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14. ABSTRACT

The Assessment of Robotic CABG Experience and Training (TARGET) Program is a collaborative project between the Thomas Jefferson University and Hospital. The award received allowed TJU/TJUH to support the purchase of the daVinci robot system with matching funds allotted by the hospital to purchase the proctoring console for future education and training of students, residents and surgical faculty. This purchase acquisition provided the foundation for recruiting a junior faculty robotic surgeon and to begin the first hospital-based CT surgery program. The TARGET Project deliverables will continue to be used and studied by the investigator teams at TJU/TJUH. Additional research is planned with skill training using the VR Simulator. The OR team training materials (Clinical Scenario DVDs) and the Competency Performance DVD will be incorporated into the existing programs for hospital staff training.

15. SUBJECT TERMS
None provided.

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INTRODUCTION

Robotic surgery recently emerged as a new technology that allows total endoscopic coronary artery bypass (TECABG) surgery. The trajectory to successfully adopt new surgical techniques requires critical steps, particularly regarding training and establishment of skill with standardized evaluations to ensure consistent practices. Metrics for monitoring performance, quality, and outcomes need to be developed and maintained. The TARGET Project proposed the development of a robust training program that included traditional education methods coupled with simulation techniques could be developed to meet identified quality and performance metrics for TECAB procedures and identified three (3) technical objectives. The focus is on one component of the TECAB, takedown of the left internal mammary artery (LIMA), as a model. A program of comprehensive training, credentialing, and monitoring for novel surgical techniques in endoscopic cardiac bypass surgery is important not only for surgeons and surgical teams just beginning to perform robotic surgery, but also for those at risk for skills degradation, which may be the case for military personnel returning from tours of duty. The Assessment of Robotic CABG Experience and Training (TARGET) Program is a collaborative project between the Thomas Jefferson University (TJU) and Hospital (TJUH). The Telemedicine and Advanced Technology Research Center, US Army Medical Research and Materiel Command award, in combination from matched funds from TJU/TJUH is dedicated to the acquisition of a da Vinci surgical robot for use Cardiothoracic (CT) Surgery procedures.

The A multidisciplinary team of Thomas Jefferson University and Hospital investigators and key personnel collaborated on the TARGET Project.

Principal Investigator:	David J. Whellan, MD, MHS Director, Coordinating Center for Clinical Research
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Key Personnel:	Suzanne Adams, RN, MPH Project Manager, Coordinating Center for Clinical Research
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BODY

Summary of TARGET Project Activity Reports (Quarter 1 to Quarter 3)
A general overview of information from the TARGET Project quarterly reports is summarized below. A detailed review is presented in **Table 1**.

Q1: During the first quarter of this project, much of the logistical groundwork was completed to the successful development of the team structure and roles.

Q2: During the second quarter of this project, the research team focused on the following activities: collection of performance metrics-conventional CT surgery (LIMA takedown procedure); collaboration with external colleagues performing robot-assisted CT surgery; collaboration with external training programs in robot-assisted CT surgery; literature review update for robot-assisted surgical skill training/performance metrics; and development of Robotic OR Team training including crisis management.

Q3: During the third quarter of this project, the research team focused on the following activities: collection of performance metrics-conventional CT surgery (LIMA takedown procedure); collaboration with external colleagues performing robot-assisted CT surgery;
collaboration with external training programs in robot-assisted CT surgery; ongoing literature review for robot-assisted surgical skill training/performance metrics; development of Robotic OR Team training materials including crisis management; and development of scripted educational content for training video modules and preparation for filming.

Table 1. TARGET Project: Overview of Progress Reports (Q1 –Q3)

Time	Activity	Action
Q1	Equipment Acquisition and OR Designation	The TJUH administration completed the purchase and took delivery of the da Vinci Robotic Surgical System SI as well as a separate "surgeon proctoring console" to be used for training activities. This equipment is set up in a designated CT OR suite on the fifth floor of the TJUH Gibbon building. Some renovations to the OR suite are in progress, including installation of a Stryker camera system and selection of a surgeon camera.
	TJU IRB	The Project Management team prepared and submitted the TARGET protocol and site survey to the TJU IRB as an exempt review. IRB approval was received on 21DEC2010; the IRB document package sent to U.S. Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO), and Col. Stephenson on 10JAN2011.
	CT Surgical Team Integration	The Project Management team established and now coordinates a bi-weekly meeting with the CT surgeons, CT OR team, and TJUH administration to manage/coordinate project activity. A robotic equipment technician has been selected for the CT team and is completing training with the current robotic coordinator from the Urology OR team. A CT OR special teams coordinator has her duties expanded to include robot-related procedures. This coordinator is preparing education and training materials for OR staff in anticipation of competency assessments.
Q2	Equipment Acquisition	TJUH arranged to purchase the Intuitive da Vinci skills simulator. We anticipate delivery of the simulator this month, APR 2011.
	TJU IRB	HRPO agreed with the TJU IRB and designated the protocol as exempt 11MAR2011.
	CT Surgical Team	The TARGET Project Management team established and now coordinates a bi-weekly meeting with the CT surgeons, CT OR team members, and TJUH

	Integration	administration to manage and coordinate project activity. A robotic equipment technician has been selected for the CT team and is completing his training with the current robotic coordinator from the Urology OR team. A CT OR special team's coordinator's duties have been expanded to include the accountability for robot-assisted CT procedures. This coordinator is preparing education and training materials for OR staff in anticipation of competency performance assessments.
Q3	Equipment Acquisition	TJUH has acquired the Da Vinci skills simulator (this purchase was completed with hospital funding outside the DoD grant award). The current software embedded in this simulator does not allow for multiple users to track individual progress. Da Vinci is planning on releasing an software update within the next few months to allow for this capability and TJU anticipated adding this upgrade when it is available. However, Dr. Lallas (Director of Robotic Surgery) is using the simulator for multiple user training and skill performance evaluation by collecting and documenting metrics independent of the internal simulator capabilities.
	CT Surgical Team Integration	The TARGET Project Management team continues to hold monthly meetings with the CT surgeons, CT OR team members, and TJUH administration to manage and coordinate project activity. Other meetings with the University Clinical Simulation Skills Center faculty and staff are held on an ad-hoc basis as needed.
	New Personnel	Dr. Gurjyot Bajwa, will join the TJU CT surgery faculty on 01JUL2011. Dr. Bajwa from the Cleveland Clinic where she completed a CT surgery fellowship under Dr. Tomislav Mihaljevic, specializing in minimally invasive and robotically assisted cardiac surgery, and valve repair and replacement.

TARGET Project –Summary Report on Technical Objectives Activity

Technical Objective 1: Establish training program using expertise from the UCSSC at TJU, including the use of computerized virtual reality simulator and advanced educational method that will enhance the basic training program currently offered.

Objective 1 has three distinct components: 1) the purchase and set-up of the da Vinci surgical equipment and the Virtual Reality simulator; 2) the survey of robotic CT surgical programs outside of Jefferson: and 3) the application of expertise from the UCSSC to the development of the robotic training program. The successful completion of these components involves coordination among various members of the project team including the project manager, TJUH administration, CT surgery, OR nurses and technicians, and the UCSSC faculty and staff

Q1: The purchase and set-up of the da Vinci surgical system has been completed. Plans for renovations of the OR where the surgical system lives are currently underway. Also, TJUH administration is currently working with Intuitive for the acquisition of their new Virtual Reality Simulator software. A price has been negotiated and we await the contract agreement from Intuitive to complete the transaction and take delivery. TJU/TJUH will be among the first centers to acquire this novel technology; we anticipate enhanced utilization because of the flexibility to work with both the robot console and the proctoring console.

The PI and project manager are working with the CT surgeons and OR Team to set up site visits to other institutions with CT surgery programs. Dr. Diehl has identified 4 sites with established robotic CT surgery programs that he would like to approach for a visit. These include Maryland, East Carolina, Atlanta, Cleveland Clinic and potentially Los Angeles Cedars Sinai. The first site visit is scheduled for

February 17, 2011 with Dr. Johannes Bonatti at the University of Maryland Medical Center. The project personnel who will attend this visit are Drs. Whellan and Diehl in addition to several members of the OR Team and the Project Management Team.

Dr. Katherine Berg of the Jefferson University Clinical Skills and Simulation Center (UCSSC) is working with Dr. Costas Lallas, the TJU/H Director of Robotic Surgery to develop robot-assisted surgery-specific scenarios that can be adapted for use in team simulation training. These scenarios will address perioperative OR set-up and patient preparation and crisis management situations.

Q2: Contract negotiations for the purchase of the da Vinci Skills Simulator are completed and we anticipate the simulator will be delivered this month (APR2011). TJU/TJUH will be among the first of a small group of robot-assisted surgical programs to receive this virtual reality simulator, presenting a unique opportunity for us to incorporate this software package into a training curriculum.

Representatives of the TARGET team completed the first site visit to an outside institution on 17FEB2011. Dr. Whellan, Dr. Lallas, and 4 other project team members traveled to the University of Maryland Medical Center to meet Dr. Johannes Bonatti and Dr. Eric Lehr and review their robot-assisted CT surgery program and training practices. The team was able to observe a full TECAB surgical procedure including OR set up, robot set-up and patient preparation. We also held a post-procedure discussion based on our observation of OR team communications and dynamics. Other topics included a surgeon discussion of learning curves for TECAB surgery and a review of performance metrics collected at U Maryland. We will explore the potential to incorporate those performance metrics into our aggregate collection. We were also able to visit the MASTRI Center which is a hospital-based simulation laboratory. There is a da Vinci robot on site that is currently devoted to research on ergonomics related to specific procedures and actions associated with robot-assisted techniques and procedures

Plans for future visits

In JAN2011, Intuitive Surgical announced that an Intra-Cardiac Robotic Symposium, focusing on team development, will take place in Atlanta at St. Joseph's Hospital from April 7 to April 9. Because of the direct relevance of this symposium to our protocol we made arrangements for the TARGET Project Manager and the TJUH Robotic Director to attend this meeting. Key presenters at this conference include Dr. Murphy from St. Joseph's Hospital, Atlanta, Dr. Trento from UCLA, and Dr. Mihaljevic from the Cleveland Clinic, two sites that we targeted for potential site visits. We will use our time at this symposium as an opportunity to meet these surgeons and discuss visiting their sites in the future.

Robotic OR Team Training

The team training component of this project will take the form of instructional team videos produced by TJU UCSSC. The content of these videos will focus on technical robot-specific team skills as well as non-technical OR team skills. The technical robotic skills are based on the TJUH's robotic set-up competency document which has already been in use as an internal training document. The non-technical skills portion is based on the "Oxford Non-Technical Skills (NOTECHS) Scale", which was developed from an aviation team training tool and applied specifically to OR team-based interactions. Skills measured through the NOTECHS system include Leadership and Management, Teamwork and Cooperation, Situation Awareness, and Problem Solving and Decision Making.[1] We are also collecting background information on training in the Crew Resource Management: Aviation Model, (http://www.aviationteamwork.com/)[2], widely used in managing interactive team communications and the Team STEPS (teamstepps.ahrq.gov/, an evidence-based team training and implementation toolkit that demonstrates techniques of effective communication and other teamwork skills available from the federal Agency for Healthcare Research and Quality.

Dr. Lallas, TJU Director of Surgical Robotics and Drs. Dale and Katherine Berg, Co-Directors of the UCSSC are working to develop robotic OR team clinical scenarios that will serve as the basis for the team training videos. There will be 2 scenarios prepared and filmed for each of the clinical scenarios; one where the team performance breaks down and the team communication and management strategies are not properly followed and implemented, and the other one where the team performance and skills are demonstrated correctly and smoothly. For each scenario, a learning objectives checklist will be included to delineate which skills are being demonstrated.

TJUH has taken deliver of the da Vinci “Virtual Reality” skills simulator. The robotic surgeons are very excited about the potential of incorporating this software into a standardized metric-based skills training program. Currently we are waiting for a software update that will allow the simulator to track the progress of multiple users on various robotic-specific virtual reality skills.

Q 3: Robotic OR Team Training

The team training component of this project will take the form of instructional team videos produced by the University Clinical Skills and Simulation Center (UCSSC). The content of these videos will focus on robot-specific team skills and non-technical operating room (OR) team behavioral and communication skills. The robotic skills are based off of TJUH’s robotic team competency document which has already been in use as an internal training document. The non-technical skills portion is based on the “Oxford Non-Technical Skills (NOTECHS) Scale”, which was developed from an aviation tool and applied specifically to team-based interactions in the Operating Room.

Our goal is to create three team training video scenarios. There will be two videos for each scenario, one demonstrating a failure to use appropriate team OR skills and one demonstrating successful implementation of team skills. Dr. Lallas, the Head of Robotic Surgery at Jefferson worked with Teresa Getz, Jefferson’s robotic coordinator and the CT surgery team to develop scenarios that demonstrate robotic OR team skills. Dr. Dale Berg of the University Clinical Skills and Simulation Center, in collaboration with the TARGET research team, has written first drafts of scripts based on Dr. Lallas’ scenarios, and is currently working on the third. The TARGET team is reviewing the scripts for content. We expect to have final versions of these scripts this month, and anticipate completed videos by late August-early September. The TARGET project management team is currently working on assembling supplemental materials to be used in conjunction with these videos that provide the framework for both the robotic skills and NOTECHS skills demonstrated in the scenarios.

Advanced Intracardiac Robotic Surgery Conference (April 7-8, 2011).

This 2 day conference was jointly sponsored by the St. Joseph’s Hospital in Atlanta, GA, and Intuitive Surgical and focused on “Complete Team Development”. The TARGET project manager, Suzanne Adams, attended the conference and reported back to the TJU research team. The content was focused on surgeon activities regarding operative case techniques, but also included presentations on anesthesia, perfusion, OR nursing staff, and hospital program administration. Additional value was provided by the opportunity to interact with several thought leader/surgeons in CT Robotics including D. Murphy (Atlanta), M. Smith (Cincinnati), T. Mihaljevic (Cleveland), and A. Trento (Los Angeles).

Technical Objective 2: Develop metrics for skills training and TECAB surgical procedure using conventional CABG surgery and current TECAB programs as a reference.

Q1: The metrics will be developed with data from two sources: an evaluation survey of TECAB programs outside of TJUH, and an evaluation of skills and metrics for conventional CABG surgeries performed at TJUH. The survey for outside TECAB programs has been developed and approved by the TJU IRB.

Topics addressed in the survey include training techniques for novice TECAB surgeons, training techniques for robotic OR team members and strategies for surgical skill maintenance. The survey also collects some general data regarding case volume and patient outcomes. The Project Management team is preparing to administer the survey to TECAB programs using the list of surgeons from the da Vinci Community. The TJUH CT surgeons have begun collecting data from their non-robotic CABG / LIMA procedures. These conventional metrics include OR time, LIMA take down time, LIMA size, and blood flow and flow quality. These metrics will be utilized as comparisons for future TECAB procedure metrics.

Q2: The survey of training methods and practices for surgeons and OR teams has been developed and approved by the TJU IRB. We have compiled a list of contact information for approximately 100 CT robotic surgeons across the United States who will receive the survey. An introductory letter/email has been composed to be sent to these surgeons describing our program goals and to gauge interest in responsive participation in the survey.

The TARGET team began collecting performance metrics data from conventional (non-robotic) CT LIMA procedures. We have collected and tabled information from 30 procedures and 5 different cardiothoracic surgeons. Our original goal was 50 sets of metrics and we expect to reach that goal within the next month. These metrics include:

- Total OR procedure time
- LIMA take down time
- LIMA vessel size
- LIMA blood flow assessment
- LIMA blood flow quality

Q3: The survey of training methods and practices for surgeons and OR teams was sent via e-mail to 101 CT surgery teams across the country. We received 31 responses and requests to share results with participants.

The TARGET team continued collecting performance metrics data from conventional (non-robotic) CT LIMA procedures. We have collected and tabled information from 43 procedures and 5 different cardiothoracic surgeons. We are approaching our goal of 50 cases and expect to have the complete dataset by the end of August 2011. These metrics are described above.

Technical Objective 3: Pilot program for the training of cardiothoracic surgeons.

Q1: Technical objective 3 cannot feasibly be implemented until the completion of Objectives 1 and 2. Currently, through data collection at the University, assessment of outside TECAB programs, and the utilization of robot-specific simulation techniques the TARGET team is establishing a basis for the Jefferson training program. The progress that has already been made for the first two objectives will directly lead to the completion of Objective 3.

Q2: The first TJUH robot-assisted LIMA takedown procedure was done in on 03MAR2011 followed by the second on 29APR2011by Dr. Diehl. A crosswalk of individual robot skills/actions has been prepared to correspond with the step by step procedures involved in performing the LIMA takedown.

Q3/Q4: The TJUH CT surgery team has not performed more than 2 robotic LIMA procedures. Dr. Gurjyot Bajwa joined the faculty as of 01JUL2011. However, her specialized training is the robot-assisted mitral valve replacement/repair (MVR). The first robotic MVR was successfully performed on 23SEP2011. The projected schedule will have one robotic case performed per week for a 2 month (time frame is flexible), a team outcomes evaluation, followed by an increase the number of cases as indicated to a 5 per week.

KEY RESEARCH ACCOMPLISHMENTS

Reported as TARGET Project Milestones Timeline

The TARGET project milestones timeline is presented below in **Table 2,** followed by a detailed description of activities and status of each of the eight (8) milestones.

Table 2. Summary of TARGET Project Milestones

Milestone	Date	Status
▪ Purchase and Setup of DaVinci System	DEC 2010	Completed
▪ Survey of TECAB Programs	APR 2011	Completed
▪ Survey of TECAB Programs (METRICS)	APR 2011	Completed
▪ Collection of Conventional LIMA Metrics	AUG 2011	Completed
▪ Create Metric Collection Methods/Tools	JUL 2011	Completed
▪ Conventional Robotic Surgeon/Surgical Team Training	OCT2011	Completed
▪ Evaluation and Modification of Program	OCT 2011	To come
▪ Collect and Track Robotic Metrics	OCT 2011	Completed

- **<u>PURCHASE AND SETUP OF INTUITIVE SURGICAL DAVINCI SYSTEM</u>**

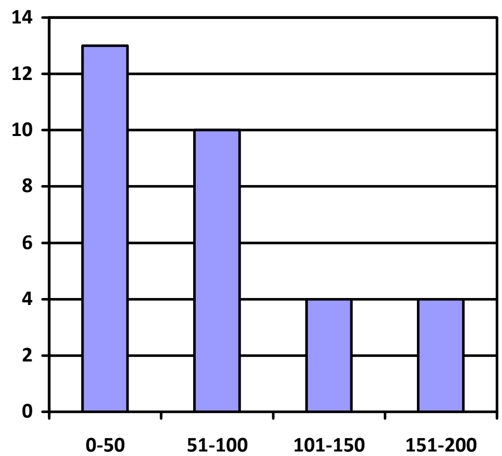
Once the TARGET Project approval was granted, the complete daVinci robot system and an additional surgeon proctoring console were available for delivery to TJUH in a timely manner. By the end of the year (2010) the equipment had arrived and was designated to OR # 24 in the Gibbon 5 Suite.

- **<u>SURVEY OF CT ROBOT-ASSISTED SURGERY PROGRAMS</u>**

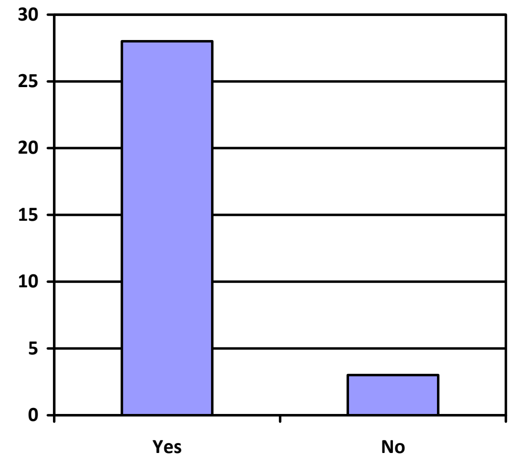
The first activity was an evaluation survey of current robot-assisted cardiothoracic surgery programs developed by the TARGET Project research team and sent to 101 CT surgeons identified through the Intuitive Surgical database of surgeons. The survey was designed in collaboration with the TARGET co-investigators, the UCSSC, and through consultation with outside TECAB surgeons to identify their experiences with current training practices. We received 31 responses, but only 28 of the returned responses were complete. The survey results are presented below under the following topic areas: 1) General Questions; 2) Current Training Techniques for Novice TECAB Surgeons; and 3) Maintenance of Robotic Surgical Skills. A stand alone copy of the survey tool is located in Appendix A.

General Questions

1. On average, how many robotic-assisted CT procedures are performed at your institution per year? (n=31)



2. Does your institution participate in the Society for Thoracic Surgeon's Database? (n=31)

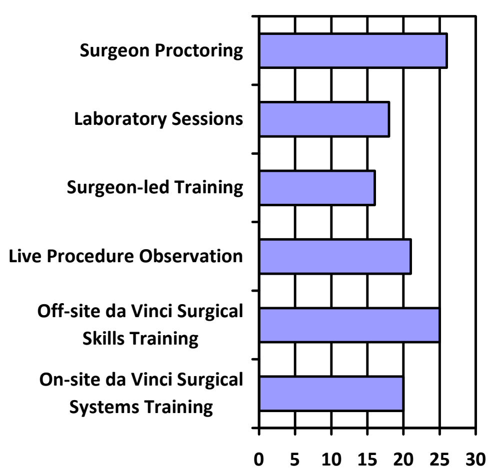


Current Training Techniques for Novice TECAB Surgeons

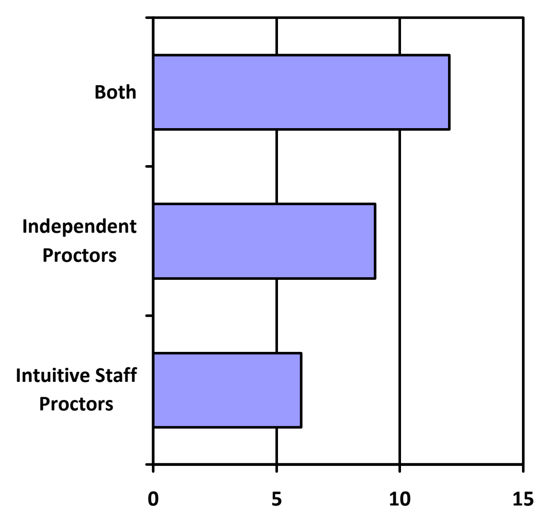
3. Are surgeons who perform robotic-assisted surgery at your institution required to complete the da Vinci system training through Intuitive? (n=28)

   YES: 28

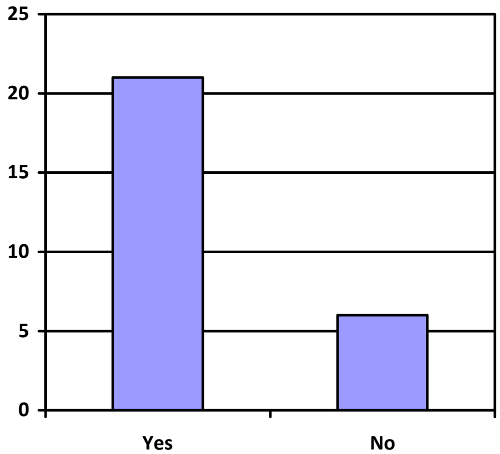
4. If yes, which of the following types of training are the surgeons required to complete through the Intuitive da Vinci system training? (Check all that apply)



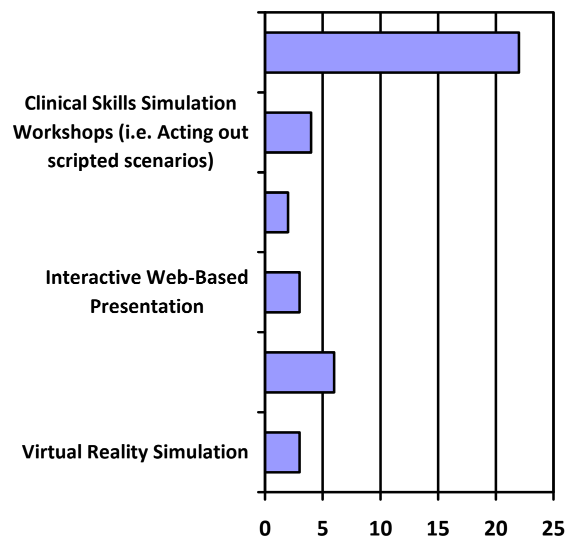
5. If surgeons at your institution are required to complete proctored cases, which type of proctors were used?



6. Aside from the intuitive da Vinci system training program, are novice robotic surgeons at your institution required to complete any additional training before performing robotic surgery? (n=27)



7. If yes, which of the following types of training are the surgeons required to complete through the Intuitive da Vinci system training? (Check all that apply)



8. Are surgeons required to take these additional trainings before they perform robotic-assisted CT procedures?
   YES: 24 **NO: 4**

9. Does the additional training address metrics for "overall motion performance" of the robot by the surgeon?
   YES: 9 **NO: 17** **N/A: 2**

10. Does the additional training address "OR system" skills?
    YES: 11 **NO: 15** **N/A: 2**

11. Does the additional training address any particular surgical skills?
    YES: 16 **NO: 10** **N/A: 2**

12. Does the additional training address any "time to completion" metrics?
    YES: 8 **NO: 18** **N/A: 2**

Maintenance of Robotic Surgical Skills

13. At your institution, are CT robotic surgeons required to undergo regularly scheduled training for skill maintenance?
    YES: 3 **NO: 24**

Comments:

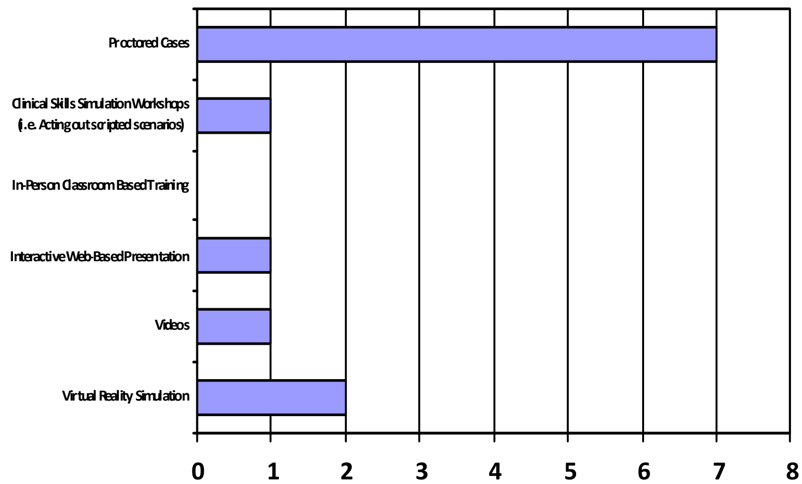
- *"Quarterly"*
- *"Depends on how many they perform per year. If < 10-20, then annually, otherwise no."*
- *Minimum yearly case volumes are required to maintain privileges."*

14. At your institution, are surgeons who have not performed a robotic-assisted CT surgery for an extended period of time required to complete training before performing these surgeries again?
    YES: 8 **NO: 18**

Comments:

- *"Must do 10 cases in a 2 year re-credent cycle"*
- *"Minimum of 10 cases per calendar year; if volume requirements are not met, then must apply again for privileges with demonstration of additional training and re-proctoring of at least 1 case."*
- *"10 cases over two years"*
- *"Hospital requires a minimum of 10 cases per year"*
- *" Must do a minimum of 12 procedures in a 2 year time frame"*
- *"10-20 per year"*
- *"Greater than 4 months"*

15. If yes, what type of training are surgeons who have not performed a robotic-assisted CT surgery for an extended period of time required to complete? (Check all that apply)



The Society of Thoracic Surgeons Database Analysis

The Society of Thoracic Surgeons (STS) is a not-for-profit organization representing more than 6,200 surgeons, researchers and allied health care professionals engaged in surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest. The STS National Database was established in 1989 as an quality and safety initiative with three components focusing on a different area of cardiothoracic surgery—Adult Cardiac, General Thoracic, and Congenital Heart Surgery. More than 100 publications have been derived from Database outcomes data. The Adult Cardiac Surgery Database contains more than 4.5 million surgical records and represents an estimated 94 percent of all adult cardiac surgery centers across the United States.

An STS Publication Task Force with expert representation from all fields of cardiothoracic medicine oversees data requests for clinical research projects. As TJU/TJUH are participants in the STS Adult Cardiac Surgery Database, the Investigator team was able to propose a TARGET-related research analysis. Through consultation with the current Task Force leader, Dr. Todd Rosengart, Professor of Surgery and Chairman of the Surgery at Stony Brook University Medical Center and Dr. Eric Peterson, Professor of Medicine at Duke University Medical Center and an Associate Director of the Duke Clinical Research Institute access to a dataset was granted. The proposed project was a utilization analysis of robot-assisted coronary bypass surgery at the site level between 2006 and 2010. The analysis evaluated non-emergent elective procedures using robotic technology for left internal mammary artery (LIMA) harvest. Because the data used in analyses of the STS represent a limited data set (no direct patient identifiers) that was originally collected for non-research purposes, and the investigators do not know the identity of individual patients, the analysis of these data was declared by the TJU Institutional Review Board (IRB) to be research not involving human subjects and therefore considered exempt. Approval was obtained on 12OCT2011. Future publication is anticipated in the Annals of Thoracic Surgery (the current draft manuscript is available in Appendix C).

SURVEY OF TECAB METRICS

As discussed in the original TARGET proposal, limited information is available in the literature that describes the learning curves and time to skill acquisition for the robot-assisted LIMA takedown procedure. The original report on data collected by Bonatti et. al. presented information on robotic LIMA harvesting time for 38 cases where the time decreased from 180 minutes at the beginning of the series to approximately 50 minutes in the last cases (median: 63 minutes, range: 35-180). The learning curve was significant ($P < .001$) and followed the function: $y = 181 - 39 \times \ln(x)$, where y = LIMA takedown time and x = consecutive LIMA takedown number.[3] We had conversations with Dr. Eric Lehr at U Maryland and Dr. Michael Halkos at Emory U. Both are CT robotic surgeons who collected data on their own learning curve training and performance times. Each reported a clear progression to approximately 30 minutes LIMA takedown time following

- **COLLECTION OF CONVENTIONAL AND ROBOTIC LIMA METRICS**

A total of 111 cardiothoracic revascularization or valve/ revascularization combination surgical cases were performed at TJUH between 29OCT2010 and 9AUG2011. All cases were monitored by the TARGET Project research team. A total of 50 cases involved the LIMA takedown procedure; only 2 cases were done using the robot-assisted method. The conventional LIMA metrics collected included: procedure time in minutes; vessel flow in millimeters/minute; vessel size in millimeters; and quality assessment. A summary of the metrics for all of the LIMA cases is presented below in **Table 3.** The 2 robot-assisted LIMA procedures were performed in MAR/APR 2011. Neither case was able to be fully completed and the cases continued via the conventional open sternum approach. A fully detailed presentation of the data collection is available in Appendix B.

Table 3. Conventional and Robotic LIMA Case Metrics

LIMA Case Data	**Number of Cases**	**Avg. Time (min)**	**Avg. Flow (ml/min)**	**Avg. Size (mm)**	**Quality**	**Comment**
Conventional	50	32.8	51.7	1.77	Good	
Robotic	2*	50/65	20/15	1.25/1.5	Good	*50-75% completed

- **Create Metric Collection Methods/Tools**

The TARGET Project research team performed a comprehensive literature search to identify performance metrics for performance of the robot by the surgeon. These skills were not found to be CT surgery specific.

The overall motion performance skills include:

- Passive positioning of the sensing mechanical arm
- Optical tracking
- Magnetic tracking
- Dead band, dexterity and motion limits
- Synchronization to visualization
- Dynamic behavior and smoothness

The surgeon's system training skills include:

- Surgeon Console Awareness
- EndoWrist Manipulation
- Camera & Clutching
- Trouble Shooting

The specific surgical skills include:

- Needle Control
- Needle Driving
- Energy & Dissection

The time to completion metrics include:

- System set-up
- Manipulation
- Dissection

- Transection
- Suturing/anastamosis
- Bypass pump/cross-clamp duration

- **CONVENTIONAL ROBOTIC SURGEON/SURGICAL TEAM TRAINING**

As described earlier and in the original proposal, the team training component of this project will take the form of instructional team videos produced by in collaboration with the UCSSC. The content of these videos will focus on technical robot-specific team skills as well as non-technical OR team skills. The technical robotic skills are based on the TJUH's robotic set-up competency document which has already been in use as an internal training document. The non-technical skills portion is based on the "Oxford Non-Technical Skills (NOTECHS) Scale", which was developed from an aviation team training tool and applied specifically to OR team-based interactions. Skills measured through the NOTECHS system include Leadership and Management, Teamwork and Cooperation, Situation Awareness, and Problem Solving and Decision.[1]

Filmed Clinical Scenarios

These digital multimedia modules, developed around video trigger clips, comprise of an educational tool kit which is designed to provide tools to help teach the competencies related to teamwork and communication. The development of these video trigger clips began with specific scenario from real clinical activities. From each clinical scenario a screenplay was subsequently created. The screenplay involved faculty with practical knowledge of the DaVinci Robot and the video is tailored to specific areas of mischief that can occur during the procedure. The production included direct consultation and review from the faculty with robot-assisted surgery expertise. The production of the video occurs within the actual clinical environment, the operating room, to optimize context and credibility. These video trigger clips can be used for individual skills attainment or with teaching venues which include small or large groups. If used as a part of a workshop the learners, review the trigger video, then in small groups diagnose the problem(s) and develop an acute and long term prescription to solve the problem. In this teaching tool there are two versions of the video trigger clips. The "F" version consists of a scenario where there are multiple deficits of the skill set to be taught each of which leads to a poor patient outcome. The "A" version is an example of the same scenario performed to a level of high proficiency. If this tool is being used in a workshop format the F version is shown first to stimulate discussion and the A version is shown last to emphasize positive progressive teaching points.

These video simulations can also be used in combination with Simulated Patients which would represent an example of a hybrid simulation. In a hybrid simulation the learners have a chance to role-play a similar situation with the simulated patients and can practice the prescription to solve the problem. This puts the new learning immediately to use, promoting the topic from an abstract concept to a personal skill. It also allows for teachable moments to occur where the learner is able to internalize and use the skills set in a credible simulated environment. Alternatively this teaching module can be used alone for individual or group skills attainment as a narration guides the learner through the learning objectives demonstrated in actual film scenarios.

Competency Performance Video Demonstration and Checklist: Preparation of the Robotic OR

The skill metrics proposed for the robotic OR surgical team include:

- Camera arm positioning
- Instrument arm positioning and port placement
- Docking
- System check
- Endowrist instrument insertion and removal
- Patient indications and selection

- Robotic-assisted surgical techniques
- Anatomical references
- Patient preparation, surgical positioning, port placement and instrument applications

A specific competency tool of the step by step procedures required to setup the robotic OR equipment, troubleshoot problems, and monitor education and clinical performance was adapted from existing educational materials used by the TJUH robotic coordinator. See Appendix D for the full list of ordered steps required to prepare the OR environment. The clinical competency assessment can be used in a variety of recognized validation methods including: demonstration; case study; self-reported checklist completion; observation, policy and procedure review; self-learning module completion with post-test; verbalization; computer-based training; video instruction; or a combination of learning and testing strategies.

The TARGET Project team produced a video demonstration of each ordered step in the OR set-up. This training video is intended for use as an adjunct tool to the Intuitive Interactive Training Tool for individual and group training, annual performance competency validation, or as a self-learning instructional aid. It is available in DVD format and as a Windows medial file on CD. Arrangements are in progress to directly deliver these materials by mail.

- **COLLECT AND TRACK ROBOTIC SURGICAL SKILL METRICS**

Background

Robot-assisted endoscopic surgery is a recent phenomenon with a Robot-assisted endoscopic surgery is a recent phenomenon with a growing role in modern surgery. Outcomes reports from early studies reported an extended learning curve for robotic skills, as well as a significant decrease in complication rates with increased experience. Outcomes reports from early studies reported an extended learning curve for robotic skills, as well as a significant decrease in complication rates with increased experience.[4-6]. The TARGET project focused on a virtual reality (VR) simulation solution. Robotic surgical simulators attempt to recreate the entire experience of the surgeon within the console, replacing camera input and other feedback with an entirely computer-generated environment. Adding to their potential utility as training tools, VR simulators allow a degree of in-depth and standardized performance analysis far beyond that possible with third-party human evaluation. The newest VR simulator, the daVinci Skills Simulator (dVSS) represents the initial foray of Intuitive Surgical, producer of the daVinci robot, into the simulator market. A joint venture with Mimic Technologies, dVSS is the first to utilize the patented technology within the daVinci surgical console. The dVSS is a 'backpack' to the console that integrates Mimic's dV-trainer software into the same machine used in actual surgery.[7] This is in contrast to earlier simulators, such as the original dV-Trainer™ and RoSS™,[8] which utilize free-standing hardware meant to function in a manner similar to the actual daVinci surgeon's console.

Through the efforts of the TJUH Hospital Administration TARGET Co-Investigator, Rebecca O'Shea, the TARGET Project was able to secure separate funding to purchase a robotic skills training simulator. We originally intended to fully explore the two systems that were available on the market at the time of our planning. These included the MIMIC and the ROSS systems described above. However, shortly after the new year (2011), we learned that Intuitive Surgical had acquired the MIMIC software and had prototypes available in a separate "back pack" configuration intended for use with the daVinci surgeon console. We were able to purchase this new product to use for real-time simulation of the surgical skill metrics described. In the last quarter of the project timeline, a team led by Dr. Costas Lallas (Director of Robotic Surgery) collected performance metrics and operator characteristics from a convenience cohort of 38 students, physicians in training, and students.

Methods

Participants were classified as novice (no robotic cases), intermediate (1-75 robotic cases) and expert (≥75 robotic cases, including 1 case within past 5 years). None of the participants had previous experience with the daVinci Skills Simulator. Each subject was asked to complete five exercises determined to be representative of the major skill sets required to perform successful robotic surgery. Prior to each exercises, the subject observed a brief instructional video. A detailed score report, including all individual parameters, was recorded following the subject's first attempt at each skill set. The scores were calculated by the simulator based primarily on 6 metrics – time to complete, economy of motion, instrument collisions, excessive instrument force, instruments out of view and master workspace range. Certain exercises also took into account other task-specific metrics such as misapplied energy time, needle drops, and missed targets.

Construct validity was assessed based on participant performance for each of the 5 exercises. Overall percentile scores for five skill areas (Camera Targeting, Energy Switching, Threading Rings, Dots and Needles, and Ring & Rail) were compared between the three skill groups. Comparisons were repeated with subjects redistributed into two skill groups, novice and experienced (combined intermediate and expert). Because of small sample size and skew in the data, non-parametric Wilcoxon tests were used. An overall p-value was generated to look for the existence of any difference between the three groups. Pairwise comparisons (novice vs. intermediate, intermediate vs. expert, novice vs. expert, novice vs. experienced) were made also using Wilcoxon tests, and their resultant p-values were adjusted for multiple comparison testing using Hochberg's method. Immediately following the completion of all six exercises, the subject was asked to complete a questionnaire pertaining to the face and content validity of the simulator (Tables 5 & 6), as well as demographics and prior experience.

Results

Summary statistics were calculated as appropriate for physician participant characteristics. Categorical data is reported as frequencies and percents by skill level (novice, intermediate, and expert). Continuous data such as age is summarized using the median, minimum, and maximum, due to the small sample size and non-normality in some variables. As some question topics were not appropriate for the novice participants, no data is reported for those cases. Overall percentile scores for five skill areas (Camera Targeting, Energy Switching, Threading Rings, Dots and Needles, and Ring & Rail) were compared between the three skill groups.

The novice group (n = 19) consisted of 18 medical students and 1 resident. All participants in the novice group had no robotic case experience. The intermediate group (n = 8) included 6 residents, 1 fellow, and 1 faculty surgeon with between 1 and 25 case experience (except the for the faculty surgeon who had a total of 130 cases but had not been on the console in over five years). The mean number of robotic cases for the intermediate group was 35.1. The expert group (n = 10) consisted of 2 residents, 1 fellow and 7 faculty surgeons. The participants in this group had at least 75 case experiences each with a group mean of 218.6.

When subjects were reorganized into novice and experienced (combined intermediate and expert) groups, there was an overall significant deference observed in all skill sets. Intermediates and experts rated the various elements of the simulators realism at an average of 4.1/5 and 4.3/5 on the visual analog scale (VAS), respectively. Intermediate and expert participants also rated the simulator’s value as a practice format and a training tool as 4/5 or 5/5 on the VAS.

The non-parametric Wilcoxon tests were chosen due to small sample size. An overall p-value was generated to identify differences between the three groups. Pairwise comparisons (novice vs. intermediate, intermediate vs. expert, novice vs. expert) were made also using Wilcoxon tests, and the resulting p-values were adjusted for multiple comparison testing using Hochberg's method. Comparisons of scores by skill level were also illustrated graphically using box-plots. Scores in comparable skill categories (such use of excessive force or number of drops) were combined across skill areas using the median. These were then compared between levels of experience (novice vs. intermediate/experienced) using Wilcoxon tests.

Participant characteristics are presented in **Table 4**. There was a overall significant difference measured in all skill sets except Camera Targeting, which was marginally significant ($p = 0.06$). With regard to pairwise comparisons, several things can be noted. In all skill sets, there is no significant difference between Intermediate and Expert users, (all p-values = 0.52). In the Camera Targeting set, there is also no significant difference between Novice and either Intermediate or Expert users ($p = 0.13$ and 0.26, respectively). In the Energy Switching set, there is no significant difference between Novice and Intermediate median scores (56 vs. 66 $p = 0.52$), however, Novices do have significantly lower median scores than Experts (56 vs. 85.5, $p = 0.05$). In the remaining three skill areas, Threading Rings, Dots and Needles, and Ring & Rail, Novices have significantly lower median scores than both Intermediate and Expert participants, see **Table 5**. These results are also illustrated in **Figures 1-5**. Table 6 presents the results of the median scores for skill categories. The experienced users outscored novices in four categories: Time, Economy of Motion, Instrument Collisions, and Use of Excessive Force ($p <0.0001$, $p <0.0001$, $p = 0.0036$, $p = 0.0071$, respectively). There was a marginal difference with regard to the category Instrument Out of View ($p = 0.0754$), and no significant difference between Master Workspace Range and Drops.

Discussion

Our study supported the face and content validity attributed to the da Vinci Skills Simulator in existing literature. Our questionnaire and answers were similar to those in the Hung et al. study, which used the beta version of the same software.[9] In regards to construct validity,[10] our results were largely similar to those of the previous study, with the notable exception of the fact that they noted a statistically significant performance difference between the three groups throughout all exercises, while one of our exercises (camera targeting 1) was not significant. A possible explanation for this is that Hung et al. used a composite score from 3 attempts at each exercise, following an unscored practice round that was unscored. In contrast, our subjects completed only one attempt, without practice, recognizing that in each trial of our study, Camera Targeting 1 was always the first exercise performed. Another notable difference that may account for some discrepancy between the two studies involves the definition of the intermediate group. In Hung, et al. the intermediate group contained subjects with any prior surgical training and 0-100 robotic cases. The result was an intermediate group with a median of 0 robotic cases, compared to a median of 20 cases in our study. Overall, our study confirmed the construct validity of the da Vinci Skills Simulator backpack unit. The simulator was able to distinguish between subjects with no experience and those with any experience, however it was unable to distinguish between intermediate users and experts. This could reflect a limitation of the exercise we used. It is possible that were the study to be continued with more difficult exercises, they would focus more closely on the skills that differentiate an intermediate from an expert. It appears, based on our results, that the simulator may be most useful to novice surgeons, helping them to gain basic robot skills. The next step would be a similar study in which subjects complete more challenging exercises, to see if more significant differences arise. Of course the ultimate evaluation of any simulator would be to test predictive validity - the extent to which the simulator predicts future performance.

Table 4. Participant Characteristics

Physician Level	Novice (n=19)		Intermediate (n=9)		Expert (n=10)	
	n	%	n	%	n	%
Video Game Experience (n=32)						
None	0	0.0	0	0.0	1	11.1
Minimal	0	0.0	3	33.3	2	22.2
Moderate	11	78.6	6	66.7	5	55.6
Substantial	3	21.4	0	0.0	1	11.1
Level						
Medical Student	19	100.0	0	0.0	0	0.0
Resident	0	0.0	6	66.7	2	20.0
Fellow	0	0.0	1	11.1	1	10.0
Faculty Attending	0	0.0	2	22.2	7	70.0
Number of Robotic Cases (n=37)						
0	19	100.0	0	0.0	0	0.0
1-25	0	0.0	8	88.9	0	0.0
51-75	0	0.0	0	0.0	2	22.2
76-100	0	0.0	0	0.0	2	22.2
>100	0	0.0	1	11.1	5	55.6
Consistent with Surgery? (n=16)						
Yes	--		7	87.5	3	37.5
No			1	12.5	5	62.5
Relevance						
4	--		3	33.3	2	22.2
5			6	66.7	7	77.8
Practical Value						
4	--		1	11.1	1	11.1
5			8	88.9	8	88.9
Prior Simulator Experience (n=37)						
Yes	0	0.0	6	66.7	3	33.3
No	19	100.0	3	33.3	6	66.7
Robotic Case in Last Year (n=37)						
Yes	0	0.0	6	66.7	9	100.0
No	19	100.0	3	33.3	0	0.0
Age; median (min, max)	25	(20, 34)	32	(29, 56)	33	(30, 41)
Cases; median (min, max)	--		20	(3, 130)	125	(65, 600)

Table 5. Robotic simulator scores by skill level

	Novice			Intermediate			Expert			p-values			
											Adjusted		
	median	min	max	median	min	max	median	min	max	Overall	Novice vs. Intermed.	Novice vs. Expert	Intermed. vs. Expert
Camera Targeting	65	23	90	81	47	92	76	46	93	0.0625	0.1319	0.2646	0.5212
Energy Switching	56	0	81	66	43	93	85.5	42	93	0.0109	0.5212	0.0495	0.5212
Threading Rings	45	2	76	89	75	93	89	69	100	<0.001	0.0042	0.0030	0.5212
Dots & Needles	45.5	13	80	76	53	84	89.5	53	94	<0.001	0.0352	0.0084	0.5212
Ring & Rail	76.5	8.4	93	94	70	99	95	91	98	<0.001	0.0410	0.0052	0.5212

Table 6. Median scores across skill categories

	Novice			Experienced			
Categories	**Median**	**(Q1, Q3)**	**(Min, Max)**	**Median**	**(Q1, Q3)**	**(Min, Max)**	**p-value**
Time	0	(0, 7)	(0, 36)	78	(61, 89)	(36, 100)	<0.0001
Economy of Motion	25	(12, 52)	(0, 76)	81	(75, 89)	(69, 100)	<0.0001
Instrument Collisions	80	(60, 100)	(0, 100)	100	(100, 100)	(40, 100)	0.0036
Excessive Force	100	(10, 100)	(0, 100)	100	(100, 100)	(100, 100)	0.0071
Out of View	100	(67, 100)	(0, 100)	100	(100, 100)	(75, 100)	0.0754
Master Workspace Range	100	(100, 100)	(45, 100)	100	(100, 100)	(97, 100)	0.2808
Drops	100	(100, 100)	(40, 100)	100	(100, 100)	(80, 100)	0.9635

Figure 1: Camera Targeting

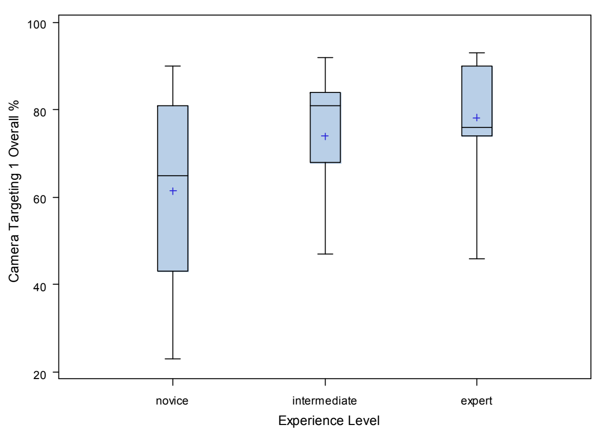


Figure 2: Energy Switching

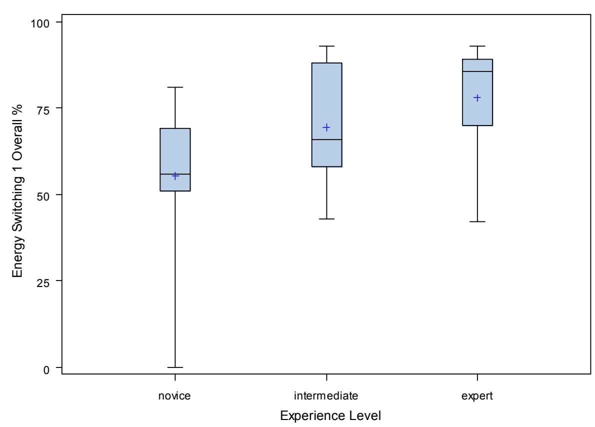


Figure 3: Threading Rings

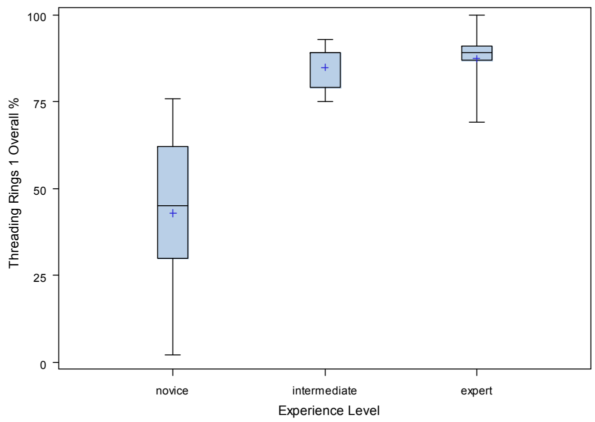


Figure 4: Dots and Needles

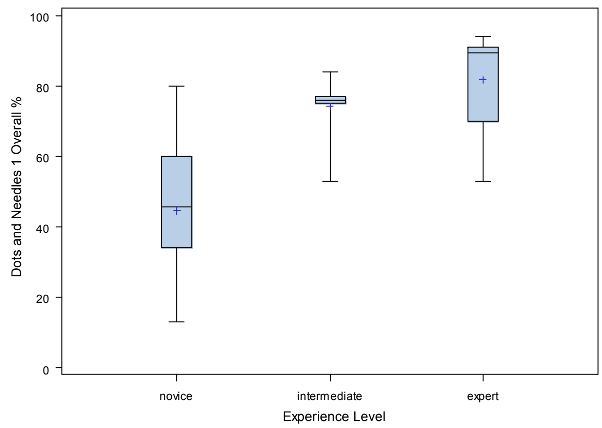
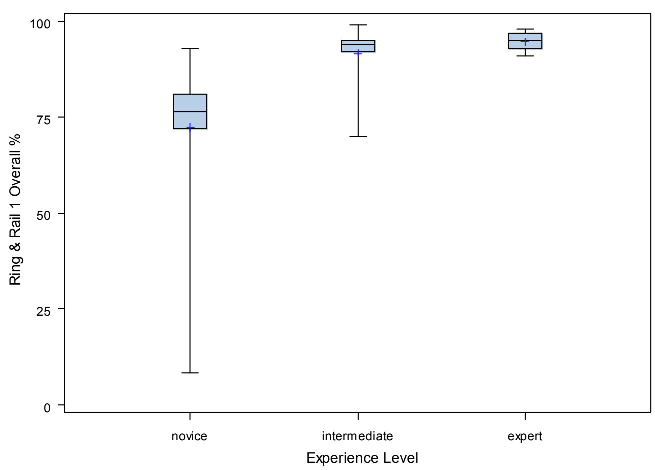


Figure 5: Ring and Rail



- **EVALUATION AND MODIFICATION OF PROGRAM**

The TARGET project team has not yet completed an evaluation and subsequent modification of the program. This is primarily due to limited number of actual robot-assisted LIMA cases. Additionally, with the arrival of Dr. Bajwa, the focus has shifted to mitral valve repair/replacement procedures. However, we anticipate continuing related work with the following ongoing projects:

1. Robotic surgical skill training and performance assessment across the surgical subspecialties.
2. TJUH OR personnel training using the prepared DVD scenarios and the set-up demonstration.
3. Creation of a Task Force within the Medical College faculty and hospital Administration to pursue the development of a formal Robotic Skills training program, based on the concepts used in the current Fundamental Laparoscopic Skill training.

REPORTABLE OUTCOMES

The TARGET Project reportable outcomes include:

Manuscripts in Progress:

Analysis of Robot-Assisted Coronary Artery Bypass Grafts Procedures 2006-2010 **(Draft)**
Face, Content and Construct Validity of the *daVinci Skills Simulator* Backpack Unit **(Draft)**
Survey of Cardiothoracic Surgery Programs: Robot-Assisted Training Practices

CONCLUSION

The award received allowed TJU/TJUH to support the purchase of the daVinci robot system with matching funds allotted by the hospital to purchase the proctoring console for future education and training of students, residents and surgical faculty. This purchase acquisition provided the foundation for recruiting a junior faculty robotic surgeon and to begin the first hospital-based CT surgery program.

The TARGET Project deliverables will continue to be used and studied by the investigator teams at TJU/TJUH. Additional research is planned with skill training using the VR Simulator.

The OR team training materials (Clinical Scenario DVDs) and the Competency Performance DVD will be incorporated into the existing programs for hospital staff training.

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Appendix A: Survey of Cardiothoracic Surgery Programs: Robot-Assisted Training Practices

♦ GENERAL QUESTIONS

○ On average, how many robotic-assisted CT procedures are performed at your institution per year?

___ ___ ___ ___ per year

○ Does your institution participate in the Society for Thoracic Surgeons database?

☐ Yes ☐ No

♦ CURRENT ROBOTIC TRAINING TECHNIQUES FOR NOVICE CT SURGEONS

○ Are surgeons who perform robotic-assisted surgery at your institution required to complete the da Vinci system training through Intuitive?

☐ Yes ☐ No

○ If yes, which of the following types of training are the surgeons required to complete through the Intuitive da Vinci system training (Check all that apply)

☐ On-site da Vinci Surgical Systems Training
☐ Off-site da Vinci Surgical Skills training
☐ Live Procedure Observation
☐ Surgeon-led Training
☐ Laboratory Sessions
☐ Surgeon Proctoring

○ If surgeons at your institution are required to complete proctored cases, which type of proctors were used?

☐ Intuitive Staff Proctors
☐ Independent proctors
☐ Both
☐ Did Not Perform Proctored Cases

○ Aside from the intuitive da Vinci system training program, are novice robotic surgeons at your institution required to complete any additional training before performing robotic surgery?

☐ Yes ☐ No

○ If yes, which of the following types of training are the surgeons required to complete that are **NOT** part of the Intuitive da Vinci system training? (Check all that apply)

☐ Virtual Reality Simulation
☐ Videos
☐ Interactive Web-Based Presentation
☐ In-Person Classroom Based Training
☐ Clinical Skills Simulation Workshops (i.e. Acting Out Scripted Scenarios)
☐ Proctored Cases

○ Are surgeons required to take these additional trainings before they perform robotic-assisted CT procedures?

☐ Yes ☐ No

○ Does the additional training address metrics for "overall motion performance" of the robot by the surgeon?

☐ Yes ☐ No ☐ N/A

○ Does the additional training address "OR system" skills?

☐ Yes ☐ No ☐ N/A

○ Does the additional training address any particular "surgical" skills?

☐ Yes ☐ No ☐ N/A

○ Does the additional training address any "time to completion" metrics?

☐ Yes ☐ No ☐ N/A

♦ MAINTENANCE OF SURGICAL SKILLS

○ At your institution, are CT robotic surgeons required to undergo regularly scheduled training for skill maintenance?

☐ Yes ☐ No

○ If yes, how often are CT robotic surgeons required to go regularly scheduled training for skill maintenance?

○ At your institution, are surgeons who have not performed a robotic-assisted CT surgery for an extended period of time required to complete training before performing these surgeries again?

☐ Yes ☐ No

○ If yes, how does your institution define an "extended period of time"?

○ If yes, what type of training are surgeons who have not performed a robotic-assisted CT surgery for an extended period of time required to complete?

☐ Virtual Reality Simulation
☐ Videos
☐ Interactive Web-Based Presentation
☐ In-Person Classroom Based Training
☐ Clinical Skills Simulation Workshops (i.e. Acting Out Scripted Scenarios)
☐ Proctored Cases

♦ TEAM TRAINING OR STAFF

○ At your institution, is there a designated OR team for Cardiothoracic robotic assisted surgeries?

☐ Yes ☐ No

○ If yes, who is included in the designated OR team for CT robotic assisted surgery? (Check all that apply)

☐ Robotic Nurse Coordinator
☐ Anesthesiologist
☐ Perfusionist
☐ Technical Specialist
☐ Other ______________________________

○ Are members of the OR staff required to complete da Vinci systems training offered by Intuitive? (Check all that apply)

☐ No, none are required
☐ Robotic Nurse Coordinator is required
☐ Anesthesiologist is required
☐ Perfusionist is required
☐ Technical Specialist is required
☐ Other ____________________________

○ Does your institution use a robotic competency tool for the OR staff?

☐ Yes ☐ No

○ If yes, how does the competency tool at your institution track competencies?

○ Aside from the standard intuitive training program, are members of the OR staff at your institution required to complete any additional training before participating in robotic-assisted surgery?

☐ No, none are required
☐ Robotic Nurse Coordinator is required
☐ Anesthesiologist is required
☐ Perfusionist is required
☐ Technical Specialist is required
☐ Other ____________________________

○ If yes, which of the following types of training are the OR staff members required to complete? (Check all that apply)

☐ Virtual Reality Simulation
☐ Videos
☐ Interactive web-based presentation
☐ Clinical Skills simulation workshops (i.e. acting out scripted scenarios)
☐ In-person classroom based training

○ Are these trainings specific to robotic-assisted CT procedures?

☐ Yes ☐ No

○ Does the training for the OR team required by your institution address any of the following?

(Check all that apply)

- ☐ Camera Arm Positioning
- ☐ Docking
- ☐ Anatomical References
- ☐ Surgical Positioning
- ☐ Instrument Applications
- ☐ Instrument Arm Positioning and Port Placement
- ☐ System Check
- ☐ Endowrist Instrument and Removal
- ☐ Port Placement

♦ COMMON POST-OP COMPLICATIONS SPECIFIC TO ROBOTIC CT SURGERY

○ For robotic-assisted CT surgeries, do you track post-op complications and other Adverse Events?

☐ Yes ☐ No

○ Are post-op complications for robotic-assisted CT surgeries at your institution reported to an internal source?

☐ Yes ☐ No

○ Are post-op complications for robotic-assisted CT surgeries at your institution reported to an independent source (STS database or other)?

☐ Yes ☐ No

Appendix B: Conventional Cardiovascular Surgery (LIMA takedown) Metrics

Date	Case Description / Notes	Time (min)	Flow (ml/min)	Size (mm)	Quality	Injury	Case Operator	Surgeon on Record
10/29/2010	Coronary Artery Bypass	29	56	2.00	Good	No	KY	JD
10/29/2010	Coronary Artery Bypass X2 Vessels, Endoscopic Vein Harvest,	40	105	2.50	Good	No	KY	JD
11/3/2010	Coronary Artery Bypass, Internal Mammary Artery, Tee	35	26	1.50	Good	No	KY	LB
11/5/2010	Coronary Artery Bypass, Transesophageal Echo	27	66	2.00	Good	No	KY	JD
11/10/2010		39	40	1.75	Good	No	BY	BY
11/15/2010		28	35	1.50	Good	No	BY	BY
11/19/2010		36	72	2.50	Thick but OK	No	BY	BY
11/19/2010	Coronary Artery Bypass Grafting X4	26	70	2.00	Good	No	KY	LB
11/22/2010	Coronary Artery Bypass Graft,	32	100	2.50	Good	No	KY	JD
11/23/2010	Coronary Artery Bypass Grafting,, possible mitral valve repair/replacement	20	45	1.75	Good	No	KY	JD
11/24/2010	Coronary Artery Bypass, Internal Mammary Artery	21	50	2.00	Good	No	KY	JD
11/26/2010	Coronary Artery Bypass Grafting, possible radial artery harvest,	22	70	2.00	Good	No	KY	JD
11/30/2010	Coronary Artery Bypass, internal mammary artery	19	40	1.50	Good	No	KY	JD
12/1/2010		37	30	1.50	Good	No	BY	BY
1/5/2011	Coronary artery bypass, internal mammary artery, EVH, TEE	37	66	2.00	Good	No	KY	LB
1/6/2011	Coronary artery bypass, internal mammary artery	30	100	2.50	Good	No	KY	LB
1/10/2011	Off pump coronary artery bypass graft X1, cardiopulmonary bypass standby, transesophageal echo	20	45	1.50	Good	No	KY	LB
1/17/2011	Coronary artery bypass graft X3, endoscopic vein harvest, TEE	19	60	2.00	Good	No	KY	LB
2/3/2011	Aortic valve replacementpossible coronary artery bypass graft x1 with SVG- LAD, endoscopic vein harvest							LB
2/4/2011	Off pump coronary artery bypass							JD
2/4/2011	Coronary artery bypass, internal mammary artery							JD
2/7/2011	Mitral valve replacement, possible coronary artery bypass							LB
2/8/2011	Coronary artery bypass, internal mammary artery x3							JD
2/10/2011	Coronary artery bypass x1, possible re-implant of right coronary artery							JD
2/14/2011	Aortic valve replacement, coronary artery bypass grafting, endo vein harvest							LB
2/15/2011	Coronary artery bypass, internal mammary artery, EVH, TEE, AVR, MVR							JD
2/16/2011	Coronary artery bypass grafting, endo vein harvest, transesophageal echo							LB
2/17/2011	Coronary artery bypass grafting x3, endo vein harvest, possible right radial artery harvest							LB
2/18/2011	Coronary artery bypass, internal mammary artery, endoscopic vein harvest, TEE							LB
2/21/2011	Coronary artery bypass, internal mammary artery	22	30	1.50	Good	No	KY	LB
2/23/2011	Coronary artery bypass graft x3							JD
2/25/2011	Coronary artery bypass grafting, endo vein harvest, transesophageal echo							JD
2/28/2011	Coronary artery bypass X3, endoscopic vein harvest, transesophageal echo	45	30		Good	No	HH	JD
3/4/2011	Coronary artery bypass grafting, transesophageal echo, endo vein harvest							JD

3/7/2011	***Blue robotic coronary artery bypass graft x3: 75% complete w/robot Insufflation at 8:55am Docked at 9:21am Console at 9:22am Got up at 10:12am***	***50****	***20***	***1.25***	***Good***	***No***	***JD***	***JD***
3/8/2011	Coronary artery bypass graft X3	29	70	2.00	Good	No	KY	JD
3/9/2011	Coronary artery bypass grafting, endo vein harvest, possible left radial artery harvest							JD
3/11/2011	Coronary artery bypass, internal mammary artery							JD
3/15/2011	Aortic valve replacement, coronary artery bypass grafting, endo vein harvest, transesophageal echo	29	135	2.00	Good	No	KY	JD
3/15/2011	Coronary artery bypass grafting, endo vein harvest, transesophageal echo	45	90	2.00	Good	No	HH	JD
3/16/2011	Coronary artery bypass graft x3							JD
3/17/2011	Coronary artery bypass graft x3 & Debranching							JD
3/22/2011	Coronary artery bypass graft, endoscopic vein harvest, TEE, possible mitral valve repair vs replacement	40	20	1.50	Moderate	No	HH	JD
3/23/2011	Coronary artery bypass grafting, transesophageal echo, endo vein harvest	28	30	1.50	Good	No	KY	JD
3/24/2011	Coronary artery bypass graft, x2 aortic valve replacement							JD
3/25/2011	Coronary artery bypass, internal mammary artery X3	29	34	2.00	Good	No	KY	LB
3/28/2011	Mitral valve repair, coronary artery bypass graft X3, maze	19	30	1.00	Good	No	KY	LB
3/29/2011	Aortic valve replacement, coronary artery bypass grafting, transesophageal echo							JD
3/29/2011	Coronary artery bypass grafting X3, endo vein harvest, transesophageal echo							JD
4/4/2011	Coronary artery bypass graft with possible left radial							LB
4/5/2011	Coronary artery bypass graft	51	30	1.25	Good	No	ST	JD
4/11/2011	Coronary artery bypass grafting X2, endo vein harvest, transesophageal echo, IABP pre induction	40	20	2.00	Good	No	HH	JD
4/12/2011	Coronary artery bypass graft X2							JD
4/14/2011	Coronary artery bypass grafting, transesophageal echo							JD
4/15/2011	Coronary artery bypass grafting, transesophageal echo, endo vein harvest, possible LVAD placement							JD
4/19/2011	Coronary artery bypass grafting x3, endo vein harvest, possible radial artery harvest, transesophageal echo							JD
4/21/2011	Coronary artery bypass graft x3	24	40	1.50	Good	No	KY	LB
4/22/2011	Coronary artery bypass grafting, endo vein harvest, transesophageal echo	24	60	2.00	Good	No	KY	LB
4/26/2011	Coronary artery bypass graft x3	40	40	2.00	Good	No	HH	JD
4/26/2011	Coronary artery bypass graft, transesophageal echo, pfo closure							LB
4/27/2011	Coronary artery bypass, internal mammary artery with EVH x3							JD
4/28/2011	Coronary artery bypass graft							LB
4/28/2011	Coronary artery bypass graft, internal mammary artery with endoscopic vein harvest, transesophageal echo, possible radial artery harvest							JD

4/29/2011	Coronary artery bypass, endoscopic vein harvest, transesophageal echo	40	42	1.50	Moderate	No	HH	JD
4/29/2011	Coronary artery bypass, endoscopic vein harvest, transesophageal echo							LB
5/3/2011	***Blue robot CABG x3 takedown: 75% complete w/robot Incision at 9:01am Ports in place at 9:18am Robot docked at 9:40am Got up at 10:45am***	***65****	***15***	***1.50***	***Good***	***No***	***JD***	***JD***
5/13/2011	Coronary artery bypass X3, endoscopic vein harvest, transesophageal echo	88	34	2.00	Good	No	ST	LB
5/17/2011	Coronary artery bypass graft x3, radial artery harvest							JD
5/17/2011	Coronary artery bypass X3, endoscopic vein harvest, transesophageal echo							JD
5/18/2011	Coronary artery bypass, aorta valve replacement							JD
5/18/2011	Coronary artery bypass graft, panendoscopy and biopsy of bilateral tonsils							LB
5/18/2011	Aortic valve replacement with St. Jude mechanical prothesis, coronary artery bypass x1, left internal mammary artery to left anterior descending, transesophageal echo	40	60	2.00	Good	No	HH	JD
5/25/2011	Coronary artery bypass grafting x2, left radial artery harvest, transesophageal echo	22	30	1.50	Good	No	KY	LB
5/27/2011	Coronary artery bypass grafting x4, endo vein harvest, transesophageal echo	22	60	2.00	Good	No	KY	LB
6/2/2011	Coronary artery bypass grafting X3, endo vein harvest, transesophageal echo							LB
6/3/2011	Coronary artery bypass grafting, endo vein harvest, tranesophageal echo							LB
6/3/2011	Coronary artery bypass x3, internal mammary artery with evh							LB
6/6/2011	Coronary artery bypass grafting, endo vein harvest, transesophageal echo							LB
6/6/2011	Coronary artery bypass grafting, endo vein harvest, transesophageal echo							LB
6/9/2011	Coronary artery bypass grafting X3, endo vein harvest, transesophageal echo	85	25	1.50	Good	No	ST	JD
6/13/2011	Coronary artery bypass x1, internal mammary artery with evh, mvr	25	80	2.50	Good	No	KY	LB
6/14/2011	Coronary artery bypass graft x3							JD
6/16/2011	Coronary artery bypass, internal mammary artery with saphenous vein graft							JD
6/20/2011	Coronary artery bypass with endoscopic vein harvest, possible radial artery harvest, transesophageal echo							AG
6/23/2011	Coronary artery bypass graft	29	40	1.50	Good	No	KY	JD
6/23/2011	Coronary artery bypass, internal mammary artery with evh, tee							JD
6/24/2011	Coronary artery bypass grafting, transesophageal echo							HH
6/27/2011	Coronary artery bypass, internal mammary artery with evh							LB
6/29/2011	Coronary artery bypass graft x3							LB
6/29/2011	Aortic valve repair/replacement, mitral valve repair/replacement, possible coronary artery bypass graft	21	50	1.50	Good	No	KY	JD
6/30/2011	Coronary artery bypass graft x3	30	26	1.50	Good	No	KY	JD
6/30/2011	Coronary artery bypass grafting, endo vein harvest, transesophageal echo	45	50	1.50	Good	No	HH	JD
7/1/2011	Coronary artery bypass, endoscopic vein harvest, transesophageal echo							LB
7/5/2011	Coronary artery bypass, internal mammary with evh							JD
7/6/2011	Mitral valve repair/replace, coronary artery bypass graft	30	25	1.25	Good	No	KY	LB
7/12/2011	Coronary artery bypass grafting, endo vein harvest,	24	120	2.00	Good	No	KY	JD

7/15/2011	Coronary artery bypass X3, endoscopic vein harvest, transesophageal echo	60	52	1.50	Good	No	ST	LB
7/20/2011	Coronary artery bypass graft							JD
7/21/2011	Coronary artery bypass, internal mammary artery with evh, tee							LB
7/22/2011	Coronary artery bypass graft, endoscopic vein harvest, transesophageal echo							LB
7/25/2011	Coronary artery bypass grafting, transesophageal echo							GB
7/26/2011	Re-do sternotomy, coronary artery bypass, left radial vein harvest, tranesophageal echo	25	90	2.00	Good	No	KY	JD
7/28/2011	Aorta valve repair/replacement, coronary artery bypass, tricuspid valve repair, possible replacement, transesophageal echo							LB
7/29/2011	Coronary artery bypass, internal mammary artery with evh	22	40	1.50	Good	No	KY	JD
8/2/2011	Coronary artery bypass, internal mammary artery with endoscopic vein harvest, aorta valve repair/replace							JD
8/3/2011	Atrial myxoma excision, coronary artery bypass grafting, endo vein harvest, transesophageal echo							JD
8/5/2011	Off pump coronary artery bypass, possible on-pump, transesophageal echo							BY
8/8/2011	Redo coronary artery bypass graft x3							JD
8/9/2011	Coronary artery bypass graft x3, endoscopic vein harvest, possible radial artery harvest, transesophageal echo							GB
8/10/2011	Blue robot cardiac assisted coronary artery bypass graft x2 (Robot canceled)	24	35	1.25	Good	No	KY	JD
8/15/2011	Coronary artery bypass, x3	25	60	2.00	Good	No	KY	JD
Data / Total		**Avg. Time**	**Avg. Flow**	**Avg. Size**				
50		32.8	51.7	1.77				
111								

Appendix C. CONFIDENTIAL DRAFT Manuscript: David J. Whellan

Analysis of Robot-Assisted Coronary Artery Bypass Grafts Procedures 2006-2010

Introduction

Coronary artery bypass grafting (CABG) techniques and technology have advanced in the United States since the first CABG surgery took place on May 2, 1960. In 2006, almost 500,000 CABG surgeries were performed in the United States according to the most recent data from the National Center for Health Statistics.[1] With the recent technological advances in cardiothoracic surgery and the development of robotic surgical system, totally endoscopic CABG procedures (TECAB) have become an option for patients undergoing revascularization. It has been shown that patients undergoing minimally invasive procedures experience faster recovery times and less postoperative pain than patients receiving more invasive surgeries.[2] Initial non-randomized studies have shown this surgical method provides similar outcomes as traditional open chest procedures.[3]

As with any new surgical technique, there are critical steps required for adoption. The technology lifecycle for usage of robotically assisted technology (RAT) has now entered into the phases of early adopters and early majority.[4] The investigators of the current analysis undertook this work to evaluate the utilization of TECAB over the past four years and to assess utilization within the United States. Given the promising results seen at early adopting centers and sales information provided by manufacturers of the robotic systems (as of September 30, 2011, there have been 2,031 units shipped worldwide according to Intuitive Surgical, Inc.[5]), we undertook the current study to examine the trends of robotically assisted CABGs (RACABs) for all CABG surgery patients in the Society of Thoracic Surgeons (STS) database. We hypothesized that TECAB use would be growing at centers participating in the Society of Thoracic Surgeons (STS) Database.

Methods

The STS Adult Cardiac Surgery Database (ACSD) was established in 1989 to report outcomes following surgical procedures.[6] Although participation in the STS database is voluntary, data completeness is high, with overall preoperative risk factors missing in fewer than 5% of submitted cases. The accuracy of data has been confirmed in independent comparison of hospital CABG volume and mortality rates reported to the STS versus those reported to Centers for Medicare and Medicaid Services.[7] Sites enter patient data using uniform definitions (available at http://www.sts.org) and certified software systems. This information is sent semiannually to the STS Data Warehouse and Analysis Center at the Duke Clinical Research Institute, Durham, North Carolina. A series of data quality checks are performed before a site's data are aggregated into the national sample. The database captures clinical information from the majority of US cardiac surgical procedures. An analysis demonstrated that more than 80% of patients undergoing CABG operations in the United States in 2007 were represented in the STS database.[8]

The present study looks at the utilization of RACAB at the site level between 2006 and 2010. For the purpose of this analysis, RACAB is defined as surgery in which robotic technology was used for the main grafting surgery, regardless of harvesting techniques. Thus, surgeries reported as using robotic technology for left internal mammary artery (LIMA) harvest are not counted as RACAB. The analysis evaluated non-emergent elective CABG surgeries involving a LIMA. To be included in the analysis, a site must have had at least one non-emergent CABG with LIMA involvement for each year between 2006 and 2010 and provided 5 years worth of data to the STS database.

Comparisons between centers performing RACAB and those not performing the study were conducted by site characteristics. Data were reported as medians and interquartile ranges

(IQRs) for continuous variables and as percentages of nonmissing values for categorical variables. Univariate comparisons between RACAB sites and non-RACAB sites were performed using the Pearson χ^2 test for categorical variables and the Wilcoxon rank-sum test for continuous and ordinal variables. Utilization of RACAB was compared over each full year (January 1 through December 31). Temporal changes were assessed for significance using the Cochran-Armitage test for trend (2006-2010).

To further describe the utilization of RACAB, site utilization was evaluated for each year of the study. Sites were identified as initiating the use of RACAB if there was no RACAB in the previous year. In addition, site continuation of RACAB was looked at both within the following year and at the end of the analysis period (2010). Site utilization of RACAB was further defined based on the percentage of RACAB compared to overall CABG volume for the site. Sites that utilized RACAB for at least 2 years were evaluated on the number of RACAB surgeries performed as a percentage of overall non-emergent CABG volume.

Since STS data was originally collected for nonresearch purposes and the investigators do not have individual patient identifiers, the Duke University Health System Institutional Review Board has decided that the analysis of the STS data constitutes research not involving human subjects and is therefore considered exempt.

Results

Between 2006 and 2010, 748 sites participating in the STS database provided data for the five years. The overall volume of RACABs in these centers increased from 0.68% (XXX RACAB out of XXX total CABG) in 2006 to 0.93% (XXX RACAB out of XXX total CABG) in 2010. (**Table 1**) The number of sites utilizing RACAB remained relatively constant between years 2006 and 2009 from 151 in 2006 to 154 in 2009, but there was a decline in 2010 to 137.

The number of sites initiating RACAB peaked in 2007 at 68, but declined to 30 in 2010. Forty percent of centers performing RACAB in 2006 were still using this strategy in 2010; and only 55% of the sites using RACAB in 2009 were using the procedure the following year.

Need to verify these numbers since 84 plus 30 does not equal 137.

Characteristics of sites that utilized RACAB at any time during the study timeline versus centers that did not use RACAB are presented in **Table 2**. Sites performing RACAB were more likely to be…… Despite this decline in the number sites in 2010, the rate of RACAB as a percentage of the total number CABGs performed increased each year, **including 2010. (Table 1)** ***Can we provide the total number of CABGs and the total number of RACAB instead of just percentage.***

Looking at the distribution of RACAB use for each year, sites using RACAB appear to increase the rate of RACAB use as a percent of total non-emergent CABGs.(**Table 3**) By 2010, at the same time the number of centers not using RACAB peaks, the number of sites utilizing RACAB in 16% or more has also peaked. This split in utilization explains the overall increase rate of RACAB seen in 2010. ***Table 3 or graphic mentioned in table descriptors. Would be good to include a figure***.

Of the 346 sites that used RACAB at one time between 2006 and 2010, 159 (46%) only used RACAB for a single year. For ninety percent of the 159 sites RACAB use as a percent of their total CABG volume the year prior to discontinuing RACAB was between 0.1% and 8%.(**Figure 1**) For the remaining 187 sites that performed RACAB for at least 2 years, sites have changed the percent of non-emergent CABGs that were robotically assisted from the first year of RACAB use to the final year of RACAB use. (**Table 4**) For those centers performing at least 2 years of RACAB, the rate of RACAB use within the site in the last year of use versus the first year of use decreased in 35.3% of sites, remained unchanged in 25.7% of sites, and increased in 39.0% of sites.

Discussion

The current analysis from the STS database provides the first descriptive analysis of RACAB use by sites in the United States. The study identified that utilization of RACAB has grown between 2006 and 2010, but remains a very small percentage of the overall non-emergent CABG with LIMA involvement. The adoption of RACAB by sites has taken a dichotomous course with a number of sites that initiated RACAB discontinuing the use of the surgery, many within one year of initiating the procedure and another group of sites increasing the use of RACAB. By 2010, the number of centers initiating the use of RACAB has decreased from a high of 68 in 2007 to 30, and the overall use of RACAB dropped to 137 sites.

The adoption of RACAB has not followed the traditional trajectory seen when a new technology or procedure is introduced. Typically, there is a continued growth as the procedure moves from discovery to early adopters and onto early majority. Instead, there has been a decrease in sites performing the procedure suggesting a disruption from early adopters to a larger use of the procedure. In contrast to the RACAB utilization, minimally invasive radical prostatectomy (MIRP), which is predominately robotic assisted, has been adopted more quickly by urologists with an increase in the procedure from 9.2% (95% CI, 8.1%-10.%%) of all prostatectomies in 2003 to 43.2% (95% CI, 39.6%-46.9%) in 2006[9,10]-2007. Similar to RACAB, men undergoing MIRP had shorter length of stay, fewer surgical complications and lower rates of anastomotic structures. Although there is no difference in overall 30-day complications or long-term mortality, patients undergoing MIRP had an increased risk of incontinence and erectile dysfunction.[10] There are very limited data on intermediate or long-term outcomes comparing RACAB to other surgical strategies for CABG, with one non-randomized multi-center study (n=85) following patients for 3 months and another single center registry study (n=19) obtaining angiography follow-up at 4 months and long-term mortality and symptom assessment at 17± 4.2 months.[3,11]

The significant discontinuation of RACAB is concerning, particularly in light of recent interest in healthcare costs. Typical cost for a robotic system to perform RACAB can be over two million dollars, and this does not take into account any renovation to the operating room that may be required to use the system, annual maintenance contract, or instruments. Although the system may be utilized for other types of surgery, establishing a RACAB program and then discontinuing it still represents a cost. Why might sites look to start RACAB? As noted by a study of urology centers in Wisconsin, centers acquiring robotic technology had an increase in mean quarterly prostatectomy volume from 16.5 in 2002 to 24.8 in 2007/2008.[12] This is in contrast to the volume at centers without robotic technology, which declined from a mean of 4.5 per site in 2002 to 3.1 in 2007/2008. After adjusting for hospital characteristics, referral region and patients age, the acquisition of a robot was associated with a 114% annual increase (95% CI, 62%-177 annual increase) in hospital prostatectomy volume. Given the outcomes for MIRP, concerns have been raised that the use of robotics for prostatectomy may be a marketing tool, and there is a need for comparative effectiveness research.[13]

There are a number of limitations to the current study. The low utilization of RACAB as a percent of total CABG volume raises some potential concerns regarding quality and outcomes. Past studies have shown a relationship between procedural volumes for CABG, valve surgery and angioplasty.[14-17]

Table 1.Number of Centers Performing Robotic Assisted CABG and the Percent RACAB Use

	2006		**2007**		**2008**		**2009**		**2010**	
Total Number of CABG										
Total Number of RACAB										
Percent of RACAB (mean, SD)	0.68±3.68%		0.69±3.36%		0.78±3.41%		0.83±3.58%		0.93±3.92%	
Sites Using RACAB	151	20.19%*	154	20.59%	152	20.32%	154	20.59%	137	18.32%
Sites Began Using RACAB	57		68		56		41		30	
Of Sites Using RACAB in Current Year Still Using RAT in 2010	61	40.40%	64	41.56%	77	50.66%	84	54.55%	-	-

RACAB-robotic assisted coronary artery bypass surgery

* percent of 748 centers providing data to STS database for each of the five years between 2006 and 2010.

Table 2. Baseline Characteristics for Sites Utilizing RACAB Between 2006 and 2010 Compared to Non-RACAB Sites

Table 3. Distribution of Rates of RACAB use for Isolated, Primary, Non-Emergent CABG with LIMA Involvement for Sites with 5 years of Data by Surgery Year

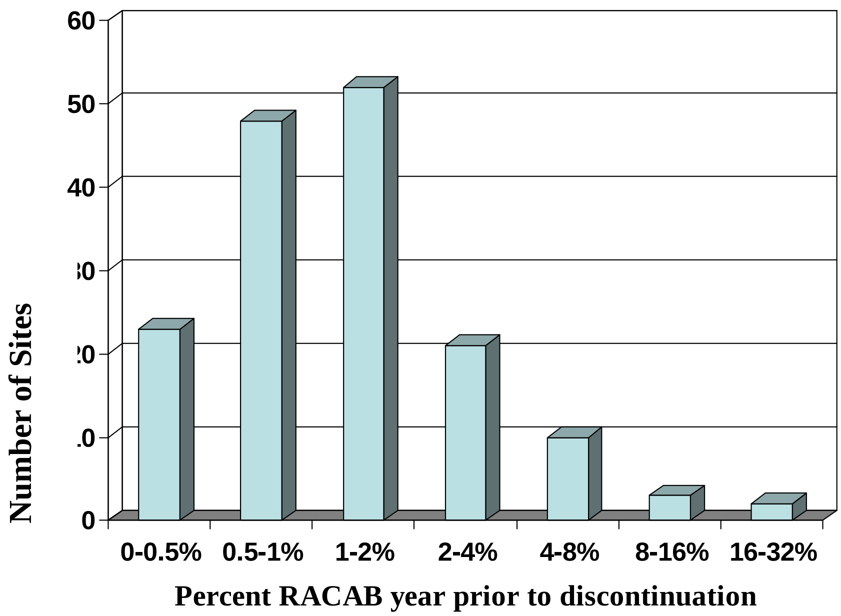
RACAB Rate	**2006**	**2007**	**2008**	**2009**	**2010**
0	597	594	596	594	611
0.5% <	21	27	26	23	23
0.5% - 1%	40	40	29	32	22
1% - 2%	39	36	40	36	28
2% - 4%	17	23	26	21	23
4% - 8%	20	14	12	21	19
8% - 16%	11	8	10	14	8
16% - 32%	2	3	7	5	10
≥ 32%	1	3	2	2	4

Shaded cells represent the highest amount among the study years for each rate value

Table 4. Change in Robotically Assisted CABG Volume from First to Last Year RAT Used for Sites with 5 years of Submitted Data, and with at least 2 years of RACAB Data (n = 187)

First Volume Category	Last Volume Category																Total
	0.5% <		0.5% - 1%		1% - 2%		2% - 4%		4% - 8%		8% - 16%		16% - 32%		≥ 32%		
0.5% <	13	41.9%	6	19.4%	7	22.6%	2	6.5%	2	6.5%	1	3.2%	0	0.0%	0	0.0%	31
0.5% - 1%	12	27.9%	10	23.3%	11	25.6%	7	16.3%	2	4.7%	1	2.3%	0	0.0%	0	0.0%	43
1% - 2%	7	15.2%	11	23.9%	10	21.7%	9	19.6%	7	15.2%	2	4.4%	0	0.0%	0	0.0%	46
2% - 4%	2	7.7%	4	15.4%	8	30.8%	6	23.1%	2	7.7%	2	7.7%	2	7.7%	0	0.0%	26
4% - 8%	4	17.4%	2	8.7%	4	17.4%	4	17.4%	5	21.7%	0	0.0%	3	13.0%	1	4.4%	23
8% - 16%	0	0.0%	1	7.1%	0	0.0%	1	7.1%	5	35.7%	3	21.4%	3	21.4%	1	7.1%	14
16% - 32%	0	0.0%	0	0.0%	0	0.0%	1	33.3%	0	0.0%	0	0.0%	0	0.0%	2	66.7%	3
≥ 32%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	0.0%	1
Total	38		34		40		30		23		9		8		5		187

Figure 1: Number of sites performing RECAB that discontinued performing RECAB the next year by percent CABG performed as RECAB



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Appendix D. Step by Step Performance Actions to Prepare the Robotic OR

The performance competency assessment is performed using a select variety of validation methods including: Demonstration, Case Study, Self-reported checklist completion, Observation, Policy and procedure review, Self-learning module completion with post-test, Verbalization, Computer-based training, and Video instruction. A companion DVD of the full procedure is included.

1.	Successfully completes the Intuitive® Interactive Training Tool for the daVinci™ Surgical System.
2.	Demonstrates plugging in all electrical parts of the robotic system.
	a. Surgeon’s console
	b. Robotic arms (surgical cart)
	c. Video Tower
3.	Demonstrates connection or three components to each other and verifies correct camera is attached.
4.	Demonstrates how to power up system and demonstrates how to verify correct system setting.
5.	Demonstrates how to correctly “home” the surgical arms.
6.	Demonstrates how to fold robotic surgical arm cart by folding arms in towards center column to protect the system.
7.	Demonstrates how to power down the system after verifying instrument use.
8.	Demonstrates how to input the camera into the system.
9.	Demonstrates proper draping of surgical cart and telescope/camera system.
10.	Demonstrates successful calibration of telescope for 0º and 30º scopes.
11.	Demonstrates proper black and/or white balancing of camera and color alignment step.
12.	Demonstrates proper maneuvering ability of surgical arms to and from the surgical field, and able to lock robot in place.
13.	Verbalizes that once the arms are docked at the surgical field the surgical table **must** never be moved.
14.	Demonstrates proper placement and removal of instruments on robotic system.
15.	Demonstrates ability to clean and irrigate robotic instruments properly. (Robotic manual for assistance).
16.	Verbalizes knowledge of the meaning of Robotic icons.
17.	Demonstrates ability to utilize the instrument usage summary display at the end of the procedure (to check the expiration instruments).
18.	Demonstrates powering down the system at the end of procedure.
19.	Verbalizes the importance of connecting “power cables” on surgeon console and surgical arm cart after moving Robotic system.
20.	Able to identify:
	a. Location of emergency wrenches
	b. Application and use of emergency wrenches in an emergency
	c. Situations of power loss or non recoverable fault.
	d. Corrective action of stabilizing and removing instruments and pulling surgical arms back.
	e. Location of reference manual and phone numbers for hospital resources, personnel and manufacturer.

Appendix E: Comparison Chart of daVinci Simulator Skill Sets and Training Exercise Activities

Skills Focus ♦ = Primary ○ = Additional	**System Settings & Controls**	**Endowrist Manipulation**	**Camera Control**	**Clutching**	**Dissection**	**Energy Control**	**Fourth Arm Control**	**Needle Control**	**Needle Driving: Basic**	**Needle Driving: Advanced**
Simulation Exercises										
Camera Targeting – Level 1			♦							
Camera Targeting – Level 2			♦	○						
Dots and Needles – Level 1		○						○	♦	
Dots and Needles – Level 2		○						○		♦
Energy Dissection – Level 1		○			○	♦				
Energy Dissection – Level 2		○			○	♦				
Energy Switching – Level 1			○	○		♦				
Energy Switching – Level 2			○	○		♦				
Falling Dominoes		♦	○	○						
Matchboard – Level 1		♦								
Matchboard – Level 2		♦		○						
Matchboard – Level 3		○	○	○			♦			
Needle Targeting		○						♦		
Overview of Controls	♦	○								
Peg Board – Level 1		♦								
Peg Board – Level 2		♦	○	○						
Pick and Place		♦								
Playground		○	○	○			♦	○		
Ring and Rail – Level 1		♦	○							
Ring and Rail – Level 2		♦	○	○						
Ring Walk – Level 1		♦	○							
Ring Walk – Level 2		♦	○							
Ring Walk – Level 3		○	○	○			♦			
Scaling	♦			○						
Stacking Challenge		♦		○						
Suture Sponge – Level 1		○						○	♦	
Suture Sponge – Level 2		○	○					○	♦	
Suture Sponge – Level 3		○	○					○		♦
Thread the Rings		○	○					♦		
Tubes		○	○	○				○		♦