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Remotely Guided Breast Sonography for Long-Term Space Missions: A Case Report and Discussion

Running Title: Remotely Guided Breast Ultrasound

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ABSTRACT

Background: Space radiation can cause different types of cancers in crewmembers, especially during long-term space missions. **Introduction:** To date, a complete bilateral breast ultrasound has not been performed at the ISS. A breast screening imaging technique could be a useful tool for early identification of breast cancer in astronauts. We hypothesized that breast ultrasound performed by a crewmember while being remotely guided by a specialist from the ground could be an essential tool for medical diagnosis in space. This project aimed to test an ultrasound screening protocol for breast tissue using real-time remotely guided telemedicine techniques. **Materials and Methods:** One female volunteer, with no previous medical experience, performed a self-scanned bilateral breast ultrasound exam guided by a remote sonographer. Dynamic ultrasound images were collected using a 25 mm broadband linear array transducer. To simulate fluid shift on the volunteer during microgravity, the bed was tilted -6 degrees. **Results:** Recorded ultrasound images were analyzed by radiologists, comparing the findings with a gold standard. The experiment demonstrated that real-time remotely guided sonography exam is feasible and can yield meaningful clinical results. **Discussion:** This case study showed that remotely guided breast ultrasound can be performed and might become an important tool for diagnosis of breast cancer in space missions. **Conclusion:** The results cannot be generalized based on one subject, and additional research is warranted in this area in addition to its validation on the ISS. This technique, however, has potential for use as part of preventive medicine procedures for long-term space missions at the ISS, and eventually for human settlements on the Moon and Mars.

Keywords: Telemedicine, extreme environments, telehealth, remotely guided, sonography, breast ultrasound, space medicine.

INTRODUCTION

The space environment is inherently dangerous to human beings due to hazardous phenomena, such as the presence of vacuum, extreme temperatures and space cosmic radiation. Since the beginning of the Space Era, one of the most difficult engineering problems that space scientists have faced is how to develop active and passive methods to reduce space radiation impacts, not only on the spacecraft, but also on the human body. In relation to the evaluation of material properties, both NASA and ESA have conducted several flight experiments in which large numbers of space material samples were exposed to the environment of space and subsequently returned to Earth for laboratory analysis. Astronauts have been travelling into space since 1961, from which time a large volume of research has taken place involving human subjects in order to understand the behavior of the human body under extreme and dangerous conditions, such as the exposure to space radiation. The findings of all these researches have defined astronaut workload and exercise protocols, as well as the medical examination routines onboard the International Space Station (ISS)^{3,7}. However, all necessary medical protocols have not yet been fully defined, especially those related to deep space missions (i.e., astronauts travelling to the Moon and Mars). Furthermore, the space environment exposes astronauts to hostile factors that can increase their risk for different types of cancer². Similarly, epidemiological studies have indicated that the incidence of female flight attendants suffering from breast cancer is higher than in the general female population^{12,13}. Since female astronauts are exposed to a high level of space cosmic radiation, as compared with flight attendant occupational conditions, they may also present a greater risk of developing breast cancer. According to the Guidelines of the American College of Radiology the breast ultrasound screening in women with dense breasts and negative mammograms during clinical examinations yielded an incremental cancer detection rate of 2.8 to 4.6 cancers per 1,000 women⁸.

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Based on the NASA ISS Ultrasound Imaging Capability Overview for Prospective Users, NASA/TP-2006-213731¹⁴, several protocols that include remote guidance for the detection of signs of diseases have been developed, focusing on different body systems during missions on the ISS⁵. It is worth mentioning that most of these medical protocols were previously validated during parabolic flights or on the ISS. However, no breast sonography has yet been performed on the ISS.

The main purpose of our project was to develop a protocol that will help in detecting abnormal breast tissue characteristics using real-time remotely guided sonography. The implementation of breast sonography protocols is an essential part of the medical evaluation of female astronauts, especially during long-term missions. The hypothesis is that it is possible to detect abnormal breast tissue characteristics that may lead to breast cancer by using real-time guidance from a sonographer on the ground in order to provide more time and treatment options. In the future, the protocols developed for the crewmembers will become a solid foundation for performing self and aided breast ultrasounds in deep space missions as preventive medicine procedures. Due to possible communication delays, the crew will need to be more independent from the ground, and they will have to run the procedure on their own. However, ground can still provide remote guidance upon receiving the video and photos collected from the ultrasound made by the crew member. They can analyze and provide feedback not only for the procedure steps but also for the diagnosis. This is similar to how results from routine medical exams are provided on Earth; a radiologist initially performs an X-ray and results are subsequently received during a second medical consultation. A computer app could eventually be developed to serve as a remote guide for crewmembers, where the tool can provide recommendations based on the imagery it receives. This could also be embedded into the design of the ultrasound machine. The available technology will dictate the procedures that will be used in space for clinical evaluation of astronauts. For example, a still under development "state-of-the-art"

approach was proposed in which astronauts can use a motorized probe transducer¹. This technology could help female astronauts to be more precise when performing self-examination of their breasts.

The authors propose a project of three phases: Phase 1: Experiment Design, Phase 2: Ground Tests, and Phase 3: Development and Validation Tests for Use in Space. This paper presents the work of Phase 1, which relates to the establishment of the experiment design. In this phase, a protocol has been developed that can be used to perform breast ultrasound tests. A pilot test was also conducted in which a test subject was remotely guided by a sonographer. Phase 2 would consist of repeating the test with other volunteers, as well as performing the test on people who have been diagnosed with abnormal breast tissue characteristics. This will help evaluate the training methods for subjects with no medical background performing self breast ultrasound. In Phase 3, the protocol would include conducting a test on the ISS to validate the proposed protocol under sustained microgravity.

MATERIALS AND METHODS

Subject. The study protocol was approved in advance by the International Space University Research Committee, through the Human Performance in Space Department. This experimental study was performed with one female subject (case study), who provided signed informed consent. The subject was in her late 30s with advanced education, and had neither a medical background, nor prior experience of performing breast ultrasounds. A breast ultrasound (gold standard medical exam for breast evaluation) was performed on the subject as part of routine exams (for clinical reasons) a month prior to this test (control exam), with the results indicating no evidence of nodules or deformations.

Equipment. The test was performed at the Ohio University Clinic, USA. The equipment used included a SonoSite M-Turbo ultrasound machine, a transducer with 25 mm broadband linear array probe with a frequency of 13-6 MHz (same frequency as the transducer used at the ISS), positioning aids, and acoustic

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3 gel^{10,16}. Images could be viewed and observed in 2D, M-Mode, Color Flow, and Pulsed Wave Doppler
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5 modes. A reference marker was used to guide image acquisition during the procedure¹⁷. This had to be
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7 understood by the ultrasound operator and interpreter, as the female volunteer had no prior experience of
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9 performing ultrasounds. The subject was in a 6 degree head-down tilt position to simulate some of the fluid
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11 shift effects of microgravity on human physiology.
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15 ***Experiment Design***
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17 The subject was provided with the protocol and was able to ask questions regarding the procedure prior to
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19 the test. The subject also watched a medical video demonstrating a person performing self-ultrasound¹⁵. It
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21 was shown that both remote guidance and a computer training tool produce a higher quality of ultrasound
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23 images^{6,9}. During the procedure, the subject performed the test while guided remotely by the sonographer,
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25 who was in a separate location from the subject. The sonographer, who has previously provided remote
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27 guidance to astronauts on the ISS, was located at NASA's Johnson Space Center and viewed the procedure
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29 via real-time video link, guiding the subject through the sonography steps set out in the protocol, and when
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31 necessary, repeating some steps or explaining them in a different manner to improve the image acquisition.
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33 The subject was located in a room at the Ohio University Clinic, where all the equipment was available. A
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35 second person was also present in the room, serving as the operator of the camera that recorded the
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37 ultrasound images, but having no participation in the remotely guided procedure itself.
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43 ***Procedure – Breast Ultrasound.***
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45 The protocol describes the equipment preparation and setup, including the ultrasound machine, transducer
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47 and positioning aids. It also explains how to apply the gel on the transducer and preparation of the breast
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49 for the procedure^{4,11,17,18}. The breast was divided into 4 quadrants, as shown in Figure 1, to facilitate the
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51 instructions from the remote sonographer. The protocol included two types of grid scanning patterns with
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53 overlapping passes and a radial scanning pattern, as shown in Figure 2. A flow chart of the protocol
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developed is shown Figure 3, and can also be accessed through this link: https://1drv.ms/w/s!AoeXZB-5sC5HgcY_tXAlvhs3MyH4fQ.

A video was used to record the ultrasound images and the subject was asked to state which quadrant was being tested as the procedure was being performed. The remote sonographer observed the process and provided further instructions or feedback, when needed. During the radial scanning pattern, the subject took a picture of the ultrasound image of each quadrant. The video and pictures were reviewed first by a radiologist immediately after the procedure and subsequently by a second radiologist. Both radiologists were blinded to the gold standard/control exam results.

Figure 1. Graphic of right and left breasts divided in four quadrants for protocol instructions. UOQ: Upper Outer Quadrant, UIQ: Upper Inner Quadrant, LOQ: Lower Outer Quadrant, LIQ: Lower Inner Quadrant. The quadrant marks repeat for both the right and left breasts, with the difference of going in a counterclockwise position.

Figure 2. Grid scanning patterns used in protocol for breast ultrasound showing probe placement.

Figure 3. Flow Chart of Protocol developed for ground test of Remotely Guided Breast Sonography

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RESULTS

Test Results and Image Analysis

Upon reviewing the video, radiologists emphasized the importance of using more gel in order to improve the quality of the image obtained. It was also noticed that, initially, the transducer was not fully touching the skin and therefore only flashes of tissue were appearing. This situation improved over the course of the procedure, through guidance given by the remote sonographer. The subject also provided feedback regarding the procedure, noting the arm position to be uncomfortable and that the bed inclination made the procedure more challenging. The amount of pressure required was not clear to the subject, who also noted a difficulty in reading the protocol while performing the test.

Another important observation was the difficulty in determining the exact location of the area being examined from the video alone, as this had no annotations. The only feedback from the video images was the voice of the subject indicating where the ultrasound was being performed. The radiologists reviewed 4 images from each breast quadrant of the radial scanning pattern, as shown in Figure 4, and did not identify any abnormalities. These images were compared with the previous (gold standard/control exam) results from the subject’s routine medical exam that indicated no evidence of nodules or deformations. The remotely guided sonography confirmed the same results, exhibiting a true negative study.

Figure 4. Representative images of ultrasound taken while scanning at each breast quadrant. The quadrant references to UOQ: Upper Outer Quadrant, UIQ: Upper Inner Quadrant, LOQ: Lower Outer Quadrant, LIQ: Lower Inner Quadrant.

DISCUSSION

Based on the NASA ISS Ultrasound Imaging Capability Overview for Prospective Users, a complete bilateral breast ultrasound has not yet been performed on the ISS¹⁴. The ability to identify normal and anomalous breast tissue is of benefit to crew health, and is a responsibility of the space program as any issues could impact mission objectives. Additionally, this tool could aid space medicine in differentiating breast lesions from normal tissue due to the fact that ultrasound increases the chances of positive findings

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and could be used as a screening tool to spearhead breast health screening on the ISS. It can also expand ultrasound as a terrestrial tool, particularly in austere environments with limited access to health care because the patient can perform the exam remotely and the images analyzed by an expert. Breast ultrasound is especially useful in detection of nodules in dense breast, even as a complement to mammography screening in these type of patient⁸.

Breast cancer affects both genders, but is more prevalent in the female population. This tool will benefit female space crew and it is an essential component for breast evaluation, especially during long duration missions.

The test environment was not a perfect simulation of microgravity, but highlighted some of the challenges faced in the performance of remotely guided sonography. Ground-based tests are important in identifying limitations and improving the protocol for further testing and validation onboard the ISS. However, remote guidance provided by a sonographer could be adversely affected by communication delays, such as on an interplanetary trip to Mars, and alternative solutions should be tested. It was also considered that the printed protocol used in this study could be substituted by a computerized protocol, which could allow for more interactivity. The video shown to the subject prior to testing provided a general idea of how to perform a breast ultrasound exam; however, it could be customized for this specific medical procedure to highlight key aspects of the test. Finally, the results of this case report cannot be generalized. The amount of pre-flight training required to perform the test in a microgravity environment has to be discussed, tested, and validated.

As discussed in the introduction remotely guided ultrasound can still be done in deep space missions. Since there will be no real time guidance by a sonographer, alternative methods can be considered, such as the remote guide app or voice guide embedded in the ultrasound machine. The crew will have more responsibility for the sonography procedure, as there would be limited real-time communication with the

ground, which could positively impact on learning skills. They could first attempt the action independently and then request remote guidance from the ground, if required. This procedure could result in better learning outcomes as the additional responsibility experienced by the crewmember should lead to increased confidence levels. For this to work, best practice should include: readily available tools and learning materials; crew able to use the tools and access any related support; and response time (even if it is just an estimation) should be known by both the sonographer on the ground and the crewmember.

From an ethical viewpoint and human factors considerations, a cabin or partitioned area at the ISS may be necessary in order to provide privacy for the performance of a breast ultrasound exam. Alternatively, draping the chest area to shield from the cabin surveillance camera may be necessary. Since gel has to be applied to the skin to improve the conductivity of ultrasound waves, a type of gel sheet could be used to deal with privacy concerns, as this could be placed on top of the breasts, decreasing personal exposure. An ultrasound video with annotation for the remote sonographer would be required to better guide the process. A second crewmember to assist with operating the ultrasound equipment and possibly with the procedure itself may be desirable rather than the female crewmember having to perform a self-scan. A few open questions still remain that would be useful to determine as part of the ISS protocol and training: What would be the best position for both the patient and the operator, seated versus supine? How much stabilization would be needed relative to the assisting crewmember? Currently water is used onboard the ISS for other types of ultrasound, is water a better coupling medium than gel for breast ultrasound? Would it be necessary to manifest a higher frequency ultrasound probe for better resolution of breast tissue? This initial study is a stepping-stone for detecting abnormal breast tissue characteristics that may possibly be related to breast cancer in future long-term missions. This does not replace a mammogram and due to the inherent limitations of a case report it cannot be generalized, yet it provides good focal directed imaging that could be used for clinical assessment if any type of injury or accident occurs during a mission.

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Using telemedicine radiology as a breast tissue screening tool on the ISS may demonstrate its clinical utility in similar austere environments without access to sophisticated clinical screening. This initial study can serve as a platform for developing treatment protocols. Further testing and validation on the ISS are needed.

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