3D Printed Surgical Instruments Evaluated by a Simulated Crew of a Mars Mission

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INTRODUCTION: The first space-based fused deposition modeling (FDM) 3D printer became operational in 2014. This study evaluated whether Mars simulation crewmembers of the Hawai'i Space Exploration Analog and Simulation (HI-SEAS) II mission with no prior surgical experience could utilize acrylonitrile butadiene styrene (ABS) thermoplastic surgical instruments FDM 3D printed on Earth to complete simulated surgical tasks.

METHODS: This study sought to examine the feasibility of using 3D printed surgical tools when the primary crew medical officer is incapacitated and the back-up crew medical officer must conduct a surgical procedure during a simulated extended space mission. During a 4 mo duration ground-based analog mission, five simulation crewmembers with no prior surgical experience completed 16 timed sets of simulated prepping, draping, incising, and suturing tasks to evaluate the relative speed of using four ABS thermoplastic instruments printed on Earth compared to conventional instruments.

RESULTS: All four simulated surgical tasks were successfully performed using 3D printed instruments by Mars simulation crewmembers with no prior surgical experience. There was no substantial difference in time to completion of simulated tasks with control vs. 3D printed sponge stick, towel clamp, scalpel handle, and toothed forceps.

DISCUSSION: These limited findings support further investigation into the creation of an onboard digital catalog of validated 3D printable surgical instrument design files to support autonomous, crew-administered healthcare on Mars missions. Future work could include addressing sterility, biocompatibility, and having astronaut crew medical officers test a wider range of surgical instruments printed in microgravity during actual surgical procedures.

KEYWORDS: digital fabrication, additive manufacturing, space medicine, surgery, fused deposition modeling, space mission surgery.

Wong JY, Pfahnl AC. *3D printed surgical instruments evaluated by a simulated crew of a Mars mission.* Aerosp Med Hum Perform. 2016; 87(9):806–810.

The surgical capabilities on a Mars mission will be limited due to mass, volume, power, skills, and training constraints.[7,14] 3D printing may play a useful role in providing surgical instruments on-site for Mars missions.[19] The first gravity independent fused deposition modeling (FDM) 3D printer became operational on the International Space Station (ISS) in 2014 and is being used to investigate whether functional acrylonitrile butadiene styrene (ABS) thermoplastic objects can be 3D printed in microgravity.[10,16] Prior research has shown that ABS thermoplastic surgical instruments 3D printed on Earth can be used by board-certified surgeons to complete four simulated surgical tasks.[19]

Medical records of analog terrestrial expeditions suggest there is a risk that the primary crew medical officer could become incapacitated and that the secondary crew medical officer may be required to perform a surgical procedure during a Mars mission.[12,15] To compound matters, many back-up crew medical officers on past long-duration space missions had little to no prior surgical experience.[7] This study seeks to determine whether Mars analog crewmembers with no prior surgical experience would be able to use FDM 3D printed ABS thermoplastic surgical instruments in four simulated surgical tasks.

METHODS

Subjects

Prior to the start of the HI-SEAS 2 mission, this study's protocol was reviewed and approved by the Office of Research

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This manuscript was received for review in February 2015. It was accepted for publication in May 2016.

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DOI: 10.3357/AMHP.4281.2016

Compliance Human Studies Program at the University of Hawaii Manoa and the Institutional Review Board of NASA Johnson Space Center. Five Mars analog crewmembers (2 men, 3 women; median age: 28 yr) with no prior surgical experience completed anonymous questionnaires that collected quantitative data on instrument performance. For this study, surgical experience is defined as: medical school education, surgical residency, or surgical practice or related skills, such as repairing or suturing a laceration. From April 2014 until July 2014, each subject completed 16 sets of 4 timed simulated tasks not on any actual humans to compare the relative speed of using the 3D printed surgical tools to conventional instruments.

Equipment

3D digital models of four surgical instruments (sponge stick, towel clamp, scalpel handle, Adson's toothed forceps) were created using SolidWorks 3D Computer Assisted Design 2012 software (Dassault Systemes SolidWorks Corp., Waltham, MA) on a Windows 7 Workstation (Microsoft Corp., Redmond, WA). These instruments were chosen because they are used for prepping, draping, incising, and suturing. Traditional stainless steel and commercially available plastic surgical instruments were utilized to guide the design of each instrument.[19] Load-bearing structures were designed to be thicker to compensate for the differences in mechanical properties between 3D printed versus traditionally manufactured plastic components. Instrument design prototypes were printed, evaluated, and adjusted to address identified deficits.

Prior to the commencement of the long-duration Mars analog mission, the instrument files in .STL format were manufactured on a ground-based Dimension Elite 3D printer (Stratasys Inc., Eden Prairie, MN) using Stratasys CatalystEX 4.0.1 3D printing software. This FDM thermoplastic 3D printer was selected for this study as it prints ABS thermoplastic, a feature shared by the first space-based 3D printer (Made In Space Inc., Mountainview, CA). When possible, the printing orientation for each instrument was selected to avoid having functional loads oriented transverse to a FDM 3D printed layer. The printing software was used at the following settings: model interior at "solid," layer resolution at 0.178 mm (0.007"), and support fill at "sparse."

This FDM 3D printer builds objects layer-by-layer by heating ABS thermoplastic material to a semiliquid state and depositing it on a platform to form a horizontal layer. Once a layer is finished, the platform shifts down and the subsequent layer is created. This process is repeated until the 3D object is completed.

Two types of printing materials (Stratasys Inc., Eden Prairie, MN) were used in the additive manufacturing of the four instruments. The first material was ABSplus-P430 plastic, which was used to print each instrument. The second material was P400 SR Soluble Support Material and was used to provide a stabilizing framework for the ABS material during the printing process. This support material was later removed.

The printing time for each surgical instrument was tabulated by the printing software and recorded for this study.[19] The majority of the support material was removed manually and any leftover material was dissolved in a heated bath of alkaline detergent solution of Stratasys WaterWorks Soluble Concentrate P400SC. The sponge stick and towel clamp instruments had the same hinge design, which permitted simple manual assembly.

Procedure

The simulated prepping and draping tasks followed a previously published protocol.[19] The incising and suturing tasks were slightly modified from the published protocol due to the HI-SEAS 2 mission requirements banning outside food products. The first task used a sponge stick to prep a 7.62 cm × 7.62 cm (3.0 in × 3.0 in) area with 10% povidone-iodine solution (Purdue Products L.P., Stamford, CT). The second task used a towel clamp to clamp a standard 41 cm × 55 cm (16.1 in × 21.7 in) cloth surgical towel. The third task inserted a #10 stainless steel surgical blade on a scalpel handle and then made a 5-cm long full-thickness incision on a 7.62 cm × 7.62 cm (3.0 in × 3.0 in) paper sheet. The fourth task utilized a toothed forceps to perform one simple interrupted instrument suture closure using a 4.0 polypropylene monofilament suture with a 26-mm tapercut surgical needle (Ethicon Inc., Somerville, NJ) on a lifelike tissue suture pad (Simulab Corp., Seattle, WA).

Statistical Analysis

The sequence of using control or 3D printed instruments for each timed task was randomized using an online random sequence generator (www.random.org) to minimize bias. The average, standard deviation, and range for time to completion values of each simulated task for 3D printed vs. control surgical instruments across all subjects was calculated using Microsoft Excel software.

RESULTS

All simulated prepping, draping, incising, and suturing tasks were successfully completed with 3D printed surgical instruments by all Mars analog crewmembers, who had no prior surgical experience (**Fig. 1**). There was no substantial difference in time to completion of simulated tasks with control vs. FDM 3D printed sponge stick, towel clamp, scalpel handle, and toothed forceps across all subjects (**Table I**).

DISCUSSION

For Mars analog crewmembers with no prior surgical experience, there was no substantial difference in speed of completion of simulated tasks with ABS thermoplastic instruments FDM 3D printed on Earth compared to conventional instruments. All simulated prepping, draping, incising, and suturing tasks were successfully performed using 3D printed surgical instruments by simulation crewmembers with no prior surgical experience. However, the four

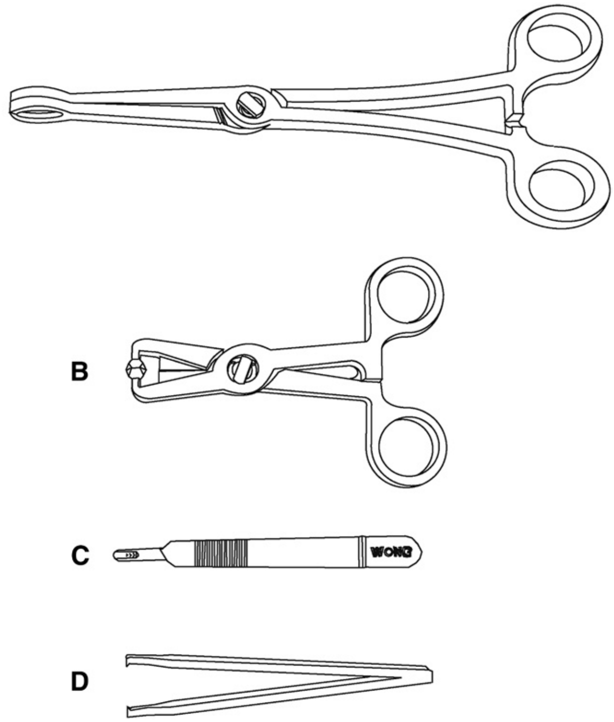

Fig. 1. A. 3D printed ABS thermoplastic sponge stick; B. towel clamp; C. scalpel handle; D. toothed forceps.

instruments and simulated surgical tasks evaluated in this study represent only a small fraction of surgical equipment and procedures that may be required to treat an ill or injured astronaut. As well, the speed of 3D printing has to be increased dramatically before utilizing FDM 3D printers to manufacture instruments on demand for surgical emergencies during a Mars mission.[19] Sterilization protocols for 3D printed surgical instruments are not currently available for space missions, and biocompatibility of the support material and its removal must still be addressed. In addition, the printing machines themselves, which represent the manufacturing process, must be validated to ensure the required manufacturing controls particularly around consistency and repeatability. Despite these limitations, the study's preliminary findings support the continued investigation of using 3D printers to support autonomous, crew-administered healthcare during a mission to Mars.

The study findings are limited by the use of a ground-based FDM 3D printer, low sample size, absence of statistical testing, and unblinded design. The inability to conduct a double-blinded study could have introduced potential investigator or test subject bias. Since the assessors and test subjects knew whether the subjects were using a 3D printed or control surgical instrument, their enthusiasm and personal experience with 3D printing could have potentially influenced their efforts in timing or completing their surgical task simulations in this pair-wise comparison study. It is also possible that simulation crewmembers with no surgical experience will not utilize surgical instruments in the same manner as experienced surgeons. Given the likelihood that all primary and secondary crew medical officers for long-duration space missions will have some degree of surgical experience, the study's findings on Mars simulation crewmembers with no surgical experience may have limited generalizability for crew medical officers assigned to long-duration space missions. Future research could involve 3D printing an expanded range of surgical instruments onboard the ISS and having astronaut crew medical officers evaluate these instruments during actual surgical procedures on the ground.

Mission architecture constraints limit the in-flight surgical capabilities for manned space missions, which could lead to unacceptable crew health and mission outcomes.[7] An onboard digital library of validated 3D printable files with appropriate regulatory clearance prior to a Mars mission could substantially expand in-flight surgical capabilities. The additional benefit of creating this digital library of validated 3D printable medical resources is that it could be potentially used in low-resource terrestrial settings. The versatility of 3D printing permits the localized production of surgical instruments or consumables to address multiple surgical scenarios for the same amount of mass in the form of printer material. Although FDM 3D printers typically take minutes to hours to manufacture a surgical instrument, 3D printing technology could be used in flight to manufacture: 1) dental instruments on demand before a procedure; 2) surgical instruments during the 8 h preoperative nil per os period; 3) instruments customized for a patient or a left-handed back-up crew medical officer with minimal surgical experience; 4) surgical consumables postoperatively; and 5) custom splints to treat musculoskeletal injuries.[17–20]

FDM 3D printing technology offers possible reclamation, self-repair, and sterilization features, which would be advantageous for manufacturing surgical instruments on site for space missions.[19] On November 25, 2014, the first space-based

Table I. List of 3D Printed Instruments, Print Times (19), and Averages, SD, and Ranges in Timing of Completion of Simulated Surgical Tasks with 3D Printed Instruments vs. Conventional Instruments for Five Mars Analog Crewmembers.

		TIME TO COMPLETION (seconds)					
		CONTROL INSTRUMENTS			3D PRINTED INSTRUMENTS		
INSTRUMENT & ITS PRINT TIME	TASK	MEAN	SD	RANGE	MEAN	SD	RANGE
Sponge stick (10 h, 24 min)	Prepping	10.3	3.1	5.6–22.8	10.5	2.5	5.8-17.0
Towel clamp (9 h, 5 min)	Draping	4.4	1.2	2.2–7.6	4.5	1.3	2.2–9.5
Scalpel handle (51 min)	Incising	19.2	7.4	10.6-56.2	16.9	4.9	9.6–36.3
Toothed forceps (1 h, 58 min)	Suturing	62.5	22.4	35.1–135.5	61.6	20.4	39.0–120.7

3D printer printed the first printed functional part, a faceplate for the 3D printer's own extruder casing.[6] This technology demonstration showed that this FDM printer is able to print its own ABS thermoplastic replacement parts. FDM printing can also minimize waste through recycling unused 3D printed material back into thermoplastic filament.[4] A recycler to convert obsolete 3D printed objects or plastic waste into ABS or polyetherimide/polycarbonate (PEI/PC) thermoplastic printer filament is now being developed for space missions.[11]

It may be possible someday to upcycle plastic waste into sterilized surgical resources on Mars missions. Early research has shown that the heating of the ABS thermoplastic during the FDM printing process can sterilize 90% of sampled printed objects.[8,13] However, the use of structural support material and the liquid solution to fully remove it later to ensure the final part is sterilized and biocompatible is a complicating factor that must be addressed in 3D printing surgical resources for long-duration space missions. It is important to note that support material is not always required for 3D printable designs. Studies have shown that it is possible to design and 3D print dental and surgical instruments that do not require the use of support material during the printing process.[17,20] Nuclear decontaminant gels and hydrogen peroxide gas plasma are being investigated as adjunct sterilization protocols for ABS thermoplastic printed surgical resources.[1,13] However, further development is required to develop and certify the most appropriate sterilization method for 3D printed surgical resources for space missions.

The next generation FDM gravity independent printer is scheduled for launch in 2016 and is designed to manufacture larger objects from a selection of materials, including ABS, PEI/PC, and high density polyethylene.[9] The Italian Space Agency has announced plans to launch a FDM polylactic acid thermoplastic 3D printer to the ISS.[2] NASA Langley Research Center has successfully tested electron beam freeform fabrication metal 3D printing in parabolic flight.[5] ESA's Additive Manufacturing Aiming Toward Zero Waste and Efficient Production of High-Tech Meal Products (AMAZE) Project is also developing a metal 3D printer for the ISS.[3] The range and durability of surgical resources that could be 3D printed in flight will increase as more printer materials become available for space missions.

3D printing technology offers the potential to provide localized and customized production capabilities of surgical resources for space missions which could lower costs, minimize redundancy, enhance the delivery of autonomous, crew-administered healthcare, and improve crew health and mission outcomes. However, significant technological and regulatory hurdles must be addressed before a digital library of regulatory cleared 3D printable files of surgical resources will be available for space missions. This library should also contain procedures on anesthesia and surgical techniques as well as pre- and post-operative and rehabilitation care to support the continuum of surgical care for space missions.

ACKNOWLEDGMENTS

We thank Patrick Corneille, Sara Backlund, Nathan Gustilo, Jason Gerold, and Bob Carter at Devicix for helping to develop and manufacture instrument designs, and Owen Devine for helping to draft the figure.

This study's preliminary findings were presented at the 62nd International Congress of Aviation and Space Medicine on October 13, 2014, in Mexico City, Mexico. These findings were published in abstract form in the conference proceedings supplemental issue of Revista de Sanidad Militar., Vol. 68, Num. 5, Suppl. 1, Sept. – Oct. 2014.

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