A Hermetically Sealed, Fluid-Filled Surgical Enclosure for Microgravity

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Introduction: Expeditionary spaceflight is fraught with significant risks to human health, including trauma and other emergency medical events. To address several of the basic challenges of surgical care in reduced gravity, we are developing the Aqueous Immersion Surgical System (AISS), an optically clear enclosure pressurized by a fluid medium. The AISS is designed to prevent contamination of the spacecraft with blood and tissue debris, reduce intraoperative blood loss, and maintain visualization of the operative field. ***Methods:*** An early prototype of the AISS was tested in reduced gravity during parabolic flight. A clear, aqueous field was created in a watertight chamber containing a mock vascular network. Hemorrhage was simulated by severing several of the analogue vessels. Experiments were performed to evaluate the benefits of surrounding a surgical cavity with fluid medium, as compared to an air environment, with respect to maintaining a clear view and achieving hemostasis. ***Results:*** Qualitative evaluation of audio and video recorded during parabolic flight confirm AISS capacity to maintain visualization of the surgical field during a hemorrhage situation and staunch bleeding by raising interchamber pressure. ***Discussion:*** Evaluation of the AISS in reduced gravity corroborates observations in the literature regarding the difficulty in maintaining visualization of the surgical field when performing procedures in an air environment. By immersing the surgical field in fluid we were able to apply suction directly to the hemorrhage and also achieve hemostasis.
Keywords: surgery, contamination, enclosure.

IN SEPTEMBER 2010 a new NASA authorization bill commanded a manned mission to an asteroid by 2025 and to Mars by the 2030s, the success of which hinges on our ability to address the unique healthcare challenges astronauts will face. After review of the medical experience of comparable isolated crews, including U.S. Navy submarine missions and Antarctic winter-over statistics, NASA predicts an average of one major medical disaster requiring serious intervention during a 3-yr deep space mission with six crewmembers (17). Anticipating the needs for long-duration missions beyond low Earth orbit, NASA published a human health and life support roadmap which specifies its technology gaps, including a sterile, closed-loop fluid management system for trauma and other surgeries (8). Fortunately for astronauts and cosmonauts inhabiting the International Space Station (ISS), evacuation to Earth within 24 h is possible aboard a Russian Soyuz (17). However, considering the reasonable duration of a one-way trip to Mars is projected to be 259 d—almost 9 mo—medical evacuation beyond low Earth orbit will simply not be an option (7).

The need for surgery during space exploration has been a subject of discussion for several decades (1,2,10). Despite thorough health screenings prior to astronaut selection, life-threatening conditions requiring surgical intervention such as intestinal obstruction, cholecystitis, and appendicitis can occur. In fact, there is suggestion of increased incidence of appendicitis and subsequent complications due to immunosuppression, based on data analyzed from the Australian Antarctic program (2). As a result, prophylactic surgery to remove the appendix may be considered for space-bound crews, as has been mandatory in the Australian Antarctic program since 1950 (2). Additionally, NASA rates trauma at the highest level of concern for mission critical risks based on the probable incidence versus impact on mission health (10).

Campbell reports several experiments designed over the past three decades to test the feasibility of carrying out surgical tasks, such as instrument and operator restraint, waste disposal, and maneuverability inside the surgical cavity in a zero gravity environment (3–5). Although the practicality of performing complex procedures is debatable given current onboard medical training and supply restrictions, conclusions from these studies are favorable and support continued investigation. This is particularly true when one considers that isolation technology for medical care is not reserved only for complicated surgeries, but is also invaluable for suturing of simple skin lacerations or debridement of electrical burns. An enclosure to prevent escape of bodily fluids into the spacecraft cabin, as well as segregate open wounds from the high bacterial count of a recycled air environment, would be a welcomed addition to the medical supply list across all durations of spaceflight.

Isolation of the surgical field has been recognized as a prerequisite for performing surgery in a reduced gravity setting for decades and stems from two basic requirements: 1) maintaining a sterile environment; and 2)

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preventing cabin contamination from blood and surgical debris. Bleeding in particular is a major concern as surface tension tends to keep fluid together and form droplets, streamers, and large domes that upon disturbance (e.g., suction) may fragment into smaller spheres and disperse in all directions (12,16). One of the first reported systems for hermetically contained surgery in space was published in 1984, by John A. Rock. The concept consisted of an inflatable plastic vinyl chamber into which an appendage is inserted with cuff tourniquet to seal off the surgical site from the cabin. The chamber had built in sterile gloves and pockets to store surgical instruments and sutures (15). Although this system was designed for use on extremities only, it revealed several difficulties of surgical site management when evaluated in the reduced gravity conditions of a parabolic flight. Most notable were collapse of the chamber walls and condensation that obscured the field of view (11). A subsequent parabolic flight evaluation of a full body, glove box style isolator was performed in 1993 by NASA researchers Campbell, Billica, and Johnston. Their rigid enclosure affords sterile access to all parts of the patient, but has a large footprint that would either require a large space for storage or time to assemble if stowed in sections (5).

One critical shortcoming of both these systems was the visual obstruction caused by large blood plumes sticking to the surgical opening and free-floating blood spheres striking the container walls. Attempts to dislodge domes interrupted the normal pace of surgery (5,11), and interior walls needed to be wiped when blood adhered to the container, impeding adequate visualization. We therefore postulated that replacement of air with a fluid medium would inhibit the atomization of blood into the operative field. Furthermore an aqueous system would permit the pressure to be transiently elevated, thereby reducing intraoperative blood loss without the risk of air embolization. This was the motivation for developing the Aqueous Immersion Surgical System (AISS).

Aqueous Immersion Surgical System

Fig. 1 is an artist's rendering of the AISS employed in a craniotomy procedure. It is comprised of an optically clear dome that is affixed to the surgical site, in contrast to previous devices that encapsulated or surrounded the anatomy. The enclosure provides several access ports for passage of surgical instruments in a manner similar to endoscopic surgery. Additional ports are provided to introduce a physiologically and surgically compatible fluid, referred to as the immersion fluid. Also built into the containment structure is a suction tube to capture blood escaping from a bleeding site. The AISS includes an external, regulated fluid delivery pump, similar to an arthroscopic fluid management system, capable of precise pressure regulation and complete fluid volume exchange in the dome. Although the conceptual embodiment illustrates the original application of the AISS during neurosurgical procedures, we envision this as a platform technology that can be tailored to many surgical circumstances, including surgical procedures conducted in the microgravity conditions of space flight. The studies

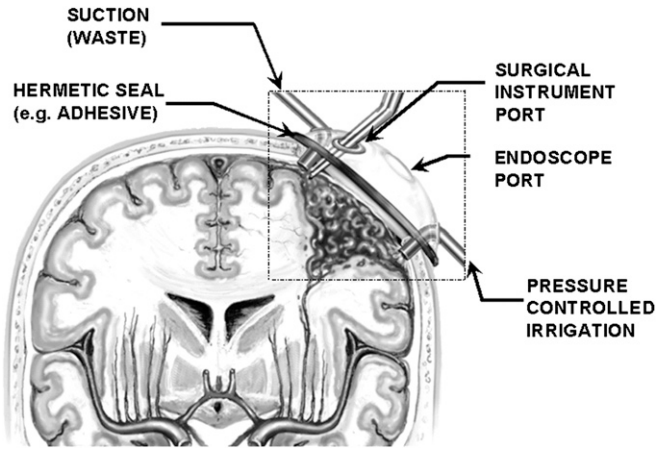

Fig. 1. An artist's concept of the Aqueous Immersion Surgical System as originally envisioned for cranial procedures. The optically clear enclosure will hermetically seal the surgical field and strategically placed ports will allow the surgeon to perform tasks in a manner similar to endoscopic surgery.

reported here aimed to evaluate the efficacy of the AISS concept in addressing several challenges of surgery in reduced gravity. The specific objectives were:

1. To investigate the mixing behavior of blood originating from severed vessels into an aqueous immersion fluid in reduced gravity.
2. To evaluate the effectiveness of focally applying suction near the hemorrhage.
3. To evaluate the effect of elevated immersion fluid pressure upon hemorrhage from the vessels.
4. To comparatively gauge the surgeon's ability to maintain visualization of the surgical site in air vs. an aqueous environment.

METHODS

Equipment

A simplified surgical simulator was comprised of a custom-designed, watertight acrylic chamber containing an array of silicone hollow fibers used to mimic a closed-loop vascular network, such as depicted within the dashed boundaries of Fig. 1. The fibers were perfused with a blood analogue fluid made from 40% glycerin in water and red food coloring. The fluid was delivered from a 1000-cc collapsible IV bag wrapped in a cuff that was manually inflated to maintain pressure, monitored by a digital pressure gauge just proximal to the inlet. Tap water stored in a second pressurized IV bag reservoir provided the immersion fluid to create an aqueous environment in the test chamber. A second pressure monitor measured the pressure inside the chamber. A commercially available endoscopic surgical port was fitted into the anterior wall of the chamber to introduce surgical instruments and a suction wand. Four fibers in the array were cut to create a hemorrhage that produced a visible stream of analogue blood at a hemorrhage flow rate of approximately 0.5 to 1.0 ml $\cdot$ s^{-1}.

The AISS evaluation station was comprised of a modified Anvil® case, which served as the support structure and operating table, and a clear canopy mounted to the top of the case for secondary containment in case of fluid leaks. The Anvil® case (52 cm $\times$ 82 cm $\times$ 106 cm,

45 kg) complied with Air Transportation Association Specification 300, Category 1, MIL-STD 810 C & D, and the FAA Airworthiness Standard and was secured to the deck of the aircraft using steel bolts. Additional ancillary equipment used in the experimental setup, including a suction pump and test chamber effluent collection reservoir, was secured inside the case. The attached secondary canopy was adapted from a standard pediatric isolette (56.5 cm × 85.5 cm × 47 cm, 25 kg) bolted to the top surface of the Anvil case. Two large access doors on each side of the canopy were used during preflight setup, but remained closed during flight. Investigators accessed the inside of the canopy through two pairs of armports with attached sleeves to perform all in-flight activities. Foot straps for all team members were mounted to the aircraft floor. In addition to the AISS test chamber and associated equipment, an accelerometer, clock, thermometer, two video camcorders, and towels to absorb spills were secured inside the canopy using Vecro® hook-and-loop fasteners, cable ties, or screws.

Procedure

Experiments were conducted during two parabolic flights sponsored by the NASA Flight Opportunities Program. Flights aboard the Zero Gravity Corporation modified Boeing 727 aircraft departed and landed at Ellington Field, Houston, TX, in coordination with the NASA Reduced Gravity Office. Approximately 40 parabolas were flown each flight in sets of 10 with periods of level flight in between. Each arc resulted in approximately 15-20 s of Martian (0.38 g), lunar (0.16 g), or zero gravity. The protocol for each flight included 4 Martian-g, 4 lunar-g, and 32 zero-g periods; however, our procedures were conducted during zero-g trajectories only. Tasks not critical to the investigation, such as aligning the video cameras or adjusting fluid pressures, were completed during the 1.8 g pullout between reduced gravity periods.

The first three experimental objectives were tested with both the analogue vascular network and test chamber filled and pressurized with their respective fluids. Lines from the human blood analogue and immersion fluid reservoirs were clamped shut during all level and hyper-g flight periods. At the start of each zero-g maneuver, the lines were opened and pressures adjusted such that the intravascular pressure was greater than the interchamber pressure. A typical starting pressure for the blood analogue was 75 mmHg, which corresponds to lower arterial pressure during surgery, and 6 mmHg for the immersion fluid. Depending on the goal of a particular maneuver, bleeding was either suctioned or allowed to mix freely with the immersion fluid. To assess the effect of elevated extravascular pressure during hemorrhage, the cuff surrounding the immersion fluid reservoir was further inflated over the course of the parabola until it was visually confirmed that bleeding had stopped. The pressures of each fluid at the time of bleeding cessation were recorded offline from the postflight video.

To compare visual clarity of the surgical site, the AISS chamber was filled (without pressurization) with either air or immersion fluid, and the vascular network analogue was closed. A bolus of blood analogue in a 60-cc syringe was delivered in less than 5 s through a luer lock port on the chamber lid. Qualitative comparisons of the resulting plume and/or deposition inside the AISS chamber was made from video recordings.

RESULTS

Postflight video analysis showed that bleeding into the test chamber without clearance by suction did not immediately obscure the visual field. The clear immersion fluid (water) became progressively pink as it mixed with the blood analogue; however, structures inside the test chamber, including the hemorrhaging blood vessels, remained easily discernible over the entirety of the experiment as the blood analogue was slow to diffuse into the solution. During the 1.8-g pullout periods, the blood analogue stratified to the bottom of the chamber due to differences in density, but did not readily disperse during the next zero-g arc. Also observed was the ability to reduce the volume of blood mixing with the immersion fluid by applying suction near the hemorrhage. Two representative still images taken from the in-flight video are shown in **Fig. 2**. In these images, the immersion fluid has become slightly opaque due to mixing of the blood analogue and unmixed analogue has settled to the bottom. There is a 1-s difference between still images A and B, during which the plume of blood analogue was pulled toward the suction wand. As seen in panel B, there were trials in which not all blood analogue streaming from the vascular network was removed from the chamber. It was also noted that with the current design of the fluid management system, transient periods of subatmospheric

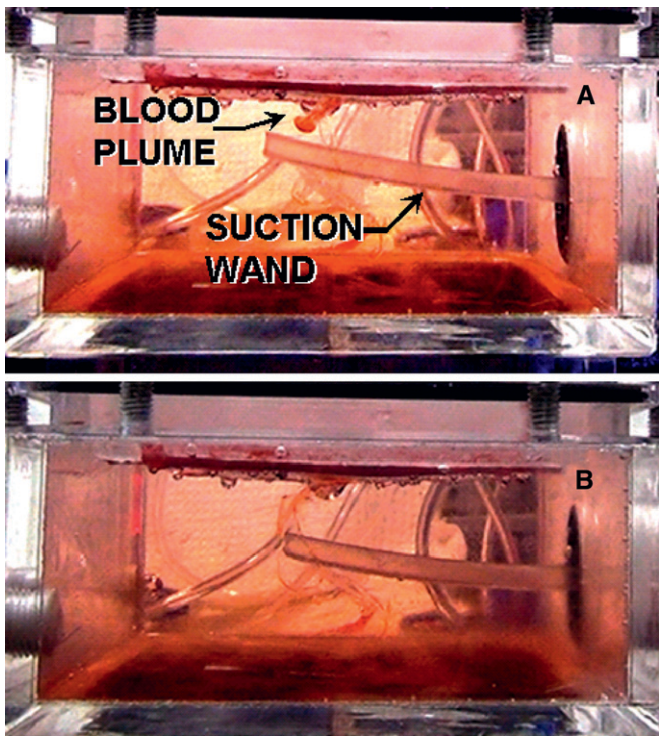

Fig. 2. A) A plume of blood analogue streaming from the severed vascular network was B) pulled toward the suction wand (contrast enhanced).

pressure occur in the immersion fluid with the application of suction.

Visual observation inside the test chamber during flight as well as postflight review of the video recordings showed bleeding from the mock vascular network ceased when the immersion fluid pressure exceeded intravascular pressure. This was demonstrated several times during the two test flights. Due to the variable increase in pressure following each incremental inflation of the cuff surrounding the immersion fluid reservoir, the pressure at which bleeding halted varied with each trial. Example pressures at the end of a test run were 84 mmHg and 96 mmHg for the blood analogue and immersion fluid, respectively.

The test chamber was also used to gauge the surgeon's ability to maintain visualization in the surgical field during procedures performed in either an air or aqueous environment. In both scenarios, the delivery of a large bolus of blood analogue immediately obscured structures inside the chamber. When the chamber contained an aqueous environment, the blood analogue evenly mixed with the immersion fluid, producing a virtually opaque field. When the bolus was delivered into the air-filled chamber, the blood analogue adhered to the chamber's walls and tended to accumulate in corners. **Fig. 3** shows representative still images captured during the trials.

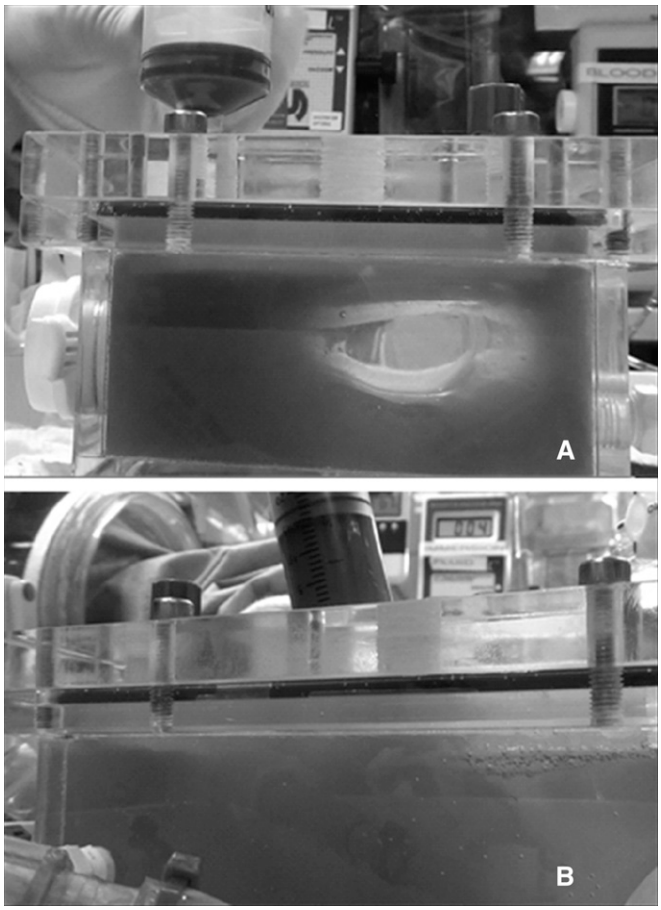

Fig. 3. Visualization was immediately obscured from a large bolus of blood analogue delivered into either A) an air-filled or B) a fluid-filled chamber.

Both situations produced a surgical field in which it was very difficult, if not impossible, to see.

DISCUSSION

Previous investigators have developed and tested enclosures to contain a surgical site so as to prevent contamination of both the spacecraft cabin with blood and other surgical debris and reduce the risk of surgical site infection related to high bacterial counts found in the recycled cabin air. Campbell, Billica, and Johnston hypothesized the addition of laminar airflow through an enclosure would capture free-floating fluids and particulate to eliminate adherence to the side walls (5). This proved to be somewhat effective; however, the researchers found that venous blood tended to pool in the wound, which immediately obscured the field, and that dislodging the resulting dome of blood was surprisingly difficult. Additionally, arterial blood sometimes formed droplet streams that were not cleared by the laminar flow and, therefore, would stick on the container wall (5). Although Earth-based techniques for blood removal and hemorrhage control (e.g., sponges, suction) can be useful in this setup, this prior study confirms the need for better visualization, particularly in time-critical trauma situations.

Results obtained during parabolic flight evaluation of the AISS indicate the technology may resolve several challenges associated with performing surgical procedures in the isolated, limited resource environment of spaceflight. The system addresses difficulties, including the aforementioned contamination of the spacecraft and patient, obstructed surgical site visualization, and also the possibility of high intraoperative blood loss with no ability to transfuse. Our experience with rapid injection of a large bolus of blood into an air filled chamber confirms observations in the literature relating to adherence of fluids to the container wall. Because the surgical site was also quickly obscured in a fluid environment, the utility of this system will necessitate the incorporation of effective suction and fluid purge. For situations in which the immersion fluid becomes unacceptably contaminated with blood, we envision a feedback controlled system that would automatically, or manually, perform a full purge and refill cycle.

Due to size and weight limitations of storing resources aboard spacecraft, reducing the immersion fluid volume needed to complete a procedure (including the possibility of processing and recycling the immersion fluid) will be critical to the success of AISS system. Fluid isotonicity and sterility must also be maintained for the duration of the mission. We expect that no more than 5 to 10 L of immersion fluid would be taken on a mission to minimize the weight and storage space needed. Immersion fluid recovered from the surgical enclosure would be processed in an on-board fluid reclamation unit similar to the IVGEN unit currently being developed and tested at the NASA Glenn Research Center (13). Such a unit would take the recovered immersion fluid and remove debris and sterilize it for reuse during the existing procedure or store it for a future procedure.

Results of this parabolic flight campaign demonstrate the usefulness of applying suction at the location of hemorrhage to minimize mixing and conserve fluid. One challenge of applying suction in close proximity to a wound is the potential to increase blood withdrawal from a vessel by creating a transient period of negative pressure inside the chamber. To mitigate this risk, it is necessary for the integrated fluid management system to simultaneously replenish immersion fluid lost to suction, thus maintaining the immersion fluid pressure.

Outcomes of the parabolic flight campaign also showed that raising the interchamber pressure with additional immersion fluid will staunch hemorrhage, providing the surgeon with time to make the surgical repair. The reduced gravity environment has a profound effect on the circulatory system, which can greatly impact patient outcomes. Astronauts are found to have a 10–20% reduction of circulating blood volume and up to 20% reduction of red blood cell mass compared to preflight measurements (9). This is comparable to a trauma patient with Advanced Trauma Life Support Class I hemorrhage (6). It is unknown at this time whether astronauts would suffer higher rates of mortality from hemorrhage compared to attribute-matched populations on Earth. Notwithstanding, the logistical challenge of transfusing blood during spaceflight is reason enough to minimize bleeding during surgery.

This investigation corroborates findings in the literature relating to operator restraint and leverage (14). Once accustomed to the zero-g environment, we did not encounter any difficulty completing tasks and found the foot straps sufficed as our only restraints. With sufficient time to acclimate and adapt mindful movement, we believe a surgeon astronaut would be capable of performing the necessary tasks required for surgical procedures.

There were several limitations to this study, including the use of analogue solutions as substitutes for whole blood and immersion fluid. Later experiments performed in the lab using whole blood exhibited far greater contrast compared to blood analogue fluid with similar dispersion patterns. Additionally, the difference in density between the blood analogue and immersion fluid influenced the fluid mechanics inside the AISS test chamber throughout the flight. Specifically, during the 1.8-g pullout maneuvers unmixed blood analogue settled to the bottom of the chamber and did not always disperse during the next zero-g arc. Although this would not occur in a true zero-g environment, it is an artifact that must be addressed in parabolic flight, especially since stratification could artificially maintain visual clarity. This is best corrected by using a physiological immersion fluid solution (e.g., normal saline) as envisioned for the clinical implementation instead of tap water.

There were also limitations associated with the simplicity of the vascular model used in this study. The AISS chamber contained a network of freely suspended micro tubes, whereas anatomically the majority of vessels are embedded in soft tissues that add structural support. We hypothesize that this tethering will inhibit collapse of intact vessels, thus maintaining distal perfusion. In the setup tested, it is possible for all mock vessels to collapse under sufficiently high extramural pressure. Accordingly, future investigations will use a more realistic vascular model and will include measurement of venous return to confirm vessel patency.

Finally, we believe it is critical for future investigations to minimize the manual tasks required to carry out testing procedures. At a maximum, each zero-g period lasts approximately 20 s, requiring fast maneuvers without sacrificing precision. Further, the use of a manual fluid management system during this flight campaign did not allow precise identification of the immersion fluid pressure at which bleeding halted, as the pressure increase following each incremental inflation of the cuff was variable. Automating fluid management is a priority for future AISS development that will increase its precision and repeatability.

In summary, parabolic flight evaluation of an early AISS prototype demonstrated the feasibility of conducting surgery in a pressurized fluid environment to address several challenges associated with performing procedures in reduced gravity. Observations in the literature indicate difficulty maintaining surgical site visualization due to pooled blood, a result confirmed during the investigation. By immersing the field in an aqueous fluid, focal suction can be used to immediately remove blood and debris. Additionally, the surrounding fluid can be used to apply an extravascular pressure to reduce intraoperative blood loss. Future focus includes development of more anatomically and physiologically accurate vascular models as well as an automated fluid management system.

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