PERCEPTIONS OF SURGICAL ROBOTICS

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Abstract

Robot-assisted surgery has become one of the most technologically advanced surgical procedures. In 1999, Intuitive Surgical unveiled the *da Vinci* system, a robotic device developed to help surgeons perform minimally invasive procedures without the disadvantages of traditional laparoscopic techniques. In this current study, surveys were developed for three different populations consisting of the general public, post-operative patients, and medical practitioners. The surveys aimed to collect data regarding each of the populations' perceptions on robot-assisted surgery. Statistical analysis was performed on the collected data, and results were compared between and within each of the three populations. Differences existed between the three populations' perceived impact of RAS on patient recovery time, length of procedure, and operator learning curve.

Acknowledgements

We would like to thank Professor Gregory Fischer for his guidance, patience, and open-mindedness with a research topic so little previously explored, Professor Laurie Fischer for her advice on designing a scientifically valid survey, the Mechanical Engineering Department that so generously donated envelopes for survey distribution, WPI Mail Services for facilitating distribution of the surveys, Dr. Nguyen and the Urology Department at Children's Hospital Boston, Dr. Parulkar, Pam Sigel, and the Urology Department at St. Vincent's Hospital Worcester, and Dr. Poston andthe Cardiothoracic Surgical Department at Boston University Medical Center for their contribution of post-operative patient populations along with general guidance throughout the research study.

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Introduction

Surgeons will often refer to three main types of surgical methods: open, laparoscopic, and robotic-assisted. Traditional surgery in its earliest form was open. The surgeon completed all procedures during the surgery by hand using small, basic surgical tools such as scalpels, scissors, and forceps inside of a large incision. From there, laparoscopic surgery developed and took rootin the 1980s.[i] Laparoscopic surgery involves minimally invasive techniques. Small "keyhole" incisions are made in the abdomen and laparoscopic tools are used including a two dimensional endoscopic camera, and larger extensions of the basic hand tools used in open surgery. Both open and laparoscopic surgical procedures involve the surgeon at the patient's side for the entirety of the procedure. The most recent surgical classification is robotic-assisted surgery, in which the same minimally invasive procedure is assisted with a robotic device. With this type of surgery, a robotic system is used in conjunction with laparoscopic technique. Computer assisted robots mimic the surgeon's hand motions inside of the patient's abdominal cavity. All three of these types of surgery are closely linked, and it is crucial to recognize that while some types are preferred over others for specific procedures, no one surgical technique will ever completely replace another.

In 1999, Intuitive Surgical introduced the *da Vinci*surgical system to the medical world.[ii]The *da Vinci* system assists in minimally invasive surgical procedures by providing the surgeon with a sophisticated tool set, increased dexterity, and superior ergonomics. This device allows for surgeons to remotely control a series of robotic arms inside of a patient to perform various surgical procedures. Surgeons have the ability to see inside of the patient with a stereoscopic camera in three dimensions and color as well as the ability to scale the motion of their hand movements via the *da Vinci* system. Unlike the first two surgical techniques discussed, robot-assisted surgery is completed with the surgeon

somewhat physically distanced from the patient, ergonomically seated at one portion of the *da Vinci*system viewing a three dimensional picture of the surgical field inside of the patient.

Figure 1 - The *da Vinci* Surgical System

Since the 1960s, robots have been used in manufacturing businesses such as the automotive industry. Robots have the capability of performing the same task repeatedly with much higher speed, precision, and reliability. Now, at the turn of the century robots are appearing in the surgical world assisting surgeons in minimally invasive surgical procedures. They are becoming increasingly integrated with our more intimate life activities, like surgery for example. The comfort with this occurrence of different members of society is expectedly directly reflected by the depth and accuracy of their understanding of RAS along with their generalized comfort with technology. Our study focuses on howpost-operative patients who have undergone robot-assisted surgery, robot-assisted surgical practitioners and the general public perceive a robotic device, like the *da Vinci* Surgical System, in an operating room. Our aim is to discover any relations between a persons'background, experience, and their perceptions of surgical robotics. Despite the exploratory nature of the current research, different specific aspects of robot-assisted surgery will be analyzed from survey results, including perceived post-operative recovery time, perceived length of the procedure itself, and perceived learning curves for achieving skilled status with the robot.

Previous Research

In order to better understand how individualsperceiverobot-assisted surgery, the project group investigated similar previously published literature. Few studies exist that coincide with any pertinent aspect of the current research study. Upon review of the existing research several factors regarding how individuals perceive surgical procedures arose: is it safe? What is the risk? What happens if the robot breaks? What will it cost? One particular study, entitled 'Robotic Prostatectomy: is it the Future?' by Thomas E. Ahlering MD, gives insight into the benefits of robot-assisted surgery and the volume-dependent costs associated with the new technology. These robotic devices require increased preparation time, and the surgical proceduresconsume more time than traditional laparoscopic surgery. Despite the increased preparation and surgical times, the recovery times and risks of complication appear to decrease. Ultimately, post-operative hospitalizationand associated costs are reduced.[iii] While this study was very telling as far as factual aspects of robot-assisted surgery are concerned, it did not delve into the softer features of robot-assisted surgery, such as social perceptions. For example, robot-assisted surgery often lengthens the actual surgical time in the operating room. Is the length of the surgery accurately perceived by people? If so, which populations?

Not everyone believes that robot-assisted surgery is the way of the future; somecritics believe that it is not a worthwhile investment. In a study performed at the Duke University Medical Center, researchers found that patients who had undergonerobot-assisted laparoscopic prostatectomy were most frequently dissatisfied with the procedure or left with feelings of regret. They propose that patients' preconceived expectations of this new surgical procedure were unrealistically higher than usual, thus they were left unsatisfied with the procedure.[iv]Researchers from the Guys and St. Thomas Hospital National Health Service Foundation Trust and Kings College London School of Medicine discovered the opposite, stating that patients were more satisfied with the treatment but that they requested more information on the procedure prior to treatment.[v]

Robot-assisted surgery, like laparoscopic surgery, is less invasive than open surgery reducingrecovery time whencompared toopen surgeries. In December 2005, The Journal of Urology published an article entitled Local Cost Structures and the Economics of Robot Assisted Radical Prostatectomy which analyzed the costs surrounding a common robotic assisted procedure. Researchers investigated the economics of robot-assisted prostatectomy and found that the costs associated with the technology are volume dependent. Their research examined how the cost of robot-assisted prostatecotmieswere economically advantageous when higher volumes of procedures were performed.[vi]

In order for a surgeon to perform surgery using a robotic device they must firstundergo extensive training. A group of Canadian researchers investigated the learning curve of robot-assisted surgery, or the time that it took a surgeon to stabilize operation time while using the *da Vinci* system. The researchers found the learning curve for performing benign gynecological procedures to be fifty operations at ninety-five minutes per operation.[vii] This assumes that the surgeon could proficiently perform the surgery with non-robotic tools. This research helped to better understand how many surgeries are necessary to become proficient using the system. Again, however, this research did not address how the learning curve is *perceived*. In addition to this, these research studies did not investigate how the nature of robot-assisted surgery is perceived by the public with regard to its comparative relationships with both laparoscopic and open surgery. Several of the interviewed doctors, including Dr. Hiep Nguyen of Children's Hospital Boston, actually commented on how robot-assisted surgery is actually more closely related to open surgery than to laparoscopic surgery.

Project Goals

The aim of this project were:

- to investigaterelations between a persons'background, experience, and their perceptions of surgical robotics by gathering data from three populations: Post-operative patients having undergone robot-assisted surgery, general public, and practitioners of robot-assisted surgery
- to analyzethe data from the responses
- to discuss the relationships found

Hypothesis

As exploratory research, this study was conducted primarily with the intent of discovering patterns and differences in opinions and feelings between the following surveyed populations: general public, patients having undergone robot-assisted surgery, and practitioners involved with robot-assisted surgery.

Our hypothesis was that differences exist between and within the surveyed populations regarding perceptions of robot-assisted surgery with regard to other factors. The corresponding null hypothesis was that the three populations under investigation will exhibit the same mean acceptance of RAS as one another. Despite the central exploratory nature of the current research, several additional specific hypotheses were evaluated:

a) For all three populations, an increase in comfort with technology would be coupled with an increase in acceptance of RAS.

b) Both the patient population and the practitioner population believe that RAS shortens the post-operative recovery time.

c) The RAS length of the learning curve as perceived by the patient population is higher than that of the practitioner population.

Methodology

Survey Development

Due to the apparent lack of research on the topic of perceptions of robot-assisted surgery, the research team identified qualitative hypotheses based on what quantitative research was available. In order to correctly test the hypotheses questions were developed. Initially, the questions started with identifying the subjects understanding and perception of robot-assisted surgery and determining how much they knew about it. It was crucial to learn who they thought was in control of the surgery, because robots are usually associated with artificial intelligence or autonomous actions. However, with the da Vinci system, the doctor has full control of the procedure and the surgical tools will not move without his input.

The research team then started to explore these preconceptions and possible causes of them. Influences such as one's familiarity and frequency of use of technology might affect how they perceive the system. The research team suspects that someone who uses a computer everyday (not only for work but also for leisure) might have a better level of comfort with and understanding of how the *da Vinci* system works than someone who rarely uses technology.

Once the possible influential factors were determined through experiences observing robot-assisted surgical procedures, interviews, and literature reviews, the group began to consider how these factors may also influence the subject's understanding of the impact of the procedure. From literature, the variables most heavily influenced by robot-assisted surgery appear to be recovery time and procedural length. Through the research team's continued research, it was deduced that other, less pursued differences might exist. For example, overall cost to the hospital was included. In addition to

cost, another variable influenced by robot-assisted surgery would be the learning curve associated with such a complex system.

The research team developed a set of survey questions and a corresponding set of responses for each question. It was vital that each answer set contained all possible answers and was easily compared to other data. We established that we would use a sequential answer key like a Likert scale, a set of answers that had increasing qualifiers. For example, when creating the answer key for the robot/practitioner control during an operation, the group thought it best to use “no control,” “minimal control,” “major control,” and “complete control.” This answer set is clearly in sequential order with a low risk of overlap between the answers. Because of this organized system of sequential possible responses, the research team could easily compare the data from a question to the data from any other question, as they would both be operating under the same system.

With the set of questions common to all three surveyed populations completed, we determined additional questions that were specific to each population. Each population would enter the survey with a different background and knowledge of the system from which we could gather additional information. For the practitioners, it might be practical to know when and why they would use robot-assisted surgery over traditional surgery. For patients, we incorporated questions regarding how they first learned of robot-assisted surgery and why they chose they chose it over traditional surgery. For the general population, we inquired if they would undergo robot-assisted surgery if it were an option and how often they thought it was used over traditional surgery. For the purposes of the current research, the intended definition of traditional surgery was laparoscopic surgery.

The research team was concerned that its own preconceived notions about robot-assisted surgery might influence how the questions were created and subsequently prime the answers of those who took the survey. To alleviate this, the group invited Dr. Laurie Fischer of Northeastern University in

Boston, MA to collaborate on the research project. Dr. Fisher is a psychologist who specializes in research methods. She helped to better understand the many facets of survey-based research studies. Through multiple meetings and multiple revisions to the surveys, Dr. Fischer guided the team in identifying and developing unbiased, effective wording for each survey question, along with appropriate response choices and proper validation of the survey questions.

Collaboration

In order to better understand the da Vinci system, the research team met with various doctors from nearby hospitals who are certified users of the da Vinci system. From these doctors, we hoped to gain knowledge of how the operations proceeded with this system as opposed to a laparoscopic surgery or an open surgery. They would also be able to help us with any research that they or a colleague of theirs had done that was similar to the current research. Furthermore, we planned on approaching them with the prospect of collaboration both on the revision of our surveys and the distribution of the post-operative patient survey.

Dr. Hiep Nguyen from the Children's Hospital in Boston, MA was the first doctor from which we sought collaboration and understanding. Dr. Nguyen offered to participate in the research study; offering not only to provide us with a source of patients' responses, but also to help obtain Internal Review Board approval from the Children's Hospital for the post-operative patient survey. He provided insight into the costs associated with the da Vinci surgical system, such as the hourly cost of operating room usage, disposable tool inserts, system maintenance, and initial costs. Over the next few months the group met with Dr. Nguyen several more times to help formulate survey questions, capable of eliciting valuable responses. Additionally, the research team observedseveral procedures using the da Vinci system and had the opportunity to operate the system.

To gain additional perspectives of the *da Vinci* system, the group met with Dr. Kethandapatti C. Balaji from UMass Memorial Hospital in Worcester, MA. Dr. Balaji helped to review our surveys and give feedback regarding currently held perceptions of robot-assisted surgery. He reaffirmed that there is minimal research regarding perceptions of surgical robotics.

Over the summer, we invited Dr. Poston from Boston Medical Center to collaborate on the research project. The research project was presented to the Boston Medical Center researchers working under Dr. Poston at the presentation, critiques of survey questions and feedback regarding research hypotheses were obtained. The research team was assisted by a fellow at Boston Medical Center to request IRB approval in order to obtain to Boston Medical's post-operative patient population.

Pam Sigel was the research group's corresponding collaborator from St. Vincent Hospital in Worcester, MA. She assisted with Institutional Review Board procedures and helped gather patient data. Study subjects were identified by having undergone a robot-assisted procedure at St. Vincent Hospital. Data was collected by retrospectively mailing a hardcopy of the survey and cover letter to the post-operative patients using their home address. The subjects had one month to complete and return the survey using the provided pre-paid envelope, ensuring patient anonymity. Once all data had been collected, Pam forwarded it to us for analysis.

Description of Surveys

The anonymous surveys consist of approximately twenty questions taking roughly ten minutes to complete. They are designed to quantify an individual's acceptance of robot-assisted surgery, perceived understanding of the technology, and its consequential impact. Following each question is either a sequential list of possible answers or a scale, each enabling the candidate's response to be quantifiably captured. The surveys will also gather information on a subject'ssocial-

economicbackground, familiarity and proficiency with modern technology, and an understanding of the robot-assisted system in order to better understand the cause of held perceptions.Although the surveys were created for each of these specific populations, they are designed to measure data that is comparable between the three populations. Exemption was granted from the WPI Institutional Review Board (IRB) before proceeding with distribution of any surveys (See Appendix C.2).

Modes of Data Collection

Patient Survey

Subjects for the post-operative patient survey were recruited from St. Vincent's Hospital while future subjects will be recruited from Children's Hospital Boston and Boston Medical Center. Recruitment methods for the post-operative patient survey consisted of identifying all eligible patients, those who have undergone a robot-assisted surgery who are also at least 18 years of age, from a database of existing patients. These patients' home addresses were used to mail the potential participant a hard copy of the post-operative patient survey and return envelope. If a patient agreed to participate in the study, they would complete the survey and return it to the participating hospital using the provided pre-addressed return envelope. This ensured that the surveys were collected anonymously. Upon receiving the survey results from the hospital correspondent, they were randomly assigned an identification number and their answers were electronically recorded. A total of seventy letters were sent through St. Vincent's Hospital's patient database. Of these seventy, we received thirty back, yielding a forty-three percent return rate. The team estimated that Children's Hospital Boston and Boston Medical Center patient populations wouldyield forty percent return rates.

Practitioner Survey

Subjects for the practitioner survey were randomly recruited by contacting an equal number of surgeons from each state. Surgeon contact information was obtained from Intuitive Surgical's website.[viii] Using the Intuitive website's "locate a surgeon" feature , surgeons were selected by state. All of the

surgeons on Intuitive's website are qualified for and have performed RAS, proving them eligible to participate in the practitioner survey. A quota of 15 per state was filled by selecting the first 15 surgeons listed per state. There is no specific order to how surgeons are listed on the surgeon-finder website. After being identified, surgeons were subsequently sent an email with a link to the online practitioner survey. Surgeons were asked to forward the survey to anyone else directly involved in their robot-assisted operating room. This includes surgeons, attendings, residents, fellows, and nurses. The team expected a return rate of approximately five percent. We received 29 practitioner responses, yielding a return rate of just under four percent. The survey and its responses were hosted and stored on www.surveymonkey.com.[ix] These online surveys are inherently anonymous, as only the IP address of the participant are visible.

General Population Survey

There were no eligibility requirements for the general population.However,two questions were added that served as filters for this survey. For the general population, the team pursued two simultaneousstrategies; surveys were both mailed out in hard copy to potential survey participants as well as posted online.The initial mailing group was a pilot group comprised offifty addresses. The addresses were selected from random listings in the phonebook, but only one address was selected per state. For each phonebook, we used a random number generator to select the page of the phonebook, and then we used a second random number generator to select which listing on that page to use. This pilot was sent out to estimate an expected return rate. The team initially estimated a return rate of ten percent. To ensure that candidates'participation were not influenced by monetary reasons, a pre-stamped pre-addressed return envelope was enclosed. From our pilot group of fifty, we received five letters back, confirming our return rate of approximatelyten percent and our decision to recruit further survey participants through mailings.

Using this ten percent return rate as an approximation, a sample size and corresponding mailing size were formulated. To achieve the desired sample size of greater than eighty returned surveys, a mailing size of one-thousand was selected. The research team searched for a means of generating a random address list of residential households across the country. Using www.leadsplease.com we issued one-thousand letters with business-reply envelopes of which sixty-three were returned (See Appendix A.1).

In addition to distributing general population surveys via mail, invitations to take the survey were posted on multiple websites and forums (listed in Appendix B). The survey, identical in nature to the mailed survey, was hosted on www.surveymonkey.com. These websites provided the research group with thirty-two more responses. Of the online and mailed surveys distributed, ninety-five were returned. As with the practitioner survey, the online responses for the general population were anonymous.

Statistical Analysis

Statistical analysis was performed using SPSS version 17. Data was manually transferred from the returned hard copy surveys to the statistical spreadsheet. Online surveys were downloaded from the hosting website and transferred into SPSS. Relationships between variables were tested with either the Tukey or Bonferroni Post-hoc tests for multiple comparisons. Statistically significant relationships were those with a p-valueof $\alpha \leq 0.05$. Perhaps for future studies a p-value of 0.01 would be more desirable, but due to such a small sample size with the current research, obtaining results with a certainty of 95% was more realistic. Survey questions were coded according to the following scheme: blank = illegitimate response, 0 = unanswered, 1 through n = scale options based on physical location left to right. Coded surveys are available in appendix A.

Results

We rejected the null hypothesis through comparison of data collected on questions that represented opinions and views regarding each population's perception of RAS. Specific results are shown below.

Acceptance of RAS vs. Level of Comfort

The general population's and patient population's acceptance of robot-assisted surgery (RAS) were measured in the survey with two different questions. For the patient population, this was measured by the question asking how willing they were to have RAS before their operation. For the general population, acceptance was measured by the question asking whether or not they would choose RAS over traditional surgery if both types were an option. Available responses to the acceptance question for the general population were 1 for yes, and 2 for no. For the patient population, responses ranged from 1 = unwilling to 5 = eager. For both population types, comfort was measured from the same question, which directly asked their level of comfort with technology. Patient responses were inverted and scaled to match the general and practitioner population responses. For the general population (M1= 1.00 SD1 = 0.00, M2= 1.30 SD2 = 0.48, M3= 1.41 SD3 = 0.50, M4= 1.26 SD4 = 0.48). For the patient population (M1= 1.38 SD1 = 0.18, M2= 1.30 SD2 = 0.11, M3= 1.23 SD3 = 0.14, M4= 1.25 SD4 = 0.14). For the practitioner population (M1= 0.00 SD1 = 0.00, M2= 0.00 SD2 = 0.00, M3= 1.36 SD3 = 0.51, M4= 1.40 SD4 = 0.51). The relationship between variables did not yield any statistically significant results at the $\alpha = 0.05$ level, although a trend is visible (see Graph 1). For the general population, as comfort levels rise on the x axis, acceptance of RAS seems to also rise. For the patient population, however, the data shows that as comfort with technology rises, acceptance of RAS seems to decrease.

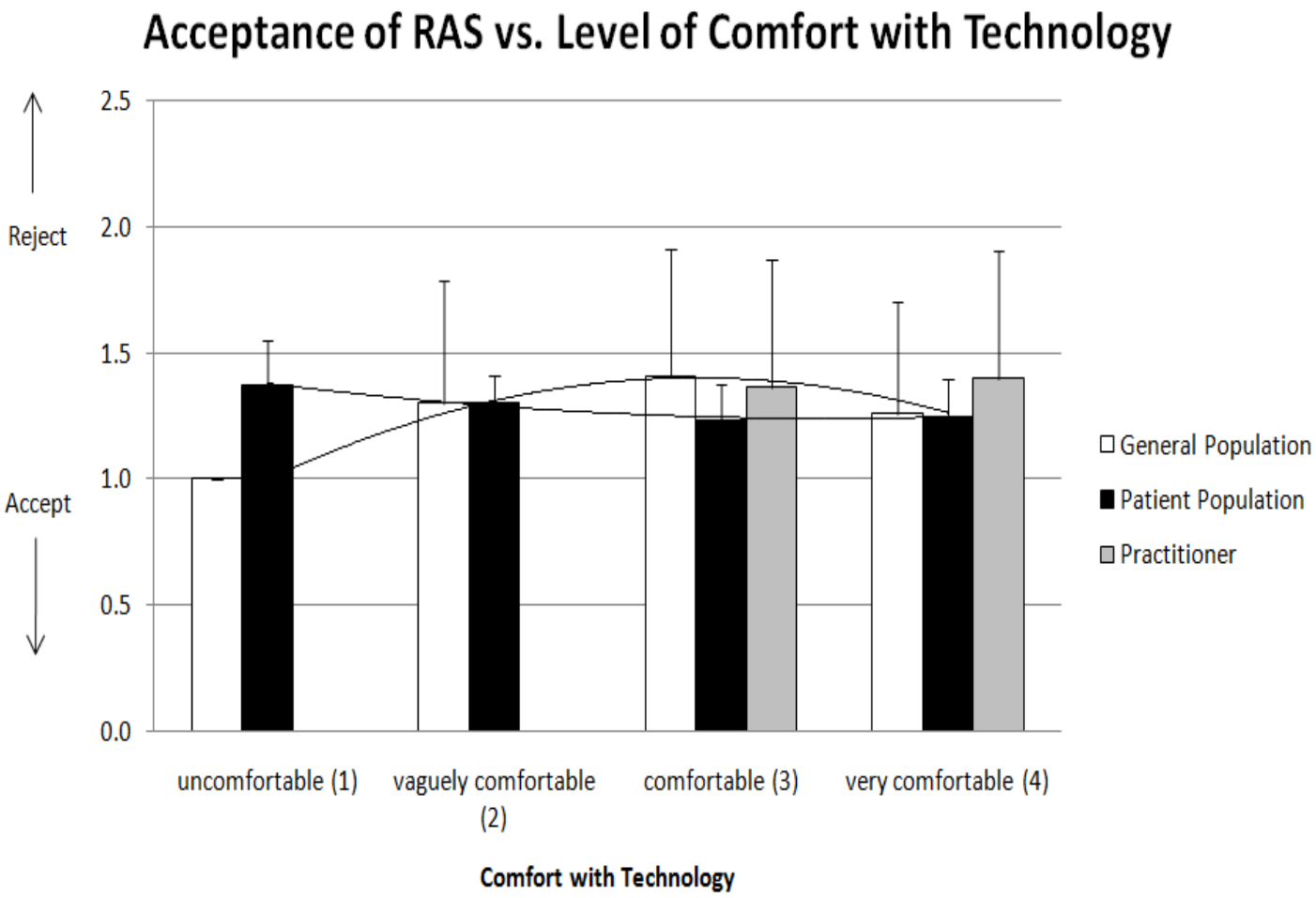

Figure 2 - Acceptance of RAS vs. Level of Comfort with Technology:

General: How would you categorize your comfort with current technology (i.e. computers, i-pods, cell phones)?
Acceptance: Would you choose robotic surgery over traditional surgery if both types were an option?

Patient: How would you categorize your comfort with current technology (i.e. computers, i-pods, cell phones)?
Acceptance: How willing were you to have robotic assisted surgery before your operation?

Acceptance of RAS vs. Perceived Level of Robot Control

Collected data was also able to illustrate a relationship between the general and patient population's acceptance of RAS with their perceived level of robot control. Both the general and patient populations were evaluated on their perception of the robot's control with the same survey question: What do you think the robot's involvement is in the control of robot-assisted surgery? The two population's acceptances of RAS were assessed with the same questions as in the graph measuring their acceptance of RAS versus their level of comfort. Available responses to the acceptance question for the general population were 1 for yes, and 2 for no. For the patient population, responses ranged from 1 = unwilling to 5 = eager. For the general population (M1= 1.46 SD1 = 0.52 N1 = 13, M2= 1.00 SD2 = 0.00 N2 = 3, M3= 1.41 SD3 = 0.50 N3 = 27, M4= 1.23 SD4 = 0.43 N4 = 31, M5= 1.20 SD5 = 0.45 N5 = 5). For the patient population (M1= 0.00 SD1 = 0.00 N1 = 0, M2= 1.25 SD2 = 0.13 N2 = 9, M3= 1.25 SD3 = 0.14 N3 = 13, M4= 1.30 SD4 = 0.11 N4 = 5, M5= 1.13 SD5 = 0.18 N5 = 2).This data was again not statistically significant at the p = 0.05 level, and did not produce any obvious trends. It appears as though there was no direct correlation with how well-accepted RAS was and perceived level of robot control.

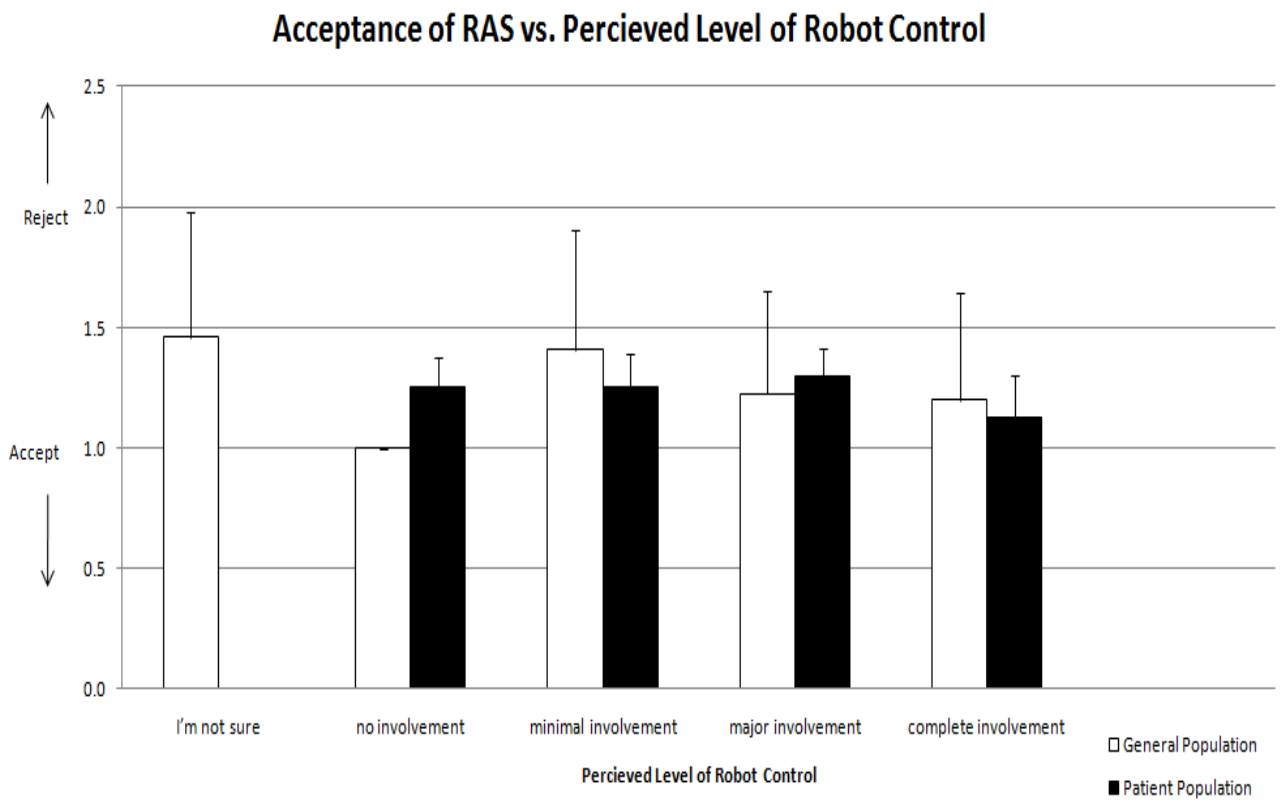

Figure 3 - Acceptance of RAS vs. Perceived Level of Robot Control:

General: What do you think the robot's involvement is in the control of robotic assisted surgery?
Acceptance: Would you choose robotic surgery over traditional surgery if both types were an option?

Patient: What do you think the robot's involvement is in the control of robotic assisted surgery?
Acceptance: How willing were you to have robotic assisted surgery before your operation?

Perceived Impact on Patient Recovery Time

Results obtained from survey questions that measured each of the three population's perceived impact of RAS on patient recovery time varied for each population. All combinations between patient and practitioner surveys (p = 0.000), patient and general population surveys (p = 0.037), and practitioner and general surveys (p = 0.000) show statistically significant differences. For Patients M = 2.25, SD = 1.11, N = 28. For Practitioners M = 3.90, SD = 0.85, N = 30. For the general population M = 2.79, SD = 1.00, N = 91. Practitioners seemed to believe more than any other surveyed population that RAS increases recovery time after surgery. The patient population believed that RAS decreases post-op recovery time. The general population seemed to believe that there was little to no impact on patient recovery time, remaining towards the middle of the survey choice selection with a mean answer averaging close to three, representing the perception that RAS has little to no impact on recovery time.

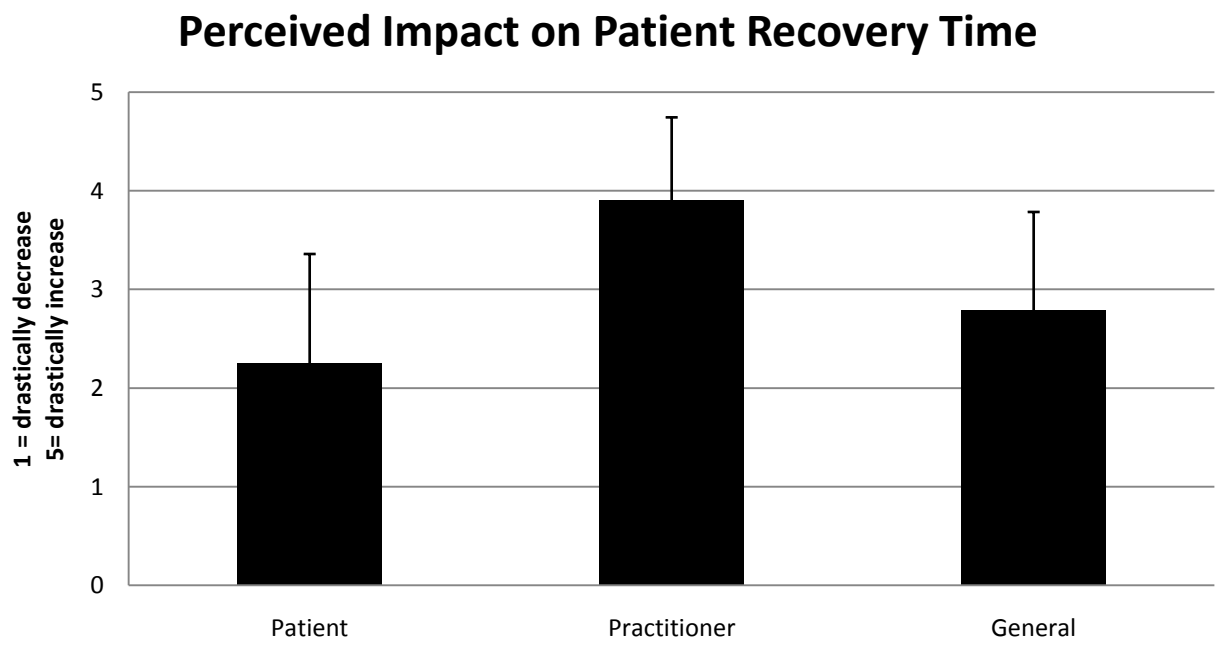

Figure 4 - Perceived Impact on Patient Recovery Time:

How do you think robotic surgery influences patient recovery time?

Perceived Impact on Length of Procedure

Data was also collected with regard to each of the three population's perceptions of the impact of RAS on the length of a surgical procedure. The practitioner survey responses are statistically different than both the patient and general population responses ($p = 0.002$ and $p = 0.000$, respectively). For Patients $M = 2.41$, $SD = 0.93$, $N = 27$. For Practitioners $M = 3.24$, $SD = 1.06$, $N = 29$. For the general population $M = 2.33$, $SD = 0.80$, $N = 89$. Results show that practitioners feel as though the use of robots during surgery slightly increases procedure time. The patient population and general population on average felt the same about the impact of RAS on the length of the surgery. Both groups felt that RAS slightly shortened the procedure's length.

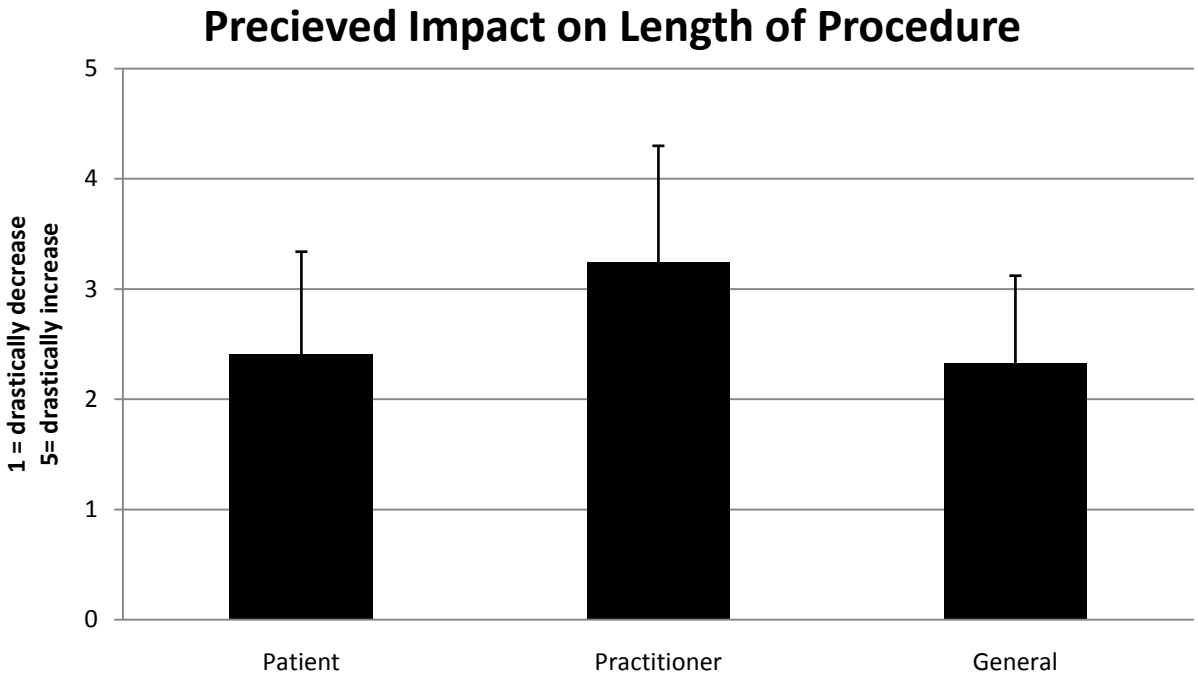

Figure 5 - Perceived Impact on Length of Procedure:

How do you think robotic surgery influenced the length of your procedure?

Perceived RAS Learning Curve

Means calculated from data regarding perceived RAS learning curves for each of the three populations were graphed. Patient and general populations have statistically significant differences ($p = 0.013$). For Patients $M = 5.14$, $SD = 1.24$, $N = 28$. For Practitioners $M = 4.59$, $SD = 1.27$, $N = 29$. For the general population $M = 4.25$, $SD = 1.51$, $N = 88$. Overall, all three populations seemed to lean towards the belief that there is a slightly high learning curve for RAS, requiring that surgeons perform a significant number of RAS operations before they become highly skilled. Surveyed patients felt that surgeons needed more practice before becoming highly skilled than participants of the other two surveyed populations. On average, the general population along with the practitioner population seemed to agree that the RAS learning curve was moderately high, though not as high as perceived by the patient population.

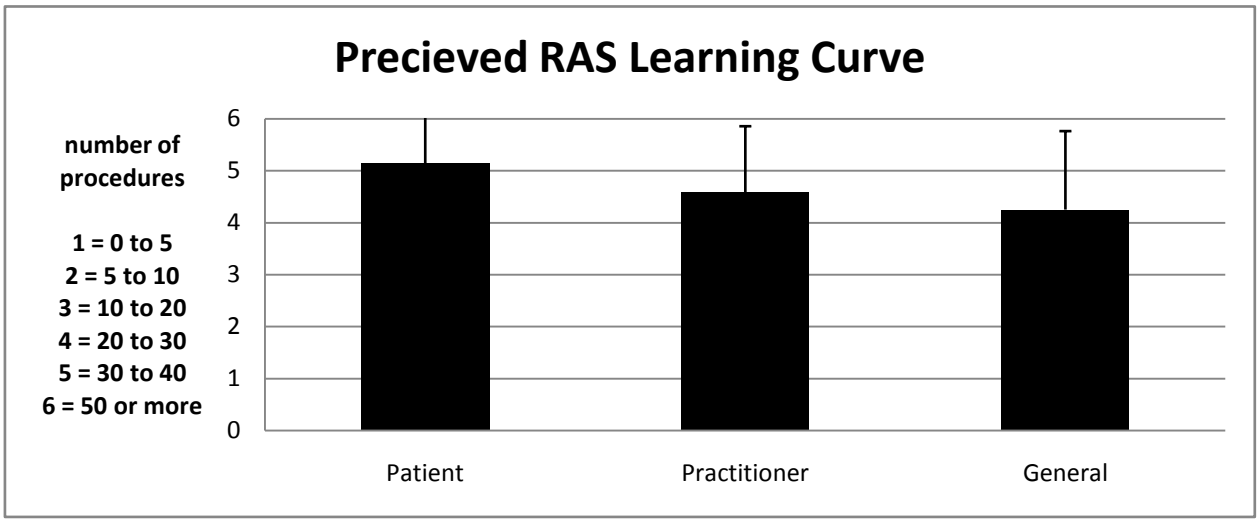

Figure 6 - Perceived RAS Learning Curve:

How many procedures do you think a surgeon needs to perform before they become highly skilled at robotic assisted surgery?

Discussion

The primary findings of this study successfully impart insight on the social perceptions of RAS, with a focus on three specific populations: general public, patient, and practitioner. Results obtained through analysis of collected data produced several focal points highlighting key differences among the populations.

One notable result was extracted from the data regarding the relationship between comfort with technology and acceptance of RAS for the general and patient populations. As the patient population's comfort with technology increased, its acceptance of RAS decreased. This result was unexpected. The general population fell in line more so with the expected relationships between these two variables, illustrating an increase in comfort with technology with an increase in acceptance of RAS.

Another unanticipated result appeared when determining the mean response for each of the three population's perceptions of the impact of RAS on surgery recovery time. The patient population illustrated an understanding that RAS decreases recovery time after surgery. Remarkably, the practitioner population demonstrated the belief that RAS actually lengthens recovery time. The research group expected the practitioner population to best understand RAS's impact on recovery time. Members of this population were the only ones with sufficient relevant experience regarding both the different procedures under question to make a knowledgeable comparison. Perhaps this unanticipated result is an artifact of the manner in which the survey question was asked.

The patient population exhibited the highest perceived RAS learning curve. This could be a result of their firsthand, intimate experience with RAS, having undergone the procedure and trusting it with their lives. It was anticipated that members of a population whose lives were put at risk for RAS would feel most strongly towards surgeons needing a significant amount of practice before being considered highly skilled. Also noteworthy, all three populations expressed the perception that leaned toward the

higher learning curve among the available survey question choices. No one group demonstrated the mindset that the RAS learning curve was significantly low relative to the choices presented.

One potential discrepancy among the surveys could have been the inadequately defined term, “traditional surgery.” The definition of this term was left open for interpretation by members across all three surveyed populations. A member from the general population could perceive traditional surgery as open surgery, whereas a member from the practitioner population may perceive the same term as referring to laparoscopic surgery. Having specified the intended meaning of this term (laparoscopic) could have circumvented inconsistencies among survey responses and made for a more valid comparison of each data set.

Future Work

Future research may help to unveil other patterns among the populations and measure perceptions regarding this growing surgical technology.The success of the technology and the extent to which it adds to the previous state of art are directly linked to how it is received by society. Negative feelings or skepticism could affect the incorporation of the technology into the field in a drastically different manner than positivity and complete acceptance could. That said, a close examination of patient and doctor perception is an important aspect of the technology. These perceptions are worth monitoring and analyzing as time passes and robot-assisted surgery becomes more prevalent in the surgical field.

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Appendix A - Surveys

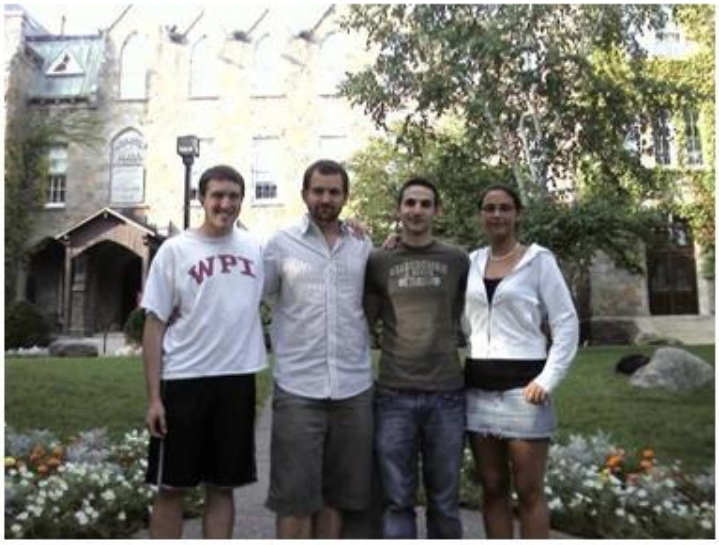
A.1 – General Population Cover Letter

Perceptions of Robot-Assisted Surgery

Dear %n,

As part of Worcester Polytechnic Institute's Interactive Qualifying Project, our research team is seeking to understand how people perceive robots used in surgical procedures. You have been selected to help our research team better understand your perception of these procedures (regardless of your exposure to the subject).

If you choose to participate in this study, you will be asked to complete the following short, anonymous survey and return it using the prepaid envelope when finished. The survey will take no more than 10 minutes to complete.



Thank you,

Demetrios Kechris Elan Pelletier Andrew Marchese Courtney Gilbert

A.2 – General Population Survey

General Survey

Age: _____

Please indicate your job title: _____

Country of origin: _____

Please indicate highest degree you have acquired:

[High School diploma]	[Master's Degree]	[J.D./Law]
[Associate's Degree]	[Ph.D/Doctoral Degree]	[M.B.A/Business]
[Bachelor's Degree]	[Post-Doctoral Degree]	[M.D./Medical]

On average, how many hours a week do you use computer technology (i.e. computers, i-pods, cell phones)?

[0 to 5] [6 to 11] [12 to 17] [18 to 23] [24 or more]

How would you categorize your comfort with current technology (i.e. computers, i-pods, cell phones)?

[uncomfortable] [vaguely comfortable] [comfortable] [very comfortable]

Regarding computers and technology, which of these categorizations best describes you?

[cannot use a computer] [start and access email/basic features] [use computers for leisure]
[troubleshoot and resolve problems] [write computer programs]

To the best of your ability, categorize your familiarity with robotic surgical systems.

[unfamiliar] [vaguely familiar] [familiar] [very familiar]

To the best of your ability, please categorize the role of a robotic system in robotic surgery.

[I'm not sure] [surgical hand utensil] [independently thinking surgeon] [pre-operative planning device]

To the best of your ability, please indicate the robotic system's control during robotic surgery.

[I'm not sure] [no control] [minimal control] [major control] [complete control]

To the best of your ability, please indicate the surgeon's control during robotic surgery.

[I'm not sure] [no control] [minimal control] [major control] [complete control]

To the best of your knowledge, how does the overall cost of robotic surgery compare to traditional treatment options?

[dramatically less] [less] [remains the same] [more] [dramatically more]

To the best of your knowledge, how does robotic surgery influence patient recovery time?

[dramatically decreases] [decreases] [remains the same] [increases] [dramatically increases]

To the best of your knowledge, how does robotic surgery influence the length of a typical operation?

[dramatically decreases] [decreases] [remains the same] [increases] [dramatically increases]

To the best of your knowledge, how does the learning curve of a surgeon changed when switching from traditional operating techniques to robotic surgery?

[dramatically decreases] [decreases] [remains the same] [increases] [dramatically increases]

How often do you think robotic surgery is used to replace traditional laparoscopic surgery, when both are viable treatment options?

[never] [infrequently] [frequently] [very frequently] [every time]

Would you choose to undergo robotic surgery if traditional operating methods were also suitable?

[yes] [no]

A.3 – Practitioner Survey

Robotic Surgery Practitioner Survey

Age: _____

Specialization: _____

Primary responsibility in OR: _____

Country of origin: _____

On average, how many hours a week do you use computer technology (i.e. computers, i-pods, cell phones)?

[0 to 5] [6 to 11] [12 to 17] [18 to 23] [24 or more]

How would you categorize your comfort with current technology (i.e. computers, i-pods, cell phones)?

[uncomfortable] [vaguely comfortable] [comfortable] [very comfortable]

Regarding computers and technology, which of these categorizations best describes you?

[cannot use a computer] [start and access email/basic features] [use computers for leisure]
[troubleshoot and resolve problems] [write computer programs]

To the best of your ability, categorize the time and effort you invest in discussing robotic assisted surgery (RAS) as a treatment option with each patient relative to laparoscopic surgery.

[much less] [less] [the same] [more] [much more]

To the best of your ability, categorize the time and effort you invest in discussing robotic assisted surgery (RAS) as a treatment option with each patient relative to open surgery.

[much less] [less] [the same] [more] [much more]

In your experience, how often is robotic assisted surgery (RAS) used to replace laparoscopic surgery, when both are viable treatment options?

[never] [infrequently] [frequently] [very frequently] [every time]

In your experience, how often is robotic assisted surgery (RAS) used to replace open surgery, when both are viable treatment options?

[never] [infrequently] [frequently] [very frequently] [every time]

To the best of your knowledge, how does the overall cost of robotic surgery compare to laparoscopic surgery?

[dramatically less] [less] [remains the same] [more] [dramatically more]

To the best of your knowledge, how does robotic surgery influence patient recovery time?

[dramatically decreases] [decreases] [remains the same] [increases] [dramatically increases]

To the best of your knowledge, how does robotic surgery influence the length of a typical operation?

[dramatically decreases] [decreases] [remains the same] [increases] [dramatically increases]

To the best of your knowledge, how does the learning curve of a surgeon changed when switching from traditional operating techniques to robotic surgery?

[dramatically decreases] [decreases] [remains the same] [increases] [dramatically increases]

Please rate the following factor's importance in choosing RAS as a treatment option?
(1 being unimportant, 5 being very important)

[ergonomics]	[1]	[2]	[3]	[4]	[5]
[patient recovery]	[1]	[2]	[3]	[4]	[5]
[patient demand]	[1]	[2]	[3]	[4]	[5]
[procedural time]	[1]	[2]	[3]	[4]	[5]
[hospital costs]	[1]	[2]	[3]	[4]	[5]
[reputation]	[1]	[2]	[3]	[4]	[5]
[state of the art]	[1]	[2]	[3]	[4]	[5]

In your experience, if RAS is chosen as a treatment method, of the following options what is the strongest motivating factor behind the decision?

[ergonomics] [patient recovery] [patient demand] [hospital costs]
[reputation] [state of the art]

To the best of your ability, please indicate the robotic system's control over an operative procedure.

[no control] [minimal control] [major control] [complete control]

To the best of your ability, please indicate a surgeon's control over a robotic assisted procedure (considering neither the procedure's effectiveness nor its outcome).

[no control] [minimal control] [major control] [complete control]

A.4 – Patient Post-Operative Survey

Age: _____

Please indicate your job title: _____

Country of origin: _____

Please indicate highest degree you have acquired:

[High School diploma]	[Master's Degree]	[J.D./Law]
[Associate's Degree]	[Ph.D/Doctoral Degree]	[M.B.A/Business]
[Bachelor's Degree]	[Post-Doctoral Degree]	[M.D./Medical]

On average, how many hours a week do you use computer technology (i.e. computers, i-pods, cell phones)?

[0 to 5] [6 to 11] [12 to 17] [18 to 23] [24 or more]

How would you categorize your comfort with current technology (i.e. computers, i-pods, cell phones)?

[uncomfortable] [vaguely comfortable] [comfortable] [very comfortable]

To the best of your ability, categorize your familiarity with the robotic surgical system prior to meeting with your physician.

[unfamiliar] [vaguely familiar] [familiar] [very familiar]

To the best of your ability, categorize your familiarity with the robotic surgical system just prior to your operative procedure.

[unfamiliar] [vaguely familiar] [familiar] [very familiar]

To the best of your ability, please categorize the role of the robotic system in the operating room.

[I'm not sure] [surgical hand utensil] [independently thinking surgeon] [pre-operative planning device]
[other: _____]

To the best of your ability, please indicate the robotic system's control over your operative procedure.

[I'm not sure] [no control] [minimal control] [major control] [complete control]

To the best of your ability, please indicate the surgeon's control over your operative procedure.

[I'm not sure] [no control] [minimal control] [major control] [complete control]

Please indicate who first suggested robotic assisted surgery as treatment option?

[I did] [family] [friends] [physicians] [advertisement] [other]

Did you research the robotic surgical system online?

[yes] [no]

How willing were you to undergo robotic assisted surgery prior to your operation?

[unwilling] [hesitant] [neutral] [willing] [eager]

To the best of your knowledge, how does the overall cost of robotic surgery compare to traditional treatment options?

[dramatically less] [less] [remains the same] [more] [dramatically more]

To the best of your knowledge, how does robotic surgery influence patient recovery time?

[dramatically decreases] [decreases] [remains the same] [increases] [dramatically increases]

To the best of your knowledge, how does robotic surgery influence the length of a typical operation?

[dramatically decreases] [decreases] [remains the same] [increases] [dramatically increases]

To the best of your knowledge, how does the learning curve of a surgeon changed when switching from traditional operating techniques to robotic surgery?

[dramatically decreases] [decreases] [remains the same] [increases] [dramatically increases]

Please rate the following factors' importance in choosing robotic assisted surgery as a treatment method?
(1 being unimportant, 5 being extremely important)

[recovery time]	[1]	[2]	[3]	[4]	[5]
[success rate]	[1]	[2]	[3]	[4]	[5]
[state of the art]	[1]	[2]	[3]	[4]	[5]
[procedural time]	[1]	[2]	[3]	[4]	[5]
[scaring/cosmetics]	[1]	[2]	[3]	[4]	[5]
[cost]	[1]	[2]	[3]	[4]	[5]

Appendix B - Forum Listings

active.com
topix.com
AskMen.com
bodybuilding.com
bodybuilding.net
modelcarsmag.com
workitmom.com
swimmingforums.com
usms.org
animecrazy.net
stoptazmo.com
anibd.net
runnersworld.com
coolrunning.com
hikingforums.net
backpacker.com
hikinghq.net
tennis.com
espn.com
footballforum.com
insidehoops.com
basketballforums.com
officiating.com
baseballforum.com
baseball-fever.com
talk-baseball.com
rivals.com
pianoworld.com
pianostreet.com
talkclassical.com
classicalmusicforums.com
rapmusic.com
automitoveforums.com
carforums.net
carsforums.com
cartalk.com
forums.about.com
autoforums.carjunky.com
batauto.com
hipforums.com
airliners.net
homebuiltairplanes.com
rcgroups.com
britmodeller.com

Appendix C - IRB

C.1 – Worcester Polytechnic Institute

WORCESTER POLYTECHNIC INSTITUTE
Institutional Review Board
Application for Approval to Use Human Subjects in Research

WPI IRB use only
IRB # _____
Date: _____

If your project has any federal sponsorship (e.g. federal funding), either prime or pass-through, the WPI IRB is not authorized to perform a review. Please contact Christina DeVries in Research Administration at (508) 831-6716 for direction to an appropriate IRB. DO NOT submit an application to the WPI IRB.

This application is for: *(Please check one)* ☒ Expedited Review ☐ Full Review

WPI IRB use only

Principal Investigator (PI) or Project Faculty Advisor: *(NOT a student or fellow; must be a WPI employee)*

Name: Gregory Fischer Tel No: 5088315261 E-Mail Address: gfischer@wpi.edu ☐

Department: Mechanical Engineering & Robotics Engineering

Co-Investigator(s): *(Co-PI(s)/non students)*

Name: Allen H. Hoffman Tel No: 5088315217 E-Mail Address: ahoffman@wpi.edu ☐

Name: Tel No: E-Mail Address: ☐

Student Investigator(s):

Name: Elan Pelletier Tel No: 9787660899 E-Mail Address: epelletier11@wpi.edu ☐

Name: Andrew Marchese Tel No: 9783393001 E-Mail Address: marchese@wpi.edu ☐

Check if: ☒ **Undergraduate project** *(MQP, IQP, Suff., other)* IQP

☐ **Graduate project** *(M.S. Ph.D., other)*

Has an IRB ever suspended or terminated a study of any investigator listed above?
No ☒ Yes ☐ *(Attach a summary of the event and resolution.)*

Vulnerable Populations: The proposed research will involve the following (Check all that apply):
pregnant women ☐ human fetuses ☐ neonates ☐ minors/children ☐ prisoners ☐
students ☒ individuals with mental disabilities ☐ individuals with physical disabilities ☐

Collaborating Institutions: *(Please list all collaborating Institutions.)*
Children's Hospital, Boston, MA

Locations of Research: *(If at WPI, please indicate where on campus. If off campus, please give details of locations.)*
WPI, Children's Hospital

Project Title: Perceptions of Robotic Surgery

Funding: *(If the research is funded, please enclose one copy of the research proposal or most recent draft with your application.)*

Funding Agency: N/A WPI Fund: N/A

Human Subjects Research: *(**All** study personnel having direct contact with subjects **must** take and pass a training course on human subjects research. There is a link to a web-based training course that can be accessed under the Training link on the IRB web site http://www.wpi.edu/Admin/Research/IRB/training.html. The IRB requires a copy of the completion certificate from the course or proof of an equivalent program.)*

Anticipated Dates of Research:

Start Date: 5/1/2009 Completion Date: 12/30/2009

WPI INSTITUTIONAL REVIEW BOARD
APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH
revised 12/11/2007
1 of 6

Instructions: Answer all questions. If you are asked to provide an explanation, please do so with adequate details. If needed, attach itemized replies. Any incomplete application will be returned.

1.) Purpose of Study: *(Please provide a concise statement of the background, nature and reasons for the proposed study. Insert below using non-technical language that can be understood by non-scientist members of the IRB.)*
To determine how both patients and doctors feel about the indroduction of robotic-assisted surgery to the field of medicine.

2.) Study Protocol: *(Please attach sufficient information for effective review by non-scientist members of the IRB. Define all abbreviations and use simple words. Unless justification is provided this part of the application must not exceed 5 pages. Attaching sections of a grant application is not an acceptable substitute.)*

A.) For **biomedical, engineering and related research**, please provide an outline of the actual experiments to be performed. Where applicable, provide a detailed description of the experimental devices or procedures to be used, detailed information on the exact dosages of drugs or chemicals to be used, total quantity of blood samples to be used, and descriptions of special diets.

B.) For applications in the **social sciences, management and other non-biomedical disciplines** please provide a detailed description of your proposed study. Where applicable, include copies of any questionnaires or standardized tests you plan to incorporate into your study. If your study involves interviews please submit an outline indicating the types of questions you will include.

C.) If the study involves **investigational drugs or investigational medical devices**, and the PI is obtaining an Investigational New Drug (IND) number or Investigational Device Exemption (IDE) number from the FDA, please provide details.

D.) Please note if any **hazardous materials** are being used in this study.

E.) Please note if any **special diets** are being used in this study.

3.) Subject Information:

A.) Please provide the exact number of subjects you plan to enroll in this study and describe your subject population. *(eg. WPI students, WPI staff, UMASS Medical patient, other)*

Males: 0-9999 Females: 0-9999 Description: We will take information from anyone willing to help us, the exact number of participants is something that we will have no control over.

B.) Will subjects who do not understand English be enrolled?
No ☒ Yes ☐ *(Please insert below the language(s) that will be translated on the consent form.)*

C.) Are there any circumstances under which your study population may feel coerced into participating in this study?
No ☒ Yes ☐ *(Please insert below a description of how you will assure your subjects do not feel coerced.)*

D.) Are the subjects at risk of harm if their participation in the study becomes known?
No ☒ Yes ☐ *(Please insert below a description of possible effects on your subjects.)*

E.) How will subjects be recruited for participation? *(Check all that apply.)*

☒ Referral: *(By whom)* Dr. Heip Nguyen
☐ Other: *(Identify)*
☐ Database: *(Describe how database populated)*

☒ Direct subject advertising, including: *(Please provide a copy of the proposed ad. All direct subject advertising must be approved by the WPI IRB prior to use.)*

☐ Newspaper	☐ Bulletin board
☐ Radio	☐ Flyers
☐ Television	☒ Letters
☒ Internet	☒ E-mail

F.) Have the subjects in the database agreed to be contacted for research projects? No ☐ Yes ☐ N/A ☒

G.) Are the subjects being paid for participating? *(Consider all types of reimbursement, ex. stipend, parking, travel.)*
No ☒ Yes ☐ *(Check all that apply.)* ☐ Cash ☐ Check ☐ Gift certificate ☐ Other:
Amount of compensation

4.) Informed Consent:

A.) Who will discuss the study with and obtain consent of prospective subjects? *(Check all that apply.)*
☒ Principal Investigator ☒ Co-Investigator(s) ☒ Student Investigator(s)

B.) Are you aware that subjects must read and sign and Informed Consent Form prior to conducting any study-related procedures and agree that all subjects will be consented prior to initiating study related procedures? No ☐ Yes ☒

C.) Are you aware that you must consent subjects using only the IRB-approved Informed Consent Form? No ☐ Yes ☒

D.) Will subjects be consented in a private room, not in a public space? No ☒ Yes ☐

E.) Do you agree to spend as much time as needed to thoroughly explain and respond to any subject's questions about the study, and allow them as much time as needed to consider their decision prior to enrolling them as subjects? No ☐ Yes ☒

F.) Do you agree that the person obtaining consent will explain the risks of the study, the subject's right to decide not to participate, and the subject's right to withdraw from the study at any time? No ☐ Yes ☒

G.) Do you agree to either 1.) retain signed copies of all informed consent agreements in a secure location for at least three years or 2.) supply copies of all signed informed consent agreements in .pdf format for retention by the IRB in electronic form? No ☐ Yes ☒

(If you answer No to any of the questions above, please provide an explanation.)
D.) Our study will be administered online and through Dr. Nguyen at the Children's Hospital. Both patients and doctors do not need to be in a private room when filling out their survey.

5.) Potential Risks: *(A risk is a potential harm that a reasonable person would consider important in deciding whether to participate in research. Risks can be categorized as physical, psychological, sociological, economic and legal, and include pain, stress, invasion of privacy, embarrassment or exposure of sensitive or confidential data. All potential risks and discomforts must be minimized to the greatest extent possible by using e.g. appropriate monitoring, safety devices and withdrawal of a subject if there is evidence of a specific adverse event.)*

A.) What are the risks / discomforts associated with each intervention or procedure in the study?
Patient confidentiality could potentially be at risk when asking them questions through a survey.

B.) What procedures will be in place to prevent / minimize potential risks or discomfort?

Our survey will make sure that we do not ask any questions that could potentially breach this confidentiality.

6.) Potential Benefits:

A.) What potential benefits other than payment may subjects receive from participating in the study?

Gratification in helping with our study

B.) What potential benefits can society expect from the study?

A better understanding of how both doctors and patients feel about robotic surgery

7.) Data Collection, Storage, and Confidentiality:

A.) How will data be collected?

Through internet surveys and interviews with doctors.

B.) Will a subject's voice, face or identifiable body features *(eg. tattoo, scar)* be recorded by audio or videotaping?
No ☒ Yes ☐ *(Explain the recording procedures you plan to follow.)*

C.) Will personal identifying information be recorded? No ☒ Yes ☐ *(If yes, explain how the identifying information will be protected. How will personal identifying information be coded and how will the code key be kept confidential?)*

D.) Where will the data be stored and how will it be secured?

Survey data will be stored with the medium in which we decide to deliver our survey (surveymonkey), and physical documents will be kept with one of the IQP members.

E.) What will happen to the data when the study is completed?

We will dispose of the raw data at the completion of the study.

F.) Can data acquired in the study adversely affect a subject's relationship with other individuals? *(i.e. employee-supervisor, student-teacher, family relationships)*

No

G.) Do you plan to use or disclose identifiable information outside of the investigation personnel?
No ☒ Yes ☐ *(Please explain.)*

H.) Do you plan to use or disclose identifiable information outside of WPI including non-WPI investigators?
No ☒ Yes ☐ *(Please explain.)*

8.) Deception: *(Investigators must not exclude information from a subject that a reasonable person would want to know in deciding whether to participate in a study.)*

Will the information about the research purpose and design be withheld from the subjects?

No ☒ Yes ☐ *(Please explain.)*

9.) Adverse effects: *(Serious or unexpected adverse reactions or injuries must be reported to the WPI IRB within 48 hours. Other adverse events should be reported within 10 working days.)*

What follow-up efforts will be made to detect any harm to subjects and how will the WPI IRB be kept informed?

There is no risk for serious or unexpected adverse reactions or injuries in our study.

10.) Informed consent: *(Documented informed consent must be obtained from all participants in studies that involve human subjects. You must use the templates available on the WPI IRB web-site to prepare these forms.* ***Informed consent forms must be included with this application.*** *Under certain circumstances the WPI IRB may waive the requirement for informed consent.)*

Investigator's Assurance:

I certify the information provided in this application is complete and correct.

I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the WPI IRB.

I agree to comply with all WPI policies, as well all federal, state and local laws on the protection of human subjects in research, including:

- ensuring the satisfactory completion of human subjects training.
- performing the study in accordance with the WPI IRB approved protocol.
- implementing study changes only after WPI IRB approval.
- obtaining informed consent from subjects using only the WPI IRB approved consent form.
- promptly reporting significant adverse effects to the WPI IRB.

Signature of Principal Investigator _____ Date _____

Print Full Name and Title _____

Please return a signed hard copy of this application to the WPI IRB c/o Research Administration.
If you have any questions, please call (508) 831-6716.

C.2 – Worcester Polytechnic Institute IRB Approval Letter

WPI

Department of
Social Science
and Policy Studies

100 Institute Road
Worcester, MA 01609-2280, USA
508-831-5296, Fax 508-831-5896
www.wpi.edu

11 May 2009
File: 2009-018

Worcester Polytechnic Institute
100 Institute Road
Worcester, MA 01609

Re: IRB Application for Exemption 2009-018: "Perceptions of Robotic Surgery"

Dear Professor Fischer,

The WPI Institutional Review Committee (IRB) has reviewed the materials submitted in regards to the above mentioned study and has determined that this research is exempt from further IRB review and supervision under 45 CFR 46.101(b)(2): "Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation."

This exemption covers any research and data collected under your protocol from 11 May 2009 until 10 May 2011, unless terminated sooner (in writing) by yourself or the WPI IRB. This approval becomes immediately null and void if this project receives any federal sponsorship and work on this study must cease until review and approval by New England IRB. Amendments or changes to the research that might alter this specific exemption must be submitted to the WPI IRB for review and may require a full IRB application in order for the research to continue.

Please contact the undersigned if you have any questions about the terms of this exemption.

Thank you for your cooperation with the WPI IRB.

Sincerely,

Kent Rissmiller
WPI IRB Chair

C.3 – St. Vincent Hospital

SAINT VINCENT HOSPITAL/FALLON CLINIC/FALLON COMMUNITY HEALTH PLAN/

RESEARCH REVIEW COMMITTEE/INSTITUTIONAL REVIEW BOARD

PROTOCOL SUMMARY SHEET FOR INVESTIGATIONS

INVOLVING HUMAN SUBJECTS

SECTION I

TITLE OF PROJECT:

Perceptions of Surgical Robotics

Project #: _____

Principal Investigator will ensure that (and sign below in agreement):

1) all staff with access to the PHI will abide by the following: "No PHI collected for this research study will be reused or disclosed to any other person or entity, except as required by law, or for authorized oversight of the research study";

2) all staff will read and abide by the Fallon Clinic "Conflict of Interest Policy"

SIGNATURES:

Principal Investigator: _____

Date:_____

SVH Or Fallon Liaison: _____
Date:_____ _____

(if not P.I.)

Study Personnel Information:

Principal Investigator (include institution /address/ and telephone number):

PI should be from St. Vincent; however if it is necessary for the PI to be from our institution below is the information:

Gregory S. Fischer (Worcester Polytechnic Institute/ 100 Institute Rd. Worcester, MA 01609 / (508) 831-5261)

Name of all other Fallon or Saint Vincent Hospital personnel involved in the study (i.e. physicians, nurses and other research staff):

Please fill-in as necessary.

SECTION I

(continued)

Will residents, fellows, students, and temporary staff be involved in the study: ___X
___ **YES** _____ NO

If yes, what functions will they be performing?

Undergraduate students will be involved in analyzing survey response once properly administered and received by St. Vincent Hospital personnel. ***(Note* we can also provide assistance mailing surveys if necessary)***

Who will be responsible for ensuring that they are all properly trained?

*Pamela Sigel****(please change if necessary and let us know what training may be required)***

PHI Status:

Will "protected health information" be removed from Fallon Clinic/Saint Vincent Hospital/ Fallon Community Health Plan? (only employees are allowed to do this) to facilitate subject recruitment for this study? No_X_ Yes_____ (If yes, you must complete the following).

List names of employees (and their departments) allowed to take PHI off premises:_____

Please note that only anonymous data will be collected. Accordingly, anonymous data will be passed along to a team of WPI undergraduate researchers for analysis. No patient identifying information is requested.

Description of Human Subjects:

Describe how subjects will be initially identified. How will they be contacted (letter, telephone, or in person) and by whom (and where, i.e., telephone interviewer from their home, physician, coordinator from Research Office…)?

Study subjects will be initially identified by the fact that they have undergone a robotic assisted procedure at St. Vincent Hospital. Data will be collected by retrospectively mailing a hardcopy of the survey and cover letter to post-operative patients using their home address. The subjects will have one

month to complete and return the survey using the provided pre-paid envelope. This ensures the surveys are returned anonymously to St. Vincent Hospital.

How many at our site _100_ **How many in total** _300_ **(nationwide) or** ____ **(worldwide)**

Ages : 18+

Source of patients:

____Fallon Clinic _____name of site

and/or

___X___Saint Vincent Hospital _(please indicate appropriate dept) dept.

and/or

_____clinic _____inpatient

_____other (please elaborate)

SECTION II

Patient Consent:

In order to use patient protected health information (PHI), staff must obtain a signed patient consent form with authorization (pre-approved by FC (Research Director) or SVH (CDRC)) attached, or receive a waiver by the IRB.

No PHI will be collected during this research. All data is collected anonymously.

If you will be using a consent form, please complete the following and proceed to Section III.

The survey contains a brief introduction page informing participants: if they choose to participate in this study, they may proceed to answering survey questions. More specifically:

"If you choose to participate in this study, you will be asked to complete a short survey by following the instructions below. The survey will take no more than 10 minutes to complete.

Participation in this study is voluntary, should you decide at any time, that you no longer want to participate simply discontinue the survey with no adverse effects. Participants are under no obligation to answer any question they do not feel comfortable with. Participants can be assured that any data they provide will be kept confidential and anonymous."

Name of person(s) allowed to obtain consent:

Consent will be obtained if the subject completes and returns the survey. Otherwise the survey is discarded by the subject.

Will subjects include minors? No_X_ Yes ___ (A SEPARATE ASSENT FORM MUST ALSO BE SUBMITTED)

Do you plan to obtain surrogate consent if patient is unable to give consent? No__X_ Yes ____ If yes; why do you feel it may be necessary to obtain surrogate consent/substituted judgment?

If you will be requesting a waiver of Patient Authorization, please check here ___X__ , and read the following:

Since there is no PHI, a waiver authorization may be applicable.

The eligibility criteria for a waiver are:

1) The research could not practicably be conducted without a waiver, and

2) The research could not practicably be conducted without access to and use of PHI.

3) The use and disclosure of PHI involves no more than minimal risk to the patient and privacy of individuals, based on, at least, the presence of the following elements:

i. An adequate plan to protect the identifiers from improper use and disclosure;

ii. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

iii. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, of for other research for which the use or disclosure of protected health information would be permitted

SECTION III (must be completed)

Patient Information:

1) Where will the data be RECORDED (data collection forms, case report forms, computer programs...)?

Initially, data will be self-reported by study subjects on the survey form. Once received by the WPI for analysis, data will be digitized and transferred into SPSS where it will be saved on a locked computer only accessible by research team members.

2) Please answer all of the following:

i)Where will patient's names and/or data be KEPT?

Neither patient names nor PHI will be kept. All hardcopies of the survey will be kept in a three ring binder, stored within a locked research laboratory. All results will be transferred to a file stored on a locked computer.

ii)Who has ACCESS to the names?

Data is only accessible by the research team.

iii)How will data be ENCODED? (patient names, code number, patient initials?)

Unique identifiers will be placed on each returned survey however there will be no references to identifying information.

iv) Will any information/data be requested from (or provided to) SVH Registry Services (Cancer Registry)? Yes___ No _x__

1) **If yes, elaborate:**_____

If human subjects cannot be identified either directly or indirectly through identifiers linked to subjects, research is automatically eligible for a waiver and you may skip to section IV. All others, continue;

Our research is eligible for a waiver.

iv)How will you protect the identifiers from improper use and disclosure and when will the identifiers be destroyed (must be the earliest opportunity)?

_____

_____

SECTION IV

(must be completed)

Background and purpose of the study (also explain the importance of this research)?

Specific Aim: This research aims to identify the current social perceptions of robotic assisted surgery held by the patient populations and to identify causal factors accounting for these perceptions.

Definitions: Perception: The way an individual qualitatively interprets/understands the new technology's existence, its intended purpose, and potential consequences both positive and negative.

Background: Three main surgical techniques exist in the medical field: open surgery, laparoscopic surgery, and robot-assisted (RAS). RAS is one of the most recent advances in minimally invasive medical technology. Previous studies show that RAS yields a short learning curve and possesses an assortment of advantageous improvements over both laparoscopic surgery and traditional open surgery. However, no innovative development in the medical field can reach its full potential until it is thoroughly understood by the public. As society's perception of RAS is better understood, subsequent action can be taken to promote a more uniform understanding of RAS.

Describe, in detail, the plan of investigation, procedures and methods. Include procedures and forms to be collected at each visit, who will be conducting visits, interviews and/or reviewing medical records.

Study Design: This study will consist of a brief, anonymous survey to RAS post-operative patients. Subjects for the patient survey will be recruited from several local hospitals including Children's Hospital Boston, Boston University Medical Center, and Saint Vincent Hospital.

Study Population: Eligibility requirements are as follows: must have undergone RAS and patients must be 18 years of age or older.

Subject Recruitment: Study subjects will be initially identified by the fact that they have undergone a robotic assisted procedure at the hospital. Data will be collected by retrospectively mailing a hardcopy of the surveyand cover letter (see attached) to post-operative patients using their home address. The subjects will have one month to complete and return the survey using the provided pre-paid envelope. This ensures the surveys are returned anonymously to the hospital.

Study Duration: Study subjects will have a 1 month period to complete the survey.

Analysis: Analysis of the data will be performed using statistical software, specifically Statistical Program for the Social Sciences (SPSS).

Please check off all types of PHI that will be collected:

___ Name

___Address (street address, city, county, zip code (more than 3 digits)

___Birth date

___Telephone number

___ Medical record number

___*Names of relatives (must list reason needed)

___*Names of employees

___*Fax Number

___*E-mail addresses

___*Social security number

___*Health plan beneficiary number account number

___*Certificate/license number

___*Any vehicle or device serial number

___*Web url

___*Internet protocol (IP) address

___*Finger or voice prints

___*Photographic images

___*Any other unique identifying number, characteristics, or code (whether generally available in the public realm or not)

***(must list reasons asterisked items are needed for study)**

_____

_____

SECTION IV (continued)

Estimated start date: *Monday, January 4th 2010*

Time required to complete study: *1 month after the approval and mailing of the survey.*

Will questionnaires be administered yes__X__ no_____(if yes, submit 5 copies of each).

Will billing information or data be abstracted from medical records yes_____ no __X____

(if yes, submit 5 copies of data collection sheet).

Will video or audiotapes be used yes ____ no__X___ if yes, submit 1 copy

Will there be advertising? Yes ____ no__X___

Please note that all advertising requires prior approval by the IRB. Fallon clinic advertising also needs approval by the communications department. Please list where advertising will be located (i.e., FC newsletter, postings at sites, Worcester telegram, radio…)

SECTION V

Inclusion criteria (include additional sheet, if necessary):

Eligibility requirements are as follows: patients must have undergone RAS and must be 18 years of age or older.

Exclusion criteria (include additional sheet if necessary):

See inclusion criteria.

SECTION VI

Risks and Benefits:

Outline potential risks to subjects and methods of management if damage occurs:

There is no risk associated with taking the survey, all questions are optional.

Outline potential benefit to subject and/or society in general:

RAS is a new technology in the medical field. This study will pioneer an investigation on perception of RAS from the post-operative patient perspective. To understand how this technology is impacting the medical field and the lives of patients, it is important to understand how the technology is perceived by groups of various backgrounds. Conclusions drawn after data analysis may narrow the focus for future research.

Will the patient receive information about the results of the experimental procedures?

No.

Will the patient's primary physician receive information about the results of the experimental procedures?

No.

Under what circumstances will a patient be removed from the study?

A patient will be removed from the study under the following circumstances:

1) *If the survey is not returned within one month of the mailing date.*
2) *A patient's response to a question will be removed if it is improperly filled out (i.e. two answers are provided instead of one).*

SECTION VII

Drugs:*This section does not apply*

If drugs are to be administered to subjects is the drug(s) approved by the FDA for this use?

no drugs will be administered

If not, please indicate phase of study and supply the IND number:

If medications are used in this trial, please explain the type of medication, its mechanism of action (if known) and how this action compares to those of the other drugs being studied as well as standard treatment.

DRUG NAMES

DOSES

DRUG SIDE EFFECTS % INCIDENCE

Where will drugs be stored? (Please note that mass DPH regulations stipulate all drugs must be kept in a locked cabinet. Controlled substances should be dispensed through the pharmacy and kept in double locked cabinet.)

Who will administer drugs?

SECTION VIII

Medical Devices: *This section does not apply*

1) Where will devices be stored?_____

A) Name Of Device_____ _____

B) FDA Approved? ____Yes ____No

C) If Not Approved: IDE#_____

D) ____Significant Risk Device ____Non-Significant Risk Device

(Please Include Supporting Materials From Sponsor & Any Correspondence With FDA)

E) How are the devices(s) obtained?

SECTION IX

(must be completed)

Funding & Support:

Source of funding: please include name of sponsor, and explain how this project will be supported.

This study will be internally supported by Saint Vincent Hospital. This support is to be determined in the near future and this field will be updated as necessary.

What clinic/hospital resources will be required to conduct the study?

none.

The mailing of the surveys to the study participants will be required.

Personnel (include nursing, clerical, medical record, pharmacy, MIS requirements & patient accounts/billing):

Please indicate as necessary

equipment:

supplies:

SECTION X (continued)

(must be completed)

This section does not apply

Who will be financially responsible for the following procedures/ office visits required for the study? Please be specific as to type and number of visit/tests(s). Please also indicate whether or not you consider these standard care.

for office visits?

there is no expense associated with this survey.

for medications and devices (list each individually)? Also, who pays if the insurer is billed but subsequently denies payment?

for medications and devices (list each individually) if the sponsor does not supply them?

for labs? (include number of blood & urine specimens and amount of blood to be drawn) (please indicate whether labs will be processed by PathLab or sent to a central lab).

for x-rays?

for ekgs and other tests? (identify other tests)

Will health care professionals receive finder's fees for referring patients to the study?

_

Will the patient be financially reimbursed for participation? If yes, elaborate.

FORM REVISED 2/11/08

mc