovation

Surgical Capabilities for Exploration and Colonization Space Flight
December 9, 2015

FDA



Center for Food Safety & Applied Nutrition
Center for Drug Evaluation & Research
Center for Biologics Evaluation & Research
Center for Tobacco Products
Center for Devices & Radiological Health (CDRH)
Center for Veterinary Medicine
National Center for Toxicological Research

C·D·R·H

2

WHO WE ARE…

- FDA is comprised of teams of dedicated, highly skilled, and internationally respected public health employees

- Biologists
- Chemists
- Physicists
- Engineers
- Statisticians
- Epidemiologists
- Physicians
- Microbiologists
- Nurses
- Pharmacologists
- Veterinarians
- Toxicologists
- Specialists in Public Health Education and Communication

C·D·R·H

3

C·D·R·H

4

CURRENT COLLABORATIONS

- Defense Health Agency (DHA)
- Army - MRMC
- Navy – Office of Naval Research
- Air Force
- CoTCCC
- DARPA and DTRA
- USAMRICD / USAMRIID
- ASPR / BARDA
- CDC
- NIH
- FCC
- ONC

- TBI
- Interoperability
- Clinical Decision Support
- Trauma
- Wound Care
- Hemostatic Agents
- Sepsis
- Diagnostics
- Cyber Security
- Physiological Closed-Loop Systems
- Critical Care
- Advanced Physiological Monitoring
- Batteries
- Prosthetics
- Sterilizers
- Pediatric Devices
- Infectious Diseases / MDROs
- PPE
- 3-D Printing

C·D·R·H

ISSUES IMPACTING MEDICAL DEVICES USED NON-TRADITIONAL SETTINGS

- Medical device performance in austere environments
  - Extreme temperature
  - Humidity
  - Fluctuating power
  - Batteries
- Devices used in transport vehicles (ground or air)
  - Display monitors
  - Inability to hear audible alarms
  - RF interference
  - Remote Control / Monitoring

What unique factors need to be considered for space??

C·D·R·H

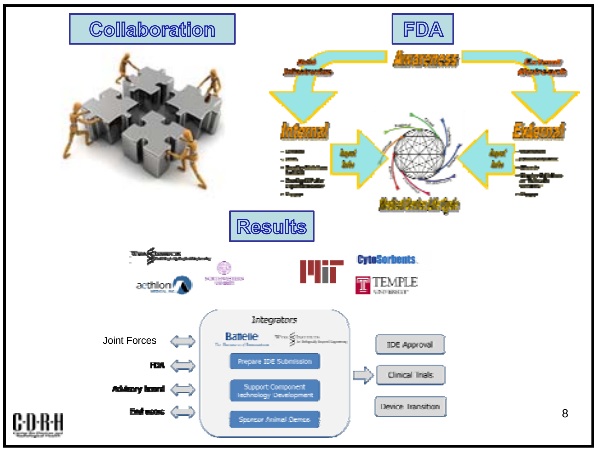
6

HUMAN FACTORS AND MEDICAL DEVICES

- **Demonstrate: The intended users can use the medical device without making errors that could result in serious clinical harm.**
  - Perception of information presented
    - Visual + auditory + tactile information
  - Cognition related to information presented
    - Interpretation + processing + decision making
  - Action taken or not taken
    - Correct or erroneous; potential for resulting harm

CDRH

www.fda.gov/humanfactors



REGULATORY SCIENCE

The science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products.

http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/default.htm

- Smart Algorithms for Advanced Physiological Monitoring
- Development and Validation of EEG Biomarkers for TBI
- Burn and Radiation Injury Workshop
- Battery-Powered Medical Devices Workshop
- Hemostatic Medical Devices used in Trauma
- Robotic Surgery
- 3-D Printing

CDRH 9

FDA PUBLIC WORKSHOP
PHYSIOLOGICAL CLOSED-LOOP CONTROLLED DEVICES

October 13 & 14, 2015 **FDA White Oak Campus**

- Focus on automation in critical care environments (anesthetic delivery, hemodynamic stability, mechanical ventilation)
- Concentrate on design, development, and evaluation challenges
- Assessment of unique benefits and risks
- Understand pre-clinical and clinical evidence needed to determine benefit/risk profile
- Initiate greater collaboration and interaction among stakeholders

Watch Recorded Webcast and View Speaker Presentations:
http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm457581.htm

CDRH

For additional information, please visit our website:
http://www.fda.gov/EmergencyPreparedness/MedicalCountermeasures

Questions?
Suzanne.schwartz@fda.hhs.gov

Allison.kumar@fda.hhs.gov

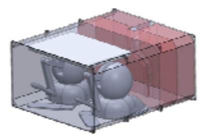
FDA
CDRH

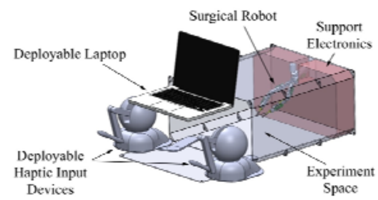
Multi-use dextrous robots for mission surgical capability

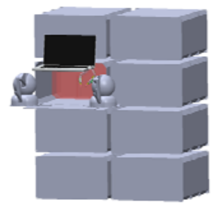
Center for Advanced Surgical Technology, University of Nebraska Medical Center

Portable system created to provide surgery capability controlled by a laptop station

- Single incision; minimally invasive
- Small, low mass, reusable
- Develop library of procedures with training protocols
- Multi-use
- Over 75 animal surgeries
- 1st human use planned for early 2016

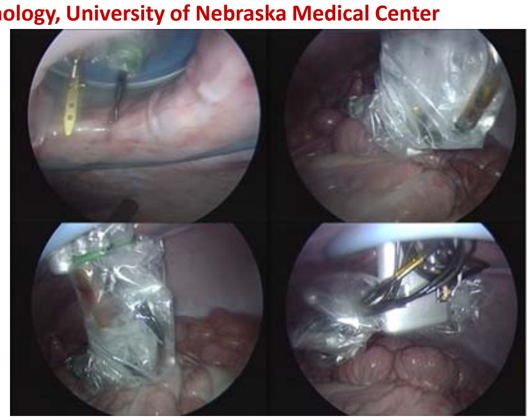


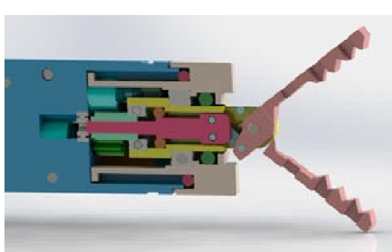


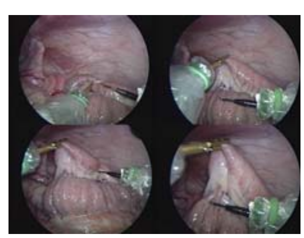


Multi-use dextrous robots for mission surgical capability

Center for Advanced Surgical Technology, University of Nebraska Medical Center







PROJECTED LEVEL OF SURGICAL CAPABILITY TRAINING FOR EXPLORATORY AND COLONIZATION SPACEFLIGHT

Degree of Complexity	Time Allowance for Training	Training Objectives
Not So Difficult	10+ hrs of training	Airway management (basic) IV/IO access Volume resuscitation as indicated Administering local anesthetic Focused PEx and FAST Obtaining hemostasis (simple) Closure simple wounds/fractures Dressing of wounds Telemedicine instructions (basic) Monitoring post-procedure condition
Fairly difficult:	1-2w externship at ACGME-accredited surgical training program	Airway management (moderate) Insertion of chest tube Administering regional anesthesia Obtaining hemostasis (moderate severity) Surgical closure of difficult wounds Telemedicine instructions (complex) Management of expected post-procedure complications Palliative care and support
Most difficult:	2-4 weeks at an ACGME accredited surgical training program	Advanced airway techniques Obtaining complex hemostasis (possibly intracavitary depending on ground FS/ground expert/CMO judgment Surgical management of large, complex wounds/complex comminuted/compound fractures Performing remote surgical procedures based on complex telemedicine instructions and/or autonomously Successfully managing unexpected post-procedure complications

NASA/TM–2014-217384

Identification of Medical Training Methods for Exploration Missions

Survey of 46 NASA providers on medical training: Summary Points
ExMC's Gap 3.01 on Medical Capabilitites

- Increase the time of training from ~ 40 hrs to ~120 hrs + OR experience
  - Exposure to live patient experiences preferred; train over time, rather than 1 block; scenario-based exercises and crew autonomy emphasized
- Train a smaller # of people in higher degree of skill set (from military)
  - Moulage scenarios, hands-on; repeated over time. "Pick 10 most common ailments, emphasize those"; refresher courses every few years
- Using a NASA panel of experts plus military data two highest ranking methods to base increased training
  - Higher levels of competency need to be achieved; Training that focuses on mission-specific info (needs)
- Given a choice of 9 areas to focus additional training; behavioral and surgery were in top 3 ranked
  - {behavioral 4.04; airway 3.93; surgery 3.77; IV/IO access 3.75; VS monitoring 3.68}
- Telemedicine training and ability to use emphasized

Blue RS, Bridge LM, Chough NG, Cushman JG, Khpal M, Watkins, S

Surgical Care in Human Space Flight – Exploration Missions

C. R. Doarn

Providing surgical care during space flight is dependent upon a number criteria and challenges. These are listed below:

Location of the space craft – LEO or transit missions to a distant location (Mars, etc). This may also include the moon. However, the moon in in close proximity

Communications – In LEO, the crew and ground will be in synchronous communications. The farther from Earth, the longer the delay in communications – therefore any communication will have to be asynchronous.

Training of the crew medical officer (CMO) – the person should be an MD but most likely will not be. It is currently not a requirement. Therefore there must be pre-flight training on systems, procedures, etc. This training will also be part of the in-flight training as well through simulations, etc. Other crew members who might support the CMO must also be trained.

Personnel – See training above. A surgeon is not likely to be on all flights to Mars. Therefore, the selection of the CMO and support personnel is critical.

Risk – The current risk matrix and future predictions of need must be reviewed and updated as appropriate. The risk must be carefully reviewed.

Surgical Care Systems

- Robotics and robotic assist devices
- Sensors
- Consumables / packaging
- Systems
- Communications
- Gases
- Sterility
- Trash management
- Decision Support Systems
- Anesthesia
- Per-operative system
- Monitoring devices
- Wound management
- Power
- Pharmaceutical (packaging and shelf life)
- Blood supply and other fluids
- Imaging
- Surgical field issues
- Containment

Challenges

- Anatomical changes
- Common terms
- Culture
- Resupply

Historical Perspective of Surgery in Space

Previous efforts/Reports

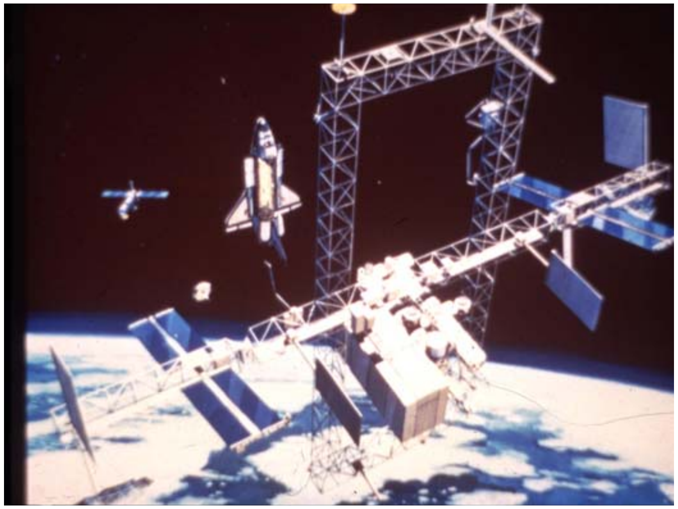
Flight experience

- 1970s – Skylab –limited surgical capabilities
- 1980s-2011 – Space Shuttle – limited surgical capabilities
- 1998 – Present – ISS – limited surgical capabilities (Neurolab)

Seminars/Subject Matter Experts

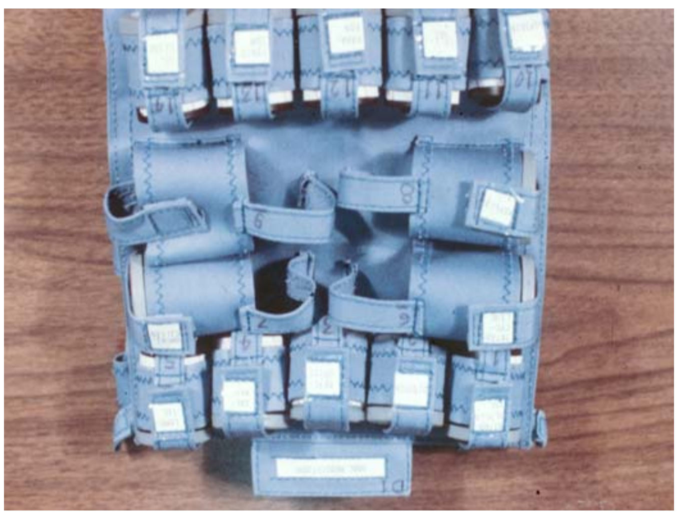
- Proceedings of SSF Medical Experts Seminar – NASA Conference Report 10069 – April 1991
- Strategic Considerations for Support of Humans in Space and Moon/Mars Exploration Missions – NAC Aerospace Medicine Advisory Committee report – 1992
- Dr. Samuel Pool / Dr. Norman McSwain Working Group
- Subject matter experts (Drs Bruce Houtchens, Mark Campbell, Smith Johnston)
- Ground-based research
- Parabolic flight experiments
- Surgery in Extreme Environments – Meeting Space Exploration Needs (USAMRMC-TATRC Contract W81XWH-05-1-0414 – PI - C. Doarn. Symposium held Dec 2005.

Dinner Presentations



History of Surgical Care in Space Symposiums

- 1983 Council of Trauma Surgeons
- 1991 Space Station Freedom HMF Consultants Conference
  - Surgical Care Issues Working Group
- 1996 Life Sciences Long Duration Spaceflight Conference
- 1997 Clinical Capabilities Development Project
  - Surgical Care Issues Working Group
- 2002 Long Duration Mission Surgical Planning Working Group (Dr. Norm McSwain)
- 2005 Surgical Science in Support of Human Space Exploration



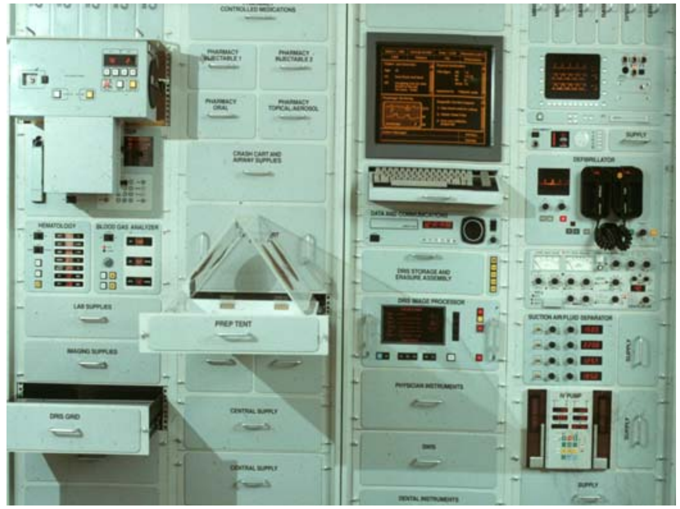
Space Station Freedom Health Maintenance Facility

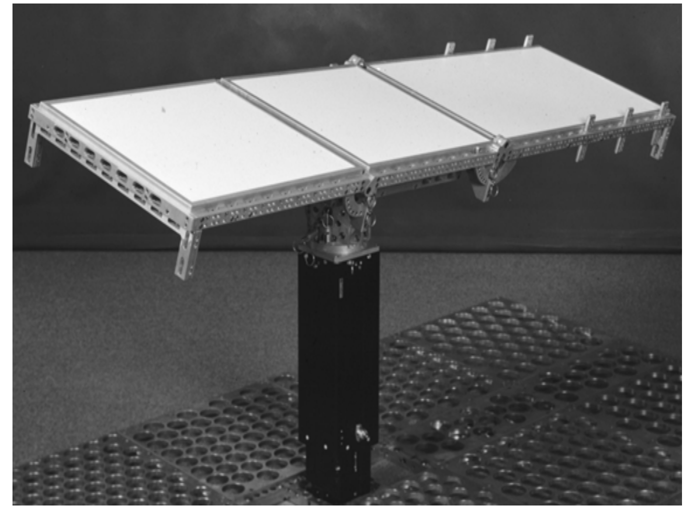
Space Station Freedom - 1984-1993
- No ACRV
- Definitive medical care time of 45 days
- CMO probably be an MD (some advocating a surgeon)

Health Maintenance Facility – 1200 lbs, 2400 sq ft
- Surgical workstation (waist level OR table)
- Digital X-Rays (DRIS)
- Task lighting
- Surgical cautery
- Ventilator, Defibrillator, IV pump
- Waste Management System, including surgical suction
- Medical computer
- Telemedicine
- Anesthesia

Space Station Freedom Health Maintenance Facility

Procedures
- Complex wound closures
- Chest tube insertion
- Tendon repair
- Appendectomy
- Amputation
- Ortho – splints or ext fixation
- Open abdomen, thoracic, vascular, ortho?
- Burr holes for head trauma?





Space Station Freedom HMF Consultants Conference

8/27-29/1990
Results published as NASA Conference Pub 10069

Charles Doarn
Roger Billica, M.D.

Changes to SSF/HMF
- Probably an ACRV present
- DRIS will probably be eliminated
- Cautery has an RFI problem
- Waist level workstation in doubt
- CMO will probably not be an MD
- Need to decrease weight, volume, and power

Space Station Freedom HMF Consultants Conference

Issues discussed in Surgical Working Group
- Cautery – not needed
- X-Rays
  - Controversial
  - Not needed for ortho
  - CXR is critical, esp for pneumothorax
  - U/S has future potential
- Capabilities
  - No open abd, thoracic, ortho, vascular, or burns
  - Need ATLS capabilities – C-Collar, Pelvic binder, Chest tube
  - Fractures can be treated with splints or ext fixation

Space Station Freedom HMF Consultants Conference

Issues that I presented:
- Concern about delayed wound healing during space flight
- Stressed need for CXR to diagnose pneumothorax
- Concern about bleeding, restraint, surgical performance
  - Unknown if a problem exists
- Concern about contamination of cabin atmosphere
  - May need containment hardware (Dr. Rock)
- "Don't put hardware onboard unless you have the CMO capability to use it."
- "Limitations will be based upon the CMO capabilities and not the hardware."

Surgical Issues in Weightlessness

- How to provide restraint to the patient, operator and equipment
- How to control bleeding and prevent cabin atmosphere contamination
- Can ATLS and ACLS procedures be performed in weightlessness?
- Can complex surgical procedures such as laparoscopy be performed?

Parabolic Flight Conclusions

Restraint can be accomplished by simple methods for patient and CMO

Instrument restraint is important and needs to be planned for in the system

Bleeding can be controlled

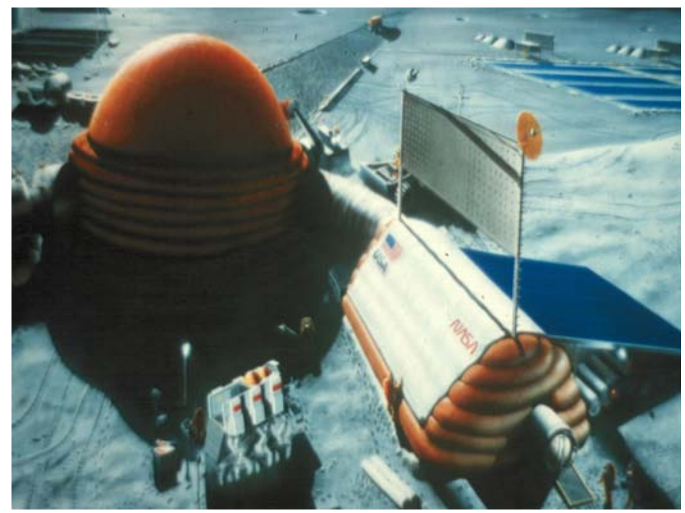
ATLS procedures can be performed

Complex surgical procedures can be performed. Not more difficult, but require increased time to perform.

Fluids behave differently than in 1g.

Life Sciences Long Duration Spaceflight Conference

- Moderated by Dr. Sam Pool
- Held over three days in 1996?
- No published results that I know of
- Concerned with prioritizing life sciences research required to enable future LDSF
- No focus on surgical issues, but surgical capabilities and limitations were discussed



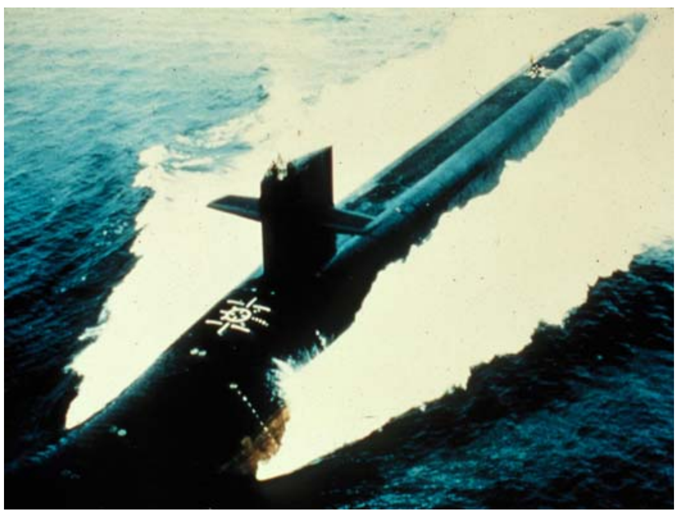
Conclusions – Most Important Challenges of LDSF

- Protection from Radiation effects
- Prevention of Deconditioning (Cardiac, Muscle, Bone)
- Psychological issues of isolation and group dynamics
- Provision of Medical and Surgical Care

  Emphasis on Surgical Care

Surgical Issues Discussed

Laparoscopy
Robotic surgery
Difficulty of telemedicine (8-56 minute time delay)
CMO capabilities (hopefully an MD)
Appendicitis and prophylactic appendectomy



SUBMARINE APPENDICITIS

	Rice	Rice	Wilken	Tansley	Glover
Population	Sub-WWII	Sub	Polaris	Polaris	Br. Polaris
Years	41-45	60-64	63-67	67-73	68-78
Appendicitis			9.88	9.75	23.5
Medevac			4.3	5.9	1.0
Sucess Tx	88.9%	84.6%	84.4%		95.0%

Antarctic Experience Australian

- One death following appendectomy
- 40% post-operative complication rate
- Difficult medical evacuation of Station Physician in 1950
- Incidence of 43.0 / Million person-days

Questions Concerning Appendicitis

- What will be the Incidence?
- How would we Treat?
  - Operative or Non-operative
  - Open or Laparoscopic
- Role of prophylactic appendectomy?

- Answers would affect design of Medical Care System
- Medical Care System design would affect the answers

Incidence of Appendicitis

U.S. - 20 YO - 1984 (Addiss)	5.6
U.S. - 40 YO - 1984 (Addiss)	3.6
LSAH - Astronauts	1.0
LSAH – Cohorts	2.1
Submarines	9.8 - 23.5
Antarctica	7.5 - 56.4
Subs -1993 (Cohen)	4.3
Antarctica -2002 (Ayton)	4.1

Non-Operative Treatment of Appendicitis

Harrison	(1953) -	47	(89.4%)
Coldrey	(1959) -	471	(89.8%)
Gurin	(1992) -	252	(84.1%)
Erickkson	(1995) -	20	(95.0%)
Vargas	(1994) -	12 (P)	(100.0%)
Skoubo	(1982) -	193 (P)	(88.0%)
Oliak	(2001) -	88 (P)	(94.2%)

Appendectomy

- Laparoscopic appendectomy
  - Faster patient recovery
  - Less contamination of spacecraft atmosphere
  - Logistics are extensive, but will improve
- Open appendectomy
  - Less equipment
  - Less training
  - Hardware and training adaptable to other surgical situations

Prophylactic Appendectomy

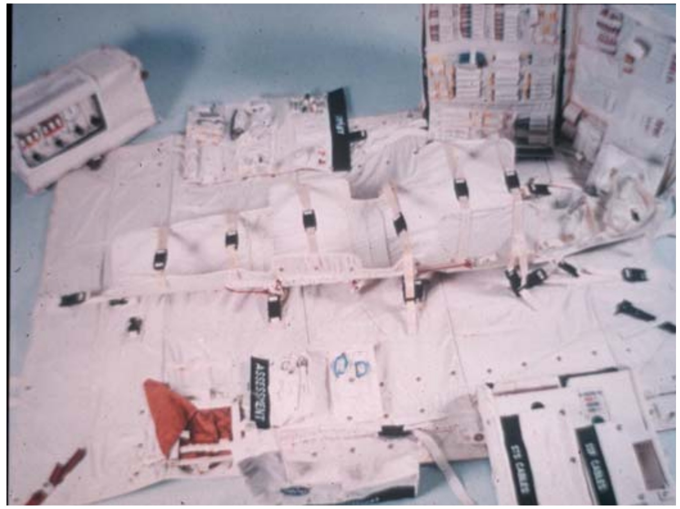
- Complications – small bowel obstruction
- Ethical considerations
- Political considerations
- Does not solve the problem of needing to be capable of treating other surgical problems

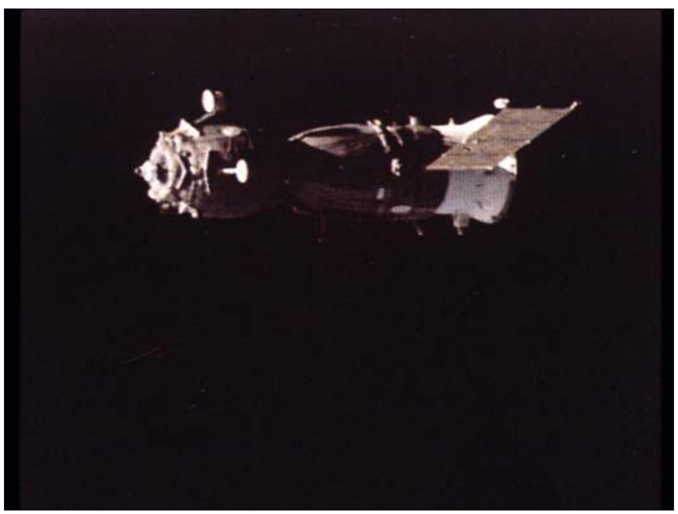
Clinical Capabilities Development Project

4/8/97
Roger Billica, M.D.
Conclusions published as a NASA document
Mostly focused on ISS, but also future LDSF

Changes - the SSF was now the ISS
- HMF at 1200 lbs was now the HMS at 200 lbs
- Waist level workstation was now the CMRS (floor level)
- ACRV was present (Soyuz or X-38)
- CMO was not an MD

Capabilities
- ATLS – Advanced Life Support Pack
  - No chest tube capability!
- ACLS – CPR, Defib, Monitor
- Ventilator – Respiratory Support Pack
- Stabilization, monitoring, transport
- No integrated surgical kit, no instrument restraint





Medical Evacuation Concerns

- Class II hemorrhage
- 1.8g return vehicle
- Deconditioned astronaut
  - 10% Plasma loss
  - Anemia
  - Baroreceptor loss
  - Cardiac deconditioning (10% loss in stroke volume)

Clinical Capabilities Development Project

Issues discussed in Surgical Working Group

- Wound healing – delayed in spaceflight?
- Increased risk of wound infection
- X-Rays, U/S
- Laparoscopic surgery - Mars
- Robotic surgery - Mars
- Use of blood substitutes
- Treatment of appendicitis – ISS, Mars
- CMO capabilities – ISS, Mars

Clinical Capabilities Development Project

Controversies

- Chest tube capability on ISS
- No integrated surgical kit on ISS
- Endoscopic stenting for ureterolithiasis - Mars
- Re-sterilization – Mars
- CMO capabilities
- Prophylactic appendectomy - Mars

Clinical Capabilities Development Project

Issues that I discussed:

- No problems with bleeding, restraint, sterile field
- Telemedicine difficulties due to time delay for Mars
- Laparoscopy – increase in hardware and training
- CMO capabilities/limitations more important than hardware
- "Not any operation performed laparoscopically that cannot be performed easier and with less hardware open."

Clinical Capabilities Development Project

"There are a thousand ways to die on the Shuttle that have nothing to do with medical care." - Ellen Baker, M.D. April, 1997

Long Duration Mission Surgical Planning Working Group

- October 2002
- Chaired by Dr. Norm McSwain
- No published results
- Members (20) were academic leaders in surgery and critical care medicine (not space medicine)
- Given Mars Design Reference Mission, what surgical events need to be treated
- What should be the Expedition Medical Officer credentials and training
- Developed detailed training curriculum

Selected Surgical Capabilities

- High incidence
- High impact to mission or crewmember
- High ability that treatment will result in a curative result
- Minimal hardware logistics
- High ability to train Expedition Medical Officer

Selected Surgical Capabilities - Examples

- Appendectomy
- Exploratory laparotomy
- External fixation of fractures
- No Vascular surgical procedures
- No laparoscopic procedures ?
- Many procedures have percutaneous options

Expedition Medical Officer Training

- Board certified in a residency pre-training
- Selected as an astronaut
- One year focused training for Expedition Medical Officer
- Would need training in a variety of fields other than surgery (only six months of surgical training)
- Could perform selected surgical procedures at level of second year surgical resident

Conclusions – NASA Surgical Training Working Group

- **Need to have enough surgical capability to perform major open procedures (exploratory lap and appendectomy)**
- **Some surgical diseases can not be treated (Vascular surgery is not trainable)**
- **Laparoscopy may not be available**
- **Many procedures can be performed with imaging and percutaneous techniques**

Conclusion

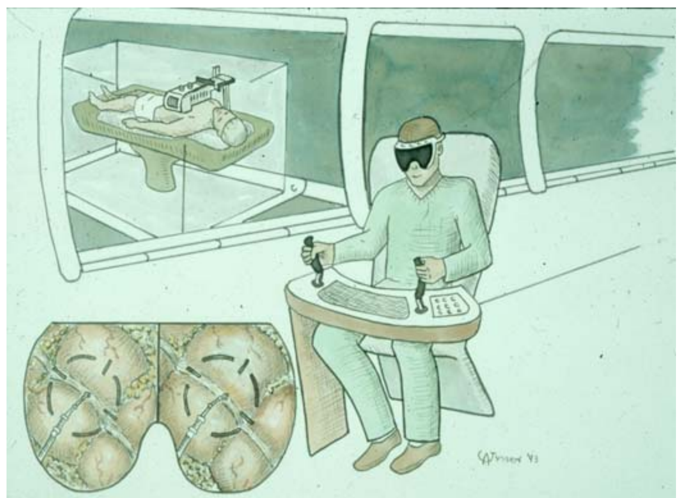
We need to have the capability (hardware, supplies, Expedition Medical Officer training) to perform a large number of surgical procedures on future long duration space flights, including but not just appendectomy.

Surgical Science in Support of Human Space Exploration

- December 2005
- Chaired by Chuck Doarn
- Published results (can be accessed via Chuck Doarn)
- Attendance
  - Desmond Lugg, MD
  - Timothy Broderick, MD
  - Richard Satava, MD
  - Dave Williams, MD
  - Ricahard Williams, MD
  - Jeff Jones. MD
  - Igor Goncharov, MD
  - Kenneth Kamler, MD
  - Ken Mattox, MD
  - Andy Kirkpatrick, MD
  - Mark Campbell, MD
  - Ellen Baker, MD

Surgical Science in Support of Human Space Exploration

- Discussed topics
  - Robotics
  - Laparoscopy
  - Urological ureteral stenting
  - Percutaneous drainage (U/S)
  - Ultrasound (FAST, PTX)



Robotic Surgery Limitations (Challenges)

- Currently still not conventional (not universily accepted) in all areas
- Hardware constraints
- Increased training time
- Equipment unreliability and is not repairable
- Limited use for specific problems
- Communication delay too large

Ultrasound in Parabolic Flight

- Pneumothorax air is centrally loculated
- Chest fluid does not loculate, but disperses within the chest cavity
- Abdominal fluid (blood) does not loculate posteriorly, but stays where it is created
- Ultrasound useful for pneumothorax detection and for percutaneous techniques
- Easily trainable and telementoring feasible

8.0 Management of the Perioperative Environment

Surgical Capabilities for Exploration and Colonization Spaceflight

Data Management

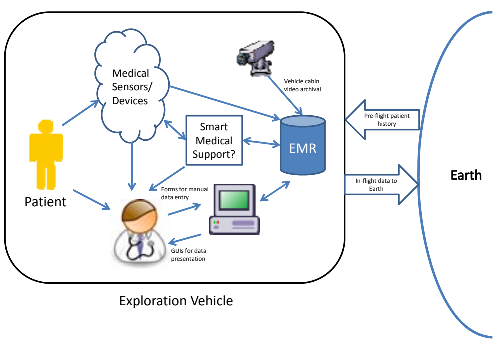
Jimmy Wu
NSBRI
12/10/2015

Exploration Spaceflight Medical Data Challenges

- Communication latency between vehicle and Earth
- Care provider medical skill level
- Radiation exposure
- No need for billing capability
- Lack of data standardization between devices

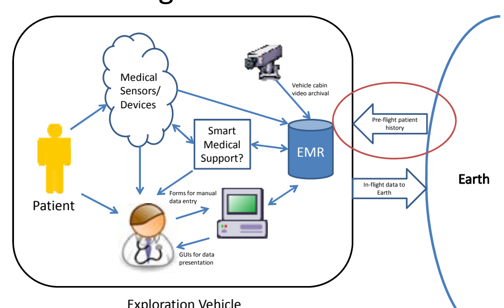
2

Data Sources and Destinations



3

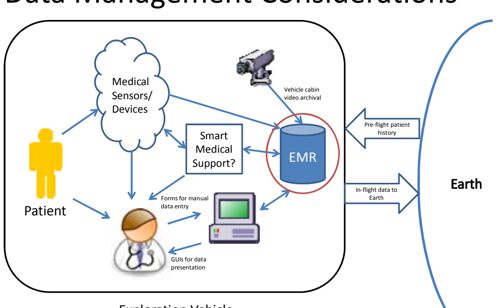
Data Management Considerations



Consideration #1: How much patient history is sent with the mission?
Consideration #2: Will CMO have full access to all crewmembers patient history?

4

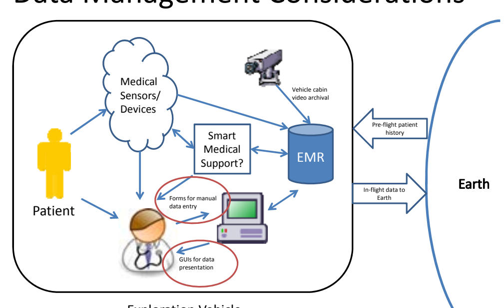
Data Management Considerations



Consideration #3: Data redundancy and backup plan

5

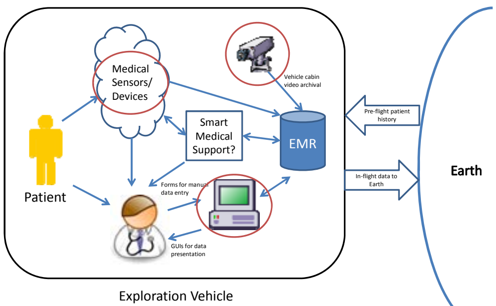
Data Management Considerations



Consideration #4: Will data entry forms be customized based on CMO skillset?
Consideration #5: Will GUIs be customized based on CMO skillset?

6

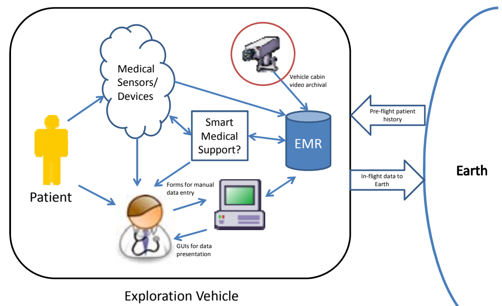
Data Management Considerations



Consideration #6: What is the purpose of data collected/managed?
Consideration #7: Data collected shall be timestamped from a universal time source

7

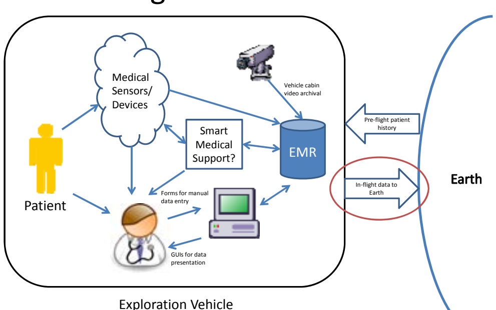
Data Management Considerations



Consideration #8: Data security

8

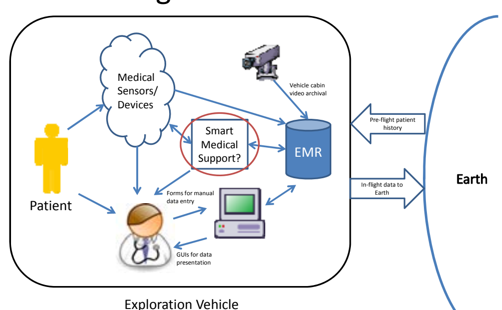
Data Management Considerations



Consideration #9: What is the plan for data transfer with ground support?

9

Data Management Considerations



Consideration #10: Will non-human autonomy be allowed?

10

Summary

- Multiple data sources and destinations
- Multiple considerations to address that accompanies every surgical capability to be flown
- Synchronization of all medical activities under universal vehicle time
- Recommend development of Surgery System Data Management Plan to address intra-vehicle and vehicle-to-Earth data communications

11

Anesthesia
for Colonization and Exploration of Mars and the Moon

Hal Doerr, MD
UT Houston

Anesthesia
for Colonization and Exploration of Mars and the Moon

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UT Houston

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Standard Induction Sequence

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Alternate Induction

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UT Houston

Anesthesia
for Colonization and Exploration of Mars and the Moon

Types of Anesthesia

- Fluids
- Medications
- Training
- Risk Assessment

Hal Doerr, MD
UT Houston

Anesthesia
for Colonization and Exploration of Mars and the Moon

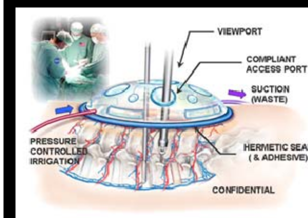
Types of Anesthesia
- Spinal/ Epidural
- Regional
- TIVA
- General Anesthesia
- Sedation With Local infiltration

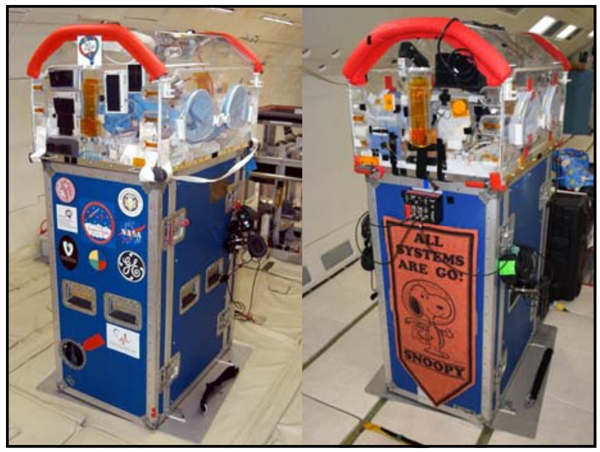
Hal Doerr, MD
UT Houston

PARABOLIC FLIGHT EVALUATION OF A HERMETIC SURGICAL SYSTEM (HESS) FOR REDUCED GRAVITY 49-P

George Pantalos, Morgan Crigger, Trey Kennedy, Ishita Jain, Elvis Joseph, Garrett Shields, Gordon Lents, Tommy Roussel, University of Louisville/CII
Jenn Hayden, Tyson Montidoro, Elif Ayvali, Cecelia Morales, Alyssa Meyer, James Burgess, James Antaki, Carnegie Mellon University/BME

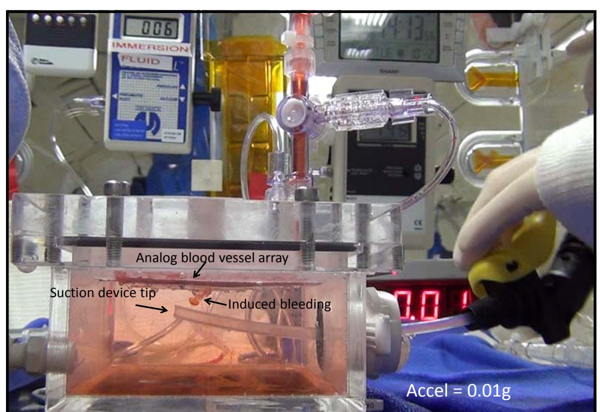
AQUEOUS IMMERSION SURGICAL SYSTEM (AISS)

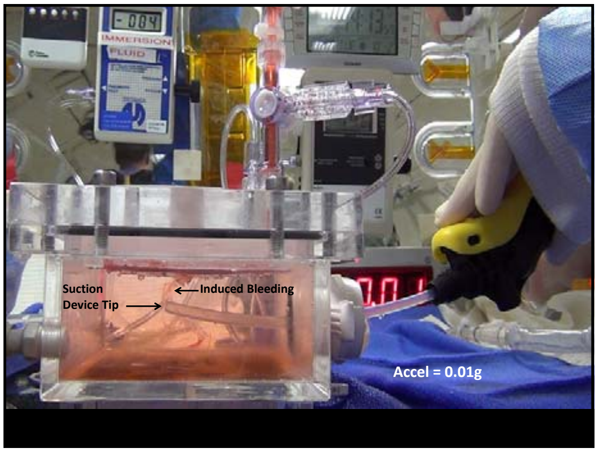




The goal of Experiment 49-P is to develop a medical device that contains and controls the surgical field while permitting surgical tasks in a reduce gravity environment. This goal is required for any surgical procedure in reduced gravity whether it is conducted by a robotic surgical system or a human surgeon and open or MIS.

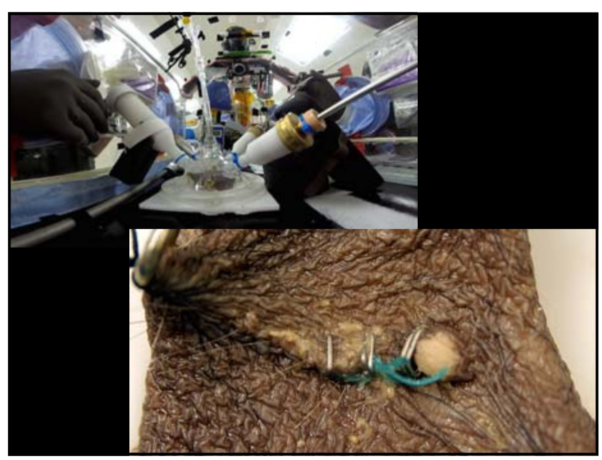
● Contaminating debris cannot enter or exit the surgical field
● Bleeding needs to be stopped and the visibility of the surgical field needs to be kept clear
● Surgical tasks need to be easily accomplished.

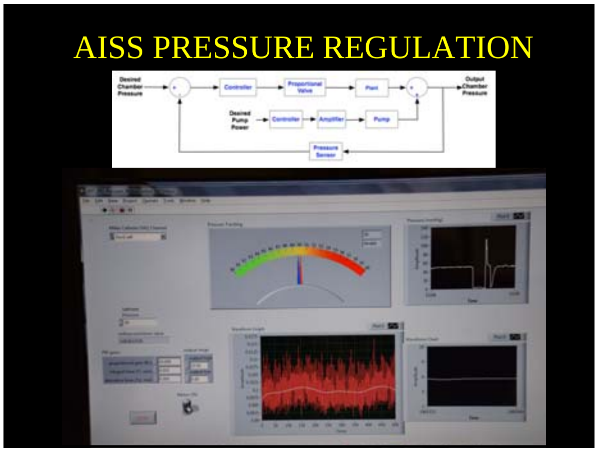


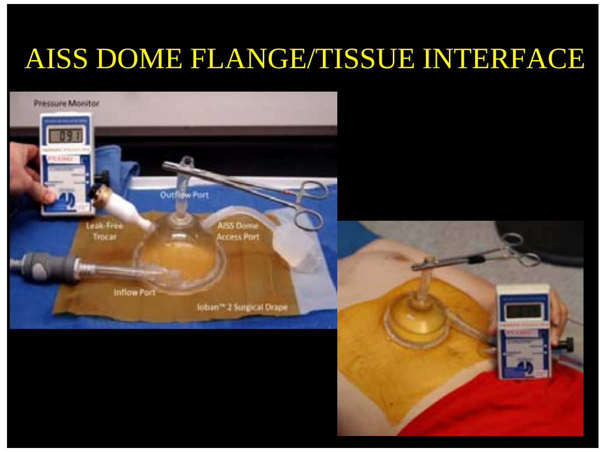

Suction
Device Tip
Induced Bleeding
Accel = 0.01g

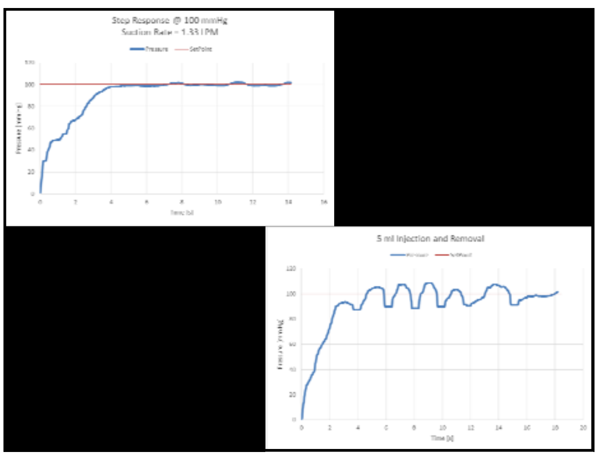

Astrosurgery Dome – Leak Tests

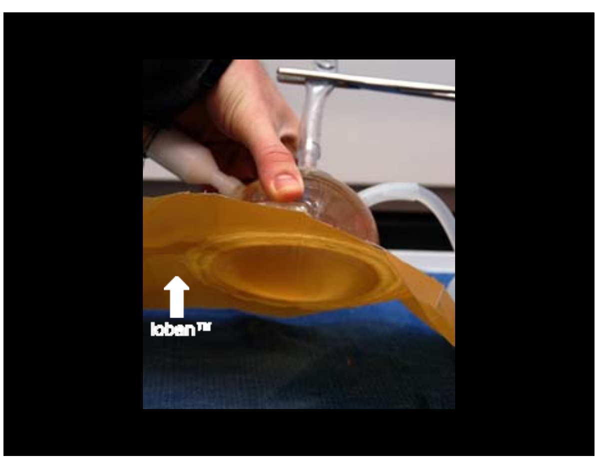

LEAK-FREE TROCAR DESIGN



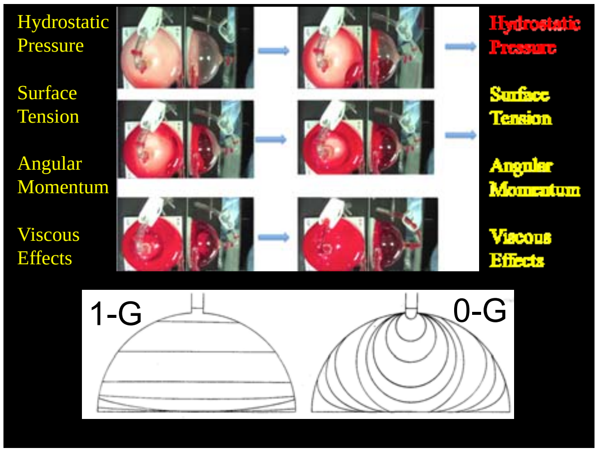

AISS PRESSURE REGULATION
Desired Chamber Pressure
Controller
Proportional Valve
Plant
Output Chamber Pressure
Desired Pump Power
Controller
Amplifier
Pump
Pressure Sensor

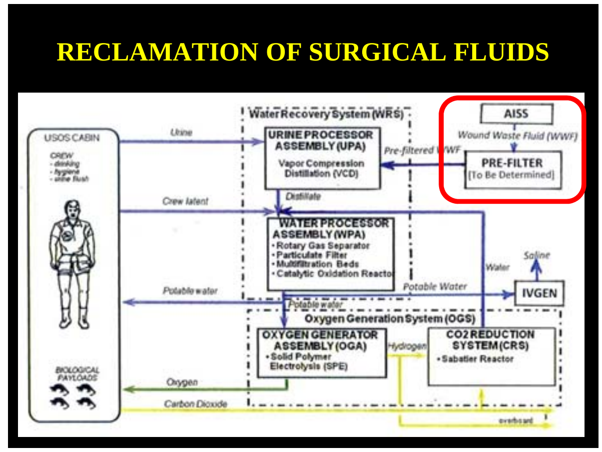

AISS DOME FLANGE/TISSUE INTERFACE
Pressure Monitor
Outflow Port
Leak-Free Trocar
AISS Dome Access Port
Inflow Port
Ioban™ 2 Surgical Drape

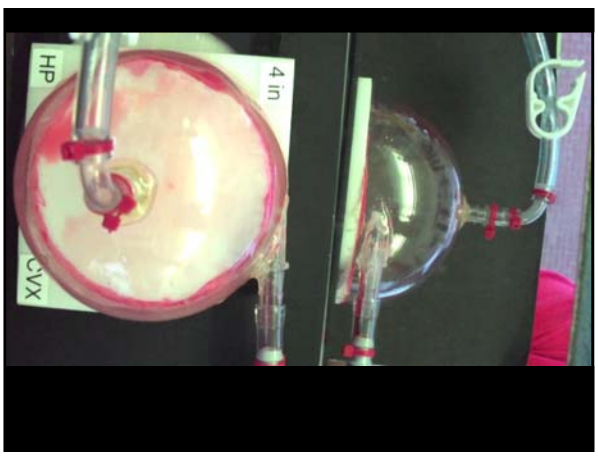

Step Response @ 100 mmHg
Suction Rate ~ 1.33 LPM
5 ml Injection and Removal

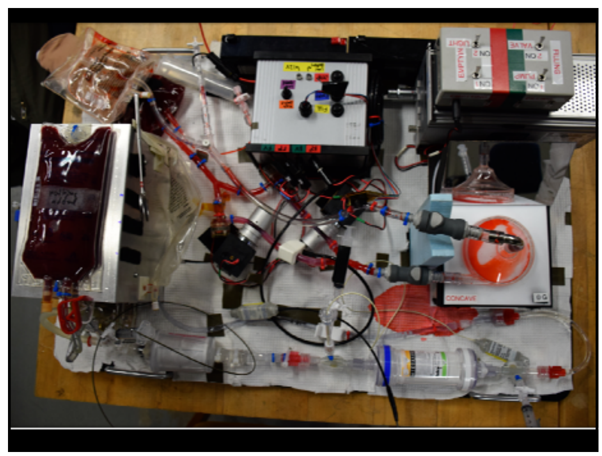

Ioban™

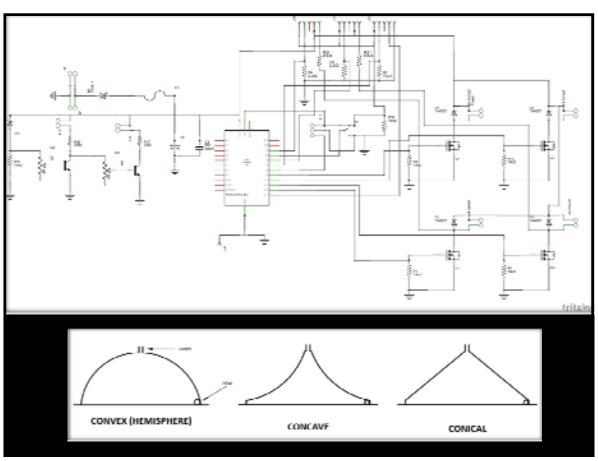

Simulated Skin
Dermabond™ Glue
Flange

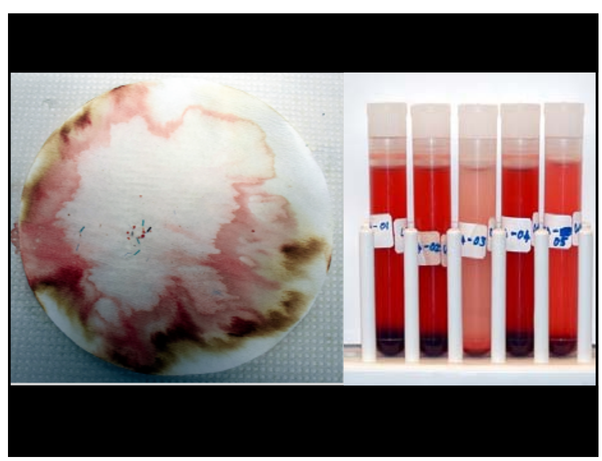

Hydrostatic Pressure
Surface Tension
Angular Momentum
Viscous Effects
Hydrostatic Pressure
Surface Tension
Angular Momentum
Viscous Effects
1-G
0-G


RECLAMATION OF SURGICAL FLUIDS
USOS CABIN
CREW
- drinking
- hygiene
- urine flush
Urine
Crew latent
Potable water
Oxygen
Carbon Dioxide
BIOLOGICAL PAYLOADS
Water Recovery System (WRS)
URINE PROCESSOR ASSEMBLY (UPA)
Vapor Compression Distillation (VCD)
Distillate
WATER PROCESSOR ASSEMBLY (WPA)
• Rotary Gas Separator
• Particulate Filter
• Multifiltration Beds
• Catalytic Oxidation Reactor
Pre-filtered WWF
AISS
Wound Waste Fluid (WWF)
PRE-FILTER
[To Be Determined]
Water
Saline
Potable Water
IVGEN
Potable water
Oxygen Generation System (OGS)
OXYGEN GENERATOR ASSEMBLY (OGA)
• Solid Polymer Electrolysis (SPE)
Hydrogen
CO2 REDUCTION SYSTEM (CRS)
• Sabatier Reactor
overboard


HP
4 in
CVX




CONVEX (HEMISPHERE)
CONCAVE
CONICAL



SUBORBITAL FLIGHT EVALUATION:
Virgin Galactic SpaceShipTwo

THANK YOU FROM 49-P!

Overview of the IVGEN Experiment

Surgical Capabilities for Exploration and Colonization Space Flight: An Exploratory Symposium

9 December 2015

John McQuillen
Sam Hussey
NASA Glenn Research Center
Cleveland, OH

Dan Brown
John Zoldak
ZIN Technologies, Inc
Cleveland, OH

Motivation

- Long duration missions increase likelihood of mishap/medical emergency.
- Need for IV Fluids:
  - 115 medical conditions listed in ISS Patient Condition DataBase (PCDB).
  - 8 drugs available on ISS.
  - Certain conditions require ≥32 L (~32kg/70.5lbs). §
- Mass limitations and lack of refrigeration may limit the type and volume of fluids that can be carried aboard the spacecraft. Due to the volume and mass requirement of the required amount of need fluid, NASA has determined that generating IV fluids onboard requires less mass and volume.
- IVGEN conducted a flight test of such a system in preparation to deploy a system on exploration missions.

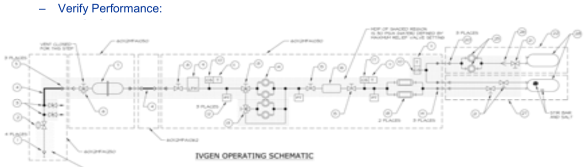
§ US Naval Flight Surgeon Handbook, 2nd Ed (1998)

Objectives

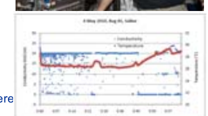
- Design a compact water purification system to reliably produce Sterile Water for Injection (SWI) in a reduced gravity environment.
- Integrate production system with reduced gravity pharmaceutical mixing capability.
- Verify a prototype aboard the ISS during Increment 24.
- Prototype system size and production rate should be the minimum necessary to meet requirements.
- Filter capacity should be easily re-scalable to meet exploration requirements and constraints.

Background

- Exploration Medical Capability (ExMC) –
  - Monitor and Treat Each Condition.
  - Gap: Lack of in situ intravenous (IV) fluid generation and resource optimization capability.
- Multiple methods of water purification and mixing were evaluated including previous shuttle experiment.
- Description of Hardware Function:
  - Acquire & Utilize ISS Potable Water.
  - Purify.
  - Mix with Pharmaceutical.
  - Sterilize.
  - Verify Performance:



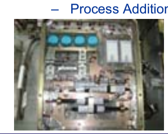
ISS Space Flight



- ISS Flight
  - Launch to ISS in April 2010.
  - Installed in MSG.
  - Operated 4 -6 May 2010:
    - 2 Bags of Saline Solution Produced.
    - 4 Bags of Purified Water Produced.
  - Saline Solution Returned for Evaluation per USP Standard.
  - Purified Water Recycled aboard ISS.
- ISS Results
  - Met On-Orbit Performance Requirements:
    - Flow Rate ~ 20 mlpm.
    - System Pressure Loss < 10 psid.
    - Purified Water to Conductivities less than 1 μS/cm.
    - With exception of gas bubbles, saline solution conductivities were uniform during transfer. Gas Bubbles were removed during purification process. However, mixing bags were not evacuated prior to filling and residual gas was mixed with liquid.
  - USP Testing:
    - Sterility Pass.
    - Endotoxins Pass.
    - Saline Concentrations Failed:
      - Bag 1, salt concentration too high – likely cause is not enough water.
      - Bag 2, salt concentration too low – insufficient salt premeasured into mixing bag.

Hardware Return Activities

- Original Plan:
  - Only the two bags of Saline Solution to be returned.
  - Sensor performance transmitted to earth.
  - Experimental hardware and spare bags to remain on orbit.
- STS-135/ULF-7 in July 2011:
  - Housecleaning exercise.
  - Returned all IVGEN hardware.
- Hardware Return:
  - Inspection:
    - No signs of obvious bacterial contamination found.
    - Evaluate "holdup volume" of system.
  - Process Additional Water in April 2012.



Additional Water Processed

- Caveats to testing:
  - USP specifies system to be dried and purged for periods of non-usage.
  - Pall specifies 96 hour lifetime for filter after membrane has been wetted.
  - Water similar in quality to ISS potable water used, approximates purified water with iodine doping.
- Testing
  - Additional Water Processed and measured using IVGen system. Processed 30 liters of purified water but did not exceed 1μS/cm criteria for acceptable purity.
  - Quantitative Analysis.
    - Cation concentration less than 1 ppm
    - Anion concentration less than 2 ppm
    - TOC ~ 6 ppm
  - Fourth bag mixed with saline and sent for USP testing.
    - Passed all tests except for conductivity (9 μS/cm) and TOC's
    - Per USP TOC is to be measured at Point of Generation; however, it was measured at Point of Consumption.
    - Conductivity measured during generation was less than 1 μS/cm.
    - ***Suspect that bag material may be contaminating samples***

Shelf Life Testing

Rationale:

- DI resin performance negatively affected by humidity and exposure to air.
- Charge on PALL filter membranes.

Prepare Cartridges:

- Used Fresh DI resin.
- Flight like with some minor differences.
- Heat Sealed in foil pouches.
- Get Baseline

Conclusions after 36 months.

- Testing show that to prevent exceeding target concentrations, for small volumes of processed water, may need to burp at least 100 ml of water through the system prior to mixing.
- While there is some removal of TOC's by DI cartridge, not sufficient to meet USP standards. It may be necessary to incorporate an activated carbon filter if spacecraft potable water does not incorporate.
- Each batch of DI resin needs to be baseline tested.

Considerations:

- System Level:
  - Items should have potential for multiple uses.
  - Resources are limited by mass, volume, power and crew availability in a HEALTHY spacecraft. Resources are diminished in a compromised spacecraft.
  - Terrestrial options are not assured in a spacecraft, e.g., batteries are a safety issue.
  - Shelf life – 6 months to pack, 36 months for round trip.
- Fluids in reduced gravity:
  - Bubbles can cause havoc:
    - Prefer areas of low pressure in plumbing systems and components.
    - Coalescence occurs much more readily.
  - Mixers separate as fluid is centrifugally accelerated.
  - Interaction of fluids with other spacecraft systems may result in toxicity issues.

Summary

- Spaceflight experiment was successful.
- Additional working on-going to validate shelf life of cartridges.
- Needed work:
  - Validating irradiation of salt crystals as method of sterilization.
  - Selection of bag material to prevent TOC contamination.
- Limited commercial market.

9.0 Technical Support for Surgery

Hemostasis Capabilities for Exploration and Colonization Space Flight

Kenton Gregory MD
OHSU Center for Regenerative Medicine
Portland, Oregon

Financial Disclosures

Financial Interests Related to Presentation

RevMedX Inc: Founder, Chairman, Chief Medical Officer, Equity

HemCon Inc: Patent owner, royalty stream

General Financial Interests (Unrelated)

Regenerative Medicine

- Tissue Genesis Inc-Founder/Equity
- Oregon Biomedical Engineering Inc-Founder/Equity/Board Member

Biotechnology

- Synedgen Inc: Founder/Equity/Board member
- Allegory Venture Partners-Scientific Advisory Board

Hemorrhage in Space Flight/Colonization- A Predictable Catastrophe

- Trauma-
  - External Hemorrhage
  - Internal Hemorrhage(Cavitary)
- Surgical Hemorrhage
- Disease States

Compared to Terrestrial Injuries:
More Blunt Trauma
Less Head Trauma

Physiological Challenges of Microgravity Amplify Consequences of Blood Loss

- Circulating blood volume reduced 10-20% at baseline
- Decreased red cell mass-10-20%-"Anemia of Space Flight"
- Thrombocytopenia
- Attenuation of adaptive responses to hemorrhage/hypovolemia
  - Decreased baro-reflexes/chronotrophic response
  - Cardiac atrophy and reduction in cardiac output
  - Decreases in vascular tone/responsiveness
- Elevated venous pressure: increased venous bleeding
- Downstream issues: What happens when the bleeding stops?
  - Blood component replacement/regeneration limitations
  - Trauma-induced Systemic Inflammatory Response Syndrome
    - Hemorrhagic Shock, ARDS, AKI, Septic Shock

Requirements for Space Based Hemorrhage Control Technologies

- Controls hemorrhage immediately:
  - Keep blood in the body because we don't start with a full tank and it is difficult to replace it
- Light weight, small volume
- Simple/fast/no mixing/easy to use
- Safe-Do not want to manage complications
- Minimal storage requirements
- No micro-gravity issues (powders, free liquids)
- Works with simple restraint systems
- Minimal need for adjunctive surgical removal
- Minimal disposal issues

Terrestrial/Space Hemorrhage Control Armamentarium

- Compression
  - Manual compression, tourniquets, internal compressive agents
- Clotting
  - Pro-coagulant dressings, powders, UTZ
- Sealing: glues, sealing dressings, foams
- Drugs: TXA, Aprotinin, Factor VIIa
- Clotting factor replacement: Lyophilized Plasma
- Surgery, clamps, sutures, repairs
- Endovascular-Coils, balloons, stents

Non-Compressible Hemorrhage Control

Military Need/Requirement

Hemorrhage is the leading cause of death on the battlefield, and one of our most challenging forms of hemorrhage has been junctional hemorrhage, or hemorrhage from deep wounds on which it is impossible to put a tourniquet or apply manual compression externally…

Dr. Anthony Pusateri, Department of Defense Hemorrhage and Resuscitation Research and Development Program

Spec Ops Fix-a-Flat Strategy

Insert a device into deep and penetrating wounds that will deploy nanoparticles, foam, or polymer to enable hemostasis.

Problems:

1. Foams wash away with torrential arterial bleeding
2. Pressure issues
3. What goes in, must come out-or biodegrade with minimal inflammation

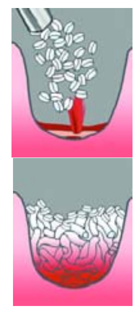
Solution

Direct pressure is the most effective way to control severe bleeding.

Compressed sponges that absorb blood and rapidly expand, generate and maintain hemostatic pressure on bleeding sites from inside out to stop hemorrhage.

"It is a capability that has never existed before, and can be used in the field setting by medics…"

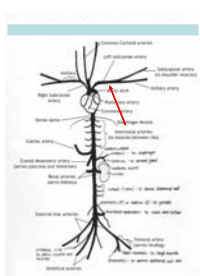
Dr. Anthony Pusateri, Department of Defense Hemorrhage and Resuscitation Research and Development Program



Swine Subclavian Artery Injury

- Non-compressible Injury
- Severe Bleeding (>1.5L/min)
- Narrow Entrance
- Deep Cavity
- Combat Relevant

…except possibly non-survivable



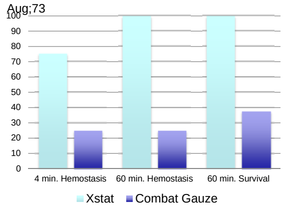
Subclavian Wound Model

Subclavian Pre-clinical Data

Xstat delivered without external compression is superior to military-standard hemostatic gauze delivered with 3-5 minutes of external manual compression

Post-treatment Primary Endpoints:
- Hemostasis at 4 min.
- Hemostasis at 60 min.
- Survival at 60 minutes

A novel sponge-based wound stasis dressing to treat lethal non-compressible hemorrhage. Mueller, et. al., J Trauma Acute Care Surg. 2012 Aug;73

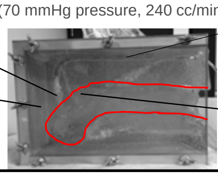


Subclavian Model – Secondary Endpoints

Metric	Combat Gauze Mean (SD)	Feasibility X Stat Mean (SD)	p-value
Hemoglobin at Study Termination (g/dL)	4.3 (13)	6.6 (1.0)	0.018
Mean Arterial Pressure at Study Termination (mmHg)	35.6 (25.8)	70.5 (5.4)	0.002
Total Blood Loss (cc)	1242.6 (907.1)	118.0 (307.9)	0.021
Total Application time (s)	420.0 (111.1)	25.1 (4.9)	0.004
Wound Cavity Volume (mL)	255.1 (102.6)	343.6 (113.0)	0.075

In vitro Uterine Simulator

- Uterine cavity formed with Perma-Gel, a synthetic reusable ballistics gel.
- Plexiglass plate allows viewing of tamponade agents in the cavity.
- Two pressure sensors connected to a data acquisition system (National Instruments USB-DAQ 6008) and controlled with a customized Labview software program.
- Bleeding simulated by passing clear, glycerol-based blood mimic through bag with pinholes (70 mmHg pressure, 240 cc/min flow rate).



In vitro Xstat Uterine Cavity Modeling

Xstat prototypes sponges proved effective at filling the uterine cavity

Xstat rapidly created and maintained high levels of fundal pressure—essential to stopping PPH

Xstat outperformed routine tamponade agents (kerlix, condom balloon catheter).

Xstat sponges filling simulated uterus during *in vitro* modeling.

Group	n	Fundus Pressure (mmHg)	Flow reduction (%)	Application Time (sec)	Removal Time (sec)
Kerlix	8	15.5 (8.0)	-55 (10)	59 (10)	9 (2)
Uterine Balloon	8	8.2 (10.4)	-19 (17)	194 (73)	18 (8)
XSTAT	8	113.0 (28.6)	-35 (9)	11 (2)	266 (85)
XSTAT bag	8	85.8 (29.0)	-74 (18)	12 (3)	10 (2)

Xstat Device

First-in-kind self-expanding wound dressing for internal use

Syringe-like applicator applies compressed mini-sponges into deep wounds (variety of applicator sizes in development)

X-ray detectable marker embedded in each sponge ensures retrieval

FDA-approval received April 2014/December 2015

First Human Use: Safe/Successful

XGAUZE: A highly absorbant, expanding guaze that can exert and maintain hemostatic pressure

XSTAT Biodegradable

Army Femoral Artery Hemorrhage Model: 6mm punch

Wound Healing in Micro-gravity

Wound Healing in Micro-Gravity

- Neuro-Lab expt show surgical wounds heal in neonatal rodents
- Neonatal animals have extraordinary healing powers
- Juvenile animals have excellent healing esp rodents
- Adult animals and humans have limited healing/regeneration
- Trauama/surgical wounds heal via SDF-1 directed resident and bone marrow stem and progenitor cell mediated responses
- Hematopoetic lineage stem and progenitor cells are repressed in microgravity
- Proliferating cells are affected by radiation

Achilles' Heel of Autologous Stem Cell Rx: Cell Functionality
The Variable Potency of Autologous Stem and Progenitor Cells

Profound variability in patient's stem cell function

Space Effects: Radiation/microgravity on proliferating bone marrow and tissue stem and progenitor cell niches

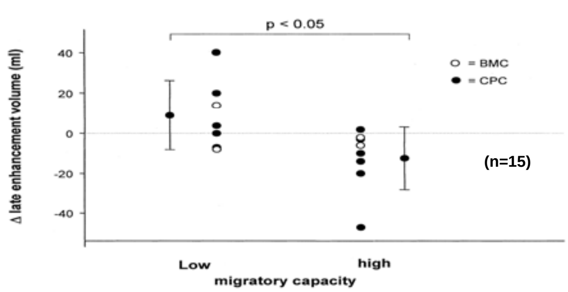
- Age of patient/stem cells
- Co-morbidities: Diabetes, TRAUMA?
- Statin use
- Cell preparation: Cell washes, manipulations, RBC contamination, heparin exposure, fresh vs. frozen

– Potency assay: Determining healthy cells. FDA regulatory need

- Cell viability (Trypan blue), CFU-not helpful
- "Consensus (MSC) Markers do not Correlate with Functional Heterogeneity" (Steve Baer)

"SDF migration is the only test that has a correlation with clinical benefit from cell treatment" Brittan MB: Circulation, 2003; 108:2212-1218

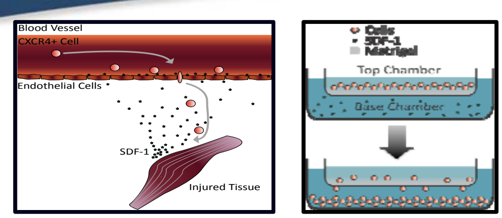
SDF-1 Migration Predicts Improved Cardiac Infarct Remodeling



(n=15)

Britten M et al. Circulation 2003; TOPCARE Trial 108:2212-2218

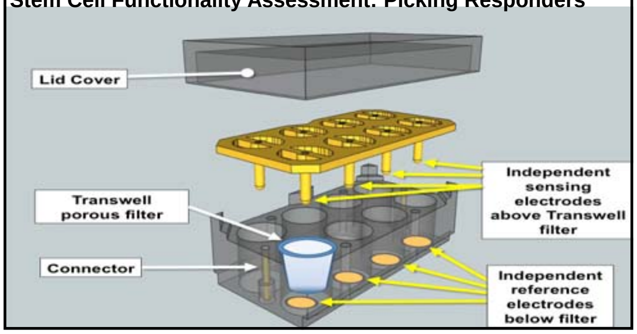
Cell Function Analysis: SDF-1 Directed Migration

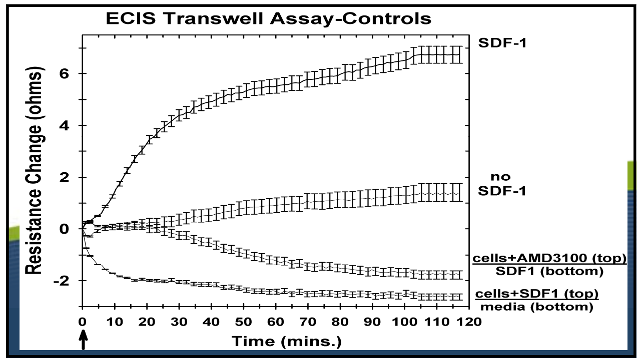


SDF-1 Directed Migration of Regenerative Cells Modeled by an Invasion Assay

Problem: Testing takes 30 hours

Stem Cell Functionality Assessment: Picking Responders

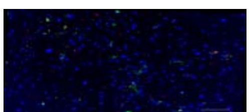


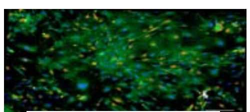


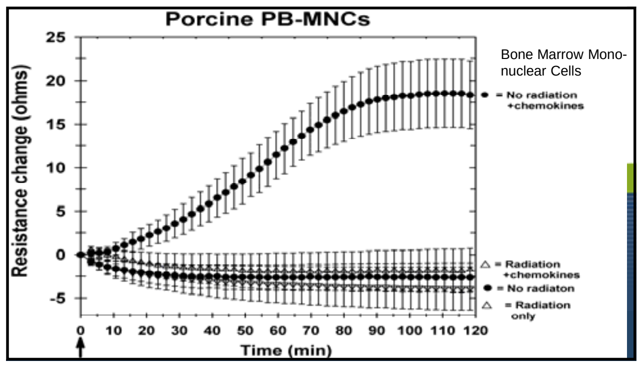
Regenerative Medicine for Cancer Survivors

Upside: Advances in cancer diagnostics and therapies have produced millions of cancer survivors.

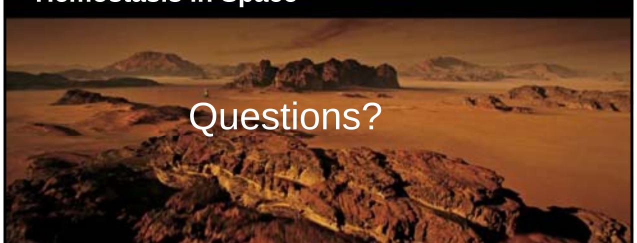
Downside: Chemotherapy and Radiation treatments very frequently cause collateral damage – 'off target' effects on normal tissues, particularly in children.


Cardiac stem cells


After Radiation (2 Gy)



Hemostasis in Space



3D Bioprinting in Space
Bioinks

Stuart K. Williams, Ph.D.

Director, Biofical Organs Program
University of Louisville
Louisville, Kentucky

Biofical Organs, LLC
Louisville, Kentucky

cvregen@gmail.com
@cvregen
cvregen.com

(502) 693 5250

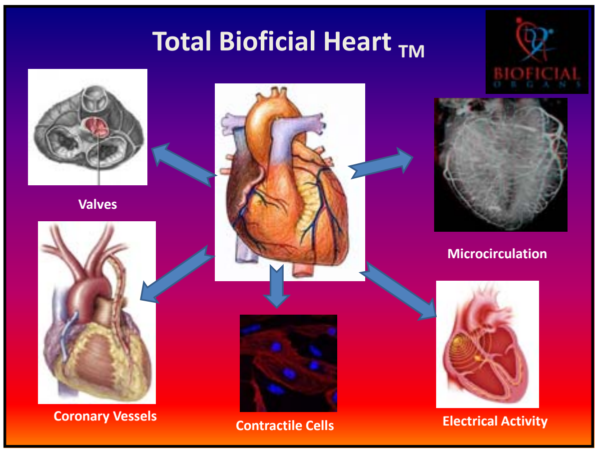
The National Space Biomedical Research Institute Surgical Capabilities for Exploration and Colonization Space Flight
December 9-10, 2015

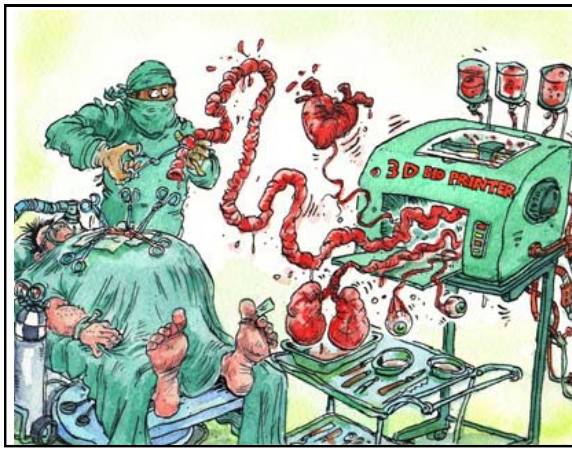
In 250 Years how will we address major medical problems during space exploration?

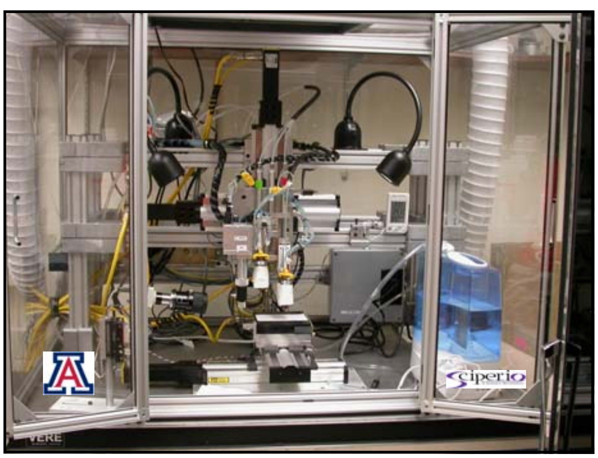
An electromagnetic near-infrared ray will cure major tissue organ defects!

But...

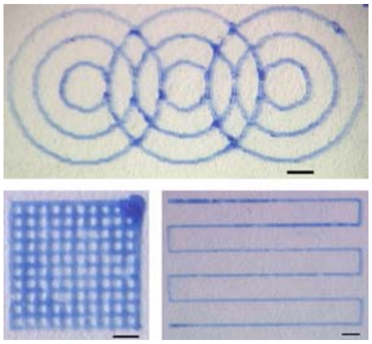
We will still be implanting
Total Artificial Hearts
made from metal and plastic????





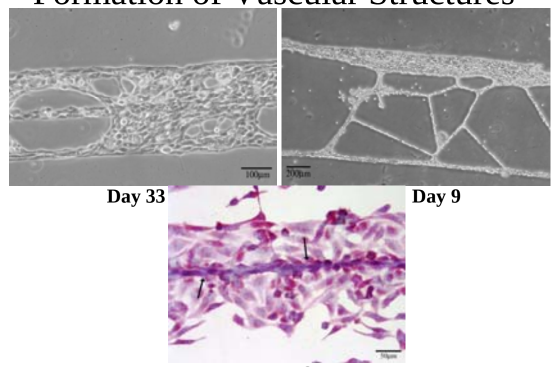


Early Capabilities of Bioprinters



Smith et al 2006. Tissue Engineering. 13(2):373-83

Formation of Vascular Structures



Components of Bioprinting

Image File → Image Processing → Image Rendering → Transfer Language → Bioprinter

Dispensing Pen → Bioprinter

Cells, Polymers, Additives → BioInk → Dispensing Pen

Pre-Fabricated Systems → Bioprinter

Bioprinter → Organs, Tissues, 3D Constructs, Structural Components

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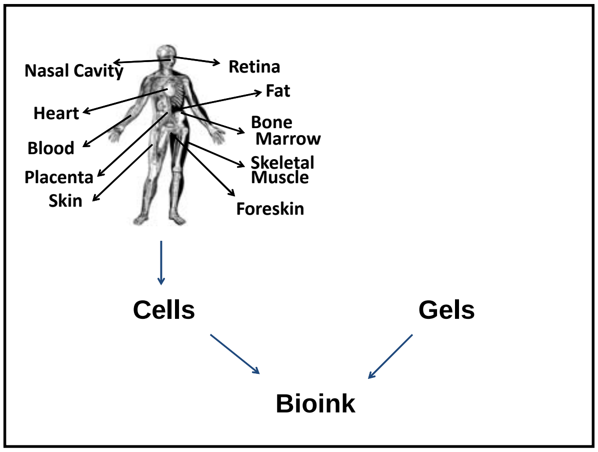
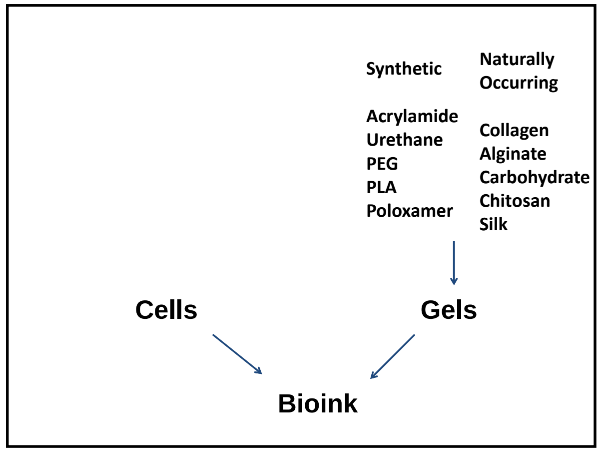
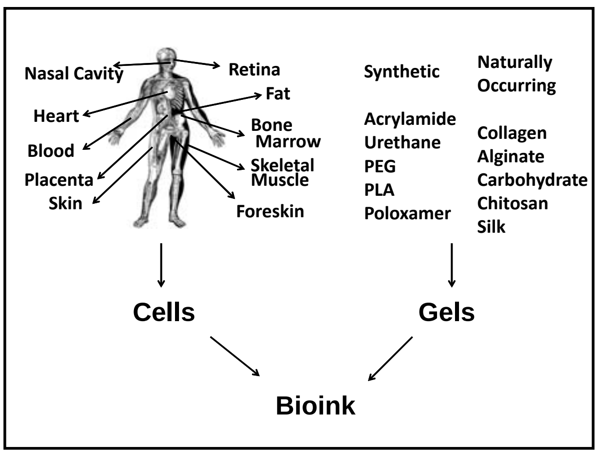
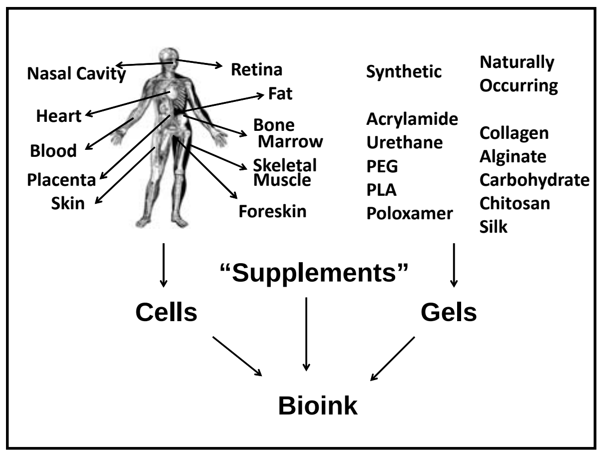
Bioprinter → Organs, Tissues, 3D Constructs, Structural Components

Cells → Bioink ← Gels

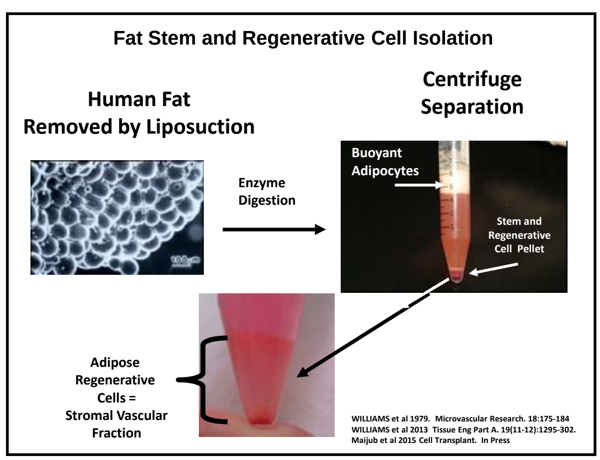






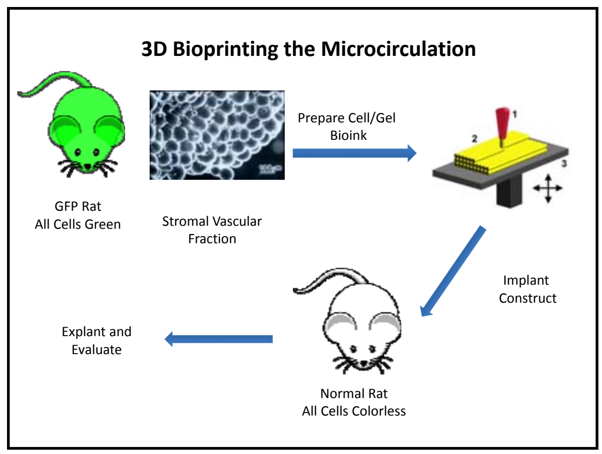


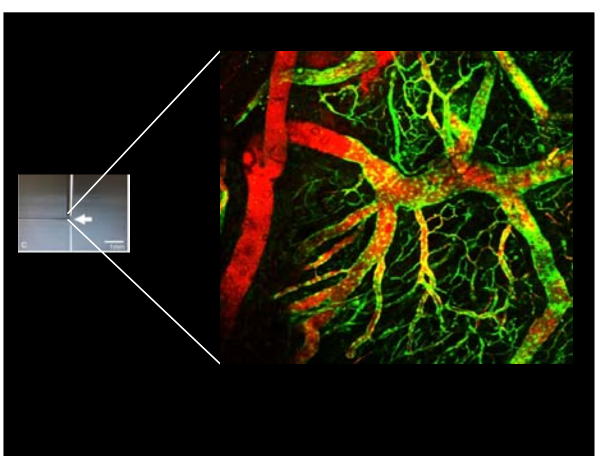
Is there an easily accessible source of autologous cells for bioprinting?

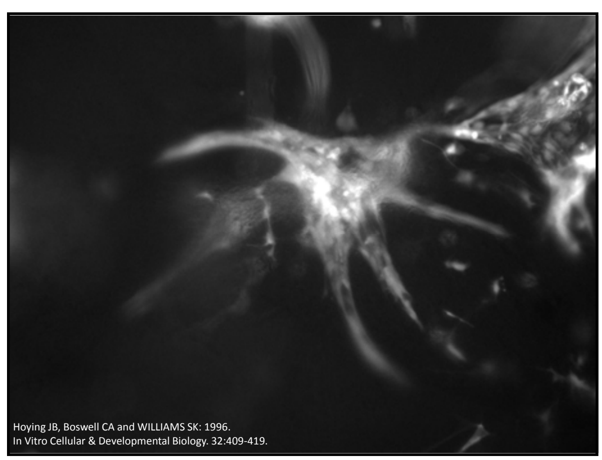


A Major Technological Hurdle in 3D Bioprinting is the Creation of a Microcirculation to Provide Nutrients to 3D Constructs

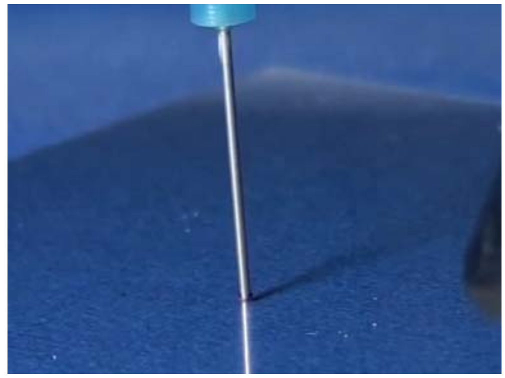
Can We 3D Bioprint a Microcirculation?







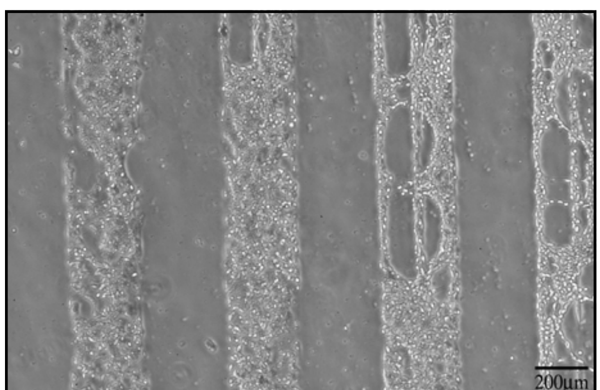
Why is Space the Ideal Environment to 3D Bioprint Complex Structures?



Our goal is to create the next generation of Bioinks for 3D Bioprinting in Space!

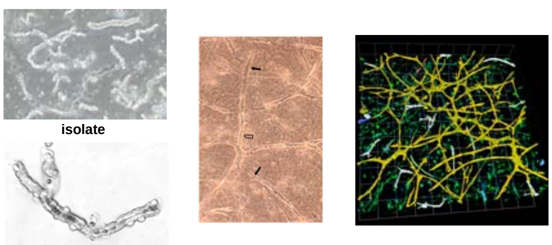
BIOFICIAL ORGANS

Stuart K. Williams Ph.D.
cvregen@gmail.com
cvregen.com
(502) 693 5250

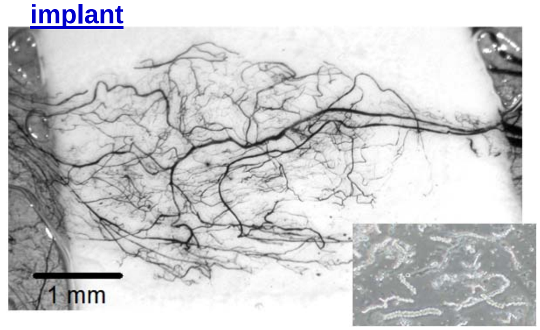


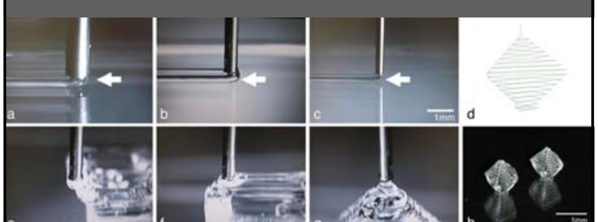
Day 29 – Cells Remain Within Printed Pattern

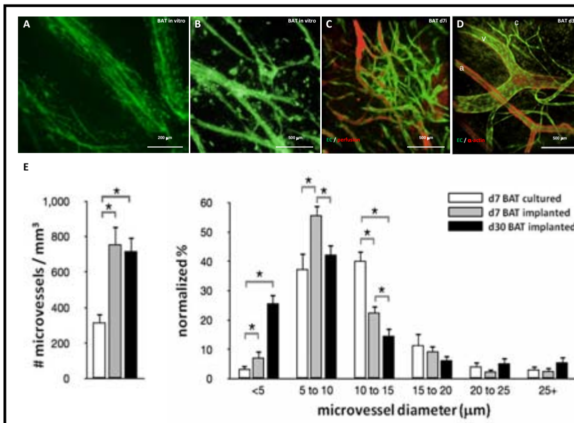
Prevascularized Constructs for Bioprinting the Microcirculation

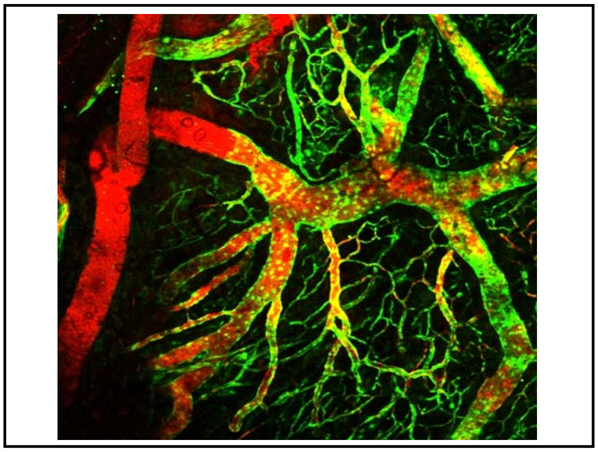


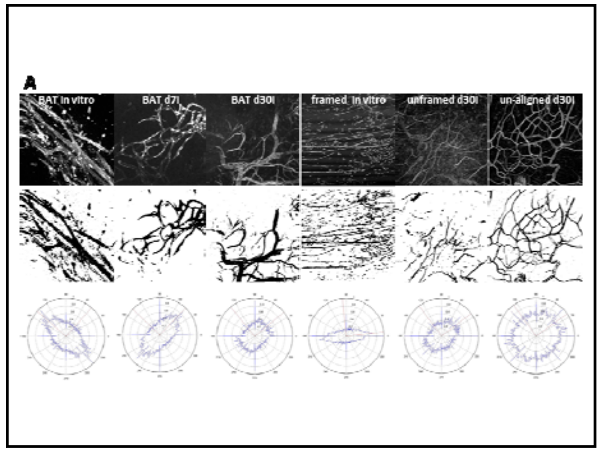
Microvascular construct: 28 day implant

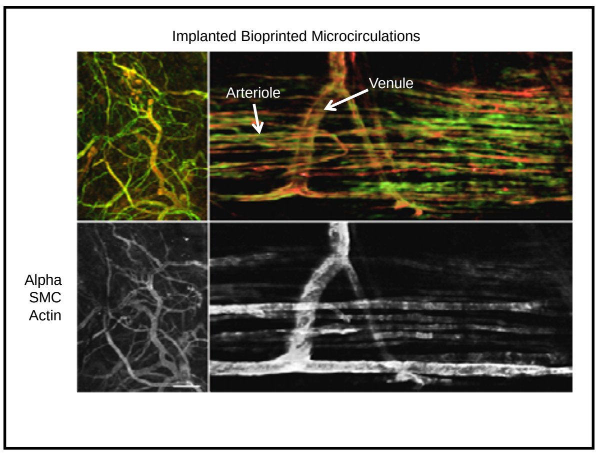


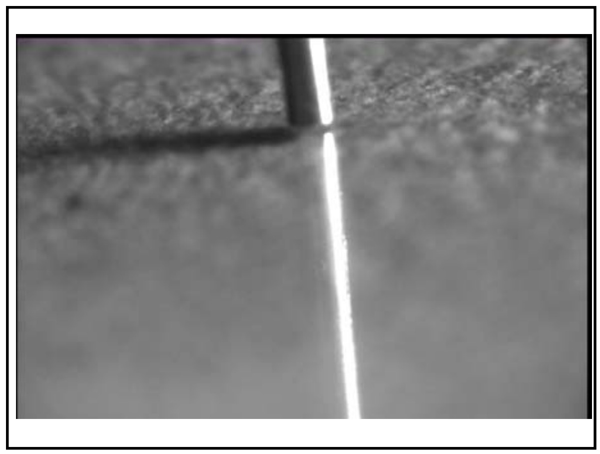


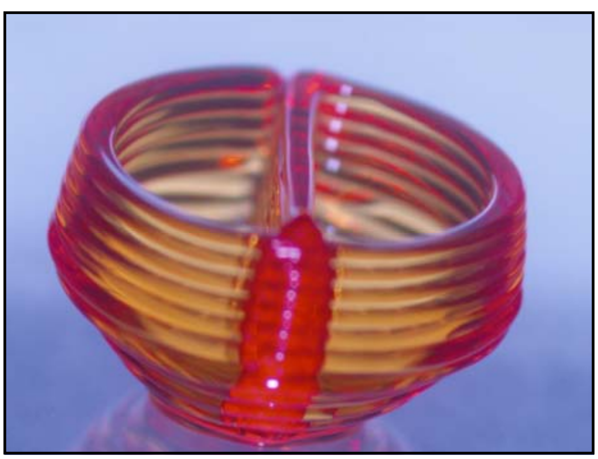


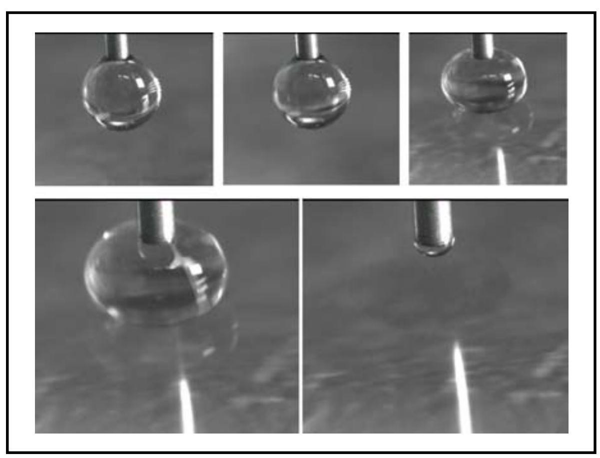


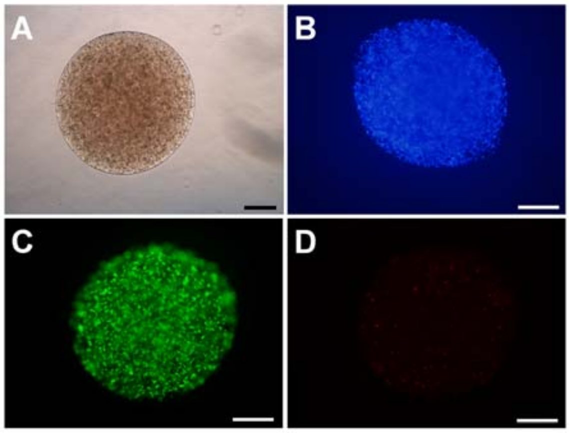

A
BAT in vitro
BAT d7I
BAT d30I
framed in vitro
unframed d30I
un-aligned d30I


Implanted Bioprinted Microcirculations
Arteriole
Venule
Alpha
SMC
Actin



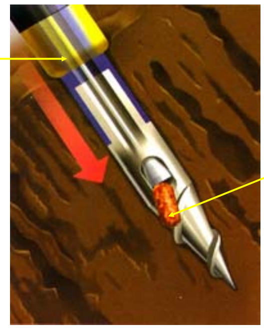






Myocardial Implantation Device

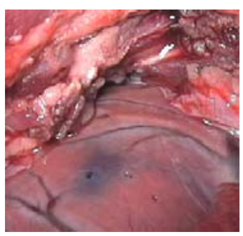
Catheter based device used to drill into the myocardium



Desired material can then be deposited in the myocardium of ischemic area

Myocardial Implants

Catheter-based drilling device for myocardial implants

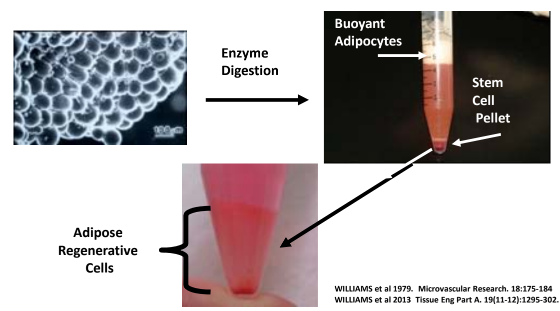


1mm channels created by device

Regenerative Cell Isolation from Fat for Bioprining

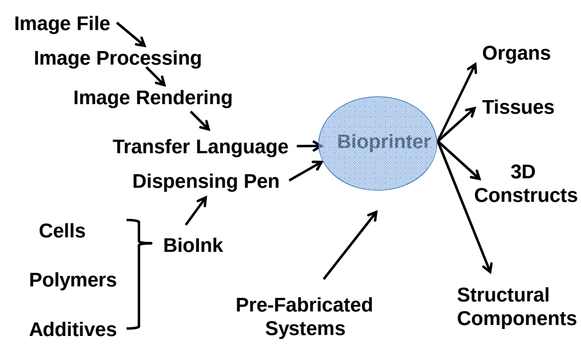
Human Fat Removed by Liposuction

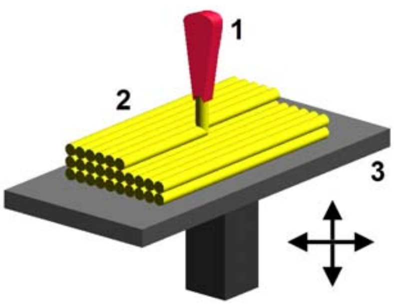
Centrifuge Separation

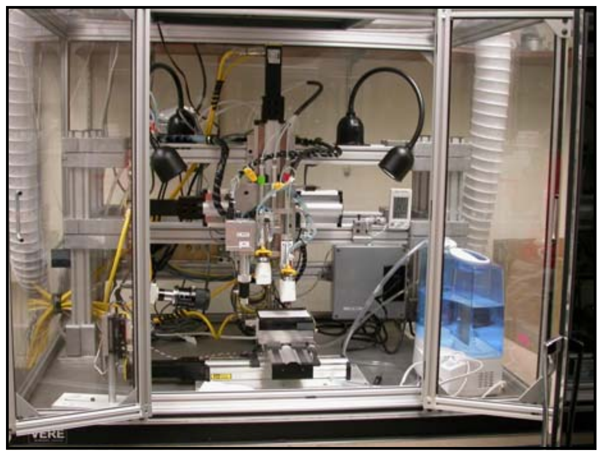


WILLIAMS et al 1979. Microvascular Research. 18:175-184
WILLIAMS et al 2013 Tissue Eng Part A. 19(11-12):1295-302.

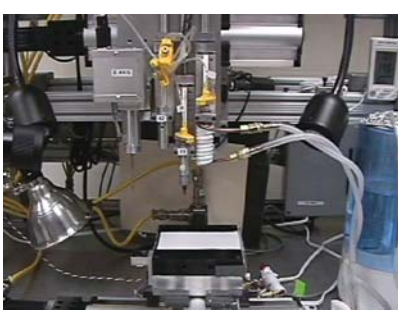
Components of Bioprinting





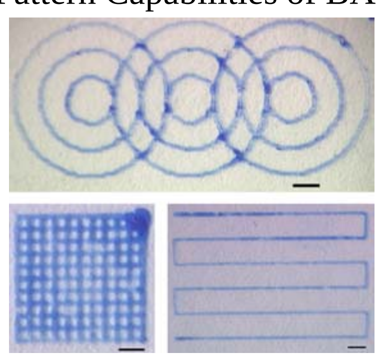


First Generation Dispensing Pens

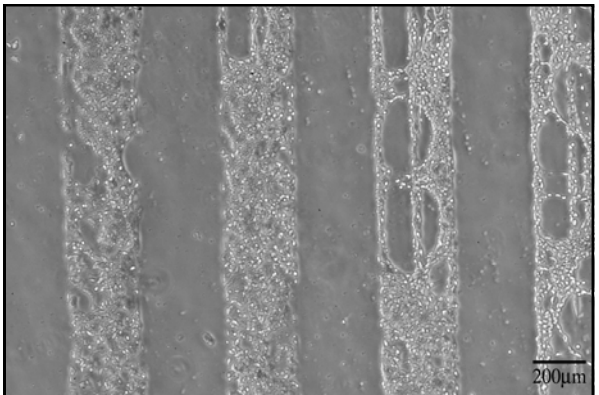


Smith et al.2004 Tissue Engineering. 10:1566-1576

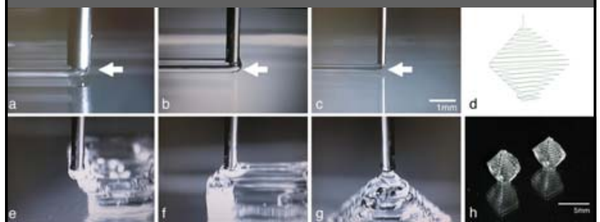
Pattern Capabilities of BAT



Smith et al 2006. Tissue Engineering. 13(2):373-83



Day 29 – Cells Remain Within Printed Pattern



Chang et al 2011 J Biomed Mater Res 98(1):160-70.

3D BioPrinting for Wound Healing Applications

Eugene Boland, Ph.D.

12/10/2015

1

Unmet Needs
(low hanging fruit)

- Extremity injury due to burns, frostbite or radiation – can progress to relatively large surface area wound similar to “degloving injury”
- Non-healing or slow healing laceration due to space related immune deficiency
- Loss of dexterity due to hand crush injury to short or irregular bones that are not conducive to splinting or external fixation.

2

Technologies

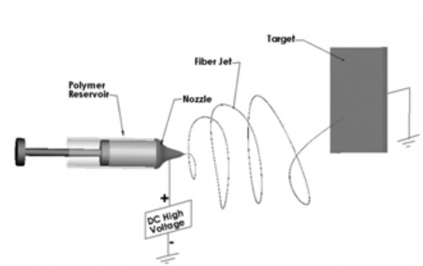
Electrospinning
- Natural vs. Synthetic polymers
- homologous or heterogeneous fibers

Thermoplastic 3D Printing
- Implantable and Non-Implantable materials
  - degradable vs. durable

Hydrogel 3D Printing
- With and Without cells
  - autologous vs. allogeneic

3

Modern Electrospinning



4

Modern Electrospinning Parameters

- Fiber Diameter
  - Direct linear relationship with solution concentration.
  - Increased voltage increases fiber diameter and risk of defects (incomplete cone formation).
  - Surface tension reduction will increase fiber diameter.
  - Increased charge density will decrease fiber diameter.
  - Solvent volatility will effect fiber thinning by changing the viscoelastic properties of the jet (i.e. if all other parameters are equal, more volatile solvents will produce thicker fibers).

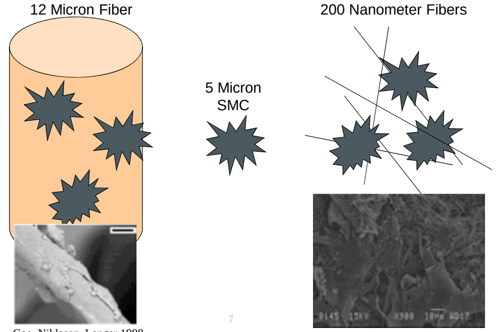
5

Modern Electrospinning Parameters, cont.

- Fiber Orientation
  - Electric Field
    - “Tuning” the field can straighten fibers.
  - Mechanical Induction
    - Target motion can induce preferential orientation.
- Materials
  - Natural and synthetic polymer solutions
  - Blended solutions – fibers reconstitute in situ

6

Diagrammatic Representation comparing commercially available fibers with electrospun fibers



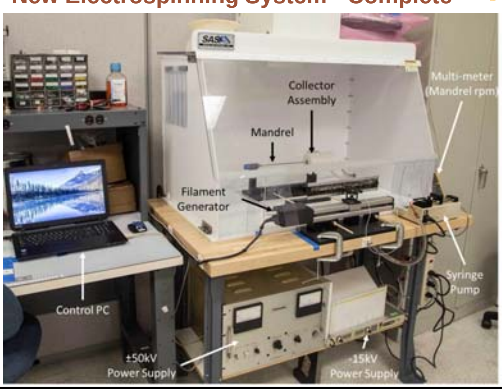
Gao, Niklason, Langer 1998

Material chose for scaffold (integration)

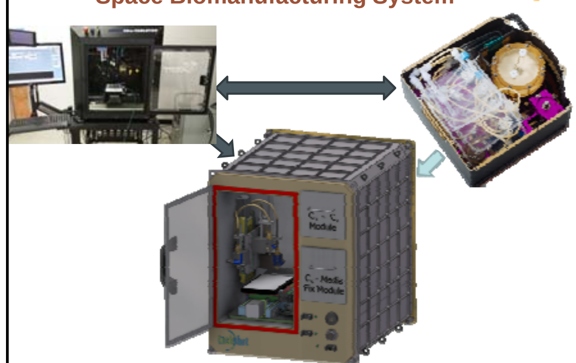
Requirements
- Biocompatible
- Maintain 3D structure in situ
- Promote cell adhesion / integration
- Degradable provisional matrix
- Mechanical integrity for surgical manipulation and implantation

Scaffold Choice
- Fibrinogen base
  - Salmon sourced – avoids regulatory issues with mammalian proteins
  - >99% conserved but lacking Staph. Aureus binding site
  - Provisional matrix to “fool” the body into seeing wound as “new”
- Collagen
  - Natural cell binding
  - New matrix building blocks
- Poly(dioxanone) for mechanical stability.
- Electrospinning for cell binding and 3D structure

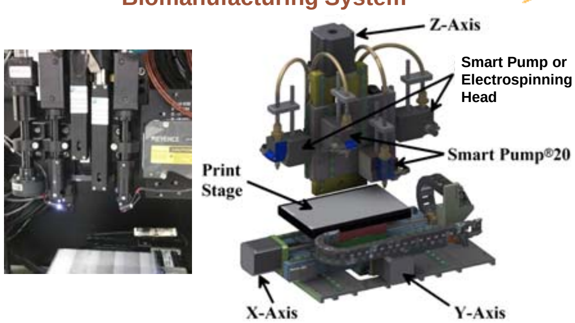
New Electrospinning System - Complete



Space Biomanufacturing System



Biomanufacturing System



Project Team

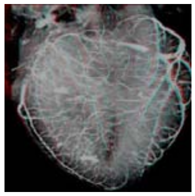
techshot: Project management (prime contractor), spaceflight hardware development, integration and operation. Space medical solutions provider. Tissue bioprint production management/supervision.

BIOFICIAL ORGANS: Implementation Leader in developing 3D printed tissues that remain viable after implantation. Recognized International leader in the fields of Cell therapy and Regenerative Medicine. Cross-licensing vital IP for cell isolation, selection and printing. Discovered the method for developing microvascularized tissues in culture and maintaining those vascular beds after implantation. Allows for viable thick tissue implants for the first time. Cross-licensing vital IP for tissue vascularization.

nScrypt: Pioneer in the Direct-Write 3D tissue printing field. Has expertise in Bioink and currently has a patent protected delivery system with the highest resolution and broadest dynamic range in terms of bioink capability. Supplier of delivery systems and control software integration partner.

Biomanufacturing System

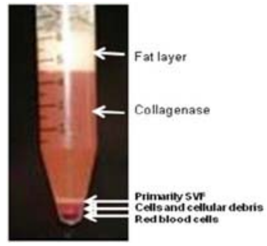
- Develop and test aboard ISS now to be ready when needed for exploration missions.
- Our scientific experts are on the leading edge of this technology.
- Our team holds the IP for the creation and isolation of micro vascular fragments – the key to manufacturing living tissue.
- N-Scrypt has the most precise bio print heads.
- Techshot understands life science spaceflight hardware development, integration and crew training and its devices are easy to operate manually, remotely and/or autonomously.



13

Cell Selection (create new tissue / quiescence site)

Adipose-derived Stromal Vascular Fraction (ADSC, SVF, AD-MSC, ASC, etc.)



- Heterogeneous population
- Stem-like properties
- Mesenchymal differentiation potential (multi-potent)
- Large quantities readily available via minimally invasive procedure
- Capability for stromagenesis and immunomodulation

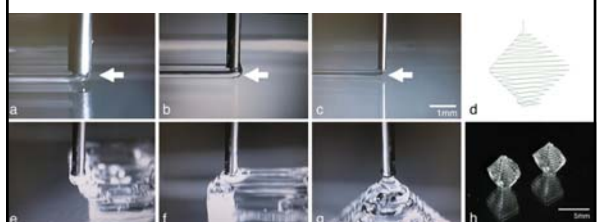
14

Combined Electrospinning and Bioprinting

- 3D mold printed and then backfilled with collagen gel containing vascular fragments and primary cells on electrospun fibrinogen mat
- Combined allows for handling, suturability, controlled ingrowth, degradation rate

15

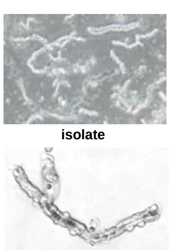
3D Printing Demo

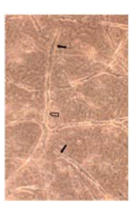


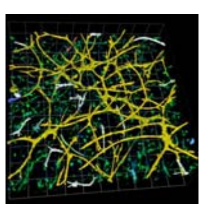
Chang et al 2011 J Biomed Mater Res 98(1):160-70.

16

Combined Electrospinning and Bioprinting

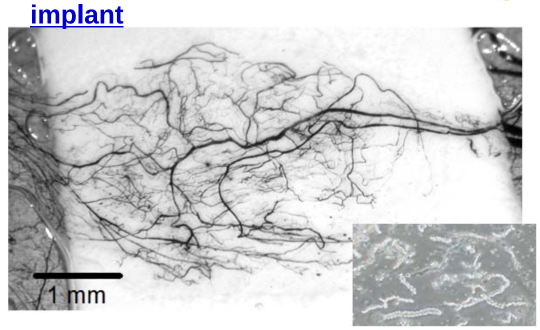






17

Microvascular construct: 28 day implant



Therapeutic Ultrasound Techniques to Augment Surgical Capabilities in Space

George R. Schade, MD

Symposium on Surgical Capabilities for Exploration and Colonization Space Flight
December 10, 2015

Disclosures: None

UROLOGY

Introduction

- Ultrasound is a diverse non-invasive tool
  - Diagnostic
  - Therapeutic
  - Theranostic
- Outputs can be tailored to desired bio-effects
- Proposed Flexible Ultrasound System (FUS) capabilities allow many options

UROLOGY

Outline

- Kidney Stones
  - Ultrasound Propulsion
  - Ultrasound Fragmentation
- Acoustic Coagulation
- Ultrasound Bloodless Surgery

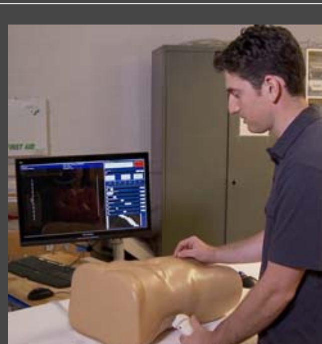
UROLOGY

Ultrasound Propulsion

- Rationale: Can we use US to
  1) alleviate obstruction
  2) facilitate treatment
  3) facilitate spontaneous passage
- Uses Acoustic Radiation Force
  - 50 ms, 2 MHz ultrasound pulses
  - ~10 fold higher amplitude than diagnostic US

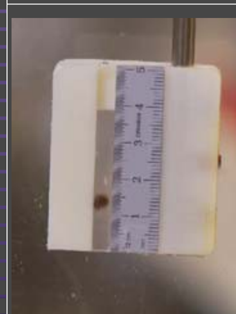
UROLOGY

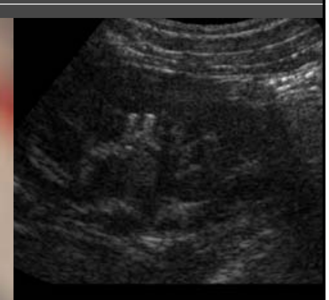
Current Device



UROLOGY

Preclinical

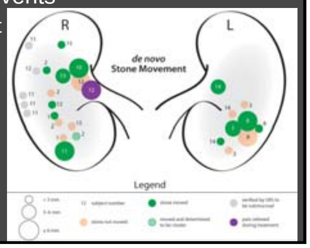




UROLOGY

Clinical Trial

- Imaged and moved stones in 14 of 15 subjects
  - 1 patient's pain improved
  - 4/6 pts s/p SWL passed fragments
- No pain or adverse events
  - 2 with mild discomfort



NSBRI FUNDED

UROLOGY

Optimization

- Modifications under pre-clinical testing now
- Code being written for the NASA FUS

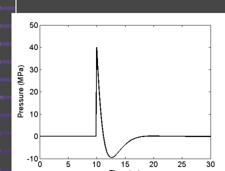
UROLOGY

If we can move them, can we treat them?

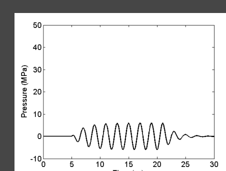
UROLOGY

Ultrasound Fragmentation: Burst Wave Lithotripsy (BWL)

Extracorporeal lithotripsy by focused ultrasound bursts without shock waves



Shock Wave



Burst Wave

UROLOGY

Hardware Design

BWL Therapy System

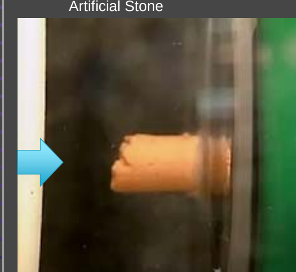
US Imaging System

UROLOGY

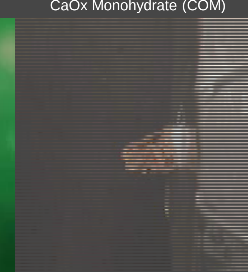
Burst Wave Lithotripsy

Fragments are generated from main stone body during exposure

Artificial Stone



CaOx Monohydrate (COM)



Burst Wave Lithotripsy

Most common stone types have been successfully fragmented

Uric Acid | Struvite | COM | Cystine

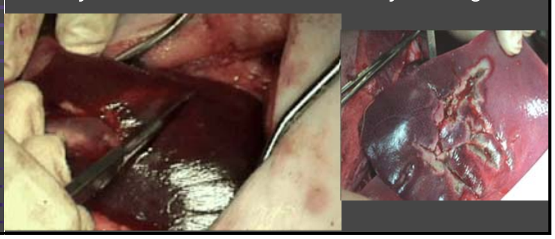
Burst Wave Lithotripsy

Ultrasound frequency controls the fracture spacing and fragment size

170 kHz | **285 kHz** | **800 kHz**

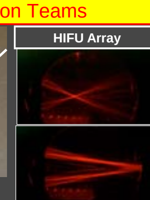
Acoustic Coagulation

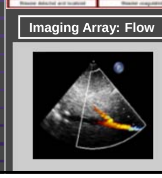
- Trauma/Hemorrhage poses major threat to soldiers/astronauts
  - Easy to use portable hemostatic device desirable
- Early work demonstrated US' ability to coagulate



Acoustic Coagulation

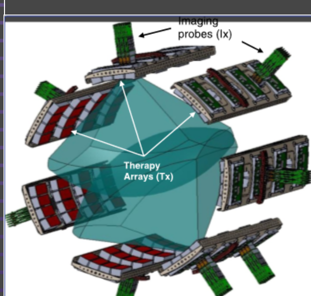
DARPA Deep Bleeder Acoustic Coagulation Project: Philips, Siemens & University of Washington Teams

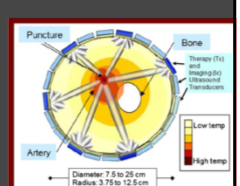




- **Imaging probe allows detection of bleeding in a variety of scenarios**
  - **Permits damaged vessels to be detected over a range of depths**
  - **Allows HIFU energy to be electronically directed at the bleeding vessel**

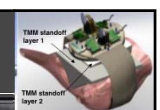
DARPA Prototype

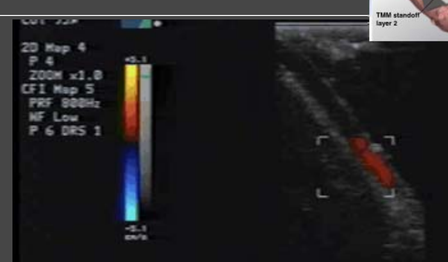




- Effective in *ex vivo* test bed

In Vivo



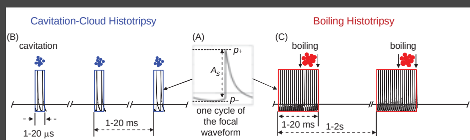


- Automated: distinguishes between vessels, branches, etc
- Successful for low flow
  - Reduced flow 20-30% in high-flow

UROLOGY

Bloodless Surgery

Histotripsy = *non-invasive "shock-enhanced"* focused ultrasound that *mechanically* fractionates targeted tissue



Histotripsy	≠	HIFU
Very high intensity		High intensity
Pulsed energy		Continuous energy
Mechanical effect		Thermal effect
Cellular fractionation		Coagulative necrosis

UROLOGY

Histotripsy

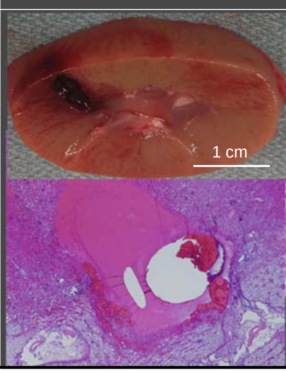
Histotripsy can be monitored in real-time on B-Mode US
- provides feedback for both targeting and effect

During Treatment

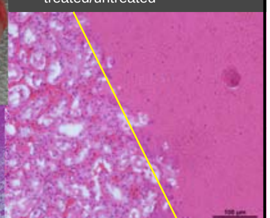
Post-Treatment

UROLOGY

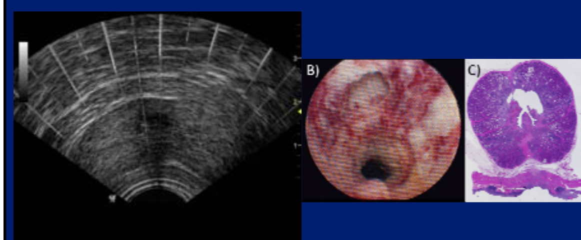
Histotripsy



Histotripsy is precise
- sharp demarcation between treated/untreated



Prostate Histotripsy

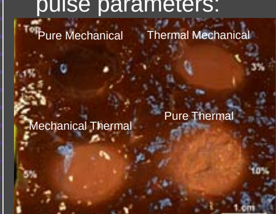


- Non-invasive treatment for benign prostatic hyperplasia
- Vortx© (Histosonics) device in Phase 1 studies now

UROLOGY

"Shock-Enhanced" Bio-effects

- Can be precisely controlled with alterations in pulse parameters:



- Potential Applications Diverse:
  - Oncologic and benign conditions: BPH, fibroids, etc.
  - Others: lyse hematoma, sterilize abscess

UROLOGY

Summary

- Therapeutic US offers many "surgical" capabilities in space
  - Stone manipulation/fragmentation
  - Coagulation/Hemostasis
  - Bloodless surgery
  - Others
- NASA's FUS offers diverse possibilities
  - Can be augmented to allow all of these capabilities in a single system

UROLOGY

Questions?

Acknowledgements

APL/CIMU

- Michael Bailey, PhD
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- Franklin Lee, MD
- Ryan Hsi, MD
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Gastroenterology

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13. ABSTRACT *(Maximum 200 words)* Surgical capabilities in human space flight, whether on a space-based platform in low Earth orbit or on a long duration planetary exploration mission, will be challenging to conduct. Some may be ameliorated by training, technology, and pre-flight planning. Early space missions did not have any surgical capability. It was not until the Skylab missions that serious consideration was given to this fundamental medical care capability. Over the past 30 years, subject matter experts have discussed a myriad of challenges and opportunities in this endeavor. As we continue to move forward with human space flight activities, the capabilities of information technology, robotics, sensors, and imaging have rapidly changed. In December 2015, through sponsorship of the NSBRI, a diverse group of individuals from government, academia, and industry representing three countries gathered in Houston, TX. This 2-day symposia included comprehensive sessions that addressed the challenges in developing, deploying, and utilizing surgical care capabilities in all human space missions, regardless of mission duration or profile. The symposium benefited from the knowledge and experience of three seasoned NASA physician astronauts, Drs. Jay Buckey, Thomas Marshburn, and Lee Morin. It is clear that the discussion of surgical capabilities is part of the larger discussion of consideration of advanced healthcare, including critical care, on exploration space missions. This report represents the culmination of the symposium, capturing knowledge, experience, conceptual dialogue, and a narrative that can be used in supporting the development of future programs and potential policy.			
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