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Evaluation of Robotic Cardiac Surgery Simulation Training

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A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Surgery

EVALUATION OF ROBOTIC CARDIAC SURGERY SIMULATION TRAINING

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by

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Abstract

OBJECTIVE: To compare the currently available simulation modalities in robotic surgery.

METHODS: 40 trainees completed two robotic cardiac surgery tasks and were randomized to: a wet lab, a dry lab, a virtual reality lab or a control group with no additional training. Participants trained to proficiency determined by two expert robotic surgeons, and then repeated the assessments. All assessments were blinded and evaluated using the GEARS scoring tool.

RESULTS: All three training streams improved their performance. The wet lab and virtual reality groups met the levels of proficiency for all tasks. The average time to reach proficiency was least for the dry lab and most for the virtual reality.

CONCLUSIONS: This is the first RCT to compare simulation modalities in robotic surgery. This work highlights key differences in current training methods and will help training programs invest resources in cost-effective, high-yield simulation methods to improve training in robotic cardiac surgery.

Keywords

Robotic Cardiac Surgery, da Vinci Robot, Simulation Training, Randomized Controlled Trial

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1 Introduction

Robotic cardiac surgery is advancing at a rate which makes assessing safety, efficacy and long-term results difficult[1]. In addition to this, there is a significant deficiency in the availability and quality of robotic surgical training[1,2]. The associated high upfront costs and increasing demand for improved outcome-based measures, reduces the exposure of cardiac surgery trainees to robotic cases and makes experience in robotic cardiac surgery, difficult to obtain by standard training practices[1].

In this era of rapidly evolving technology, an efficient and reproducible training model for robotic surgery is essential. A reliable training program would help to shorten the difficult learning curves and allow surgeons in training to reach levels of competency at faster rates[1]. One potential form of training that has started to produce these desired results is simulation based exercises performed outside of the operating room. However, to date no reliable comparison of the currently available simulation training modalities exists[1,2]. In order to understand the challenges training programs face in providing adequate exposure for their trainees and how simulation based training offers a reasonable solution to these problems, we must first understand the history of robotic cardiac surgery and simulation.

1.1 History of Robotic Cardiac Surgery

The development of robotic technologies capable of surgical applications, first began in the late 1980's when researcher working at the National Air and Space Administration (NASA) became interested in developing "telepresence" [3]. The idea of telepresence, referred to a variety of technologies that serve to give an individual the appearance of being present, when they are in actuality at a remote location[3]. Researchers at NASA paired with individuals at Stanford University to develop the first telemanipulators which were able to mimic hand movements and were immediately intended for surgical

applications[3]. Shortly after this, the United States Army became interested in these systems for their potential to decrease war time casualties and supported their early development[5]. Their original intention was to create a system where wounded soldiers on the battlefield could be loaded onto armored trucks carrying robotic surgical equipment and be operated on by a surgeon who was located off the battlefield at a nearby Mobile Advanced Surgical Hospital (MASH) unit, through telerobotic surgery in an attempt to decrease mortalities associated with delayed time to surgical intervention[5,6].

In the following years, several individuals from the original NASA and Stanford development teams eventually started commercial ventures for the application of the technologies that they developed. This lead to the development of Computer Motion Inc. (Santa Barbara, CA), who used the investments from the US military to fund the development of the Automated Endoscopic System for Optimal Positioning (AESOP) robot, which opened the door for similar technologies to be brought into the operating room[5,6].

The AESOP robot (Computer Motion Inc., USA) was first used to assist in cardiac surgery in 1998[7,8]. Its success led to the development of both the ZEUS (Computer Motion Inc., USA) and the da Vinci (Intuitive surgical Inc., USA) robots. Over the years these systems continued to advance and through the development of endowrist stabilizers and techniques in “off-pump” surgery, robotic total endoscopic coronary artery bypass (TECAB) and minimally invasive robotic-assisted mitral valve surgery are now possible and carried out routinely at specialized centers[1,2,6].

Although advances in robotic cardiac surgery have been made over the years, only a small amount of cardiac surgery cases are done robotically and are performed at specialized centers with unique experiences[1,2]. The failure for the adoption of robotics in cardiac surgery is strikingly different from other surgical specialties, such as gynaecology and urology, where the number of robotic-assisted surgeries has increased worldwide since 2007, from 80,000 to 205,000 in 2010 with a strong patient preference for robotic surgery[9]. There are multiple potential reasons for the delay in acceptance by cardiac surgeons, which have been suggested to include; the large up-front costs to obtain a robot

and a properly equipped operating room, the need for specialized allied health professionals in the operating room (nurses, anesthetists, respiratory therapists, etc.) and a steep learning curve for the entire surgical team with limited access to any standardized training[1,2,10].

1.1.1 AESOP

As previously mentioned, the AESOP robot was developed by Computer Motion Inc. (Santa Barbara, CA) in the mid-90s[7]. AESOP consisted of a robotic arm that held an endoscope with up to four degrees of freedom, controlled entirely by voice commands given by the surgeon. The benefit of the AESOP robot was that it eliminated the need for a member of the surgical team to hold and constantly position the endoscopic camera for the entire case[6]. In addition to freeing up an extra set of hands from the surgical team, this system decreased problems with operator fatigue over long laparoscopic cases and eliminated any inherent tremor of the operator. The AESOP system returned control of the visual field and the sight of the surgeon performing the operation, back to the surgeon[8]. Until the development of AESOP, all laparoscopic surgeons needed to rely on assistants to control, position and focus the camera on the operating field. The original model required the surgeon to pre-record their voice for up to 23 different commands[7]. AESOP proved to be beneficial in many studies and was widely adopted in the laparoscopic community with excellent results[5]. At the time of its development AESOP could handle 240 cases per year and cost approximately $65,000. AESOP was the first widely integrated robotic system in the operating room allowing for all participants of the operation (surgeon, assistant, scrub nurse, anesthesiologist) to become familiar and more comfortable with the man and machine interface for the first time, paving the way for the adoption of future generations of surgical robots in the years to come[5].

1.1.2 ZEUS

The ZEUS robot, also created by Computer Motion Inc., was the next step in surgical robotics that incorporated the endoscopic camera arm from AESOP, with two arms with 6 degrees of freedom, controlled by the surgeon's hands[5]. This was the first example of the "master-slave" or telemanipulation system that actually allowed surgeons to control the robot away from the operating table[5]. For the ZEUS system, the surgeon would sit at a console with their hands in the master robotic controls. These telemanipulation controls had the capacity to decrease inherent tremors of the surgeon or scale down movements by a factor of 2-10 times, resulting in smoother and more accurate movements[5]. While the surgery is being performed the operative field is displayed through the AESOP arm, controlled by the surgeon who is wearing a headset to give voice commands for each movement. The image depicted on the robotic display unit is a 2-dimensional image, however the special glasses can be worn with lenses polarized at a different axis for each eye, that created the perception of a 3D image of the operating field for the surgeon[5].

Numerous initial anatomic animal and cadaver studies carried out with the ZEUS robot showed the system to be advantageous for certain complex tasks including various anastomoses[1,5]. Initial prototype testing of the ZEUS robot began in 1995 in animals. The first clinical uses of the robot were largely performed in cardiac surgery cases and the first closed-chest beating-heart coronary artery bypass grafting with this system was completed in 1999 at University Hospital of the London Health Sciences Center by Dr. Douglas Boyd[4].

The ZEUS robot received FDA approval in 2001 and became fairly successful over the next few years with a variety of other firsts. This included the first transatlantic telesurgery in 2001, where a cholesystectomy was performed on a patient in Stratsbourg, France by a team of surgeons in Manhattan, New York[5].

1.1.3 da Vinci

At the same time that the ZEUS robot was being developed by Computer Motion their competitors, Intuitive Surgical Inc. (Sunnyvale, CA), were developing a similar telemanipulation system after reworking the original telepresence system created by the group at Stanford[5]. This original prototype varied from other robotic systems in that an additional joint was added to the end of each instrument, making the instrument capable of mimicking the surgeon's hand and wrist movements exactly with seven degrees of freedom[1,2]. The company combined this technology with force-feedback and 3D visualization in the second prototype, that they called the da Vinci robot. The system was composed of three parts; the surgeon console, the surgical trolley (which contained the articulating arms of the robot) and the imaging system[5]. The surgeon console contained a binocular stereoscopic vision system that displays images from the robot's 12mm diameter camera. This camera was composed of two 5mm cameras that transmit their image to different eyes within the surgeon console. The resulting affect is the production of a 3D representation of the surgical field for the surgeon[1,2]. In addition to this, the camera arm also contains the insufflation connections and a light source. The surgeon console consists of two handles or joysticks that were used to transmit the surgeon's hand movements to the robotic arms, instruments and camera[1.2]. This system also has the capacity to scale down movements by a factor of 1 to 5 times and a filtration module to eliminate inherent tremor for smoother and more controlled robotic movements[1]. The system employs a pedal system to switch control of the arms to allow for camera movements and clutching of the control as well as pedals that control monopolar and bipolar cutting and coagulation depending on the instrument that is attached. The da Vinci system was originally designed for cardiovascular surgery and the first reported case in a human was the closure of an atrial septal defect (ASD) through a mini-thoracotomy in 1998[10].

Heavy competition existed between Computer Motion and Intuitive Surgical with Computer Motion filing a patent infringement lawsuit against Intuitive Surgical during this time. In 2003, Intuitive Surgical bought out Computer Motion, acquiring all of its patents and in doing so formed a monopoly over the surgical robot market[5].

To this date, Intuitive Surgical has continued to introduce advancements in their robot and have developed several newer version of the da Vinci system[10]. In 2002, the standard model of the da Vinci was introduced. This model differed from the previous model as it introduced a fourth robotic arm. This arm was identical to the other surgical arms but its addition improved the surgeon's ability to expose anatomical structures through its periodic manipulation as a retractor. This improved robotic efficiency as control of the additional arm allowed the surgeon to operate without relying on a bedside assistant to help position the tissue correctly using laparoscopic instruments[5]. In 2006 the da Vinci S system was introduced. With this newest model, Intuitive Surgical Inc. increased the ease of handling the instruments as well as the amplitude of arm and instrument movements. This change to the system allowed surgeons to perform surgery involving multiple quadrants of the abdomen without repositioning of the robotic ports and facilitated the use of the robot in colorectal resections[5]. The next version of the da Vinci system was released in 2009. The da Vinci Si system had improvements involving the manipulators as well as relocation of some of the pedal system for more ergonomic positioning[5]. The Si system was also equipped with an improved camera system capable of displaying images in high definition[5]. One of the biggest advancements made with the release of the Si system was the addition of a second console that now allowed for coaching of novice surgeons by a mentor during the procedure[5]. This marked a major change in the traditions of surgical teaching as now trainees were able to see exactly the same image as their staff surgeons and through the robot's telestration capabilities, the surgeon had the ability draw the attention of the trainee to important anatomical structures without obstructing their vision[10].

1.2 Current State of Robotic Cardiac Surgery

Although robotic surgery has existed for nearly two decades recent technological advancements as well as an ever increasing push for less invasive procedures has increased the popularity of robotic cardiac surgery in recent years[11]. The advancements in

robotic technology in conjunction with improved minimally invasive techniques, myocardial protection strategies and perfusion systems have demonstrated that robotic cardiac surgery is a safe and advantageous alternative to traditional approaches at specialized centers[10,11]. Currently the da Vinci system is employed in cardiac surgery for coronary revascularization, including; harvesting of the internal thoracic artery (ITA), total endoscopic coronary artery bypass (TECAB), and hybrid procedures, as well as in robotic-assisted mitral valve surgery[10-14]. In addition to this, reports exist within the literature describing the use of the da Vinci robotic system for; ASD closures, resection of intracardiac masses, epicardial lead placement and arrhythmia ablation surgery[15-18]. Recent publications have presented convincing results that robotic cardiac surgery is increasing substantially in popularity worldwide as it is being adopted by more surgeons, at more centers, for a wider variety of patients and procedures[11]. Kaneko et al. report the experience of one of the initial centers in the world to adopt robotic cardiac surgical procedures in their program in the late 1990s[11]. At that time, the difficulties associated with the procedures excluded any individual with an ejection fraction <35%, a previous cardiac surgery, a previous right-sided thoracotomy or any significant aortoiliac disease, from consideration for robotic cardiac surgery[11]. Today, with the progress that has been made at this institution and centers like it around the world, the techniques they have developed and experiences that have gain have obviated many of these initial concerns. The authors highlight that today, none of these original concerns are still considered absolute contraindications for consideration of robotic cardiac surgery at their center[11]. Furthermore as an indication of improved robotic equipment and surgical techniques, the authors report a reduction in total operating times, cardiopulmonary bypass times and cross-clamp times for individual cases, improved patient outcomes, and decreased costs. These improvements have now made minimally invasive robotic cardiac surgery a viable option for a wide variety of patients[11].

Over its development the acceptance of robotic techniques for coronary bypass surgery has been slower than that of mitral valve surgery[19]. This is largely due to the common need for multiple grafts in a variety of regions on the heart which are not always accessible from stationary trochar sites placed for robotic surgery. In addition to this, the coronary anastomosis still requires carefully placed sutures as no reliable automated graft

connector has been developed, and lastly the limitations on cardiac stabilization in beating-heart surgery[19]. All of these factors have slowed the development of robotic multivessel coronary artery bypass grafting. However, to date four different techniques are currently used for robotic coronary revascularization; (1) robotic assisted ITA harvesting with a direct hand-sewn anastomosis through a left anterior minithoracotomy with the used of cardiac stabilizers (2) arrested-heart robotic TECAB, (3) beating-heart robotic TECAB, and (4) hybrid procedures using both percutaneous coronary intervention (PCI) and one of the previously listed robotic bypass grafting techniques[15]. All of these techniques have been described at different specialized centers with excellent patient outcomes, some with patency rates as high as 100% at the time of discharge from hospital[15].

Robotic cardiac surgery continues to evolve at a rapid rate and advancements in this field indicate that robotics and minimally invasive approaches will become a major part of the surgical disciplines in the future[10]. Many surgeons remain concerned about the increased costs as well as the complexity of the procedure to want to adopt these new techniques and undergo the necessary retraining, and in doing so many of them have become critics of the techniques[19]. However, it remains clear that developing technologies will advance the field of robotic cardiac surgery and provide surgeons with new techniques to help treat patients with cardiac diseases[10].

1.3 Current training and Exposure

As these developments in the field of cardiac surgery start to answer skeptics of minimally invasive approaches, the need for a more structured and standardized approach to training becomes more important[19].

The US Food and Drug Administration (FDA) mandated that Intuitive Surgical, Inc. provide comprehensive training for all surgeons, as well and any institutional team, planning on using the da Vinci system for clinical purposes[19]. In Canada, the Canadian

Surgical Technologies & Advanced Robotics (CSTAR) center at the University of Western Ontario was selected as the national training center for the da Vinci robot in 2013. In the United States, East Carolina University was selected as the original training center for the da Vinci, as the divisional chief of the department of cardiac surgery at the University was Dr. W. Randolph Chitwood, one of the earliest adopters of the da Vinci system and a pioneer in robotic cardiac surgery[19]. The East Carolina University training program was developed shortly after their successful completion of their first clinical da Vinci procedures and was the first standardized training program for robotic surgery[19]. To obtain credentialing, surgical teams underwent intensive training with multiple hands on sessions for two days, for the general surgery program and three days for the cardiac surgery program[19]. During these sessions, two surgeons could be trained at once, one at the surgeon console and the other as the bed-side assistant. The other members of the surgical team included two or three operating room nurses and an anesthesiologist. In addition to this, a perfusionist was included for the cardiac surgery training[19].

The objectives with this training course, for the two surgeons, included comparison of surgical robotic methods to those of the traditional methods that they were familiar with from previous training and clinical experiences, to gain exposure to the different system components, be able to troubleshoot common problems, and finally to master the manipulation of the robotic instrumentation and delineate the procedural steps involved in specific operations to become both an accomplished robotic surgeon and bed-side assistant[19]. The course also focused on team based training and highlights the importance of a well functioning team in the operating room. Objectives for this aspect of the course focus on applying the sterile drapes, arranging the operating room appropriately and general maintenance of the robotic instrumentation[19]. Teams were also exposed to troubleshooting of the robot and the emergency shutdown protocols[19]. These sessions included didactic teaching sessions, dry lab, wet lab and cadaver training, which all occurred under direct supervision of an expert robotic surgeon. The goals of the robotic training program are listed in Figure 1. Initially training for mitral valve surgery involved wet labs with sheep's hearts placed in a special thoracic trainer made to mimic the geometry of the human chest for robotic instrument port and camera placement. This

model was felt to give a realistic representation of the workable valve and annular tissues for suturing and mitral valve repairs[19]. Following this, cadavers were used to help identify the nuances of port placement, arm position and shoulder mobility[19].

Table 1: da Vinci Credentialing Course Levels of Robotic Surgical Training

I. Didactic overview
• Understand robotic vision and electronics
• Understand robotic instrumentation
• Understand robotic ergonomics
• Understand robotic limitations
II. Inanimate laboratory
• Master operative console
• Master robotic operative cart
• Master instrument and camera control
III. Animal laboratory
• Console surgeon—master suturing, tissue cutting, suture tying
• Patient-side assistant—master:
○ Instrument exchanges
○ Camera cleaning
○ Cauterization
○ Clip application
○ Retraction
○ Trocar positioning
IV. Cadaver laboratory
• Master trocar positioning
• Apply I–III to human anatomy
• Apply I–III to variable body habitus
V. Operative observation
• Determine differences from I–IV
• Observe interaction with adjunctive surgical technology

List of the exercises and techniques used in the da Vinci Credentialing course provided by Intuitive Surgical Inc.

This training protocol is provided by Intuitive Surgical Inc. and the only additional stipulation for training is that surgeons must be proctored for their initial cases within a set period of time after completing this training. Although it represents the minimal amount of training that is required by the FDA to receive credentialing for clinical use of the robot, it utilizes a variety of different simulation training methods to maximize learning over a short training course[19]. It is unreasonable to think that in just three days of a robotic cardiac surgery training course anyone would reach a level of proficiency to take on the responsibility of operating on an actual patient, but in fact this is what

happens[19]. Many of the world leaders in robotic surgery were pioneers, in their respective fields, out of necessity as they never had any formal or structured training with any robotic system in addition to this course[19]. This deficiency in the training of robotic surgeons was highlighted in a 2010 Dutch Health Care Intspectorate, who published a report that stated 50% of hospital's had insufficient criteria for surgeon competence prior to starting robotic surgery[20].

In addition to this, staff surgeons who have completed this da Vinci credentialing course and obtained robotic privileges at their institution, are then expected to teach surgical trainees on the job as they are trying to perform these complex operations themselves[19]. Currently robotic cardiac surgery is taught by traditional surgical training methods[21]. This usually involves a step-wise approach where a trainee is entrusted with a small portion of the procedure and allowed to complete it with ongoing feedback and guidance under careful watch of the more senior individuals in the operating room[20,21]. Once proficiency with this task has been accomplished by the trainee, they are entrusted with another task and so on, until they are completing a greater and greater portion of the overall procedure[21]. This method of training requires a great deal of time to gain the adequate experience needed with each task, as well as a more senior member of the surgical team to be present to provide ongoing feedback[20]. With the increased cost and resources invested to create a surgical robotic program as well as the high operating costs, there is increased pressure placed on surgeons for improved patient outcomes as administrators and tax payers demand a return on their investments. This increased pressure usually results in staff surgeons preferring to complete the entire case themselves and very little of the procedure being completed by trainees.

2 Literature Review

The following provides a brief overview of the relevant studies that have contributed to identifying the benefits of robotic surgery and the current methods used to train surgical residents and fellows.

2.1 Benefits of Robotic Surgery

Despite the fact that robotic assistance is used in a small portion of all cardiac surgeries, its benefits have been shown at experienced centers. Poston, et al. from the University of Maryland showed this in a 2008 publication in the Annals of Surgery[22]. Here the authors demonstrated a significant reduction in total intubation time (4.80 ± 6.35 vs. 12.24 ± 6.24 hours), hospital stay (3.77 ± 1.51 vs. 6.38 ± 2.23 days), and need for blood transfusions (0.16 ± 0.37 vs. 1.37 ± 1.35 U) compared to traditional coronary artery bypass grafting (CABG) with a sternotomy[22]. Despite increased upfront costs the researchers showed no significant differences in total costs at the time of discharge[22]. In this study, minimally invasive CABG was also a predictor of earlier return to work by 2.15 days ($p = 0.04$) after adjusting for confounders, and decreased rates of major adverse cardiac and cerebrovascular events (MACCE) (HR, 3.9; 95% CI, 1.4 –7.6)[22].

As previously mentioned robotic surgery has been more successfully adopted in other surgical disciplines. Robotic surgery has been associated with a decreased length of hospital stay and reduced blood loss when compared to laparotomy and laparoscopy based on a large meta-analyses from the gynecologic oncology literature[9]. Similar findings have been seen in urological oncology patients, where robotic surgery has demonstrated a distinct benefit with shorter lengths of hospital stay, less blood loss and blood transfusions, compared to retropubic and laparoscopic surgery[9]. With these similar benefits, it is reasonable to believe that robotics will play a larger role in the field of cardiac surgery at some point in the future. As robotic surgical technologies advance,

surgical systems will become smaller, more affordable, more efficient and easier to use, which addresses most of the concerns and obstacles with implementing a robotic program today. However, advancement of these technologies is dependent on continued efforts to improve training and outcomes today[19].

2.2 Current Robotic Surgical Training

Robotic surgical training is being presented with challenges that are both novel and unique compared to other surgical techniques of the past[20]. The currently available literature indicates that there is an inability to appropriately train novice surgical trainees at the same rate that these technologies are being developed. In 2003, Novick et al. demonstrated the learning curve associated with telerobotic beating heart CABG in the first 90 patients at our center[23]. Their results showed a steep learning curve associated with suboptimal outcomes with the first 18 to 20 patients who underwent robotic off-pump coronary bypass surgery, which was moderated with ongoing experiences in the remainder of the cases[4]. This learning curve was also identified by Schachner et al. in 2009 when they reported the experience of two junior surgeons in training as they progressed to senior roles in a robotic cardiac surgery program and tracked their times for pericardial lipectomy, pericadiotomy, left and right internal thoracic artery harvesting and coronary suturing as compared to senior surgeons[21]. The authors showed that over time as these surgeons progressed to more senior roles, their time to complete these tasks decreased and their level of proficiency approached that of a senior surgeon. With this information the authors concluded that TECAB can be taught well through a stepwise approach, where portions of the entire operation are entrusted to the trainee with increasing responsibilities as their surgical skills improve[21]. This method of training represents the classic model of education and knowledge acquisition in surgical training, and is neither efficient nor does it utilize the impressive advantages of new training modalities available in all surgical disciplines such as simulation training[20].

2.3 Simulation Training

Currently, a wide variety of training methods exist in robotic surgery which include; live case observation, skills laboratories, virtual reality simulation, animal or cadaveric models, proctoring, mentoring, telestration, and serious gaming, but to date no standardized training method exists[20]. This was demonstrated in a 2011, systematic review by Schreuder et al. who after analyzing the available information from the robotic literature argued for the formal organization of a competency based training system and a step-wise approach to procedural training with objective assessments of each step[20]. The authors also identified the benefits of virtual reality (VR) simulation training including; a high fidelity of training experience, the ease of set-up and the reduced cost, and postulated that VR simulation will play an important role in training and learning robotic surgery in the near future[20].

Simulation appears to offer great benefits to surgical trainees by allowing for repeated practice of a specific skill set in a controlled and safe environment[27-31]. This style of training is vastly different from the "see one, do one, teach one" mentality of historical surgical training which moves the acquisition of surgical skill outside of the operating room. This form of training has been necessitated by a lack of exposure in the operating room for trainees due to; increasing costs and an ever increasing administrative focus on outcomes-based initiatives compounded with older and frailer patients now being considered surgical candidates[27]. The three main areas of simulated surgical training currently in use are; cadaveric and animal models (wet labs), dry labs and virtual reality simulation[27]. Each has its benefits and drawback which will be discussed in greater detail here.

2.3.1 Wet Lab Training

Animal and cadaveric surgical models offer the highest fidelity simulated experience (also referred to as 'realism') for surgical trainees in regards to anatomy and tissue handling[32]. Some training centers have increased this experience even further by using anesthetized live animals, or reinfusing these models with pulsatile blood flow in order to recreate the sense of urgency and a higher risk environment consistent with an actual operating room experience[31]. However, providing adequate exposure to these models is prohibitively expensive and very labor intensive for tissue preparation to the point where only specialized facilities are able to offer such an experience, but repetitive training is very limited[31]. Furthermore, because there are no objective measurements or feedback with this training, a skilled surgeon is required to be on hand to optimize teaching and provide guidance and feedback to ensure the trainee is learning the surgical techniques correctly[31]. Wet lab simulation in cardiac surgery has been done previously with cadaveric and porcine models[119]. Although the cadaveric model is more anatomically correct it is far more expensive compared to the porcine model.

The porcine model for cardiac and chest wall anatomy (used for internal thoracic artery dissection), is a reasonable substitute but some differences do exist. For harvesting of the internal thoracic artery (ITA) off of the porcine chest wall, the first difference is that the model has far more developed intercostal muscles which must be peeled off in order to see the internal thoracic artery and vein pedicle. This requires a significant amount of preparation time for each chest wall, usually between 20-30 minutes for an experienced lab tech. Removal of this layer requires the removal of the overlying interthoracic fascia which is normally scored and used to provide retraction during dissection of the ITA. Because this layer of fascia is removed the fat and muscle tissues underneath must be handled during dissection which are a bit more delicate. Once this muscle layer has been removed and the ITA pedicle exposed, the final difference is that the internal mammary veins are much larger in the porcine model than those in a human as compared to the artery. This is usually not a concern when the artery is being dissected in a pedicled fashion where the ITA is dissected with its two corresponding veins. Overall, this model provides a high fidelity representation of the actual human anatomy and the actual

experience of dissection out the internal thoracic artery. For the mitral valve annuloplasty, porcine heart models have been widely used as they provide nearly identical anatomy of the heart and cardiac valves and are of similar size to humans.

2.3.2 Dry Lab Training

A dry laboratory allows for repetitive training of a variety of basic surgical techniques in a low risk environment with standardized objectives to be obtained by the trainee without direct supervision of a skilled surgeon making it ideal for incorporation into a surgical training curriculum[31]. Although the dry lab is an inexpensive and reproducible training tool it lacks the realistic experience of the operating room without exposure to relevant anatomy or actual tissue handling[31]. The best example of this the 'Fundamentals of Laparoscopic Surgery (FLS)' which was adapted from the McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) and first proposed by Ritter et al. in 2007[33]. This program consists of five different psychomotor tasks unique to laparoscopic surgery across a variety of surgical specialties (Peg transfer, Pattern cut, Ligation Loop, Extracorporeal suture, Intracorporeal suture)[33]. In this paper, the levels of proficiency for these tasks were determined by having; two fellowship-trained advanced laparoscopic surgeons, whose practices consisted of mainly minimally invasive surgery, but who were not overly familiar with the FLS tasks prior to initiation of the study, complete each of the five tasks 5 times. It was decided a priori that these values would be pooled and any outlier more than 2 standard deviations from the mean were excluded (there were none). The time for proficiency of these tasks was then set as the mean time to completion from this data set[33]. This training model has been so popular it has been adopted into the general surgery residency training program and provides an inexpensive, reliable, objective and reproducible model for laparoscopic skill development that a trainee can work on independently outside of the operating room to obtain the basic skills needed for any laparoscopic surgery[33].

2.3.3 Virtual Reality Training

Virtual reality (VR) simulation is a rapidly developing training tool used across a variety of different surgical training programs[34]. The benefit of VR is that it offers a reasonably realistic experience of the actual tasks performed on the robot in the operating room at an off-site location that can be accessed anytime a surgical trainee is available[31]. This allows for easily reproducible repetitive practice with little set-up time that is relatively inexpensive[33]. VR simulation also offers powerful evaluation software capable of providing objective feedback on a variety of potential surgical errors that previously could not be measured, alleviating the need for a skilled surgeon to be present[31]. Currently the two robotic surgical simulators to dominate the market are the da Vinci Surgical Skills Simulator (Intuitive Surgical, Sunnyvale, CA) and the da Vinci-Trainer (Mimic Technologies, Inc. WA), both of which run the Mimic software which includes the MScore evaluation tool for defining errors and proficiency[31].

Similar to the FLS protocol, the scoring system used in the Mimic software is proficiency based and derived from the mean performances of experienced surgeons, the standard deviation of their performances and a proficiency multiplier[35]. The program is also capable of measuring components of each task that previously would have been exceedingly challenging to objectively quantify (ex. time, number of drops, number of instrument collisions, missed targets, broken vessels, blood loss, excessive force, angle of approach, etc.). Users are given a complete breakdown of their performance and each individual metric that composed the total score in the MScore summary after finishing an exercise. This allows them to see exactly what they did wrong during the exercise, what they can improve on and how far they were from a passing score[35]. This powerful tool allows for real time objective feedback of a trainee's performance without the need for a skilled surgeon to be present[31]. The MScore software has been validated in multiple papers published in the urology and gynaecology literature for its usefulness as a training tool, realistic experience, and ability to distinguish experienced from novice users[36-41].

Recently, Culligan et. al were able to demonstrate the usefulness of virtual reality simulation on robotic surgical training by comparing real operative outcomes between

experienced robotic surgeons(>75 cases/year) and surgeons without prior robotic training who trained with the virtual reality simulator[38]. For this study the researchers examined the available exercises offered through the Mimic Technologies Inc. surgical simulation software and with the help of expert robotic surgeons rated each exercise from "not very helpful" to "definitely helpful" for a novice robotic surgeon in training. From this they selected the 10 exercises that were rated as "definitely helpful" by all of the expert surgeons surveyed, to create a simulation protocol that addressed; camera control and clutching, endowrist manipulation, basic and advanced needle driving, needle control, fourth arm control, dissection and energy control[38]. A group of novice robotic surgeons were allowed as much time as needed to reach the level of proficiency that was set by the experts for all ten exercises on the simulator. Participants then completed the da Vinci pig laboratory required for all new robotic surgeon followed by their first ever supracervical hysterectomy within two weeks of completing the training curriculum. Outcomes (time, blood loss, and blinded assessment) were compared to a third group of surgeons who had robotic certification but were performing less than 75 cases per year[38]. Time and blood loss were found to be significantly improved for the VR trained surgeons compared to the control group and similar to that of the experienced surgeons[38]. The researchers also used the Global Operative Assessment of Laparoscopic Skills (GOALS) to demonstrate an improvement in surgical technique for the test group over the control[38]. The GOALS scoring tool was developed and validated in laparoscopic surgery to objectively assess intraoperative laparoscopic surgical skills for a variety of laparoscopic procedures[42]. It has been shown to be superior to other intraoperative scoring systems and to correlate well with scores of the FLS program[42.] A similar scoring system that is specific to robotic surgery exists, based on the GOALS tool principles for laparoscopic surgery[47].

2.4 Methods for Robotic Surgical Proficiency Assessment

GOALS proved to be a user friendly, objective and reproducible tool for the assessment of laparoscopic surgical skill, and so it was used as a model for developing a similar tool specific for robotic surgery[47]. In 2012, Goh et. al, validated a clinical assessment tool for robotic surgical skills known as the Global Evaluative Assessment of Robotic Skills (GEARS)[47]. The development of this training tool involved 29 evaluations of 25 trainees (ranging from 4-6 years of post-graduate training) and 4 attending surgeons. When stratified for year of training, the researchers were able to detect a significant difference in the overall score on the assessment tool between 4th and 5th year residents when compared to attending surgeons[47]. The author's of this work validated their findings by estimating the internal consistency of each component of the GEARS scoring tool using Cronbach's α analysis (0.90-0.93), which is used to estimate the reliability of a psychomotor test. Furthermore the authors used a technique for to assess similarity between the groups known as intra-class correlation coefficients to demonstrate interobserver reliability. This showed this value to be 0.80 ((95% CI 0.65-0.90), indicating low variability among different evaluators using the scoring tool[47]. GEARS is composed of six areas of robotic surgery; depth perception, bimanual dexterity, efficiency, force sensitivity, autonomy, and robotic control. Each quality is ranked on a five-point Likert scale with one being the lowest score and five representing an accurate, confident and efficient robotic surgeon[47]. Within this study, expert robotic surgeons were capable of obtaining scores greater than 26/30, indicating a high level of proficiency where as trainees scored below 20/30 indicating room for improvement with robotic skill[47]. The actual GEARS scoring tool is shown in Figure 2.1.

Figure 2.1: Global Evaluative Assessment of Robotic Skills (GEARS) Scoring Tool

	1	2	3	4	5
Depth Perception	Constantly overshoots target, wide swings, slow to correct		Some overshooting or missing target, but quick to correct		Accurately directs instruments in the correct plane to target
Bimanual Dexterity	Uses only one hand, ignores nondominant hand, poor coordination		Uses both hands, but does no optimize interaction between hands		Expertly uses both hands in a complementary way to provide best exposure
Efficiency	Inefficienct efforts; many uncertain movements, constantly changing focus or persisting without progress		Slow, but planned movements are reasonably organized		Confident, efficient and safe conduct, maintains focus on task, fluid progression
Force Sensitivity	Rough moves, tears tissue, injures nearby structures, poor control, frequent suture breakage		Handles tissues reasonably well, minor trauma to adjacent tissue, rare suture breakage		Applies appropriate tension, negligible injury to adjacent structures, no suture breakage
Autonomy	Unable to complete entire task, even with verbal guidance		Able to complete task safely with moderate guidance		Able to complete task independently without prompting
Robotic Control	Consistently does not optimize view, hand position, or repeated collisions even with guidance		View is sometimes not optimal. Occasionally needs to relocate arms. Occasional collisions and obstruction of assistant.		Controls camera and hand position optimally and independently. Minimal collisions or obstruction of assistant

GEARS Scoring tool, adapted from Goh et al. 2012 J Urol.

The authors of this paper point out that the well adopted and validated FLS curriculum, has been demonstrated to have a high positive correlation to trainee intraoperative performance as measured by GOALS and therefore they suggest that the similar robotics assessment tool, GEARS, may serve as a guide to developing a robotic training simulation curriculum[47].

Virtual reality simulation has an added benefit for determining proficiency by using a far more complex evaluation tool. As previously mentioned, the MScore software (Mimic Technologies Inc. USA), is powerful objective evaluation tool incorporated into the virtual reality simulation software. At the completion of each exercise trainees are presented with a screen that contains their overall score as well as the scores of different

metrics that were recorded for that particular exercise. These metrics may include; time, total distance travelled, excessive force, instrument collisions, blood loss, master workspace range, etc. Each exercise within the software tracks a different set of these parameters that are important to the successful completion of that particular exercise[35]. The benefit of this scoring tool comes from its ability to track small errors in robotic performance that affect surgical efficiency and overall robotic proficiency. The scoring tool was created by having 100 experienced robotic surgeons from six different institutions complete the exercises. Surgeons had to have completed over seventy-five robotic cases to be designated as 'experienced' for these purposes[35]. Each surgeon was allowed to complete each exercise as many times as they wanted until they felt that they had completed the task to the best of their ability. For each task this took between 10 and 137 attempts for each individual experienced surgeon to complete[35]. After this work was completed, software developers looked at the average scores for each individual metric to calculate the default proficiency baseline of each individual metric. The equation for the Profociency Baseline Scoring is shown in Figure 2.2.

Figure 2.2: Proficiency Baseline Scoring for MScore Software

$$Proficiency\ Baseline = \mu + 1 * \sigma$$

where

- μ = Mean experienced-surgeon raw value on this particular metric and exercise
- 1 = Proficiency multiplier
- σ = Standard deviation experienced-surgeon raw value on this particular metric and exercise

Proficiency Baseline Scoring Equation fof the MScore Software.

This formula indicates that any individual performing a specific exercise on the virtual reality software must perform one standard deviation better than the average score set by these experienced surgeons. This must occur for each metric that is tested in the particular exercise to contribute to the overall score. Proficiency baseline scores for metrics that use whole numbers such as; drops, instrument collisions, missed targets or broken vessels were rounded to the nearest integer[35]. Failure to reach the set proficiency

baseline in any of the tested metrics results in a critical error and failure of the entire exercise[35].

However, it must also be taken into consideration that some metrics are more important than others. For example, a mistake of colliding the instruments or operating with a large master control workspace range may decrease the efficiency with which one is able to control the robot but it is hardly as critical of a mistake as applying excessive force or carrying a needle off screen, which are both potentially dangerous maneuvers. To account for this, the different metrics are weighted in their contribution to the overall proficiency score. The overall proficiency score is composed of the weighted averages (denoted by W_i) of the individual metric scores and is calculated using the formula shown in Figure 2.3.

Figure 2.3: Overall Score Calculation for MScore Software based on Individual Metric Weighting

$$Score = 100\,\frac{\sum_{i=1}^{n} W_i\, Clamp\left(\frac{RV_i - ZV_i}{HV_i - ZV_i}\right)}{\sum_{i=1}^{n} W_i}$$

where

- n: number of metrics of the exercise
- RV: Raw value user performs on the metric
- ZV: 0% Score Value of the metric
- HV: 100% Score Value of the metric
- Clamp(x) = 1 if x >= 1, 0 if x <= 0, x otherwise

Overall Score calculation for the MScore software using the particular weighting(W_i)for each metric whose total sum give the overall score.

This formula will generate the overall score of each exercise as a percentage from 0-100%, where a pass based on the standard simulator settings is a proficiency score of 80%, while passing each individual metric[35]. A passing grade is denoted on the system with a green checkmark that signifies a score was reached between 100% and 80% which is predefined as the acceptable threshold[35]. If the individual fails to reach this acceptable threshold but scores over 50% they will see a yellow triangle for this metric which indicates a warning and encourages the individual to attempt to improve this score. A yellow triangle on any metric is not considered a fail and the individual can still pass the exercise if they obtain an overall score >80%, while failing to reach the acceptable threshold on an individual metric in the exercise with the simulator on its default settings[35]. Failure to reach the 50% mark will result in a failure of that metric and is defined as a critical error. For this the individual will be prompted with a red "X" to signify their inability to reach the predetermined level of proficiency for either that metric or the overall proficiency score[35]. The simulation software has the ability to set different levels of proficiency for the overall score or an individual metric, if a training program wishes to do so to individualize the training exercises[35].

Although the actual calculation of each individual metric and score may seem complicated, the MScore software is a powerful and very user friendly tool that provides feedback for trainees on an ongoing basis and allows them to objectively compare their results with improvements they make over time or with that of colleagues and experts[31].

3 Methodology

The purpose of this study is to determine the most effective method for robotic cardiac surgery training through a prospective randomized controlled trial comparing wet lab, dry lab and virtual reality simulation with an untrained control group. This work forms one of the largest trial available of its kind in the current literature and the first ever randomized controlled trial (RCT) comparing the currently available robotic training modalities in

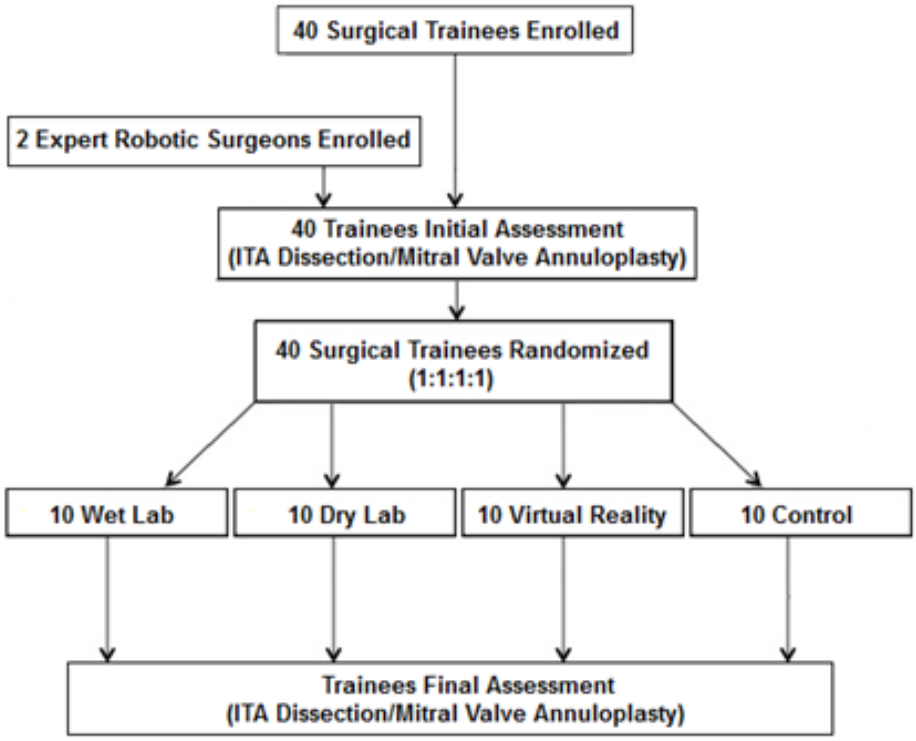
cardiac surgery. The trial involves a parallel RCT with four different treatment arms utilizing both time-based assessments as well as a single-blinded assessment of robotic surgical skill with a validated scoring tool for intraoperative robotic surgical skill.

At the onset of the study, we hypothesized that the Virtual Reality Training curriculum would offer trainees the best simulation experience by providing a comprehensive evaluation of a variety of important metrics for each exercise and this would allow individuals randomized to this group to score the highest on the final assessments.

3.1 Trial Design

Our study used a parallel-group randomized controlled trial design, with four different treatment arms. After the initial assessment trainees were randomized to either a; wet lab, dry lab, virtual reality curriculum or a control group, that received no additional training. All trainees in the 3 training streams were allowed to practice on the da Vinci robot or simulator until they reached a level of proficiency that had been previously set by our expert robotic surgeons for each specific task. All trainees were then brought back to repeat the original assessment. All assessments were recorded, de-identified and coded to be assessed by a single blinded investigator to control for inter-observers variability at a later date. The flowchart for the study design is shown here in Figure 3.1.

Figure 3.1: Parallel RCT Study Flowchart



Study participant flowchart for the current study.

3.1.1 Ethics Board Approval

The Western University Health Science Research Ethics Board (HSREB#106343) approved this trial. Documentation of HSREB approval is provided in Appendix B. The trial was also registered into the public domain on clinicaltrials.gov (NCT#02357056).

3.1.2 Source of Funding

This trial was supported by a St. Jude Medical resident education grant valued at $3000 Canadian Dollars, distributed to the department of cardiac surgery at the University of

Western Ontario. Internal support for the project was also provided by CSTAR. No other sources of external funding were required to support the administrative or completion of the study. The authors have no conflict of interest to disclose.

3.1.3 Randomization

Proper randomization of each participant into one of the three training streams or the control group was paramount to ensure the best possibility of controlling for differences in baseline demographic variables and performances as well as success and progression in the training streams. Although a variety of different randomization techniques are possible, at the time of enrollment of this study we needed to assess the first few participants to look for variability and comparison to the experts in order to complete our power calculations. Because of this, we opted for a simple randomization technique congruent with the ongoing enrollment. After each participant completed the initial assessment they selected one of four identical cards that indicated the training stream that they would be allocated to, that were held in an opaque container. This process allowed for each individual to be assigned independently of one another and with the same chance of ending up in any of the four treatment arms of the study.

3.1.4 Blinding

Blinding in scientific methodology refers to the lack of awareness of the evaluators as to the allocation of the treatment groups for the study participants. This helps to control for biases with observer evaluations but as well as participant performance and willingness to provide examiners with specific information. For this a double-blinded design is usually preferred which indicates that both the participants and the investigators are unaware of

the treatment allocation. Commonly it is impossible for a double-blinded design for studies within the surgical literature as the surgical team or patients are always aware of the treatment that they received or the procedure performed. In these instances, a third party evaluator is commonly used to assess post-operative changes and this is referred to as a single-blinded design. This was the case for the current study, where blinding would have been impossible for the study participants who spent considerable amount of time training in their specific treatment arm. During the initial and final assessments each study participant had every evaluation recorded through the da Vinci video system. This was also done with the experts for each of their five attempts of the ITA dissection and mitral valve annuloplasty. This produced a short video of the participant's performance, as seen from the surgeon's console and contained no identifying information. Each video was then coded and evaluated at a later date by a single invigilator who was unaware of the participant's training stream, or if they were evaluating one of the experts performances.

3.2 Recruitment

Recruiting the correct population for a study is necessary to ensure the results are applicable to the larger population. The current study involves basic training in robotic cardiac surgery and so our ideal study population was cardiac surgery trainees with limited exposure to robotic surgery. At our institution there are not enough cardiac surgery trainees to correctly power the study and so enrollment was expanded to include surgical trainees from other disciplines. Every attempt was made to include trainees from surgical specialties that also use the da Vinci robot. This was to ensure the commitment and participation of each trainee to complete the training stream in their own free time as no other incentive was given out, other than a unique exposure and opportunity to train on the da Vinci system, which is rarely available during surgical training.

3.2.1 Eligibility and Exclusion

Departmental secretaries at our institution for the departments of; cardiac surgery, general surgery, thoracic surgery, obstetrics and gynecology, and urology were contacted with information for the study and asked to disseminate this information among their residents and fellows. Trainees were asked to contact the study investigators if they were interested in participating and at this point they were deemed eligible or not. Because this study involved basic training in robotic cardiac surgery we wanted to exclude participants with significant exposure to the da Vinci console. Therefore, participants were only considered for enrollment if they had less than 10 hours of experience at the da Vinci surgeon console or any of the da Vinci simulators (da Vinci Skills Simulator, da Vinci trainer, etc.).

In addition to this, the dry lab training stream was adapted from the FLS program and in order to ensure that no trainee was at a disadvantage when starting this stream, we made sure that each trainee was familiar with the FLS program prior to enrollment. Because of this, any first year surgical residents were not enrolled in the study until they had completed the FLS requirements of the Principles of Surgery course that is required for all junior surgical residents to complete at our institution.

3.2.2 Informed Consent

Informed consent was obtained from each study participant as outlined in our health science research ethics board (HSREB) submission at the time of the initial assessment. A copy of the written consent form is provided in Appendix C. Signed original consent forms were kept in a locked room in a secure facility at University Hospital. The Western HSREB requires that these consent forms be maintained for ten years after completion of the enrollment phase of the study.

3.3 Initial Evaluation

After successful enrollment participants were shown a five-minute video of an intra-operative robotic harvest of the internal thoracic artery and a robotic assisted mitral valve annuloplasty. These videos summarized basic operative techniques and the relevant anatomy of each procedure. Next, a very brief overview of the standard da Vinci surgeon console was given to each participant including uses for; clutch, camera and coagulation pedals. Participants were then required to harvest a 10cm length pedicle off a porcine chest wall, consisting of the internal thoracic artery (ITA) and the corresponding veins, using robotic Debakey forceps and a monopolar spatula cautery.

Following this, participants were given porcine hearts with the left atrium removed to expose the mitral valve, and asked to place the first three sutures of a mitral valve annuloplasty. Two 3-0 Ethibond Excel (Ethicon, USA) sutures were passed to the participant by an assistant, and placed through both the posteromedial and anterolateral trigones of the mitral valve. A third suture was given to the participant and placed through the annulus of the mitral valve next to the posteromedial trigone suture. A SJM Tailor Flexible Annuloplasty band (St. Jude Medical, USA) was then given to the participant and they were required to place both ends of the suture through the band and hand the ends back to the assistant.

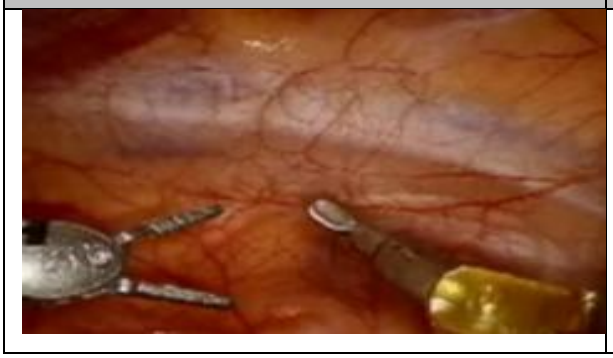
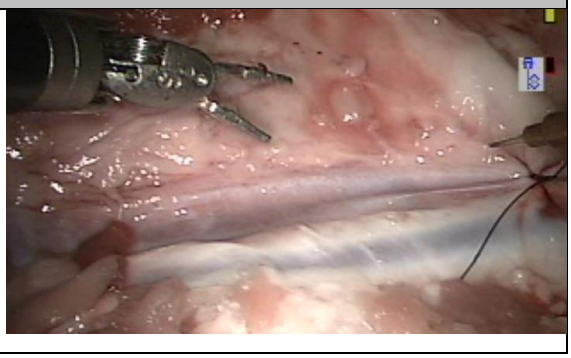
Both of these tasks were timed and recorded on the robot's camera using a Stryker 1288 HD Camera Control Unit, and coded for blinded assessment at a later date. The technique involved and the scoring systems for each task will be discussed in more detail in the following chapters. Following the initial assessment, participants were randomized to one of four different robotic training streams: wet lab, dry lab, virtual reality simulation, or a control group.

3.3.1 10cm Dissection of the Internal Thoracic Artery

The internal thoracic artery (ITA) has proven to be the best conduit for coronary artery bypass grafting, with patency rates greater than 90% at ten years. Because of its excellent patency and the proven survival benefits to patient of grafting the ITA to the left anterior descending (LAD) artery, the ITA is grafted in nearly every bypass surgery if it is possible, for both open and robotic surgeries[43]. During robotic coronary artery bypass grafting, three external ports are placed in the 3rd, 5th and 7th intercostals spaces in the left anterior axillary line. With the left lung deflated from single lung ventilation, the ITA pedicle can be easy seen running under the anterior chest wall (See Figure 3.2) containing both the ITA and its two corresponding veins. Dissection of the ITA involves scoring the interthoracic fascia on both the medial and lateral sides of the ITA pedicle from where the phrenic nerve crosses superiorly, down to the 6th intercostals space inferiorly which is where the ITA usually bifurcates into the superior epigastric and musculophrenic artery. A pair of robotic DeBakey forceps is used to grasp the interthoracic fascia and provide downward traction, while monopolar spatula cautery is used to dissect the pedicle off of the chest wall. The pedicle is then clipped at its most inferior aspect and cut by the bedside assistant using laparoscopic instruments through the robotic port placed in the 7th intercostals space. In order to simulate this complex skill a porcine chest wall model was chosen due to availability, cost and anatomic similarities. The other wet lab simulation exercise for this task that has been described within the literature is a cadaveric model. This model although a perfect replication of the actual anatomy, is prohibitively expensive for both our purposes with this study as well as with integration into a reproducible training program. The porcine model was composed of pigs between 80-100kgs, with chest walls and ITA pedicles nearly identical to that of an average human patient (See Figure 3.2). The porcine model differs from human anatomy by only a few small aspects. Typically the porcine models have much larger internal thoracic veins compared to that of humans and identification of the ITA is not always possible. However, this does not change the dissection technique when taken as a pedicle as score marks are made on the lateral and medial aspects and the entire pedicle is lifted off of the

chest wall. The largest difference between the porcine model and the normal human anatomy is the overly developed interthoracic muscles of the porcine chest wall. In order to identify the ITA pedicle, running along the chest wall, the porcine chests must be prepared by paring off these muscles to expose the pedicle underneath. In order to do this the interthoracic fascia must be removed as well, although this does not change the technique for ITA dissection in the lab, trainees do not have the ability to handle the fascia and provide consistent traction on the pedicle while it is being dissected. With the facia removed trainees are still able to handle the underlying muscle and fat tissue to provide the necessary traction for dissection, however the tough fascial tissue provides much stronger tissue for retraction. Figure 3.2 shows first the intraoperative image of an actual ITA dissection from the surgeon console, followed by the laboratory simulation of this task using a porcine chest wall. It can be seen that the porcine chest model gives a fairly high fidelity experience where the ITA pedicle artery and corresponding veins can easily be identified in both.

Figure 3.2: Intraoperative and Wet Lab Images of ITA Dissection

Intraoperative	Wet Lab
	

Both intraoperative and wet lab images for the ITA dissection are shown here. The left image depicts that actual intraoperative image from a human and the right image depicts the robotic camera view in the wet lab with a porcine model. Both images clearly demonstrate the relevant anatomy and depict the high fidelity of this type of simulation.

In order to assess baseline robotic skill the initial assessment involved dissecting a 10cm portion of the porcine ITA. For this, the porcine chest was prepared as previously described. The ITA pedicle was identified and two silk stitches were placed 10cm apart. The trainees were required to watch a five minute intraoperative video, highlighting the

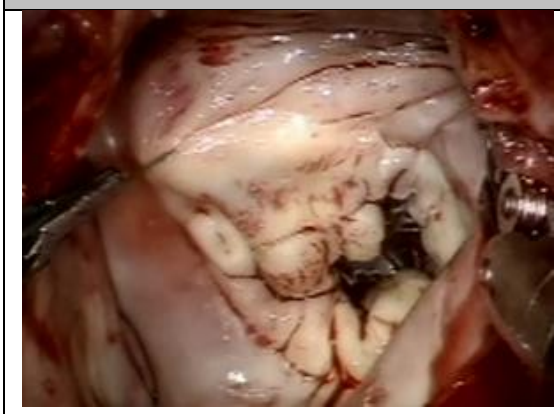
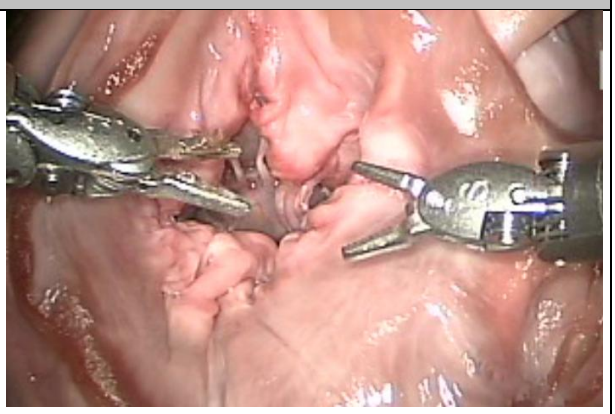
relevant anatomy as well as basic dissection technique. The da Vinci System was set up with a monopolar cautery instrument placed in the robotic right or left arm depending on the trainee's preference and a robotic DeBakey forceps placed in the other arm. The trainees were allowed to proceed with the dissection without any guidance. Timers were started as soon as the first scoring mark was made on the chest wall and all the assessments were recorded on video to be evaluated at a later time. The actual scoring of the exercise will be discussed in the following chapters.

3.3.2 Mitral Valve Annuloplasty

A downsizing mitral valve annuloplasty is one of the simplest and quickest repairs of mitral regurgitation and is often a necessary component of more complex repairs. During robotic assisted mitral valve repair a small right sided thoracotomy is made usually in the 3rd or 4th intercostals space at the mid-axillary line depending on pre-operative imaging. Ports are placed in the intercostals spaces above and below this incision and access is gained to the mediastinum through left sided single lung ventilation. Lateral access to the ascending aorta from this position allows for an antegrade cardioplegia cannula to be placed and a minimal access Chitwood clamp is used for cross-clamping the aorta. Venous and arterial cannulation is possible through the femoral vessels and access to the mitral valve is gained through development of Sondergaard's groove. After administration of cardioplegia, the 4th arm of the da Vinci robot is inserted through the thoracotomy with a custom scissoring mitral valve retractor through the left atrium to expose the mitral valve. 2-0 Ethibond sutures are then placed in the fibrous trigones found at the commisures of the valve. The fibrous trigones are composed of the fibrous skeleton of the heart and therefore will not be affected by mitral annular dilation and serve as a reference for appropriate mitral ring or band sizing. After sizing is complete sequential interrupted sutures are placed around the annulus with the help of the bedside assistant. As every suture is placed each end is brought through the annuloplasty band and handed back to the assistant who is in charge of keeping all these sutures organized.

After all the sutures are placed around the posterior leaflet clockwise from trigone to trigone, the sutures are tied by the bedside assistant in an extracorporeal fashion with a knot-pusher. The surgeon then assists with the cutting of each suture by the bedside assistant. Figure 3.3 shows first the intraoperative image of an actual mitral valve annuloplasty for the surgeon console, followed by the laboratory simulation of this task using a porcine heart. It can be seen that the porcine heart model gives a fairly high fidelity experience where the mitral valve and surrounding structures can easily be identified in both.

Figure 3.3: Intraoperative and Wet Lab Images of Mitral Valve Annuloplasty

Intraoperative	Wet Lab
	

Both intraoperative and wet lab images for the mitral valve are shown here. The left image depicts that actual intraoperative image from a human and the right image depicts the robotic camera view in the wet lab with a porcine model. Both images clearly demonstrate the relevant anatomy and depict the high fidelity of this type of simulation.

In order to assess baseline robotic skills associated with this task, the first three sutures were placed in the mitral annulus of a porcine model. For this a pig heart was prepared by removing the left atrium and great vessels to expose the mitral valve, in a view very similar to the actual intraoperative experience (See Figure 3.3). Although there is some variability with regards to leaflet thickness and size, very few differences exist between the porcine and human model, making this a very high fidelity model for simulation training. The trainees were required to watch a five minute intraoperative video,

highlighting the relevant anatomy as well as basic technique of a mitral valve annuloplasty. For the initial assessment the da Vinci robot was set up with the needle driver and DeBakey forceps in the right or left arm as to the trainee's preference. A timer was started as soon as the first 3-0 suture was handed to the trainee and they were required to place this through the anterolateral trigone and then hand it back to the assistant. A second suture was then given to the trainee, which was placed through the posteriormedial trigone and again handed back to the assistant. A third double ended suture was given to the trainee and it was placed in and out on the annulus next to the suture placed in the posteriormedial trigone in a horizontal mattress fashion. An annuloplasty band (St. Jude Medical) was then brought into the surgical field and the trainee was required to place the suture through the band and hand it back to the assistant. Lastly the other end of the last stitch was handed to the trainee and they were required to pass it though the band and hand it back to the assistant again. This signified the end of the exercise and the timer was stopped. The entire exercise was composed of the surgeon's responsibilities for placing the first three sutures of the annuloplasty. No guidance was provided to the trainees throughout the exercise and the entire exercise was recorded on video to be evaluated at a later time. The actual scoring of the exercise will be discussed in the following chapters.

3.3.3 Pre-test Questionnaire

In order to assess the amount of prior surgical training and expose to the da Vinci system the participants in the study had prior to starting the study, a questionnaire was completed prior to the initial assessment. This questionnaire focused on age, level of surgical training, surgical specialty, and previous experience on the da Vinci master console or any other robotic simulator. As per the inclusion criteria of the study, all participants had less than a total of 10 hours driving the robot's master controls or using a robotic simulation system. This allowed us to assess the validity of our randomization process, by distributing participants equally among all training streams so that more senior

surgical trainees, or trainees with more robotic experience at baseline were not allocated to the same stream, skewing the data. In addition to this we also asked participants, how many robotic cases they had been exposed to so far in their training (even if not involved in operating the robot), how important they feel robotic surgery will be in their specialty in the future and the likelihood that they will incorporate robotic surgery into their own practice. Lastly, we used a Likert scale (1-10) to assess how prepared each candidate felt to complete a variety of robotic tasks prior to the initial assessment. These tasks included; Camera Movement & Clutching, Device Movement, Transferring, Cutting, Suturing, Knot Tying, completing a mitral valve annuloplasty and dissecting out the ITA. The pre-test questionnaire can be found in Appendix D.

3.4 Treatment Arms

In order to assess and compare the most common forms of simulation based training a wet lab, dry lab and virtual reality curriculum were created. A fourth group was created to serve as a control, that would receive no addition training after the initial assessment and would be brought back to the lab to complete their final assessment after a duration of time similar to the duration of training among the other three groups. This was to control for two specific confounders in the data. The first was that it was expected that all participants would perform better on the second assessment, simply because they had gained knowledge and insight as to what was expected of them during the initial assessment that they could apply to the final assessment. And secondly, as each participant in the study continues to progress during their surgical training for the duration of the study they may be exposed to more robotic procedures or gain more experience in their regular surgical training that may improve their score on the final assessment.

3.4.1 Wet Lab

The wet lab consisted of the same tasks the participant completed in the initial assessment. Two expert robotic fellowship trained surgeons, whose practices regularly involve minimally invasive surgery, performed the robotic ITA harvest and mitral annuloplasty tasks five times each. Each expert surgeon had extensive experience with robotic simulation, and was familiar with FLS tasks, but had no significant time practicing or training on our wet lab model prior to this assessment. The level of proficiency for these two tasks was taken as the pooled mean time for completion of these tasks by our expert surgeons, with any value more than two standard deviations from the mean excluded to account of any outlying values. If however the study participant damaged any tissue through cauterization, avulsion, or inappropriate tissue handling, their attempt would not be considered successful even if the target time was reached and a score of "0" was applied. Each participant was able to attempt each task up to 80 times in order to reach the predetermined level of proficiency. To ensure the achievement of proficiency was not a random occurrence, each participant was required to pass each task two consecutive times. Both the ITA dissection and mitral valve annuloplasty tasks were timed and time-based scores were determined by the following equation shown in Figure 3.4, derived from the FLS scoring system.

Figure 3.4: Wet Lab Time-Based Scoring Equations

10cm ITA Dissection:

Score = 1320 - Time(s)

*Any damage to tissues through cautery, grasping or avulsion resulted in a score of 0

Mitral Valve Annuloplasty:

Score = 720 - Time(s)

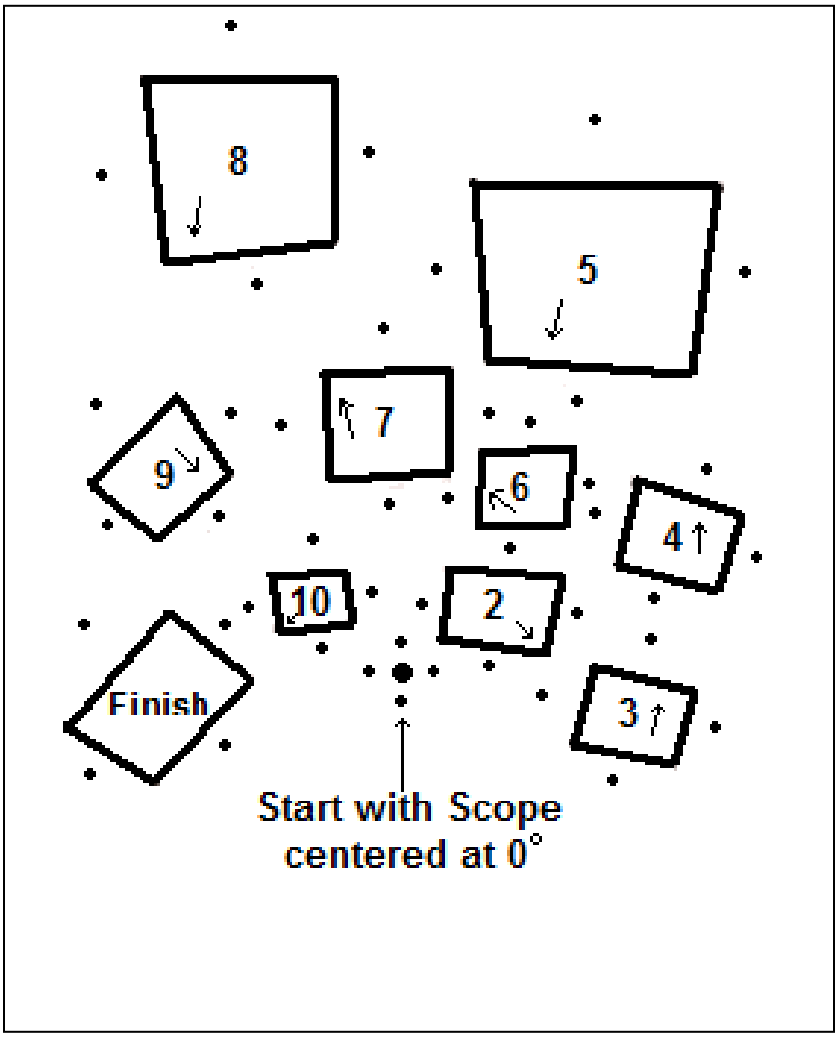
*Any damage to tissues, annuloplasty band or sutures resulted in a score of 0

Breakdown of the scoring system for each of the two tasks that made up the initial assessments and the wet labs.

3.4.2 Dry Lab

The dry lab training stream consisted of three tasks to address camera movement and clutching, transferring and endowrist manipulation, and needle control, needle driving, suturing and intracorporeal knot tying. The first task used a predrawn template with 10 numbered boxes of varying shapes and sizes, each of which was surrounded by a dot on all four sides. Each participant was required to clutch and move the camera through each box and focus the image on each such that all four corners of the box could be seen and all of the surrounding dots were excluded. The template is shown here in Figure 3.5.

Figure 3.5: Dry Lab Camera Movement and Clutching Template



Standardized stencil used in the first task of the dry lab where individuals had to move from box to box and focus the camera in to exclude the surrounding dots. Each box is numbered and contains an arrow pointing the trainee to the next box in the sequence.

The exercise was timed and a score was determined by the equation shown in Figure 3.6, derived from the FLS scoring system.

The second and third tasks of the dry lab used the Peg Transfer and Intracorporeal knot tying materials from Tasks 1 and 5 of the standard FLS skills program[8]. The methods for these tasks were exactly as what has been previously described by the FLS manual skills program with laparoscopic instruments replaced with the daVinci robot. Both exercises were timed and a score was determined by the following equations:

Figure 3.6: Dry Lab Time-Based Scoring Equations

Task #1: Camera Movement and Clutching
Score = 480 - Time(s) – 10(# of Errors)
Errors: 1 point for each red dot visualized
1 point for each corner not in view

Task #2: Peg Transfer
Score = 480 - Time(s) – 10(# of Errors)
Errors: 1 point for peg dropped

Task #3: Intracorporeal Knot Tying
Score = 480 - Time(s) – 10(# of Errors)
Errors: 1 point per mm needle passed outside of each dot
1 point per mm between model edges (air knot)
Score of 0 if: Suture is broken
-Incorrect knot
-Frayed Suture
-Avulsion of model

Breakdown of the scoring system for each of the three tasks that made up the dry labs.

For each of these tasks the predefined errors listed here area adapted directly from the FLS curriculum and scoring system.

The level of proficiency for these tasks was taken as the pooled mean time for completion by our expert surgeons five attempts, with any value more than two standard deviations from the mean excluded. Each participant was able to attempt each task up to 80 times in order to reach the predetermined level of proficiency. To ensure that the achievement of proficiency was not a random occurrence each participant was required to pass each task two consecutive times.

3.4.3 Virtual Reality

We established a VR training protocol specific to robotic cardiac surgery using the da Vinci Skills Simulator (Intuitive Surgical, USA), a commercially available robotic surgical simulation platform. At the time of this study over 50 exercises were available on this simulator with the Mimic Technologies software. We surveyed our expert robotic cardiac surgeons to assess which of these exercises they felt would be important to develop the skills necessary for robotic cardiac surgery. From this we were able to generate a list of useful virtual reality simulation exercises and after testing each decided on the exercises we felt best tested these skills. From this we created a 9 exercise curriculum, specific to the skills required for robotic cardiac surgery. We named our virtual reality simulation curriculum the “Western Protocol” which consisted of the tasks shown here in Figure 3.7 along with the primary skill tested in each.

Table 3.7: Western Protocol for Virtual Reality Training

Exercise Name – Level	Primary Skill Tested
Camera Targeting -2	Camera Control
Energy Switching – 2	Energy Control
Pegboard – 2	Endowrist Manipulation
Matchboard – 2	Endowrist Manipulation
Ring Walk – 3	4th Arm Control
Matchboard – 3	4th Arm Control
Energy dissection – 2	Energy Control
Suture Sponge – 3	Needle Driving - Advanced
Vertical Defect Suturing	Needle Driving - Advanced

List of all the 9 exercises that were included in our VR training curriculum can be found on the left column with the primary skill of each exercise that was tested listed on the right column.

Levels of proficiency for each task were set by allowing our expert surgeons to complete each exercise as many times as they liked until they felt they had performed to a level indicative of their abilities. The MScore software (Mimic Technologies, Inc.) was used to calculate a variety of parameters for each skill to give an overall score. The software uses an overall score of 80% with no critical errors as a cutoff for a successful attempt at each exercise. However, because our expert surgeons were consistently achieving a higher average score than this, our level of proficiency for each task was set at 90% or greater with no critical errors. Each participant was allowed to repeat each exercise up to 80 times in order to reach an overall score >90%. In order ensure successful completion of the exercise was not a random occurrence, each participant was required to score >90% on each exercise without any critical errors, two consecutive times.

3.4.4 Control

A control group was utilized to assess for an improvement in skill from the initial assessment due to reasons other than the training that the other groups received. Individuals randomized to this group following the first assessment received no

additional training on the robot or any robotic simulation. These individuals were brought back and retested on the original robotic ITA harvest and mitral annuloplasty tasks at a later date, similar to the duration between the initial assessment and retesting of the other groups.

3.5 Final Assessment

Upon achieving the predetermined proficiency score for each task in their respective training stream, all individuals were brought back and retested on the original robotic ITA harvest and mitral annuloplasty tasks. All attempts were timed and recorded. Times for each group were compared to their original assessments and to each other, to determine if any significant difference existed between performances. The de-identified recordings of the initial and final assessments were objectively assessed for intraoperative surgical skills using the GEARS assessment tool in a blinded fashion by a single investigator to control for inter-observer variability.

3.5.1 10cm Dissection of the Internal Thoracic Artery

For the final assessment, participants repeated the dissection of a 10cm portion of the porcine ITA as they had done in the initial assessment. The porcine chest wall was prepared as previously described and the ITA pedicle was identified with two silk stitches placed 10cm apart. For this assessment the trainees did not watch the orientation video as before but were reminded of the task requirements. The da Vinci System was set up with a monopolar cautery instrument placed in the robotic right or left arm depending on the trainees preference and a robotic DeBakey forceps placed in the other arm. Timers were

started as soon as the first scoring mark was made on the chest wall and all the assessments were recorded on video to be evaluated at a later time.

3.5.2 Mitral Valve Annuloplasty

The second part of the final assessment repeated the task of the initial assessment where the first three sutures of a mitral annuloplasty were placed in a porcine model. As previously described, a pig heart was prepared by removing the left atrium and great vessels to expose the mitral valve. The trainees were not required to re-watch the orientation video, but were reminded of the task's steps and requirements. Again, the da Vinci robot was set up with the needle driver and DeBakey forceps in the right or left arm as to the trainee's preference. A timer was started as soon as the first 3-0 suture was handed to the trainee and they were required to place this through the anterolateral trigone and then hand it back to the assistant. A second suture was then placed through the posteriormedial trigone and a third suture was placed on the annulus next to the suture placed in the posteriormedial trigone. The trainee then placed both ends of this suture through an annuloplasty band (St. Jude Medical), in the exact same manner as the initial assessment. Timers were started as soon as the trainee took control of the first stitch and all the assessments were recorded on video to be evaluated at a later time.

3.5.3 Post-test Questionnaire

Upon completing the specific training stream and final assessment all participants were asked to complete a second questionnaire. This questionnaire focused on their experience with the training program and how their perception of robotic surgery may have changed. Again we asked participants to indicate how much experience they had with the da Vinci robot outside of the training program to assess if any trainees were participating in robotic surgeries as part of their surgical training while the study was being conducted.

Next, we enquired as to the trainee's satisfaction with the experience by using a Likert scale (1-10) focusing on Comfort, Easy of set up, Realism, and Reproducibility. Next we repeated the same section on trainee preparedness, as what was in the pre-test questionnaire, including; Camera Movement & Clutching, Device Movement, Transferring, Cutting, Suturing, Knot Tying, completing a mitral valve annuloplasty and dissecting out the ITA, in order to assess for changes in the trainee's perception of these tasks due to the training they had received. Lastly, we asked participants of the study to rank their overall experience that they had with the training program, provide any specific benefits or drawbacks that they found with the training stream that they were assigned to, and lastly a section was provided so that they were able to provide any general comments and feedback about the whole experience. The post-test questionnaire can be found in Appendix E.

3.6 Data Collection

Data collection began once participants had been formally enrolled into the study and had undergone the initial assessment. At this time, the data was recorded from the pre-test questionnaire and the scores for both the ITA dissection and the mitral valve annuloplasty tasks were recorded and kept in a password-protected Microsoft Office Excel spreadsheet (Microsoft Corporation, Redmond, WA) with de-identified participant data for analysis. All videos from the initial assessment were recorded on a password protected USB key and kept with the questionnaire forms in a locked file cabinet, in an office at University Hospital, only assessable by with PIN entry.

Data were recorded during each training session and included scores on each attempt for every training exercise as well as the total time spent on each exercise. This data was recorded in the same password protected USB key.

After completing the final assessment, data including final ITA dissection and mitral valve annuloplasty scores and video recordings of these attempts, were recorded on the

same password protected USB key and kept with the post-questionnaire forms in the same locked file cabinet at University Hospital. In this fashion, confidentiality of patient information was ensured throughout the duration of the study as outlined in the HSREB protocol.

3.6.1 Demographics

The demographic information for each participant was recorded in the pre-test questionnaire. This was done prior to the initial assessment and analysis of this information after randomization was done to verify that there was an appropriate randomization process and all training and control groups are similar. All demographic variables pertaining to this study can be found in Table 3.8.

Table 3.8: Demographic Variables

Participant-Specific Demographic Data
Age
Gender
Year of Training
Hours of Robotic Experience

List of the baseline demographics that were recorded for every study participant.

3.6.2 Primary Outcome Measures

The benefits of simulation based training and exposure to the da Vinci system does not replace the formal training of a surgical residency program, but serves to allow trainees an opportunity to become familiar with the operation of the da Vinci system. To assess robotic surgical acumen a variety of characteristics can be tested. The most easily assessed is time, which gives an indication of the efficiency with which a trainee is able to complete a task. However, a more valuable scoring tool such as the GEARS assessment provides an objective assessment of global robotic skill.

3.6.2.1 Time-Based Scores

The time-based scores for dissection of 10cm of the porcine ITA pedicle and the first three sutures of mitral valve annuloplasty were scored in a similar fashion to the FLS scoring system. Here, the time in seconds for successful completion of the task was subtracted from a specific number to give a final score. This specific number was the total time in seconds that the participant had to complete the test before a score of "0" was given. For the ITA dissection, the participant was given 22 minutes (1320 seconds) to complete the task and for the mitral valve annuloplasty they were given a maximum of 12 minutes (720 seconds) to complete the task. Beyond these times, the trainee's performance would have to be so inefficient that a score of zero was appropriate. Lastly, if any gross damage was inflicted by the cautery, needle driving or tissue handling with either of these exercises, a score of zero was given to the participant for that attempt. All times and scores were recorded by a single investigator and recorded on the participants pre- and post-test questionnaires which were kept in a locked file cabinet, in an office at University Hospital, only accessible by with PIN entry.

3.6.2.2 GEARS Assessment Scores

All initial and final assessment for every participant and the 5 attempts of both the annuloplasty and ITA dissection by our two expert surgeons were recorded from the da Vinci system on a password protected USB key. Every video was given a random 6 digit code that was assigned by the recording system at the time of the test and gave no indication to the type of assessment (initial or final) or the individual performing the task (expert or trainee). All videos were then reviewed after all 40 trainees had completed all required tasks by a single investigator, in order to control for inter-observer variability, and scored according to the GEARS scoring tool. These values were all recorded and then after analysis was complete, these scores were decoded from our concealed master list to reveal which attempt belonged to which training stream.

3.6.3 Secondary Outcome Measures

Secondary outcome measures are usually hypothesis generating data that can hopefully give some insight to explain the primary conclusion of a study or provide some supporting information. However, secondary outcomes differ from primary in that the study is not powered appropriately to detect a significant difference in between them, and that is why they can only identify trends but are unreliable to use as a foundation for making any significant conclusions. The secondary outcome measures that were evaluated during this study were recorded through the pre- and post-test questionnaires. These included trainee satisfaction with the training experience as well as their perception of how prepared they felt they were before and after training with a variety of robotic tasks. Each trainee was also afforded the opportunity to give feedback on the training process which has the potential to identify any specific aspect of the process that the trainee found beneficial or detrimental that we had not initially included in our surveys. In addition to this we tracked the total time it took an individual to complete all of the required tasks of their specific training stream to evaluate the efficiency that robotic skill

can be obtained between different training modalities. Lastly, we recorded the total amount of time between the initial and final assessments to make sure one group was not exposed to a significantly longer period of clinical training while completing the study protocol.

3.7 Statistical Analysis

Statistical analysis is one of the most important aspects of any study as it enables the investigators to make reasonable and well-founded conclusions based on the data collected. The current study is a prospective RCT with the goal of comparing multiple indicators of robotic surgical skill among four independent populations and to compare their performances to those of expert robotic surgeons completing the same tasks. The sample population was meant to be representative of the population of surgical trainees who have very limited exposure to controlling the robot.

All of the scoring metrics recorded in this study were independently taken and mutually exclusive from each other. Data analysis was based on the original random allocation of each participant into each training stream they were assigned. Although there was no crossover among the groups during the study, one individual from the virtual reality stream did not complete the final assessments and another from the dry lab group did not finish the final ITA dissection. Both of these individuals were included in the original assessments and contributed to overall averages of their respective groups.

3.7.1 Sample Size Calculation

Determining the appropriate sample size prior to commencing this study was necessary in order to have valid results and is of particular importance given the prospective randomized controlled design of the study. The statistical power of the study refers to the probability a test will correctly reject the null hypothesis. This is refered to as a Type II error, where a null hypothesis is accepted when there is in fact a difference between the two groups. Statistical power is dependent upon three factors; sample size, standard error, and level of significance.

For the current trial, no previous or similar study exists within the literature and in addition to this we employed some novel technique with our training protocols. Because of this we were unable to predict the standard error and significant changes of our primary outcomes of our trainees compared to the experts in our assessments, prior to participant enrollment. In order to account for this, we had one of our expert robotic surgeons and the first ten trainees complete the original assessments in order to use this information to calculate the appropriate sample size. The calculation used to determine appropriate sample size is shown in Figure 3.9.

After obtaining this information as a surrogate “pilot-study”, we were able to use this information to estimate the standard deviation (SD), population means (μ) and the level of significance needed to complete our sample size calculations. In order to properly power this study for both our time-based scoring and GEARS assessment primary outcomes, we completed the calculation found in Figure 3.9 for each of these outcomes to determine which would require the largest sample size to be able to detect a meaningful difference between the training groups and the experts. After completing the necessary calculations we determined that a sample size of 5 people in each of the training streams would be necessary to detect a significant difference between the trainees’ and the experts’ time-based score for dissection of 10cm of the ITA. Similarly, a sample size of 7 and 8 subjects in each training stream would be necessary to detect a significant difference for the mitral valve annuloplasty and the GEARS score, respectively. Based on these calculations, a minimum enrollment of 8 subject to each stream would power the

study appropriately to detect a significant difference for all three primary outcomes, however because a second expert surgeon was required to set levels of proficiency we opted to expand enrollment to 10 participants to account for this increased variability. It was felt that this number was also not too large it would allow for the unavoidable logistical and financial constraints surrounding the study design.

A level of significance set at an α value of 0.05, is the standard for reporting RCTs. This signifies that there is a 5% chance that the outcome is due to chance alone. Statistical power for the study (1-β) was set at 0.90, which indicates that there is a 90% chance of identifying a significant difference in the primary outcomes between the two independent samples, should one exist. This is superior to the standard for reporting an RCT, where power is usually set to 0.80, however in this situation, increasing the sample size of each group from 8 to 10 dictated an increase in the power of the study based on our initial sampling data.

Figure 3.9: Sample Size Calculations

$(\mu_1-\mu_2)^2 = \Delta^2 = f(\alpha,P)\ \sigma^2\ (1/n1 + 1/n2)$

$n1=n2$

$\Delta^2 = f(\alpha,P)\ \sigma^2\ (2/n1)$

$n1=2(\sigma^2)\ f(\alpha,P)/\Delta^2$

$n1=[2(164^2)(1.96+1.28)^2]/(573-279)^2$

$n1=(53792)(10.49)/294^2 = 6.53..$

$n1=7=n2$

$n2=7$

Where, σ = SD, μ = mean, $f(\alpha,P) = (1.96 + 1.28)^2$ *for* α *of 0.05 and* β *of 0.90,* $\Delta = (\mu_1-\mu_2)$ = 573-279 (mean time-based annuloplasty scores from our experts and trainees)

*Equation for determining sample size for significance tests taken from Bland, M. an introduction to medical statistics third edition. Oxford University Press. 2000; Chapter 18.3:336-339.

3.7.2 Outcome Comparison

All measured values within the study were continuous variables. Because we had small sample sizes (<50) with continuous variables, we completed a Wilk-Shapiro analysis to confirm that the data was normally distributed. See Figure 3.10 for results. This analysis gave a p-value > 0.05 for all outcomes measures and therefore showed that our values were not normally distributed. In order, to compare the efficacy among the 3 training streams, all three were compared to the control group using a Kruskal-Wallis ANOVA, which does not assume normality of the data but gives a more stringent level of significance. This was done as; more than two groups were compared, all samples were independent of one another, the data was not normally distributed and all values were continuous. We confirmed that the variance between the data collected for each of the four groups was similar as seen in Figure 3.11, which shows there is no significant difference between the variability of each group based on a Lavene Statistic significance >0.05. Each group was then compared to the scores of the experts individually, using a Mann U Whitney test, which again does not assume normality of the data but is able to compare the means between two groups (training group and experts) for a measured variable.

Table 3.10: Wilk-Shapiro Analysis of Normal Distribution of Data

Characteristics	Wet Lab (n=10)	Dry Lab (n=10)	Virtual Reality (n=10)	Control (n=10)	Experts (n=10)
ITA Score	0.678	0.360	**0.023**	0.469	0.897
ITA GEARS	0.651	**0.043**	0.136	0.104	0.362
Annuloplasty Score	**0.006**	0.289	**0.023**	**0.012**	**0.048**
Annuloplasty GEARS	0.473	**<0.001**	0.093	**<0.001**	0.451

p Values for our Wilk-Shapiro analysis of each for each set of measured values within the study. All groups have at least one p Value < 0.05 indicating that the measured values do not have a normal distribution.

Table 3.11: Test of Homogeneity of Variances

Test of Homogeneity of Variances

	Levene Statistic	df1	df2	Sig.
Ann1GEARS	1.235	4	45	.310
ITA1GEARS	1.984	4	45	.113
Ann1	3.867	4	45	.099
ITA1	2.144	4	45	.091

Results for the Lavene test are reported here, non-significant p-values indicate that there is similar variance in the measured values among the different treatment groups.

4 Results

4.1 Treatment Arm Allocation

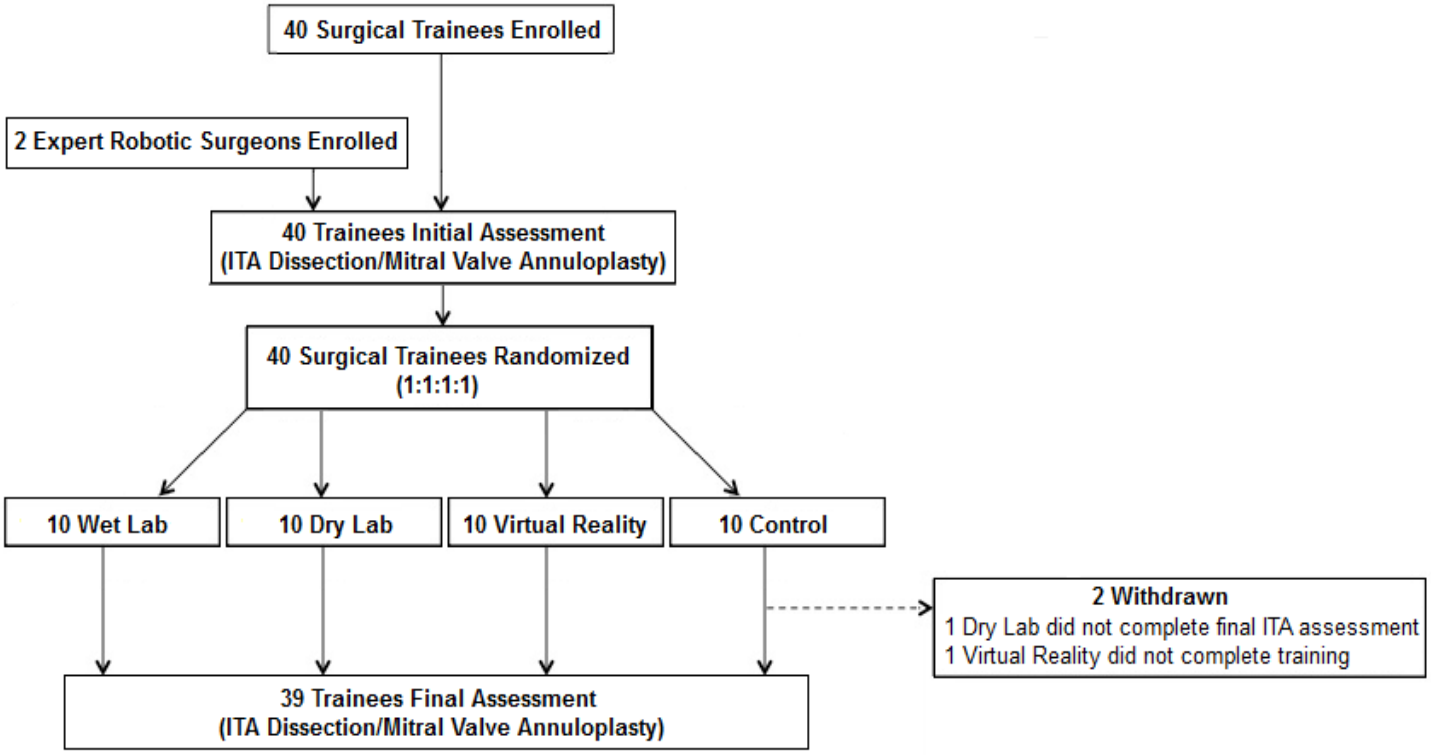
Figure 4.1 displays the flowchart of the study completion and depicts the results of randomization. After calculation of the appropriate sample sizes were completed, as previously described, 40 surgical trainees who met the inclusion criteria were enrolled. After each completed the initial assessment they were randomized in a 1:1:1:1 ratio to one of the four groups. Very few candidates who volunteered to participate in the study were deemed ineligible based on the inclusion criteria. Only two were excluded from consideration for the study as one had significant experience with the robot (>10hrs) and

the other felt they could not make the commitment to complete the training given their clinical responsibilities.

Each study participant was allowed as much time as they needed to reach the level of proficiency for each task of their training stream, as defined by the average scores of our expert surgeons on the same task.

The vast majority of participants completed the initial assessment, training stream requirements and final assessments without any complications. One individual randomized to the dry lab group completed the training program and half of the final assessment. This person was able to complete the final mitral valve annuloplasty assessment, but because we had run out of porcine chest models that day in the lab they were not able to complete the final ITA dissection assessment. Unfortunately, this individual was a clinical fellow and their work term at our institution ended shortly after this and we were unable to reschedule another time in the lab to have them complete the final ITA assessment. The only other individual in the study that did not complete the entire training program and assessments was a junior resident randomized to the virtual reality group. They completed 1-2 training sessions on the robot virtual reality simulator, but unfortunately left the province for several months on a clinical elective and the study had been completed by the time they returned. Despite these problems, the overall completion rate of the entire study was 96.25%, which is excellent for an RCT. There was no crossover among the groups within the study, as per the initial prospective parallel design. Very few participants had any exposure to the da Vinci robot in a clinical setting over the duration of their training during this study. Only 3 clinical fellows from the department of cardiac surgery or obstetrics and gynecology actually got any time driving the robot in the operating room and this amounted to less than 2 hours for each individual.

Figure 4.1: Treatment Allocation Flow Chart



4.2 Demographics

Table 4.2 outlines the group comparisons for the listed demographic variables collected as part of the study protocol. At baseline, it can be seen here that the participants in all four training streams are similar for all variables.

Table 4.2: Demographic Characteristics of Study Participants

Characteristic	Wet Lab (n=10)	Dry Lab (n=10)	Virtual Reality (n=10)	Control (n=10)	p value
Mean Age, Years ± SD	31.3 ± 4.0	32.3 ± 5.8	32.7 ± 6.1	29.9 ± 2.4	0.579
Gender, n (%)					
Male	8 (80.0)	6 (60.0)	8 (80.0)	6 (60.0)	0.619
Female	2 (20.0)	4 (40.0)	2 (20.0)	4 (40.0)	
Year of Training, Year ± SD	5 ± 2.5	5 ± 2.9	5 ± 3.0	4 ± 2.4	0.801
Previous Robotic Experience, Hours ± SD	1.7 ± 3.9	0.3 ± 0.7	2.6 ± 3.2	0.8 ± 2.5	0.305

Table shows the baseline demographics of all study participants. Within this group 13 individuals were from the department of Cardiac Surgery, 10 from General Surgery, 9 from Obstetrics and Gynaecology, 5 from Urology, 2 from Thoracic Surgery and 1 from Orthopedic Surgery.

As can be seen from Table 4.2, there is no statistically significant difference between any of the training streams in regards to age, gender, year of training or previous robotic experience. This is displayed with all p values being >0.05, based on the Kruskal-Wallis ANOVA analysis.

Table 4.3 outlines the comparison among all training streams with regards to the primary outcomes measured at the initial assessment.

Table 4.3: Initial Assessment Scores

	Wet Lab (n=10)	Dry Lab (n=10)	Virtual Reality (n=10)	Control (n=10)	p value
10cm ITA Dissection, Score ± SD	488.8 ± 228.6	388.9 ± 295.1	457.6 ± 259.9	451.0 ± 264.1	0.859
ITA GEARS, Score ± SD	10.3 ± 2.4	9.4 ± 3.4	12.5 ± 5.1	9.2 ± 3.0	0.942
Annuloplasty, Score ± SD	381.1 ± 107.8	304.9 ± 197.0	409.5 ± 106.1	402.3 ± 147.2	0.361
Annuloplasty GEARS, Score ± SD	8.2 ± 1.8	7.8 ± 1.8	7.8 ± 1.9	7.5 ± 2.4	0.178

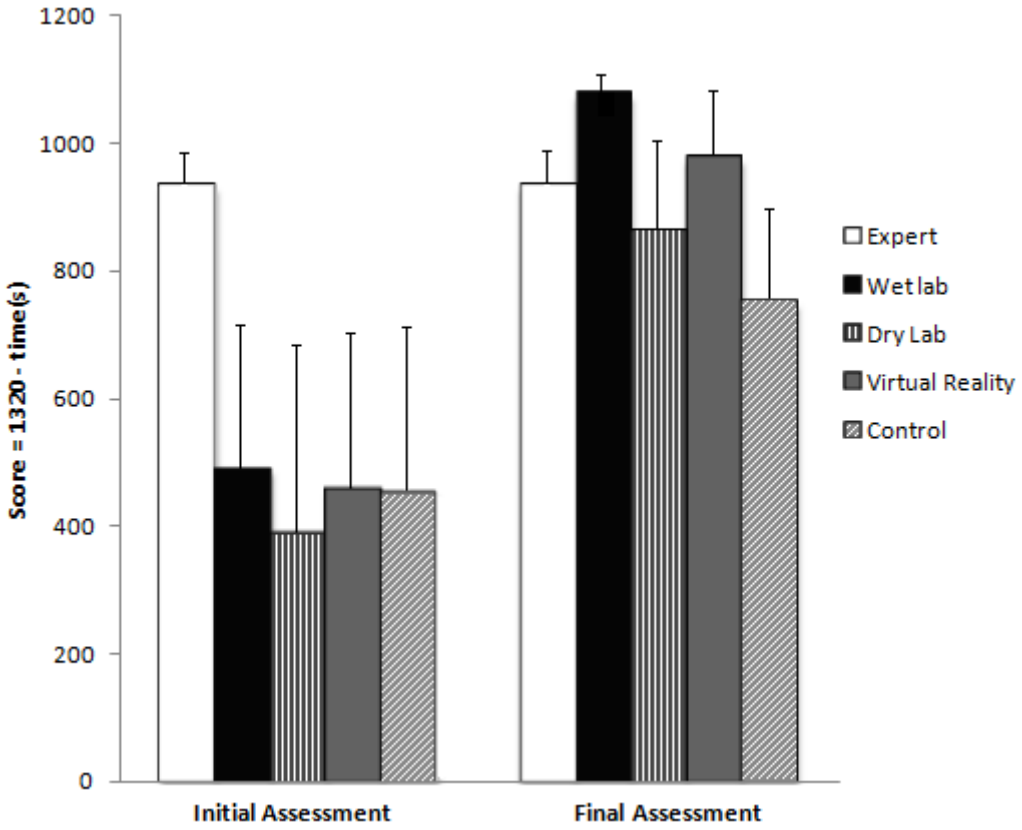
Again, from Table 4.3, there is no statistically significant difference between any of the training streams in regards to their performance for the ITA dissection or mitral valve annuloplasty in either the time-based scoring or GEARS assessment. This is displayed with all p values being >0.05, based on the Kruskal-Wallis ANOVA analysis.

4.3 Primary Outcome Measures

4.3.1 10cm Dissection of the Internal Thoracic Artery

Figure 4.4 shows the time-based scores for the 10cm ITA dissection for each training stream at both the initial assessment as well as the final assessment. The expert surgeons scored significantly higher than the trainees in the original assessments (1035.8 ± 54.7 vs. 488.8 ± 228.6, 388.9 ± 295.1, 457.6 ± 259.9, and 451.0 ± 264.1). Kruskal-Wallis ANOVA analysis of the initial assessment shows that there was no significant difference between the 4 training streams ($p = 0.859$). However the significant improvement in trainee performance is demonstrated by their scores, compared to the experts for the three training streams at the final assessment (1076.1±25.8, 859.0±143.2, and 957.3 ± 98.9). Despite a moderate improvement, the trainees in the control group achieved scores that were significantly lower than that of the experts (1035.8 ± 54.7 vs. 749.1 ± 171.9, $p = 0.008$). The wet lab training group actually achieved scores that were significantly higher than the expert group (1035.8 ± 54.7 vs. 1076.1±25.8, $p = 0.003$). While the dry lab and virtual reality group both improved their scores from the initial assessment, there was no significant difference in their scores at the final assessment when compared to the experts by Mann Whitney U analysis ($p = 0.191$ and 0.624), indicating that they have reached the same level of proficiency with this task.

Figure 4.4: Time-Based Scores for 10cm ITA Dissection



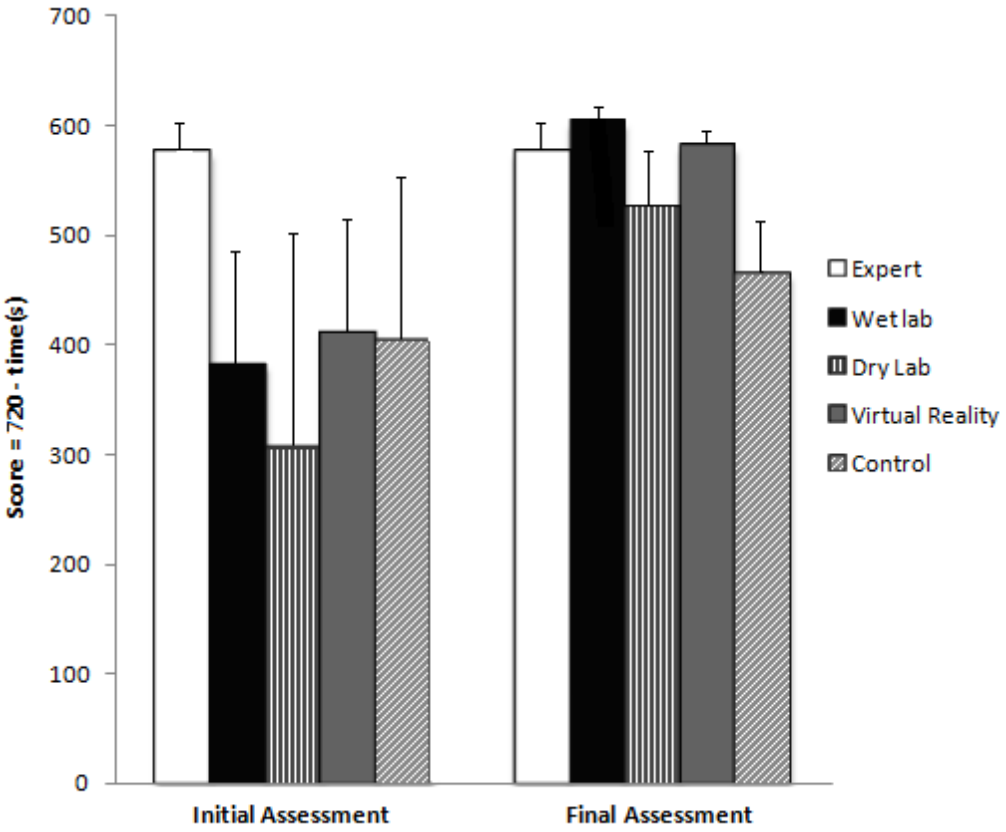
	Wet Lab (n=10)	Dry Lab (n=10)	Virtual Reality (n=10)	Control (n=10)
Initial 10cm ITA Dissection, Score ± SD, p value	488.8 ± 228.6	388.9 ± 295.1	457.6 ± 259.9	451.0 ± 264.1
Final 10cm ITA Dissection, Score ± SD, p value	1076.1±25.8 **0.003**	859.0±143.2 0.191	957.3 ± 98.9 0.624	749.1 ± 171.9 **0.008**

4.3.2 Mitral Valve Annuloplasty

Figure 4.5 shows the time-based scores for the mitral valve annuloplasty for each training stream at both the initial assessment as well as the final assessment. The expert surgeons

scored significantly higher than the trainees in the original assessments (573.0 ± 24.0 vs. 381.1 ± 107.8, 304.9 ± 197.0, 409.5 ± 106.1, and 402.3 ± 147.2). Kruskal-Wallis ANOVA analysis of the initial assessment shows that there was no significant difference between the 4 training streams ($p = 0.361$). However a significant improvement in trainee performance is demonstrated by their scores, compared to the experts for the three training streams at the final assessment (602.2 ± 11.4, 523.6 ± 48.9, and 580.4 ± 14.4). The trainees in the control group again had a moderate improvement in their scores for the final assessment but were still significantly lower than that of the experts (573.0 ± 24.0 vs. 463.8 ± 86.4, $p = 0.001$). The wet lab training group again achieved scores that were significantly higher than the expert group (573.0 ± 24.0 vs. 602.2 ± 11.4, $p = 0.031$). While virtual reality group improved their scores from the initial assessment and no significant difference was demonstrated in their scores at the final assessment when compared to the experts by Mann U Whitney analysis ($p = 0.967$), indicating that they have reached the same level of proficiency with this task. The dry lab showed a modest improvement, but a statistical difference between their final scores and that of the experts was found to be significant ($p = 0.013$) indicating that like the control group, they did not reach the level of proficiency set by our experts.

Figure 4.5: Time-Based Scores for Mitral Valve Annuloplasty



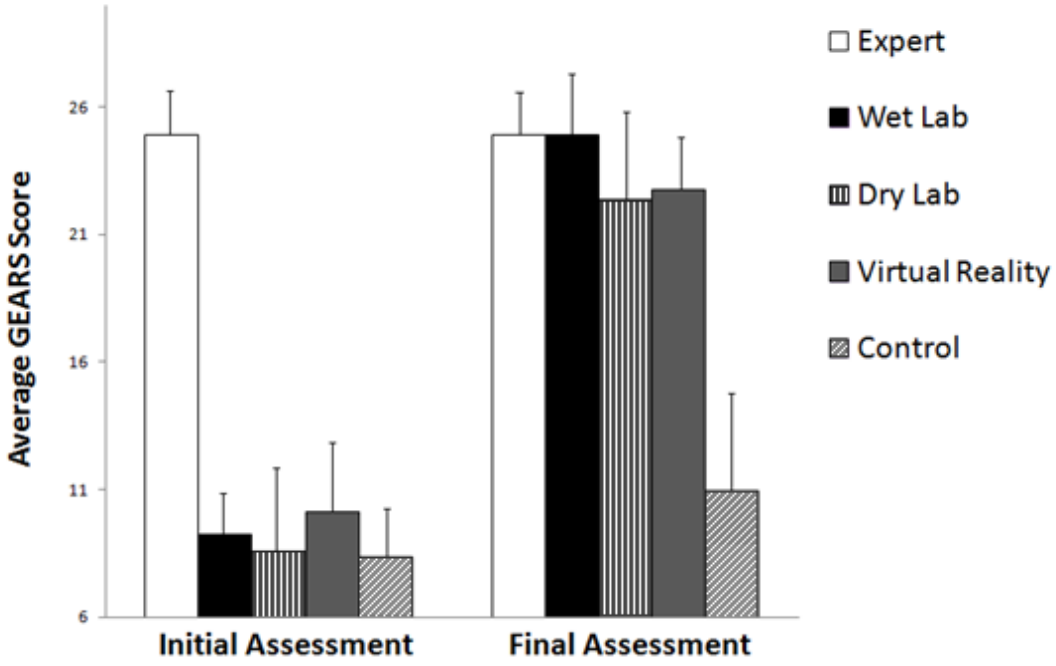
	Wet Lab (n=10)	Dry Lab (n=10)	Virtual Reality (n=10)	Control (n=10)
Initial Mitral Annuloplasty, Score ± SD, p value	381.1 ± 107.8	304.9 ± 197.0	409.5 ± 106.1	402.3 ± 147.2
Final Mitral Annuloplasty, Score ± SD, p value	602.2±11.4 **0.031**	523.6 ± 48.9 **0.013**	580.4 ± 14.4 0.967	463.8 ± 86.4 **0.001**

4.3.3 GEARS Assessment

Figure 4.6 shows the combined average GEARS scores for the 10cm ITA dissection and mitral valve annuloplasty tasks, for each training stream at both the initial assessment as

well as the final assessment. The expert surgeons scored significantly higher than the trainees in the original assessments (24.9 ± 1.7 vs. 9.3 ± 1.7, 8.6 ± 3.3, 10.2 ± 3.0, and 8.4 ± 2.0). Kruskal-Wallis ANOVA analysis of the initial assessment shows that there was no significant difference between the four training streams ($p = 0.417$). Significant improvement is seen in the wet lab, dry lab and virtual reality trainee performances as no significant difference was detected in their scores compared to that of the experts during the final assessment by Mann U Whitney analysis (24.9 ± 2.6, $p = 0.704$, 22.5 ± 3.7, $p = 0.160$, and 22.8 ± 2.7, $p = 0.110$). The trainees in the control group did not show a significant difference in their performance despite a modest increase in scores, and were significantly lower than the expert scores (24.9 ± 1.7 vs. 11.0 ± 4.5, $p = <0.001$).

Figure 4.6: Average GEARS Scores



	Wet Lab (n=10)	Dry Lab (n=10)	Virtual Reality (n=10)	Control (n=10)
Initial GEARS, Score ± SD, p value	9.2 ± 1.7 **<0.001**	8.6 ± 3.3 **<0.001**	10.2 ± 3.0 **<0.001**	8.4 ± 2.0 **<0.001**
Final GEARS, Score ± SD, p value	24.9± 2.6 0.704	22.4 ± 3.7 0.160	22.8 ± 3.7 0.103	11.0 ± 4.5 **<0.001**

4.4 Secondary Outcome Measures

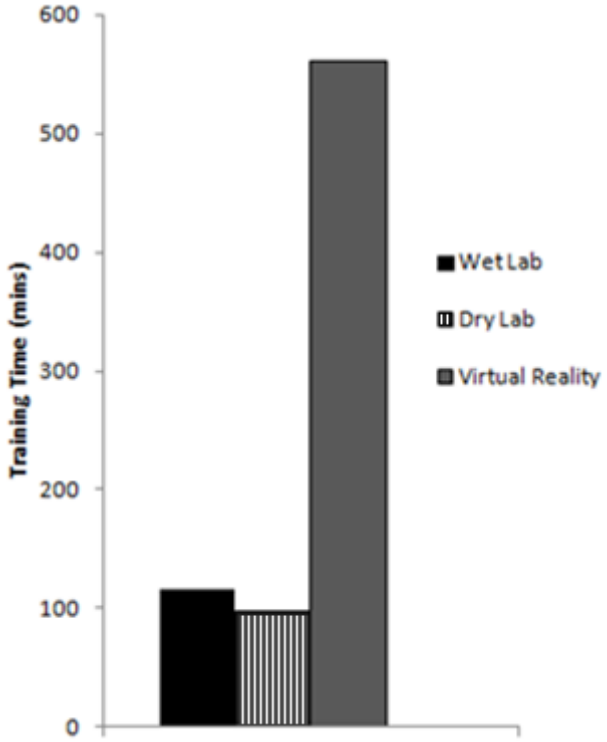
The secondary outcome measures that were recorded in this work were not entered into our original calculations for sample size to power the study appropriately. None the less, this data and its analysis allow for hypothesis generation and help to answer questions regarding conclusions based on our primary outcomes. As trainees progressed through each of the three training streams we kept track of the total amount of time that was spent on each exercise in order to reach the levels of proficiency set by our expert surgeons. We also recorded the dates of the initial and final assessments to track the total amount of time that trainees were involved in the study. After completion of the study we compared the relative costs of implementing each of the three training programs to reproduce these exercises and train a surgical trainee to the same level of proficiency.

4.4.1 Training Times

Figure 4.7 shows the average total training time spent in each of the three training streams (wet lab, dry lab, and virtual reality lab) to meet the levels of proficiency set by our expert surgeons. The average time is similar for the completion of the two tasks of the wet lab and three tasks of the dry lab, but we found the virtual reality lab to be

considerably longer (116.5 ± 32.1min vs. 98.0 ± 52.2min vs. 560.5 ± 167.4min, respectively). Kruskal-Wallis ANOVA analysis of these times shows that this difference is statistically significant (p <0.001).

Figure 4.7: Average Training Time

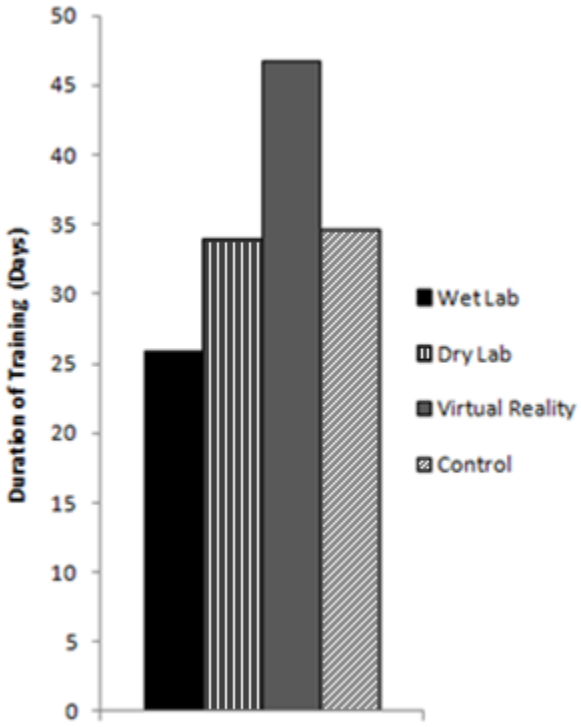


	Wet Lab (n=10)	Dry Lab (n=10)	Virtual Reality (n=10)	Control (n=10)	p value
Total Training Time, mins ± SD	116.5 ± 32.1	98.0 ± 52.2	560.5 ± 167.4	-	**<0.001**

4.4.2 Duration of Training

Figure 4.8 shows the average total duration of time between the initial assessment and the final assessment for each of the four groups. The average time was longest in the virtual reality group and shortest for the wet lab group (46.7 ± 21.3days and 25.9 ± 13.5days, respectively). Both the dry lab and control group had average times that were similar and between these two (34.0 ± 32.9 and 34.6 ± 24.1 days). Despite these differences Kruskal-Wallis ANOVA analysis of these times shows that there is no statistically significant difference between these groups (p = 0.116).

Figure 4.8: Duration of Training

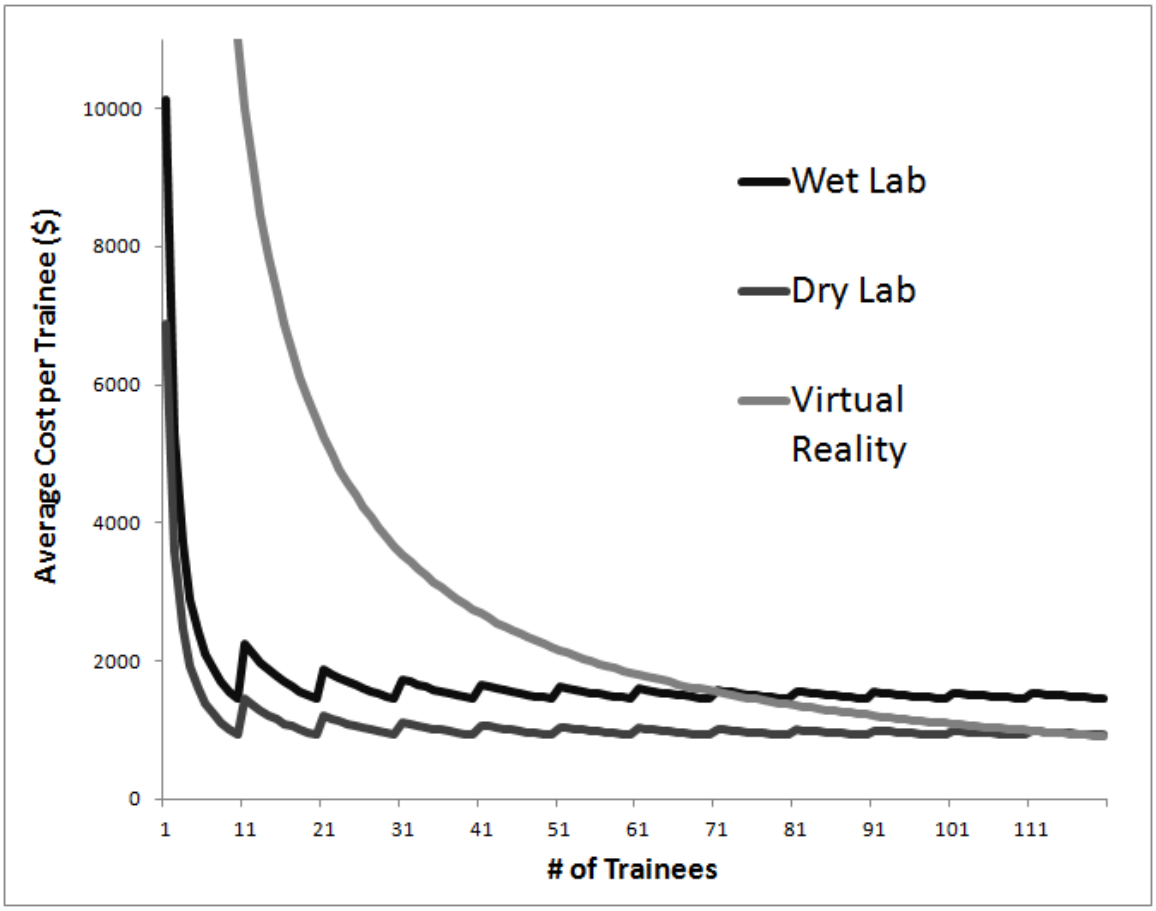


	Wet Lab (n=10)	Dry Lab (n=10)	Virtual Reality (n=10)	Control (n=10)	p value
Duration of Training, days ± SD	25.9 ± 13.5	34.0 ± 32.9	46.7 ± 21.3	34.6 ± 24.1	**0.116**

4.4.3 Cost Analysis

Assuming the institution already has a da Vinci system to operate with, the best costs estimates of each of the three simulation training modalities from the current study, for the average study participant, amortized over ten trainees, are shown in Figure 4.9.

Figure 4.9: Simulation Costs



Graph shows comparison of total costs between the training streams averaged over the total number of trainees who have been trained using each method.

	Materials	Number Required	Cost	Total
Wet Lab	-da Vinci Robotic Instruments (DeBakey Forceps, Needle Driver, Monopolar Spatula cautery)	-1 of each (10 uses)	-$9629* ($962.90)	$1,453.09
	-Porcine Chest plate	-3	-$60	
	-Porcine Heart	-1	-$10	
	-Lab Assistant	-2hrs	-$50	
	-AV/Robotic Tech	-2hrs	-$120	
	-Lab Space	-2hrs	-$40	
	-3-0 Ethibond Sutures	-1 box	-$210.19	
Dry Lab	-da Vinci Robotic Instruments (DeBakey Forceps, Needle Driver)	-1 of each (10 uses)	-$6445* ($644.50)	$941.56
	-3-0 Silk SH Sutures	-1 box	-$64.76	
	-FLS Peg Transfer	-1	-$105¶	
	-FLS Suture Block	-1	-$39¶	
	-FLS Penrose Drains	-100 (10)	-$79.20* ($7.90)	
	-Lab Assistant	-2hrs	-$50	
	-AV/Robotic Tech	-2hrs	-$120	
	-Lab Space	-2hrs	-$40	
Virtual Reality	-da Vinci Surgical Simulator (Intuitive Surgical, Inc.)	-1	-$100000¶	$11,000.00

*- da Vinci Instruments must be purchased at this price for the first individual trained, but can be used up to 10 times. The FLS Penrose drains are purchased in a package of 100, but these may be used for several trainees. Therefore the total price for these items and the cost for one trainee are both shown.
¶ - These items are non-consumables and must only be purchased to train the first trainee and then can be reused indefinitely afterwards. Their cost is included in the Totals, but is actually amortized over every person who trains.

From this is can be seen that the high costs of the da Vinci instruments that are required for the wet lab and dry lab training make up the majority of the costs. These instruments, which run between $3000 and $3500 each, are disposable and will not be recognized by the da Vinci system after their 10th use. Intuitive Surgical Inc. has proclaimed that the intentional designing of the instruments this way, was to keep costs down by using less expensive materials that would only need to be used ten times, and to avoid high maintenance costs of indefinitely reusable instruments whose durability may be tested over time. It may be possible to allow for multiple individuals to be trained on the same day without shutting down the system, in order to reduce costs, however this requires increased coordination between trainees and the training facility staff, and makes this form of training less desirable. From the data it can be seen that the virtual reality simulator becomes cheaper than the wet lab simulation after the 70th person is trained, and cheaper than the dry lab after the 115th.

5 General Conclusions and Discussion

Analysis of the data that was recorded for participant characteristics, shows that there was no significant difference among the groups in regards to age, gender, year of training or time of previous expose to the da Vinci system. This taken with the information that no statistical difference could be detected in any of the three primary outcomes between participants in the four different treatment arms during the initial assessment, indicates that our randomization was appropriate and no group was at an advantage or disadvantage compared to the others at the commencement of their robotic training.

With regards to our time-based primary outcomes for both the 10cm ITA dissection and mitral valve annuloplasty it can be seen that individuals in the wet lab group performed better on their final assessments than any of the other groups and actually were found to be significantly better than our experts. This is a reasonable result as it would be expected that the exercise that is most similar to the actual operative experience would yield the most efficient method of training. Not only were the wet labs the most similar to the actually operative experience, they were the model used for our initial and final assessments. Exposure to these models allowed trainees in the wet lab group to become familiar with the relevant anatomy and robotic instrumentation, delineate the steps involved in each procedure, and repeat them as necessary to develop a safe and efficient technique for their completion. This represents perfectly the three phases of simulation training (familiarization, delineation and repetition), and in this setting it is the ideal method for simulation based training in robotic cardiac surgery.

The virtual reality group improved their scores from the initial assessment and met the same levels of proficiency set by our experts for time-based scores as no statistical difference could be detected between the two groups for both the ITA dissection and the mitral valve annuloplasty. Although they did not reach the same scores of the wet lab, this method of training certainly allows for the acquisition of robotic skill through the familiarization of the robotic instrumentation and its manipulation. The merits of virtual reality are demonstrated by the fact that the level of proficiency set by our experts was met for all primary outcomes, despite the fact that these individuals were never exposed

to the porcine tissues or the technique involved in either of these robotic tasks for the entire duration of their training. Their ability to reach these scores on the final assessment came from an understanding of the robot's functions as a competent technician of the robot. The major advantage of this type of training comes from the powerful scoring tool built into the simulation software. This tool provides ongoing feedback for the trainees to improve robotic proficiency by monitoring a variety of different metrics (ie. total distance travelled, work space range, excessive force, etc.) in addition to the time of completion. This gives the trainee a better idea of what they have done wrong during an exercise other than performing it too slow, which is the only insight gained from the time-based scoring systems of the dry lab group. This allows trainees to not only become more efficient with repeated practice but allows them to do so while avoiding bad habits of robotic performance. This scoring tool and the multiple metrics required to pass each task explains the significantly longer amount of time needed to reach proficiency for our subjects in the virtual reality group. For each exercise trainees not only had to be efficient to meet time goals, as in the wet lab and dry lab groups, but they needed to meet these goals in addition to a variety of others which required significantly more time to be spent practicing these individual tasks and learning how to complete them successfully.

The dry lab group improved their time based scores on the final assessment but trainees were only able to reach the level of proficiency set by our experts for the dissection of the internal thoracic artery and not for the annuloplasty stitches. It can be seen from the reported data that the average scores for each exercise was the lowest in the dry lab compared with the other two training groups for all outcomes. All this information taken together indicates that even though the levels of proficiency were met in some cases, the average trainee had deficiencies in the training that they received compared to the wet lab and the virtual reality groups. The dry lab group did however make rapid improvements in their scores over a very short training period and had the shortest average training time of all the three training streams at a mere 98.0mins to complete each of the required exercises to the level of proficiency set by our experts.

Lastly, the control group showed minor improvements in between the initial and final assessments, but without any extra exposure to the robot they were not able to meet the

level of proficiency set by our experts for any of the three primary objectives. The largest improvement we did see in their scores came in the final assessment of their ITA dissection where they improved on average from 451.0 to 749.1 for their time-based score. This improvement likely represents an improved familiarization with the ITA anatomy and dissection technique after completing the same task prior to randomization at the initial assessment weeks before. It is very likely that the same is responsible for the improvement in scores with the mitral valve annuloplasty task as well, however this improvement may not be as dramatic, as the ITA anatomy and its dissection technique seemed to be more of an abstract concept that trainees from surgical specialties outside of cardiac surgery had more difficulty grasping at first. The inclusion of the untrained control group allowed us to control for these occurrences and to make sure that the improvement we saw on the final assessment for the three training streams was not due to the exposure to the surgical techniques and robotic instrumentation that the subject received at the time of their initial assessment. Furthermore, because we had enrolled trainees who were concurrently progressing through surgical residency programs at the same time that they were participating in this study, we were unable to prevent them from gaining exposure to robotic cases in their clinical duties during the completion of their robotic training. In addition to this, surgical trainees may continue to acquire and improve upon their surgical skills as they gain more clinical experiences in the operating room while this study was being completed. The addition of the untrained control group in this study allowed us to control for any of these potential confounders. Because there was no significant difference in the total duration of training between the four treatment arms from the initial to the final assessment, and the control group failed to reach all levels of proficiency despite ongoing clinical experiences and potential exposure to robotic cases outside of the study, it is reasonable to assume that the improvements seen in the three training groups that allowed them to reach the levels of proficiency above the control group was due to the experience and skill they gained during the training exercises of this study.

The findings of this study after its successful completion indicate that our original hypothesis was incorrect. Trainees seemed to perform significantly better with the wet lab training as compared to the VR lab. Despite the more stringent criteria for reaching

levels of proficiency with the robot, this could not replace the benefits of gaining experience handling the actual tissues and delineating the exact steps of the procedure as in the wet lab. In addition to this, individuals in the wet lab were exposed to some degree of anatomical variability in their training which was not possible with the other simulation methods.

Although two of the three primary outcomes for the study were time-based scores, the more important marker of overall surgical proficiency is likely the GEARS score. This scoring tool is not specific to any one robotic surgical procedure in particular, but it does account for the overall efficiency of robotic surgery which is a reflection of the total time it takes to complete that task. In addition to this the GEARS scoring tool also focuses on depth perception, bimanual dexterity, force sensitivity, autonomy and robotic control. These aspects of robotic surgery have been shown in the literature to be important in evaluating overall robotic proficiency[47]. As our results show, all three of the training groups showed a drastic improvement in their average GEARS score between the initial and final assessments. This highlights how these aspects apply to all robotic procedures and can be learned in any of the three training streams that are compared here. Despite the significantly better time-based scores the wet lab had compared to the experts at the final assessment, they were not significantly better in the GEARS score but had reach the level of proficiency along with the wet lab and virtual reality group as no statistical difference was detected between any of the groups' GEARS score and that of the experts. The very modest increase in the GEARS score for the control group on the final assessment is far less than the increase seen in their time-based scores. This likely represents an improved familiarity with the anatomy and techniques gained from the initial assessment improving time-based scores as previously discussed, without an improvement in technical expertise to affect the GEARS score to the same degree. Because being more familiar with the procedural techniques involved in the assessments will be reflected in the efficiency and autonomy sections of the GEARS scoring tool, this helps explain why the control's final GEARS scores improved slightly.

The current study demonstrates the high cost of this type of training, which must be taken into consideration when developing a reliable training program. The largest cost that

applies to the wet lab and dry lab training is the cost of the robotic instruments, which range between $3000 and $3500 each. The fact that these instruments are only capable of 10 uses before they must be replaced makes these two training methods even more expensive. Setting aside these costs, the actual operating costs for the consumable items that must be replaced, or the operating costs for each trainee was $490.19 for each individual in the wet lab group, and $282.66 for the dry lab. The virtual reality simulator has a much higher upfront cost of $110,000, but this is a one-time investment and can be shared among different specialties at the center who are using the robot for clinical purposes. Given the cost of the instruments for both the wet and dry lab training, the virtual reality simulator becomes cheaper than the wet lab after the 70^{th} person completes the training and cheaper than the dry lab once the 115^{th} person is trained.

5.1 Clinical Relevance

Exposure to robotic surgery in the operating room is becoming ever more difficult for surgical trainees due to increasing health care costs and a demand for improved patient outcomes. This leads to less of the procedure being entrusted to trainees and more being completed by the staff surgeons. Robotic cardiac surgery is only performed at a few specialized centers and comparatively small numbers of these cases are performed compared to traditional “open” procedures with a sternotomy. Within 2015 and 2016 Intuitive Surgical Inc. loses many key patents in their portfolio, including the original patents obtained from IBM and Computer Motion Inc which helped form the company, which will weaken their monopoly on the surgical robot market[11]. This increased market competition has the potential to lower the barriers to entry for new robotic programs, as well as decrease the high operating costs and make robotic surgical cases more common in cardiac surgery as well as other specialties. These current problems and the timing of changes that are on the horizon, highlight the need for an efficient, cost-effective and reproducible training program in robotic surgery as urgently as possible. Simulation

based training helps fill this need and allows for the acquisition of robotic surgical skills outside of the operating room.

Robotic simulation training in isolation does not replace the traditional clinical training methods that are currently in use but can be employed to supplement these methods for more in-depth training, acquiring greater robotic surgical skills at a faster rate. Liu et al. have reported that surgical education and the acquisition of robotic skill is effected by a combination of clinical, educational and technical expertise, with each adding to the overall training experience in surgical robotics as seen in Figure 5.1.

Figure 3: Expertise Effecting Robotic Training

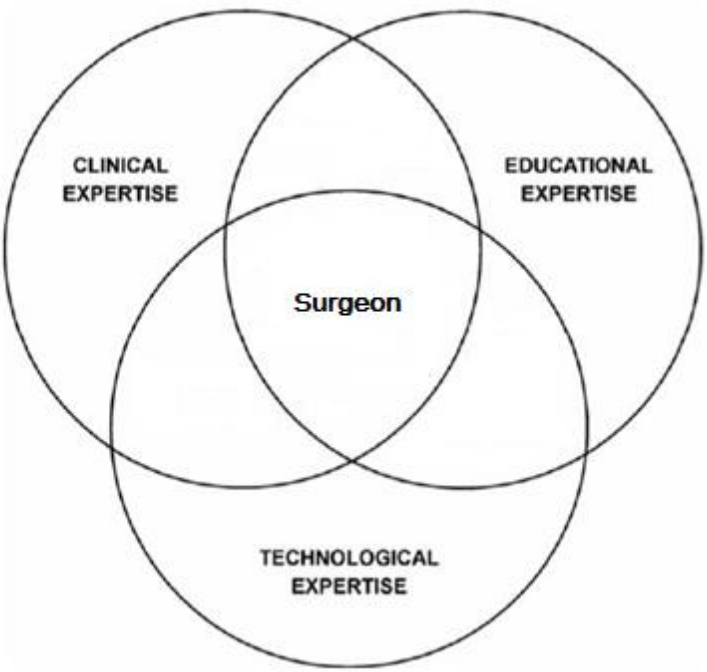


Diagram showing the equal parts of clinical, education and technical expertise that are required to be a competent robotic surgeon.

With this in mind, it can be understood how simulation based training in itself without any clinical and educational context can only supplement the technical expertise portion of this training. And therefore, simulation training, particularly training of simple or non-procedural tasks, allows trainees to become proficient technicians of the robotic system

but not complete robotic surgeons as they still require the necessary clinical and educational experience. However, technical skill is not a trivial thing and it is difficult to obtain by the current training methods, as previously discussed.

A simulation based training curriculum, like the ones compared in the current study, would allow trainees to gain experience with the robotic system and be allowed to operate the technical aspects of the robot before ever entering into the operating room, allowing them to use the limited exposure that they have with these operations to help focus on the procedural steps involved and make better use of their limited time.

From the data reported in the current study, it can be seen that wet lab training in porcine models gives the highest fidelity simulation experience when compared to the actual operative experience. This perfectly explains how this simulation modality allows for the greatest acquisition of robotic skill and does so in a very rapid time frame. However, the feasibility of implementing a wet lab as a reproducible training model is not as desirable. The first concern with this modality is the cost and difficulty in acquiring these tissues. Cadaveric models, despite giving the most realistic experience, can be very expensive and are in a very limited supply. The porcine model that we chose to use in the current study was far easier to obtain and cheaper than a cadaver model. However, the internal thoracic artery dissection that required a porcine chest had to be purchased from an abattoir that was willing to be a supplier. The porcine chest wall model, infringes on the pork side-ribs that are the most lucrative part of the animal for these businesses. Because of the fact that many of these companies have to supply regular customers with ongoing orders, they are unwilling to provide the tissues for educational or research purchases as it takes away from their necessary quotas and they are unwilling to jeopardize certain customer contracts, even for an inflated price. If you are able to find a supplier, who is willing to supply these tissues the next concern with these models is the difficult preparation. In many cases, the porcine chests that were obtained for this study did not include the internal thoracic artery pedicle as the abattoir had cut too thin a section from the sternum in order to leave as much side rib as possible and had cut medial to the pedicle or damaged it with the saw. For the chest models that did contain the desired ITA pedicle a clear difference can be seen between human and pig chest anatomy. The

porcine chest has thick, overdeveloped intercostals and inner thoracic muscles which lay overtop of the ITA pedicle. Unlike humans, who have readily visible ITA pedicles usually running under only a thin layer of inner thoracic fascia, the porcine chest usually has several centimeters of thick muscles which must be removed to expose the ITA pedicle underneath to give a similar view of what is seen in humans intraoperatively. Once the porcine tissues have been obtained and properly prepared for a robotic training session, the next concern is the need for a specialized center that can be used to perform the training. At the University of Western Ontario, we have the Canadian Surgical Technologies & Advanced Robotics (CSTAR) centre, which is focused on researching, developing and testing in robotics. This center offer the simulation training of minimally invasive surgical technologies and techniques and is one of only eight international centers certified for training of the da Vinci robotic system. This center has the personnel and expertise to handle the acquisition, storage, preparation and disposal of these tissues but it is obvious that most centers do not have such resources. It must also be pointed out that due to health and safety concerns regarding sterility and contamination any wet lab simulation exercises must be completed on a robotic unit that is dedicated for research or training purposes and not on the units used on actual patients in the operating room. Because of the high costs of the actual robot, this makes it even more unlikely to be feasible for a reliable and reproducible training program as most centers do not have the luxury of having multiple robotic systems for a variety of different purposes. Lastly, the anatomical tissue variation in the animal and cadaver models, require small differences in the surgical approach and techniques for the skills learned. This necessitates the participation of a trained staff surgeon who is able to use their experience, familiarity and expertise to provide ongoing guidance and feedback for the trainee in order to develop the correct skill and proper habits. For all of these logistical reasons combined with the higher relative costs of this type of simulation, it can be seen how other methods of simulation may be preferred at the cost of not being as effective of a training modality.

These considerations make virtual reality simulation more attractive as a reliable training method. This study has shown that virtual reality simulation gives results that are similar to the wet lab group and allows for proficiency to be reached in both the time-based scores, as well as the GEARS assessments. In contrast to the wet lab no tissues need to be

acquired, prepared or disposed of, robotic instruments are not necessary and no set up of the robot or any other materials is required. VR simulation can occur at almost any time the trainee is available, as most of the time the robot is not in use and no other personnel (staff surgeons or lab technicians) are required. After completion of this study the limitations identified with robotic virtual reality simulation training, seem insignificant compared to the other training methods given the fact that we have shown its potential in allowing trainees to reach a satisfactory level of proficiency compared to our expert. However, these shortcomings include first the high upfront cost, which is not as unreasonable given the comparative costs of the other training modalities as shown in this analysis. Secondly, it was observed that the mechanical movements of the actually robot are not always represented properly in the virtual reality simulations. The virtual reality environment has a fluid motion to the movements of the robotic instruments as well as tissues and objects that are not necessarily representative of the gears and mechanical parts that move in the actual robot. A good example of this is the fact that the MScore system tracks instrument collisions for every task, which many times is not noticed by the trainee completing the assignment, particularly on very fine transferring tasks such as those that include needle-handling. Conversely, when the robot is used in the wet or dry labs, a collision of the instruments usually results in increased vibrations that travel through the entire system destabilizing the instruments as well as the camera view for short periods of time. Similar effects are seen with fast, whipping movements of the camera or instruments with the actual robot, which are not seen in the virtual reality simulation exercises. Although this does change the actual experience, the clinical significance of this may not be that important, as was demonstrated in this study by the improvement in performance of the trainees in this group. Overall, virtual reality simulation gave the trainees an excellent simulation experience, due to the ease of set-up, ability for repetitive practice and the powerful scoring tool to provide ongoing feedback without compromising the effectiveness of the training.

5.2 Strength of the Study

The work presented here is the first prospective randomized controlled trial to ever compare the currently available simulation modalities used in robotic surgical training. Although individual validation studies exist within the literature for each simulation method tested here, the vast majority of them deal with only one method of simulation and sample sizes in the single digits. In addition to this very few of these studies are actually comparison trials where more than one method of simulation training is being compared to another. The current study, with forty surgical trainees enrolled, makes it one of the largest studies of its kind to ever be completed. This speaks to the difficulty in conducting this type of research both in the resources necessary to complete it, as well as the recruitment of multiple surgical trainees willing to donate their free time to train on the robot. At the University of Western Ontario we are one of very few centers internationally that would be capable of this type of work. Having not only a world class robotic cardiac surgery program with experts to provide guidance and feedback, but also a center such as CSTAR in which there is access to virtual reality simulators and both animal and inanimate models can be used to train on a da Vinci system designated specifically for research and training purposes, is necessary for completion of a project of this scale. The small sample sizes and the difficulty we had in recruiting some trainees, or at least scheduling them for training sessions after they were enrolled is not uncommon in this type of work. As can be seen from our demographic characteristics from each group the average participant in the study was a senior resident in a surgical program (PGY 4 or 5). The average work week for these individuals is usually around 100 hours, with frequent call shifts making scheduling training session in the lab exceedingly difficult. Because of these factors, this study was very ambitious from the very beginning and after its successful completion it is unlikely that this work will be reproducible at any other center without the investment of significant resources.

The conclusion of this study was quite successful in that we had a 96.25% completion rate for all our trainees at the final assessment. This is far greater than the average reporting guidelines of most RCTs at 80%. Of the 40 participants, who had to complete two tasks of the final assessment we had 38 complete the entire training session and the

two final tasks. One other individual completed the training and one of the two final tasks as his Canadian work permits expired and his fellowship was cut short before his last session in the lab and one other individual was unable to complete his training after he was randomized due to clinical responsibilities.

Our sample size of 10 participants in each treatment arm was powered appropriately to detect differences in the scores between novice trainees at baseline and the scores of our expert surgeons. Also the inclusion and exclusion criteria for the study, made our sample populations consist of surgical residents from a variety of specialties and increases the external validity and applicability of this study to the general population in surgical training who desire to become more proficient with robotic surgery.

The methodology of the study was created entirely from validated and well founded protocols of highly accepted simulation methods. The time-based scoring system used for the ITA dissection as well as the mitral annuloplasty was designed after the FLS scoring system and the exact same protocol was followed in order to set the level of proficiency by our experts for these two tasks as what was done for the FLS program. The peg transfer and intracorporeal knot tying exercises were taken directly from the FLS protocol with the exact same scoring system and predefined errors that were applicable to the robot. Again the levels of proficiency were generated in the exact same manner as the FLS program. The virtual reality curriculum was generated in the same fashion as the 'Morristown Protocol' published by Culligan et al. We defined the tasks and proficiency scores in advance based on our expert performances in a similar fashion and found that these levels were similar to those found on the same exercises as reported in that publication. The study uses an untrained control group to compare the three other training streams. This proved to be very important as we not only showed that familiarization with the robot occurs fairly rapidly and each training method is beneficial to some degree. The control group also showed a mild improvement in all cases, indicating that even the very short time spent on the robot for the initial assessment has some benefits in providing familiarization with the robotic instrumentation, its manipulation and the delineation of the steps involved in the tested robotic tasks.

Lastly, the use of the well validated, objective scoring tool, GEARS score, in a blinded fashion, helps increase the reproducibility and external validity of this work. The GEARS score proved to be very easy to use when evaluating deidentified videos of each robotic assessment. The breakdown of overall surgical proficiency into these six different aspects allowed the investigators to make reliable evaluations of major components of robotic skill, independent of the actual procedure being attempted. The addition of this scoring tool to the time-based scoring system helps give a more robust picture of the overall surgical proficiency that was acquired through each training stream.

5.3 Limitations of the Study

Attempting to complete an RCT comparing different training modalities used in robotic cardiac surgery proved to be difficult to recruit our ideal sample population, which would have been cardiac surgery trainees. Given our sample size calculations, it was necessary to expand our enrollment and include individuals from all surgical training programs in order to appropriately power our study. This may have altered some of the data on our final assessments, particularly in regards to the dissection of the internal thoracic artery task. This proved to be a more difficult procedure for individuals who were not from the department of cardiac surgery and who were not familiar with the anatomy of the ITA pedicle or the technique for its dissection. Analysis of the data indicates that the individuals who were cardiac surgery residents and fellows did better among their groups for the three training streams, but not for the control group. This difference indicates that the individuals in the training streams likely gained the technical skills to operate the robot efficiently but may not have appreciated the nuances of the task at the time of the final assessment. The fact that this was not the case for the few cardiac surgery trainees in the control group, indicates that even though they may have the knowledge and experience to appreciate this task they did not acquire the technical skills to manipulate the robot as the individuals in the three training streams did. Ideally all participants in the study would have been cardiac surgery trained to help minimize the differences in

clinical knowledge and experiences among the groups however, having representation from a wide variety of surgical specialties may indicate that these results are applicable to all robotic surgical training and not just specific to robotic cardiac surgery.

Another limitation with regards to this study is the differences in anatomy of the wet lab when compared to humans and the variability among these models. In regards to the anatomical differences, the porcine chest wall model is not entirely similar to that of a human. The ITA pedicle has significantly larger veins that run along the artery as compared to the human where all three vessels are of similar size. This difference is minimized by utilizing the pedicled dissection technique of the vessels as opposed to the skeletonised technique, where only the artery is dissected off the chest wall and the veins are left in place. As mentioned previously the preparation of the chest wall requires stripping off of large intercostals and inner thoracic muscles to expose the pedicle underneath. Unfortunately, this results in stripping off of the inner thoracic fascia which is generally used to score the borders of the dissection in humans and can be used to provide traction during the dissection. With this removed the dissection technique was slightly more difficult as individuals had to be even more careful not to avulse fat and muscle tissue surrounding the ITA pedicle. With regards to the variability between porcine models, this may have lead to artificially increased or decreased times based on the difficulty of the particular anatomy of the model used for the assessment. Although this is indicative of real life, it is not ideal for standardizing a technique and scoring system in a study like this. This highlights the relative importance that should be placed on the time-based scoring system, which is easily effected by this variability, and the GEARS scoring tool, which is not. In addition to this it shows the need for an expert to be present at all times in the wet lab, to provide ongoing guidance and feedback.

5.4 Final Remarks and Further Direction

This study serves to highlight the benefits and limitations of different training methods currently used in robotic surgical training. We have shown that even limited exposure to the robot can have significant benefits in the ability of surgical trainees if they are guided properly.

With the current state of robotic surgery and its training, simulation based exercises must be incorporated into training programs in order to keep up with the advancements in robotic technology and allow for an improved experience during each robotic operation that trainees are exposed to. Training programs must evaluate their own institutional resources and the restrictions applied on the availability of robotic equipment for trainees to use for training purposes, in order to determine the optimal simulation training that they can offer. If a center has the ability to provide all forms of simulation training, the results of the current study would highly favor the high fidelity wet lab simulation, under the guidance of an expert robotic surgeon for the fastest acquisition of robotic skill and the ability to reach the highest levels of proficiency. However, from the considerations that must be made for this type of expensive training, virtual reality simulation offers a reasonable alternative with a better overall training experience and still allows the trainee to become familiar with the manipulation of the robot's instrumentation and reach levels of proficiency similar to that of expert robotic surgeons.

At our own institution we have a large number of fellows who come from training centers across the world to train with our experts in robotic cardiac surgery. These fellowships usually run between 6 to 12 months. Based on those numbers they will get exposure to 25-50 robotic cardiac cases. With this limited exposure we can improve their experience and the training that they receive by making the most of each robotic operation. Because our institution already has the da Vinci Surgical Simulator (Intuitive Surgical Inc. USA), the implementation of the virtual reality training curriculum can be easily instituted. By requiring all trainees of the robot to complete the robotic virtual reality training curriculum that we have created here on their own time prior to coming to their first robotic cardiac surgery operating room, we will optimize the training they can receive in

the short number of cases they will see, starting from the first day. If this curriculum is completed, trainees would start their first robotic operation of their fellowship as satisfactory technicians of the robot and be able to focus on learning and mastering the procedural steps involved in the operation instead of taking several sessions with the robot to learn how to control the camera and instruments. Having the simulator available as their training progresses is also a nice option for the continued acquisition and development of surgical robotic skill.

The methods for simulation based training that are examined here apply to traditional non-robotic surgeries as well. The use of wet lab, dry labs and virtual reality simulation has been impl emented in all surgical specialties, some of which are highlighted in this work, such as in laparoscopic surgical training. Simulation lends itself nicely to robotic training as the surgeon is already removed from the operating table and the exact same images and operating field that they would experience in an actual operation can be created in a simulation exercise. In addition to simulation training, the robot has other features which improve the learning experience for trainees such as the telestration feature. With this feature, the surgeon and trainee are looking at the same image in their two consoles and the surgeon can highlight areas of interest and speak directly through the console's microphone system to the trainee in another console. All of these aspects of robotic surgical training add to our ability to train new surgeons and augment the traditional learning curves in surgery. As robotic surgery becomes more mainstream in different surgical specialties, all of these aspects will need to be employed and the need for a reliable robotic training program becomes paramount. This work will serve to guide training programs invest resources in cost-effective, high yield simulation exercises to improved training of new robotic cardiac surgeons.

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Appendices

Appendix A: List of Abbreviations

ANOVA	Analysis of variance
AESOP	Automated Endoscopic System for Optimal Positioning
CSTAR	Canadian Surgical Technologies & Advanced Robotics
CABG	Coronary artery bypass grafting
dVSS	da Vinci Surgical Skills Simulator
dV-Trainer	da Vinci-Trainer
FDA	Food and Drug Administration
FLS	Fundamentals of Laparoscopic Surgery
GOALS	Global Operative Assessment of Laparoscopic Skills
GEARS	Global Evaluative Assessment of Robotic Skills
HSREB	Health science research ethics board
ITA	Internal thoracic artery
IBM	International Business Machines
LAD	Left anterior descending artery
MISTELS	McGill Inanimate System for Training and Evaluation of Laparoscopic Skills
MACCE	Major adverse cardiac and cerebrovascular events
MASH	Mobile Advanced Surgical Hospital
NASA	National Air and Space Administration
PCI	Percutaneous coronary intervention
PGY	Post Graduate Year
RCT	Randomized controlled trial
TECAB	Total endoscopic coronary artery bypass
VR	Virtual reality

Appendix B: Ethic Board Approval

Western Research

Research Ethics

Western University Health Science Research Ethics Board
HSREB Delegated Initial Approval Notice

Principal Investigator: Dr. Bob Kiaii
Department & Institution: Schulich School of Medicine and Dentistry\Surgery,London Health Sciences Centre

HSREB File Number: 106343
Study Title: Evaluation of Robotic Cardiac Surgery Training Modalities
Sponsor:

HSREB Initial Approval Date: April 30, 2015
HSREB Expiry Date: April 30, 2016

Documents Approved and/or Received for Information:

Document Name	Comments	Version Date
Other	References	2014/04/13
Letter of Information & Consent		2015/04/30
Other	PDF version of completed Post-test Questionnaire (received Mar.31/15)	
Western University Protocol	Final PDF version of Western Protocol with all recommended changes made (Received Mar.31/15)	
Other	Observed standardized assesment of technical skills scoring information (received Feb.04/15)	

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

[redacted]

Ethics Officer to Contact for Further Information

Erika Basile ebasile@uwo.ca	Grace Kelly grace.kelly@uwo.ca	Mina Mekhail mmekhail@uwo.ca	Vikki Tran vikki.tran@uwo.ca

This is an official document. Please retain the original in your files.

Appendix C: Participant Consent Form

London Health Sciences Centre

Western

Bob Kiaii MD, FRCSC, FACS
Professor and Chair, Division of Cardiac Surgery, Western University
Hospital Chief of Cardiac Surgery, London Health Sciences Center

Project Title: Comparison of Robotic Cardiac Surgery Training Modalities
Principal Investigator: Bob Kiaii, MD, Department of Cardiac Surgery, London Health Sciences Center

Letter of Information

1. **Invitation to Participate**

   You are being invited to participate in a research study to test different training modalities in robotic surgery and how they apply to robotic cardiac surgery because you are a surgical/medical trainee with limited robotic surgery experience.

2. **Purpose of the Letter**

   The purpose of this letter is to provide you with information required for you to make an informed decision regarding participation in this research.

3. **Purpose of this Study**

   The purpose of this proposed research is to objectively compare various training modalities currently available in minimally invasive and robotic surgery to determine the most effective training methods specific to robotic cardiac surgery. The current simulation modalities that are available include; computer simulation, da Vinci simulation, dry labs and wet labs with animal or cadaveric models on a training robot. All of these methods have advantages and drawbacks with regards to operative realism, ease of reproducibility, set-up, and cost.
   With this research we plan to compare the previously stated characteristics of each of these simulation models for training purposes to determine the efficacy and reliability for robotic cardiac surgery training.
   Our objective is to identify the best training modality in robotic cardiac surgery in regards to accuracy of a realistic representation, ease of reproducibility and set-up, and cost of implementation.

4. **Inclusion Criteria**

   Individuals who are surgical or medical trainees who have not had more than 10 hours of experience with robotic surgery are eligible to participate in this study.

University Hospital • PO Box 5339 • 339 Windermere Road, London, Ontario, Canada N6A 5A5
Clinical Telephone (519) 663-3153, Facsimile (519) 663-3044
Administrative/Research Telephone (519) 685-8500 ext 32271

London Health Sciences Centre

Western

Bob Kiaii MD, FRCSC, FACS
Professor and Chair, Division of Cardiac Surgery, Western University
Hospital Chief of Cardiac Surgery, London Health Sciences Center

5. **Exclusion Criteria**

Individuals who have used the da vinci robot, skills simulator or trainer for more than 10 hours are not eligible to participate in this study.

6. **Study Procedures**

If you agree to participate, you will be asked to complete a series of tasks while being observed by a single evaluator, these tasks include a robotic dissection of 10cm of the internal thoracic artery and three stitches of a mitral valve annuloplasty in a pig model with the da Vinci robot. You will then be randomized to either; a wet lab group which will repeat the same two tasks, a dry lab group that will focus on basic robotic skills (camera movements, needle handling, transferring, etc), a virtual reality group that has a 9-exercise curriculum to complete covering a wide variety of basic and complex robotic tasks, or a control group which will receive no additional training. If you are randomized to one of the three training streams you will be able to repeat each task until you are capable of performing the task to a level of expertise set my our staff robotic cardiac surgeons. After this level of competency has been reached each trainee will then repeat the original evaluation. Lastly you will be asked to complete a short (2 page) survey on your experience. It is anticipated that the entire task will take 3-4 hours, over 2-3 sessions. The task(s) will be conducted at University Hospital, London Health Sciences Center, London, Ontario. There will be a total of 30 participants selected for this project.

7. **Possible Risks and Harms**

There are no known or anticipated risks or discomforts associated with participating in this study.

8. **Possible Benefits**

The possible benefits to participants include increased experience and training with robotic surgical technology and exposure to simulation training and observed standardized technical skill evaluation. The possible benefits to society include; standardization and streamlining of robotic training in cardiac surgery lowering the substantial cost and time required to train a robotic cardiac surgeon.

9. **Compensation**

You will not be compensated for your participation in this research.

10. **Voluntary Participation**

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future academic status.

University Hospital • PO Box 5339 • 339 Windermere Road, London, Ontario, Canada N6A 5A5
Clinical Telephone (519) 663-3153, Facsimile (519) 663-3044
Administrative/Research Telephone (519) 685-8500 ext 32271

Bob Kiaii MD, FRCSC, FACS
Professor and Chair, Division of Cardiac Surgery, Western University
Hospital Chief of Cardiac Surgery, London Health Sciences Center

11. Confidentiality

All data collected will remain confidential and accessible only to the investigators of this study. If the results are published, your name will not be used. *If you choose to withdraw from this study, your data will be removed and destroyed from our database. *While we will do our best to protect your information there is no guarantee that we will be able to do so. * Representatives of The University of Western Ontario Health SciencesResearch Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research. All data from the study will be kept on a password encrypted USB key or laptop kept at University Hospital in a locked file cabinet in a private office requiring card access and a password to enter.

12. Contacts for Further Information

If you require any further information regarding this research project or your participation in the study you may contact either:

Dr. Bob Kiaii, (519)685-8500, bob.kiaii@lhsc.on.ca
Dr. Matthew Valdis, (519)860-2567, matthew.valdis@lhsc.on.ca

Representatives of the Lawson Quality Assurance (QA) Education Program may review the study data for QA purposes.

If you have any questions about your rights as a research participant or the conduct of this study, you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute (519) 667-6649.

13. Publication

If the results of the study are published, your name will not be used. If you would like to receive a copy of any potential study results, please contact {insert Dr. Matthew Valdis

14. Consent

Completion of this form is indication of your consent to participate. By signing this form you do not waive your legal rights.

This letter is yours to keep for future reference.

University Hospital • PO Box 5339 • 339 Windermere Road, London, Ontario, Canada N6A 5A5
Clinical Telephone (519) 663-3153, Facsimile (519) 663-3044
Administrative/Research Telephone (519) 685-8500 ext 32271

London Health Sciences Centre

Western

Bob Kiaii MD, FRCSC, FACS
Professor and Chair, Division of Cardiac Surgery, Western University
Hospital Chief of Cardiac Surgery, London Health Sciences Center

Consent Form

Project Title: Comparison of Robotic Cardiac Surgery Training Modalities
Study Investigator's Name: Dr. Bob Kiaii

I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

Participant's Name (please print): _____

Participant's Signature: _____

Date: _____

Person Obtaining Informed Consent (please print): _____

Signature: _____

Date: _____

University Hospital • PO Box 5339 • 339 Windermere Road, London, Ontario, Canada N6A 5A5
Clinical Telephone (519) 663-3153, Facsimile (519) 663-3044
Administrative/Research Telephone (519) 685-8500 ext 32271

Appendix D: Pre-test Questionnaire

Evaluation of Robotic Cardiac Surgery Training Modalities

Pre-Test Questionnaire

	Age:	Date:
Residency Training Program:	Current Year of training:	Video #:

1) Is robotic surgery used in your surgical discipline?
   - ☐ Yes
   - ☐ No

If yes, what percentage of total cases are robotic or robot assisted?

2) How many surgical robotic cases have you seen in your training so far?

3) How many hours of experience do you have using the daVinci controls (robot or simulator) in a clinical, training or research setting prior to today?

4) Please rate how well you are prepared for the following:

	Not at all prepared	Very prepared
Camera movement	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Device movement	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Transferring	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Cutting	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Suturing	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Knot Tying	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Mitral Annuloplasty	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
ITA Dissection	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	

5) Do you expect robotic surgery to be used in your discipline in the future?
- ☐ Yes
- ☐ No

If yes, what percentage of total cases will be robotic or robot assisted?

6) Do you expect to use robotics in your future surgical career?
- ☐ Yes
- ☐ No

If yes, what percentage of total cases will be robotic or robot assisted?

7) Other comments in regards to the training experience:

Appendix D: Post-test Questionnaire

Evaluation of Robotic Cardiac Surgery Training Modalities

Post-Test Questionnaire

Age	Video #:	Date:
Residency Training Program:	Current Year of training:	Randomized Robotic Training □ Dry Lab □ Simulation □ Wet Lab

8) How satisfied were you with your training experience?

	Not at all satisfied	Very satisfied
Comfort	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Ease of Set-up	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Realism	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Reproducibility	1– 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	

9) Please rate how well you were prepared **after** the training period for:

	Not at all prepared	Very prepared
Camera movement	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Device movement	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Transferring	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Cutting	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Suturing	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Knot Tying	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
Mitral Annuloplasty	1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	
ITA Dissection	1– 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10	

10) How realistic do you think the exercise was compared to the actual operative experience?

Not at all realistic Very realistic
1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

11) Please rate your overall experience with the training program you were assigned to:

Negative Positive
1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10

12) Do you think this training modality is an effective method for surgeons in training?

- Yes
- No

If no, please elaborate on any specific concerns and how this could be improved:

13) Please list any specific benefits in regards to the training modality you were assigned to:

14) Please list any specific drawbacks in regards to the training modality you were assigned to today:

15) Other comments in regards to the training experience:

Curriculum Vitae

MATTHEW VALDIS

EDUCATION

Residency	University of Western Ontario, London	Present
	Cardiac Surgery	
MSc	University of Western Ontario, London	Present
	Department of Surgery	
MD	University of Western Ontario, London ON	2007-2011
BScH	McMaster University, Hamilton ON	2003-2007
	Honours Biochemistry	
	Graduated Summa Cum Laude	

RESEARCH

Summer Research Training Program, 2007-2010

Developed a novel method for the extraction and isolation of mesenchymal stem cells (MSCs) from umbilical cord blood. Identify the mechanism of immune-suppression of MSCs involves the induction of FOXp3+ regulatory T-cells.

MSc in Surgery Thesis Project 2014-2015

Completion of the first prospective randomized controlled trial evaluating different simulation-based training modalities in robotic surgery.

PUBLICATIONS & MANUSCRIPTS

Valdis M, Iosef C, Burke AM, Han VK. Mesenchymal Stem Cells Induce Immuno-tolerance Through the Generation of Regulatory T-Cells; a Potential Therapy for Cell Mediated Autoimmune Disease. 2009.

Valdis M, Burke AM, Keeney M, Iosef C and Han VK. Mesenchymal Stem Cells derived from placenta and umbilical cord blood induce maternal-fetal tolerance through CD4+CD25+FOXp3+ T-regulatory cells by nine weeks gestation. 2010.

Leeper RW, Valdis M, Arntfield R, Guo L. Extracorporeal membrane oxygenation in the acute treatment of cardiovascular collapse immediately post-partum. Interact Cardiovasc Thorac Surg. 2013 Nov;17(5):898-9.

Fernandes, P. Allen, P. Valdis, M. Guo, L. Successful use of extracorporeal membrane oxygenation for pulmonary embolism, prolonged cardiac arrest, post-partum: a cannulation dilemma. Perfusion. 2015 Mar;30(2):106-10.

Valdis M, Gelinas J, Guo L. Invasive MRSA Endocarditis Resulting in Right Ventricular Pseudoaneurysm and Fistulation to Previous Bypass Graft. Ann Thoracic Surg. 2015. Article in print.

HONOURS & AWARDS

Dr. L. Dewitt Wilcox Award in Medical Research, 2009

Awarded to a medical student who has demonstrated initiative, drive, awareness of research and the ability to persevere in completing a project under the Summer Research Training Program. This is the highest research award at the Schulich School of Medicine.

Canadian National Medical Student Research Symposium, 2010

Received the 3rd place award for best presentation in basic and translational research at the 2010 CNMSRS.

Resident Teaching Award 2013-2014

Voted the most outstanding resident teacher in the Division of Cardiac Surgery at UWO.
