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14. ABSTRACT

This report details our first year of research activity on technologies that support sonographer-supervised robotic systems for breast ultrasound imaging with quantitative elastography. Major objectives achieved in this period included development of a research platform including a compliant robotic manipulator, a force/torque sensor, a wrist-mounted ultrasound transducer, and an ultrasound scanning device. A force-velocity controller has been implemented and characterized to operate the manipulator. In parallel, ultrasound pulse sequences have been developed allowing co-registered strain and shear wave elastograms to be generated. Acoustic output parameters for these sequences have been measured, and IRB approval obtained for human subjects studies.

15. SUBJECT TERMS

None listed

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1. Introduction

The overall objective of this project is to research technologies that support sonographer-supervised robotic systems for breast ultrasound imaging with quantitative elastography. Elastography provides tissue metrics independent of B-mode image features to deliver improved lesion classification, but current techniques are hampered by sensitivity to variations in probe motion and pressure, resulting in significant operator dependence. By delivering advanced, operator-independent elastography data, the proposed system will address the urgent need to improve the positive predictive value (PPV) of ultrasound to spare women unnecessary biopsies, anxiety, and cost while maintaining quality of care. Our goals in this first year of the project have been to implement robot control algorithms, ultrasound imaging algorithms, evaluate these algorithms on tissue phantoms, and prepare for human subjects research.

2. Keywords

Ultrasound elastography, breast cancer, robotics, human-robot teaming

3. Accomplishments

3.1 What were the major goals of the project

The overall goal of this research is to investigate technologies for improving the positive predictive value (PPV) of ultrasound screening. The specific aims for this research include implementation of a robotic arm control system with haptic interface for breast ultrasound scanning and elastography (SA1) and perform experiments with robotically-assisted elastography in vivo (SA2). Year 1 is focused on developing technologies to support human-robot ultrasound scanning systems, while Year 2 and Year 3 will transition towards studies and refinement of the control system and haptic interface.

3.2 What was accomplished under these goals

The research tasks involving development of technologies for robotic ultrasound scanning hardware, software, and systems (RT1) were led by PI Thomas Howard of the Robotics and Artificial Intelligence Laboratory at the University of Rochester. Tasks involving development of elasticity software and ultrasound imaging (RT2), imaging patients pre-biopsy (RT3), and analysis of in vivo data (RT4) were led by PI Stephen McAleavey in the Department of Biomedical Engineering at the University of Rochester.

Subtasks of RT1 include final arm and haptic interface selection, ultrasound transducer/robot end-effector design and machining (RT1-ST1, McAleavey/Howard), implementation and testing of arm/haptic interface control system (RT1-ST2, Howard), and validation of inverse kinematic model and force measurement, constant pressure/constant position mode validation, and human safety verification (RT1-ST3, Howard). The milestone for RT1 included the design goals achieved with quantification of arm mechanical properties (RT1-M1, McAleavey/Howard).

Under subtask RT1-ST1, we developed a system architecture for a platform that investigates technologies for collaborative robotically-assisted ultrasound scanning which includes a compliant robotic manipulator, a force/torque sensor, a wrist-mounted ultrasound transducer, a haptic interface device, and a ultrasound scanning device. For the compliant robotic manipulator we are using a Rethink Robotics Sawyer Collaborative Robot and the force/torque sensor we are using a Robotiq FT 300 Force Torque Sensor. For the ultrasound scanning system we are using a Verasonics Vantage 64 LE with an L11-4v ultrasound probe embedded within a 3D printed enclosure made from ABS plastic. For the haptic interface device we have acquired a Geomagic Touch X. Images of the collaborative robotically-assisted ultrasound platform is illustrated in Figure 1.

Figure 1: Images illustrating the research platform we are developing for investigating technologies on robotically-assisted medical ultrasound. The platform, which consists of a robotic manipulator, force/torque sensor, ultrasound transducer mount, and haptic interface device, is shown in the leftmost image. In one approach to human-robot interaction that we are investigating a person (called the "spotter") positions and orients the ultrasound transducer to a point of contact on a subject as illustrated in the center image. The hybrid force/velocity control is then engaged with a button on the wrist cuff of the robot as illustrated in the rightmost image (highlighted in green oval).

Software for the research platform is being developed using a private gitlab repository that is shared across the project members and hosted by the University of Rochester's Center for Integrated Research Computing, which contains software for sensor integration, manipulator control, simulation, visualization, and acquisition and processing of ultrasound scans. The software is principally developed in C++ and MATLAB and leverages ROS for interprocess communication and CMake build management.

Under subtask RT1-ST2, we implemented a hybrid force/velocity controller to provide force control along the z-axis of the force/torque sensor and position/velocity control along the other position and orientation dimensions. A block diagram illustrating the structure of this control architecture is illustrated in Figure 2. In this, desired linear velocities in the wrist frame x-axis and y-axis directions and angular velocities in the wrist frame x-axis, y-axis, and z-axis directions and provided with a desired force setpoint in the wrist frame z-axis direction that is coincident with the z-axis of the force/torque sensor. Twist and wrench estimators are used to provide feedback to the controller to adjust the manipulator inputs to minimize the error between the desired and estimated force values.

We have also investigated different approaches for interfacing between the human and manipulator for controlling the ultrasound scanning platform. Under the first approach we utilize the wrist cuff buttons of the Sawyer Collaborative Robot to transition control modes between the hybrid force/velocity controller and a gravity compensation control mode that enables a person to directly position and orient the wrist-mounted ultrasound transducer. The person directly interacting with the end-effector of the robot (called the "spotter") then engages the hybrid force/velocity controller with the desired force setpoint by pressing a separate button on the wrist cuff of the robotic manipulator. The controller can be stopped by engaging with buttons on the wrist cuff, by an intervention from a person stationed at a workstation computer (called the "operator"), or by the subject or spotter engaging the electronic stop (e-stop) button. The second mode of interaction that we are investigating involves greater influence over the wrist velocities and feedback of the forces experienced by the force/torque sensor through the haptic interface device. Integration of the haptic interface device with the hybrid force/velocity controller is still underway, as research has focused on development of the first human-robot interface approach.

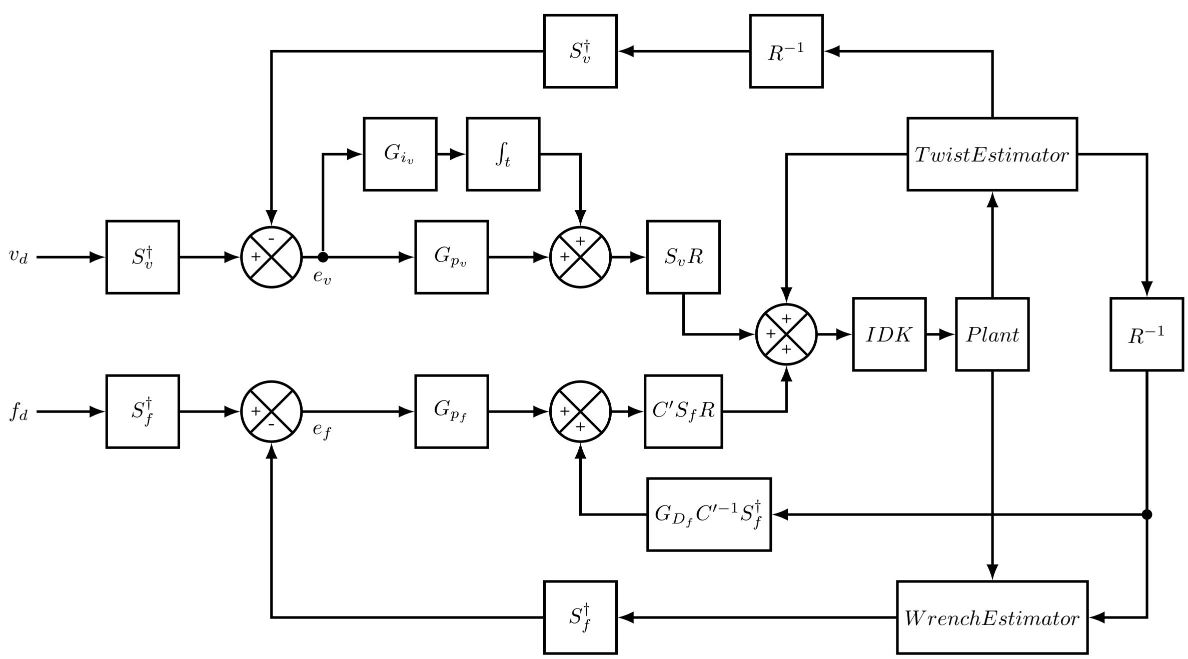

Figure 2: A block diagram illustrating the implementation of our hybrid force/velocity controller.

Under subtask RT1-ST3, we have performed a series of experiments to quantify the performance of the hybrid force/velocity control system. An illustration of our experimental procedure is shown in Figures 3-5, which shows the controller engaged with a phantom under constant or transient force and velocity setpoints after calibration of the force/torque sensor.

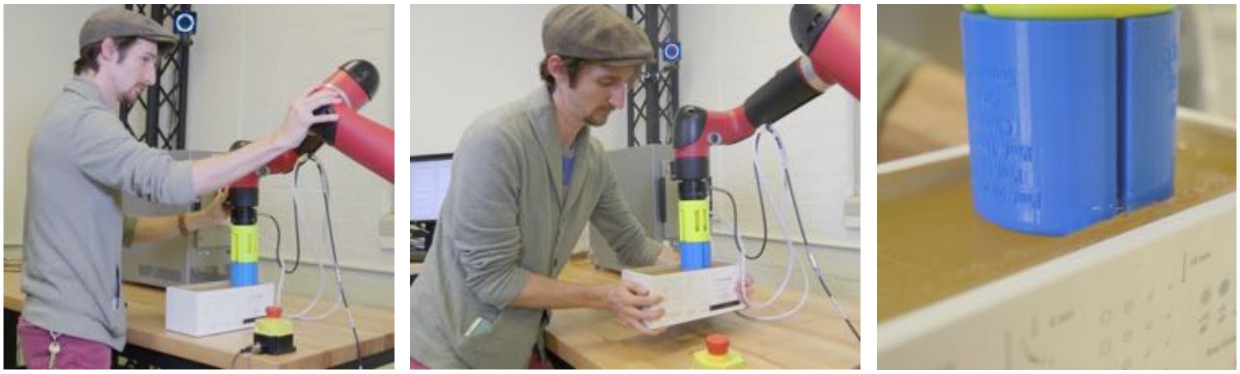

Figure 3: Illustrations of experiments to evaluate the performance of the force/velocity controller subject to displacements of the phantom, simulating movement or respiration of the subject.

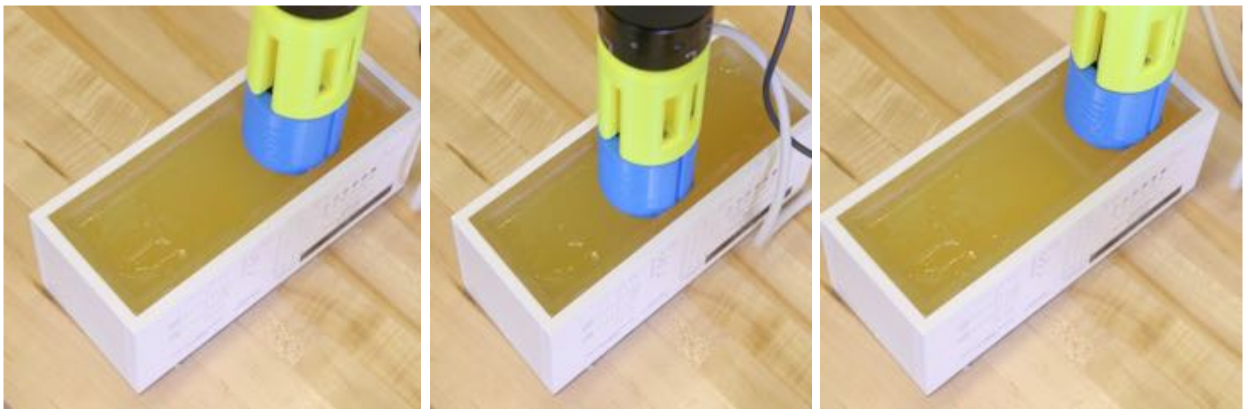

Figure 4: Time sequenced images of lateral end-effector motion under a constant force setpoint on a rectangular phantom.

Figure 5: Time sequenced images of lateral end-effector motion under a constant force setpoint on a physiologically inspired phantom.

These experiments allow us to evaluate the performance of the hybrid force/velocity controller under step responses that simulate engaging and disengaging the force setpoint and varying the force setpoint through small incremental adjustments during the scan (Figure 6). We are currently investigating the impact of our stiffness estimate in our hybrid force/velocity controller and have observed underdamped and overdamped transient response behaviors with stiffness estimates that are too low and too high respectively (see Figure 7), which supports our current investigation on feeding back the stiffness estimate acquired through elastography to the controller to incrementally improve the performance of the transient response during imaging. We continue to test the safety of our platform for investigating technologies for robotically-assisted medical ultrasound by testing our ability to interrupt motion of the robot through the aforementioned modes of interaction.

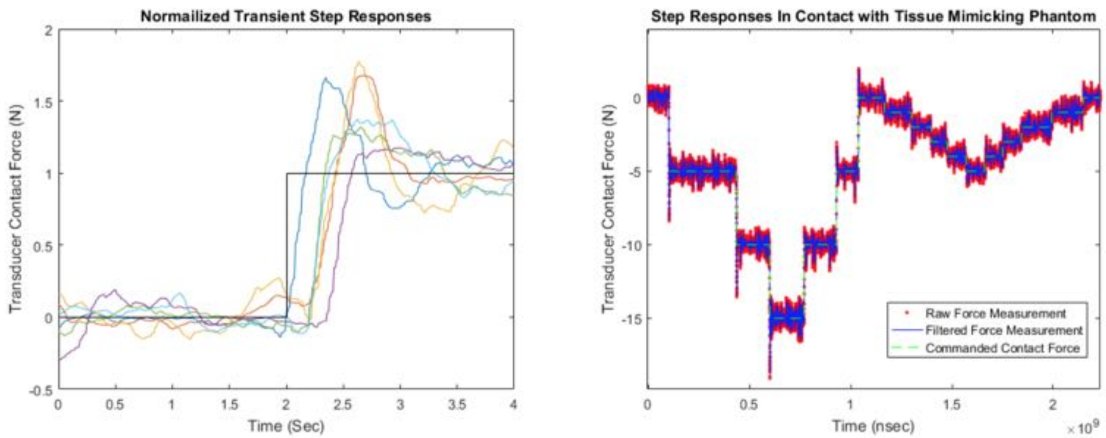

Figure 6: Transient behavior of the hybrid force/velocity controller with a step response illustrated in the leftmost image and varying force setpoint values in the rightmost image.

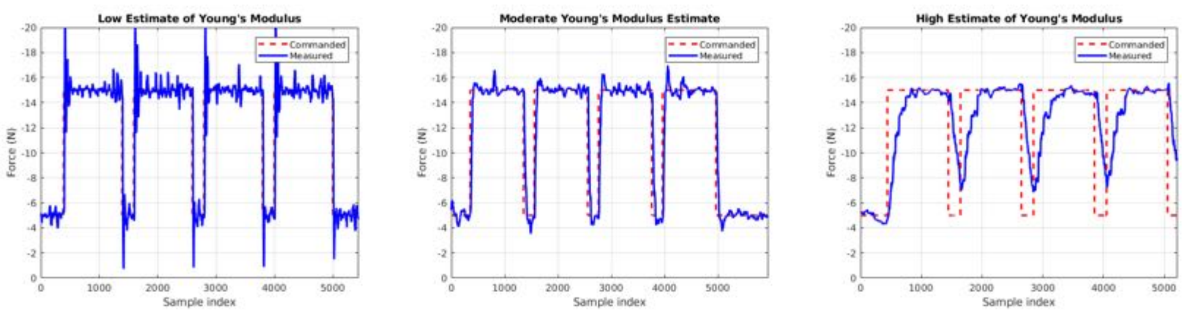

Figure 7: Transient behavior of the hybrid force/velocity controller while varying values of estimated stiffness. A well-tuned controller with an accurate stiffness estimate should exhibit the transient behavior of the centermost plot, which exhibits little overshoot and fast settling times.

We consider the RT1-M1 milestone satisfied by demonstrating the performance of force/velocity control of the device for investigating robotically-assisted medical ultrasound using a method of interaction that is suitable for performing studies in vivo, though we will continue to refine our system under RT1 and RT2 activities.

Subtasks of RT2 include phantom design (RT2-ST1, McAleavey/Doyley), implementation of combined shear wave and strain elastography for viscoelastic, poroelastic, and non-linear modulus imaging (RT2-ST2, McAleavey/Doyley), phantom validation of elastography software using laboratory systems (RT2-ST3, McAleavey/Doyley), and phantom validation of elastography software using robotic arm system (RT2-ST4, Howard/McAleavey/Doyley). The milestones for RT2 are in vitro validation of robotic arm elastography system (RT2-M1, Howard/McAleavey/Doyley) and publish a paper on implementation of robotically assisted elastography (RT2-M2, Howard/McAleavey/Doyley). Milestones RT2-M1 and RT2-M2 are both targeted for year 2, as per the original statement of work.

To complete RT2-ST1 we have created facilities for fabrication of gelatin and cryogel phantoms with controllable acoustic properties and geometry. We evaluate the mechanical properties of these phantoms through mechanical testing (unconfined compression) as well as shear wave elastography. We have also obtained commercial ultrasound breast anatomical phantoms containing stiff inclusions for elastography imaging.

Under RT2-ST2 we have implemented combined shear wave and strain elastography imaging sequences on the Verasonics 64 LE system. We have successfully implemented both methods on the Verasonics 64 LE system. Figure 8 presents a representative image obtained with the system of a stiff inclusion in a CIRS 049A elastography phantom.

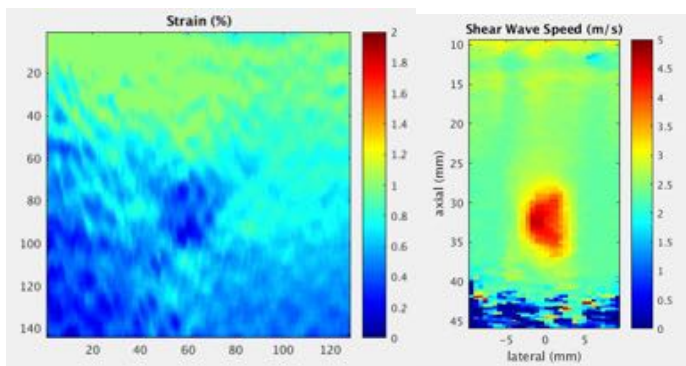

Figure 8. Strain elastogram (left) and shear wave speed image (right) of a 6.5 mm in diameter inclusion a in CIRS 049A phantom obtained with our system. Note the decreased strain in the inclusion, consistent with its greater stiffness relative to the background. The increased shear wave speed likewise is consistent with increased stiffness; in an elastic material, shear wave speed is proportional to the square root of shear modulus: G=ρc^2

Under RT2-ST3 we have validated shear wave speed estimates obtained with our Verasonics shear wave sequences and have studied the effects of target motion and ultrasound system beamforming parameters on shear wave speed estimate variance. To provide guidance for the eventual use of these sequences in vivo, measurements of shear wave velocity were performed in homogeneous tissue mimicking phantoms with physiologically relevant modulus. Velocity estimate variance was characterized as a function of transmit and receive F/#, shear wave pixel size, and ARFI push beam size. Effect on usable depth of field of the shear wave speed image as a function these parameters was also measured.

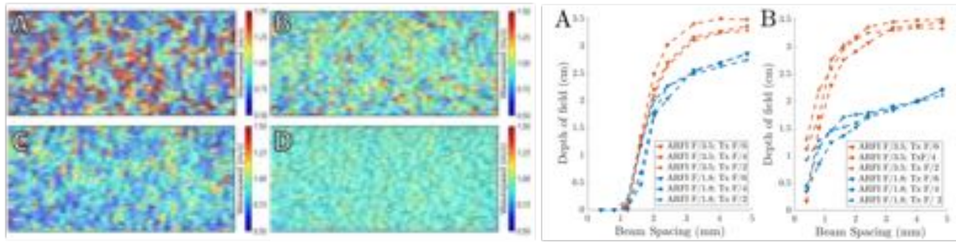

Figure 9: Illustration of beam sequence effects on elastographic SNR (left panel) with A&C representing conventional (MTL) shear wave elastography data at 0.4 and 1.6mm spatial resolution, and B&D representing our improved method (STL) at identical spatial resolutions. (right panel) Depth of field of elastograms as a function of beam sequence parameters for MTL (A) and STL (B).

As per the original statement of work, activities to complete RT2-ST4 are planned for next the next quarter. We are in the process of integrating the elasticity estimates obtained with the Verasonics scanner with the robotic arm system controller.

The research tasks involving SA2 include imaging of patients pre-biopsy (RT3) and analysis of in vivo data (RT4). Subtasks of RT3 include submitting documents for IRB review (RT3-ST1, McAleavey), train sonographers and students in scanning procedure (RT3-ST2, McAleavey/Howard/O'Connell), recruiting 72 patients for imaging (RT3-ST3, McAleavey/O'Connell), and scanning patients (RT3-ST4, McAleavey/O'Connell). Milestones of RT3 include IRB approval received (RT3-M1, McAleavey) and 72 patients scanned (RT3-M2, McAleavey). Subtasks of RT4 include collecting histology data (RT4-ST1, McAleavey/O'Connell) and statistical analysis of poroelastic, viscoelastic, and non-linear parameters vs histology and BiRADS category (RT4-ST2, McAleavey). The only milestone of RT4 is to publish the results of in vivo measurements and statistical analysis (RT4-M1, McAleavey/Doyley/Howard/O'Connell).

Under RT3-ST1, we have submitted and received our letter of initial IRB approval for the proposed human subjects experiments. The research protocol was approved as a minimal risk study, with the Sawyer robotic arm considered a non-significant-risk (NSR) device, and Antares and S3000 ultrasound scanners used according to FDA approved indication. Informed consent documents are approved, with subjects to be recruited in person from patients in the University of Rochester Medical Center Breast Clinic. We consider milestone RT3-M1 achieved.

In support of our submission to IRB for approval of our research protocol, we have assembled a system for acoustic output quantification, and performed acoustic output measurements on the shear wave imaging sequences used above.

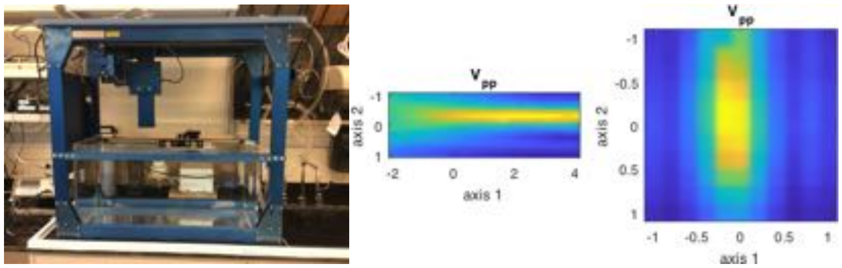

Figure 10. (left) Acoustic output measurement system, consisting of 3-axis positioner, water conditioning system, hydrophone, amplifier, and digital oscilloscope. (center and right) Representative axial (center) and transverse (right) plots of ultrasound push beam patterns obtained with the system under control of custom Matlab software.

3.3 What opportunities for training and professional development has the project provided?

This project has provided support to two graduate students in PI Howard's Robotics and Artificial Intelligence Laboratory. The research on hybrid force/velocity control for acquiring ultrasound scans under constant force and position setpoints supported the work of Christian Freitas in preparation of his Master's thesis in Electrical Engineering that he is scheduled to defend in March 2018. The work on stiffness estimation from strain elastography for adaptive hybrid force/velocity control is one of the principal research topics of Michael Napoli's doctoral research. Michael joined the research project after Christian accepted a full-time engineering position earlier this year.

This project has supported one undergraduate and one graduate student in PI McAleavey's ultrasound imaging laboratory. Undergraduate Katelyn Offerdahl worked to quantify the performance of shear wave elasticity imaging methods during periods of transducer motion. Her work led to a conference publication as well as 2 papers in preparation. Graduate student Soumya Goswami has begun training in the last month of the project period.

3.4 How were the results disseminated to communities of interest?

Results were disseminated to communities of interest through publication of refereed conference papers and research presentations at academic conferences as outlined in Section 6.1.

3.5 What do you plan to do during the next reporting period to accomplish these goals?

During the next reporting period (2/2018-1/2019) we plan to prepare and begin in vivo experiments of our platform for research in robotically-assisted medical ultrasound. This will include working with Dr. O'Connell to train sonographers and develop a suitable scanning procedure. We will also revise our statement of work to more precisely define subtasks and milestones for robotic technology development that will be performed during this reporting period, including integration of more sophisticated modes of human-robot interaction and studies on transient response of controller performance.

4. Impact

4.1 What was the impact on the development of the principal discipline(s) of the project?

Nothing to report for this period beyond the publications and presentations listed below.

4.2 What was the impact on other disciplines?

Nothing to report for this period.

4.3 What was the impact on technology transfer?

There was no technology transfer that occurred under this project during the 2017-2018 period of performance.

4.4 What was the impact on society beyond science and technology?

Nothing to report for this period.

5. Challenges / Problems

5.1 Changes in approach and reasons for change

On the robotic technology development research tasks, integration of the haptic interface device was pushed later in the schedule to promote a more direct method of positioning and orienting the end-effector that is enabled through the wrist-mounted buttons on the manipulator that was selected for this research platform. We still plan to continue integrating the haptic interface device to test modes of issuing adjustments of position and orientation to the ultrasound transducer as a second mode of interaction for performing in vivo experiments of technologies for robotically-assisted medical ultrasound. IRB protocol submission occurred later than originally planned to allow us to construct a prototype of the system that we will use for these studies, which informed the procedures that we eventually submitted for approval. Nonetheless IRB approval has been obtained as originally scheduled.

5.2 Actual or anticipated problems or delays and actions or plans to resolve them

There are no problems or significant delays to report.

5.3 Changes that had a significant impact on expenditures

Some of the expenditures for components of the robotic system (sensors, workstation) that we had originally scheduled to order and integrate during the first year of the period of performance was postponed to the following year. We have spent less than anticipated on graduate student support due in part to students supported by this project accepting full-time engineering positions and delays in graduate student recruiting due to fixed admissions schedules.

5.4 Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

There were no significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents.

6. Products

6.1 Publications, conference papers, and presentations

Papers, articles, and theses on the adaptive stiffness estimation for control of the robotically-assisted ultrasound platform are in preparation for submission to academic conferences at this time. Papers published and presentations given during this year's period of performance are listed below.

Publications:

1) Katelyn Offerdahl and Stephen McAleavey, "Influence of Transmit Beamforming Parameters on Image Quality in Quantitative Elastography," Proceedings of the 2017 IEEE International Ultrasonics Symposium, Washington, DC

Presentations:

1) Katelyn Offerdahl and Stephen McAleavey, "Influence of Transmit Beamforming Parameters on Image Quality in Quantitative Elastography," presented at 2017 IEEE International Ultrasonics Symposium, Washington, DC

2) Rifat Ahmed, Stephen McAleavey, Marvin Doyley, "A Novel Tracking Strategy for Single Tracking Location Shear Wave Elasticity Imaging," presented at 2017 IEEE International Ultrasonics Symposium, Washington, DC

3) Stephen McAleavey, "Towards the Goal of High Resolution, Low Noise, and Low Variance in Shear Wave Elastography," presented at the 2017 International Congress on Ultrasonics, Honolulu, Hawaii (Invited)

6.2 Website(s) or other Internet site(s)

Announcement of project: http://www.hajim.rochester.edu/bme/news-events/news/archives/2017/2017-01-31_mcaleaveygrant-.html

6.3 Technologies or techniques

There are no technologies or techniques to report.

6.4 Inventions, patent applications, and/or licenses

There are no inventions, patent applications, and/or licenses to report.

6.5 Other products

There are no other products to report.

7 Participants & other collaborating organizations

7.1 What individuals have worked on the project?

Name:	*Stephen McAleavey*
Project Role:	*PI*
Researcher Identifier:	*eRA Commons User ID: smcaleavey*
Nearest month worked	*2*
Contribution to Project:	*Human subjects protocol development and approval, ultrasound shearwave elastography systems development*
Other Funding Support:	*NIH, NYSTAR*

Name:	*Thomas Howard*
Project Role:	*PI*
Researcher Identifier:	*IEEE PIN: 107736*
Nearest month worked	*2*
Contribution to Project:	*Development of the ultrasound transducer mounting, software architecture, implementation and integration of the hybrid force/velocity control software, Rethink Robotics Sawyer Robot interface, and Robotiq Force/Torque sensor interface.*
Other Funding Support:	*NSF, ARL*

Name:	*Marvin Doyley*
Project Role:	*Co-PI*
Researcher Identifier:	*eRA Commons User ID: mmdoyley*
Nearest month worked	*1*
Contribution to Project:	*Strain elastography system development lead*
Other Funding Support:	*NIH*

Name:	*Christian Freitas*
Project Role:	*Graduate student*
Researcher Identifier:	*IEEE PIN: 224766*
Nearest month worked	*4*
Contribution to Project:	*Development of the hybrid force/velocity control software, Rethink Robotics Sawyer Robot interface, and Robotiq Force/Torque sensor interface for control of the manipulator in the human-robot system.*
Other Funding Support:	*NYSCoE in Data Science*

Name:	*Michael Napoli*
Project Role:	*Graduate student*
Researcher Identifier:	*IEEE PIN: 198132*
Nearest month worked	*2*
Contribution to Project:	*Performing experiments on hybrid force/velocity controller software capabilities for strain elastography, integration of the elastography software stack with arm control software, interfaces, and sensors.*
Other Funding Support:	*NSF*

Name:	*April Wang*
Project Role:	*Graduate student*
Researcher Identifier:	--
Nearest month worked	*1*
Contribution to Project:	*Ultrasound phantom fabrication*
Other Funding Support:	*NIH*

Name:	*Rifat Ahmed*
Project Role:	*Graduate student*
Researcher Identifier:	--
Nearest month worked	*1*
Contribution to Project:	*Shear wave and strain elastography sequence development*
Other Funding Support:	*NIH, NYSTAR*

Name:	*Katelyn Offerdahl*
Project Role:	*Undergraduate student*
Researcher Identifier:	--
Nearest month worked	*2*
Contribution to Project:	*Quantification of ultrasound beam sequence parameters on signal-to-noise and contrast-to-noise ratios of shear wave elastograms. Quantification of elastogram noise due to probe or tissue motion. Development of test fixtures*
Other Funding Support:	

7.2 Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

PI Howard has new funded activities under a National Science Foundation Smart and Autonomous Systems grant titled “S&AS: FND: COLLAB: Probabilistic Underactuated Motion Adaptation” with a period of performance from 10/1/2018-9/30/2020 and an Army Research Laboratory Robotics Collaborative Technology Alliance subtask titled “Adaptive Models for

Human-Robot Interaction in Diverse Decentralized Human-Robot Teams” with a period of performance from 1/1/2017-2/28/2018.

PI McAleavey and Co-I Doyley have newly funded activities under a Center for Emerging and Innovative Sciences grant titled “Towards Automated Clinical Evaluation Of Tendon Through Shear Wave Elastography”, with a period of performance from July 2017-June 2018.

Co-I Doyley has two new NIH-funded grants: An R21 titled “Super-harmonic ultrasonic imaging of the coronary artery” and an R56 “Surrogate imaging biomarkers for tracking anti-stromal therapy”.

7.3 What other organizations were involved as partners?

There are no other organizations involved as partners in this research.

8 Special reporting requirements

There are no special reporting requirements. This report reflects the work of PI McAleavey under Award Number W81XWH-17-1-0021 and PI Howard under Award Number W81XWH-17-1-0022. Leadership and organization of research tasks have been marked with the responsible PI and site of the research activities.