Performance Analysis and Safety Enhancement of Robot-Assisted Hysterectomy Procedures

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Abstract

Technological advances are embedded in multiple disciplines causing positive societal impacts particularly in healthcare delivery such as robotic applications. Patient community has become receptive to robot-assisted procedures, especially hysterectomies. While the number of robot-assisted hysterectomy procedures is increasing, there are still some safety concerns. The objective of this paper is to review the designs of robots used to assist in hysterectomies, analyze the performance and failures of robot-assisted systems, and propose recommendations for enhancing overall safety.

Hysterectomies are the second most common surgical procedure for women. Robot-assisted hysterectomies have yielded significant benefits to the patients and doctors, including less incisions, shorter operation times, quicker recoveries, and less probabilities of infections. Some reported failures in robot-assisted operations such as 4.5% in hysterectomies and 2.5% in general robot-assisted surgeries are clinically unacceptable and have raised safety concerns. Review and analysis of published literature and reported adverse events on robot-assisted hysterectomies highlight the associated safety concerns.

Based on review of articles published in medical journals, magazines, news-clips and the MAUDE database by FDA, the major failures of the robot-assisted systems and procedures are analyzed. Salient factors attributed to the failures are operator errors, lack of training, mechanical malfunctions, software glitches, lack of tactile feedback, etc. To achieve higher levels of safety, it is necessary to ensure that the clinical operations are carried out in strict conformance with good operating procedures, rigorous design reviews are conducted, thorough testing during subsequent phases to apply appropriate modifications are performed, comprehensive user training is provided, and robotic system performance is continuously refined.

Introduction

Technological advances are embedded in multiple disciplines causing positive societal impacts, particularly for healthcare robotic applications. Robot-assisted surgery has become a popular trend for technological advancements. . In 2009, 84,155 women were diagnosed with gynecological cancer within the United States and 27,813 cases were fatal. Cervical cancer, one of the five main gynecologic cancers, is the second leading cause of death among women in the United States and is a leading cause for surgical removal of the uterus is cervical cancer. Ovarian cancer, also one of the five main gynecologic cancers, is the eighth most common cancer and fifth leading cause of cancer related death. In 2009 ovarian cancer was the cause of death for 14,436 women in the United States [1]

Since 2000, more than 1 million robot assisted surgeries have been performed. The use of the robotic assisted surgery is becoming more widely used and accepted by the public. The number of procedures performed has drastically increased by more than 400% in the United States and 300% internationally between 2007 and 2011. Throughout the 1 million procedures, there have been 245 complications with 71 resulting in death. Gynecologic cases were reported to have the most complications; 22 of the 71 deaths were during a gynecologic procedure. Hysterectomy had an astonishing 43% of the injuries within the gynecological cases [2]. Safety has become an imminent concern for doctors when performing the robot assisted surgery. The objective of this paper is to review the designs of robots used to assist in hysterectomies, analyze the performance and failures of robot-assisted systems, and propose recommendations for enhancing overall safety.

Background

Hysterectomies may be performed on patients for various possible reasons. In addition to cancer, fibroids and endometriosis can also be treated by hysterectomies. A fibroid is a muscular, non-cancerous tumor that grows within the walls of the uterus. Cells within the uterus will repeatedly divide and create a firm mass that is individual from the surrounding tissue. A fibroid can alter or expand the uterus causing anemia from substantial blood loss. As far as treating uterine fibroids, hysterectomies are the only proven permanent solution. Endometriosis is an extremely painful condition in which the tissue that usually lines the inside of the uterus lines the outside of the uterus instead. The tissue acts as it normally would, breaking down and bleeding with each menstrual cycle. The tissue then has no way to be extorted from the body and becomes confined [3]. Although a hysterectomy is not entirely effective, it is the best treatment option.

Robotic technology has evolved to be accepted within today's society. Recently, robotics has made a breakthrough into the medical field and become a pressing new advancement in the operating room. Technology with robot assisted surgery is advancing at such a fast pace that the safety, training, and other precautions are being overlooked.

Before robotics were brought into the medical field, a traditional surgery included opening the patient up to get a clear visual of the operation at hand. This method of surgery is exceedingly invasive and generally takes an extensive amount of recovery time. As the medical field advanced, the surgery became less invasive. The long incisions that would usually exist in an open surgery became smaller, which reduces the risk of infection and drastically cuts down recovery time. With minimally invasive surgery, surgeons have an increased vision and precision.

Although minimally invasive surgery has many benefits over the traditional open surgery, there are still many disadvantages. Limitations become prominent with the technical nature of the equipment used. Because of the long surgical procedures, the tremors of the surgeons were translated through to the instrumentation. The limitations instigated engineers and doctors to develop a robot assisted surgery. The technology provides surgeons with a more precise surgery. The imagining used is far beyond what was available in the past. The minimally invasive robot assisted surgery compensates for hand tremors of surgeons and has improved dexterity.

Design and Methods

Surgical systems have many different configurations and designs. Figure 1 displays the setup of a characteristic operating room during a procedure assisted by a surgical robot. A surgical robot assistant, such as the da Vinci surgical system, has a particular design which consists of a patient side cart that includes four arms that perform operations following the surgeon's directions. The patient side cart is where the patient is positioned during the surgery. The four robotic arms move around fixed pivot points, reducing the trauma to the patient and increasing the overall precision. The patient side cart requires the direct control from the surgeon at the surgeon console. The surgeon is seated and views a high definition 3D image of the inside of the patient's body. Controls are naturally placed relative to the surgeon and they impeccably translate the surgeon's hand, wrist, and finger movements into real-time motion of the surgical instruments positioned on the four arms. Each robotic arm is equipped with instruments which provide seven degrees of motion, a wider range than the doctor's wrist. Each instrument attached to the arms has a specific medial task; clamping, suturing or tissue manipulation for example. Using the high-definition 3D endoscope and image processing system, real life images of the volumes of interest are provided on a widescreen view to the entire operating room team. This vision system allows the surgical assistants to have a broader perception and conception of the procedure.

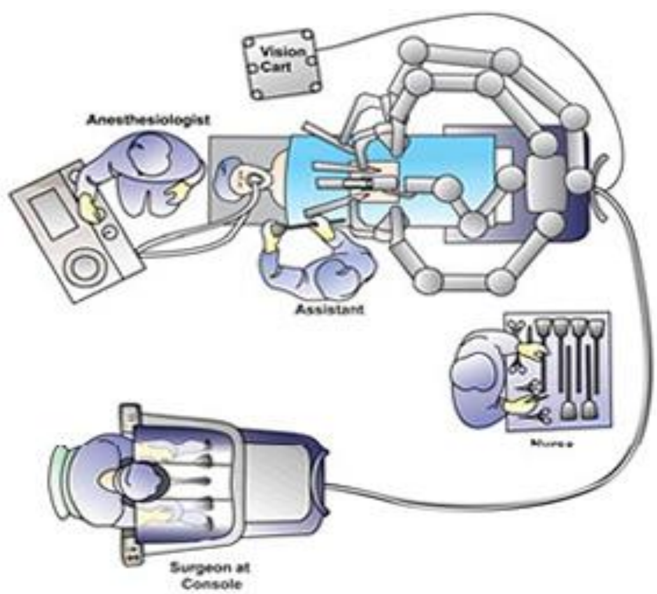


Figure 1: Operating room utilizing a surgical robot assistant setup (4)

Performance Analysis

Robot assisted hysterectomy provides several benefits to the patient, doctor, and the hospital. As a patient the robot assisted hysterectomy provides a safer surgical practice. The robotic assisted hysterectomy provides drastically less amount of blood loss during surgery. In one procedure performed with the assistance of a robot the patient lost a total of 100ml of blood. In comparison most patients who have open hysterectomies lost two to three times more blood [5]. The less blood lost during surgery alludes to less blood transfusions needing to be performed. The da Vinci surgical system provides doctors with a magnified 3-D, high-definition image which permits superior visualization of the uterus, other organs, and blood vessels involved in the surgery. Both of the wide angled cameras improve the surgeon's ability to identify tissue planes and nerves while performing surgery.

The pelvis of a female is such a confined space it is hard for the surgeon to view all aspects of it with the naked eye. Not only is it difficult to view the organs, blood vessels, and tissue of the female pelvis, it is challenging to maneuver instruments throughout the confined region of the body without limited dexterity, hindering the surgeon's ability to execute precise tasks without causing error within the procedure. The wristed instrumentation that is used in a robotic assisted surgery permits the surgeon to achieve exact instrument angle while eradicating the fulcrum effect; the surgeon's need to move their hand in the opposite direction to the intended location of the distal instrument tip [6]. The enhanced dexterity and control that is provided with the wristed instrumentation sanctions advanced, more gentle, tremor-free dissection, abstraction, or reconstruction of tissue.

Open hysterectomies require around a six to eight week recovery time for patients. Because of how minimally invasive the da Vinci hysterectomy procedure is, having only four dime-sized incisions, there is an immensely reduced recovery time for robot assisted hysterectomy patients. The average post-operative recovery for a patient after a da Vinci hysterectomy is around two to three weeks [7]. This is an average of a third less time for a patient to return to normal activities. The pain for the patient is dramatically reduced as well due to the reduced amount of manipulation of the incision sites with the da Vinci as compared to laparoscopic surgery. The reduction in manipulation of incision sites creates a safer procedure for the patient as well. Additionally, since the robot-assisted hysterectomy is a drastically less invasive procedure, the patient's body is not handled and put through as much stress as it would be forced to go through in a traditional hysterectomy.

The procedure is safer for both the patient and the doctor. The procedure is not as physically demanding for the surgeon, so the factors of fatigue and physical discomfort are eliminated. This extracts a main contributor to many surgical incidents that occur worldwide.

System Failures

Table I: Results of MAUDE Database Case Study

Date	Location	Re-admittance to ER	Factor Attributed to Failure	Description of 2nd Procedure
9/19/2013	N/A	Yes	Manufacture malfunction	Cytoscopy
11/30/2010	N/A	Yes	Manufacture malfunction	Cytoscopy
4/27/2012	N/A	Yes	Operator error	Diagnostic laparotomy
4/11/2013	N/A	No	Operator error	N/A
12/12/2012	N/A	Yes	Operator error	Implementation of double j stent
5/6/2013	N/A	Yes	Operator error/lack of tactile feedback	Infection dehiscence
11/11/2011	N/A	Yes	Operator error/lack of tactile feedback	N/A
6/21/2013	N/A	Yes	Operator error	Pelvic transvaginal ultrasound
4/16/2013	N/A	Yes	Operator error	Chemotherapy
2/9/2009	N/A	Yes	Operator error	Open laparotomy
2/27/2013	N/A	No	Manufacture malfunction/operator error	N/A
12/6/2012	N/A	No	Manufacture malfunction	N/A
12/6/2012	N/A	No	Manufacture malfunction/operator error	N/A
12/12/2012	N/A	No	Manufacture malfunction	N/A
12/17/2010	N/A	Yes	Manufacture malfunction/operator error	Several procedures
12/12/2012	N/A	No	Manufacture malfunction/software glitch	N/A
1/4/2013	N/A	Yes	Operator error/lack of tactile feedback	Laparoscopic hysterectomy
12/19/2012	N/A	Yes	Operator error/lack of tactile feedback	Several procedures
2/12/2013	N/A	Yes	Operator error	Laparoscopic hysterectomy
2/26/2013	N/A	Yes	Operator error	Diagnostic laparotomy
5/23/2013	N/A	No	Software glitch	N/A
7/17/2013	N/A	No	Manufacture malfunction/software glitch	N/A
2/17/2013	N/A	Yes	Operator error/lack of tactile feedback	Proctoscopy and diagnostic laparotomy
7/31/2013	N/A	Yes	Operator error/lack of tactile feedback	Bilateral retrograde pyelogram
3/8/2010	N/A	Yes	Operator error/lack of tactile feedback	Robot-assisted laparoscopic ureteral re-implantment

The failures of the robot-assisted hysterectomy procedures are separated into four main categories; manufacture malfunctions, operator errors, software glitches, and lack of tactile feedback. The most common factor that attributed to a reported failure is operator error. An example of this failure is a surgeon mistakenly removing the right ovary or even severing the bladder by mistake. This can be directly accredited to a lack of training. The doctors are not able to have enough practice with the da Vinci machines before they are expected to perform complex and challenging procedures. The surgeons need ample amounts of training, similar to the time given to mastering and perfecting traditional forms of surgery. Because of this inability, operator error becomes the most common category of failure.

Due to deficiencies in design, malfunctions pose grave concern to patients and doctors. The system has four separate robotic arms which at times can malfunction and not correctly follow the surgeon's instructions. Because the surgeries are exceptionally precise, any small malfunction can cause internal damage. Malfunctions due to design deficiency have been seen in surgery through the bipolar energy device catching fire, the surgeon being unable to control the forceps, and the ECM cannula mount breaking.

The third component that contributes to failures in robot-assisted hysterectomy is software glitches. The software involved in the da Vinci surgical system is particularly complex. Communication between the interface of the patient side cart and surgeon console causes most of the software glitches. Software glitches can cause currents in the surgeon's console to be activated without being pressed and system errors to occur. The four components have direct correlation to the reported failures of the robot-assisted hysterectomy. The absence of tactile feedback plays a major role in the reported failures. It is a major drawback to the da Vinci system to not have the sense of touch. Without tactile feedback the surgeon is unable to know if contact has been made to internal components, making the surgery more challenging as a result. The surgeon is more apt to make incisions too deep and create unintended complications during the procedure. Examples of this failure in surgery are damage to the uterus, severing the bladder, and injuring the vaginal cuff. [8, 9, 10]

A case study was performed using the MAUDE database to get a closer look at 25 cases from 2009 to 2013 as seen in Table I. Each failure during the robot-assisted hysterectomy procedure was attributed to one or more of the four factors related to system failure. The distribution of the factors of failure are displayed in Figure 2. Operator error was accredited to about 50% of the error. Absence of tactile feedback, manufacture malfunctions, and system errors were divided among the remaining 50%.

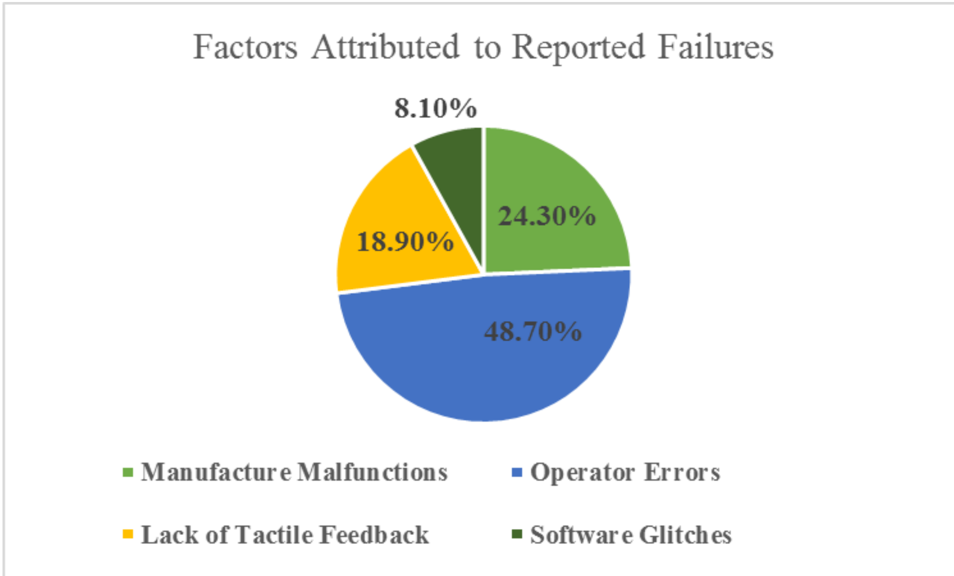
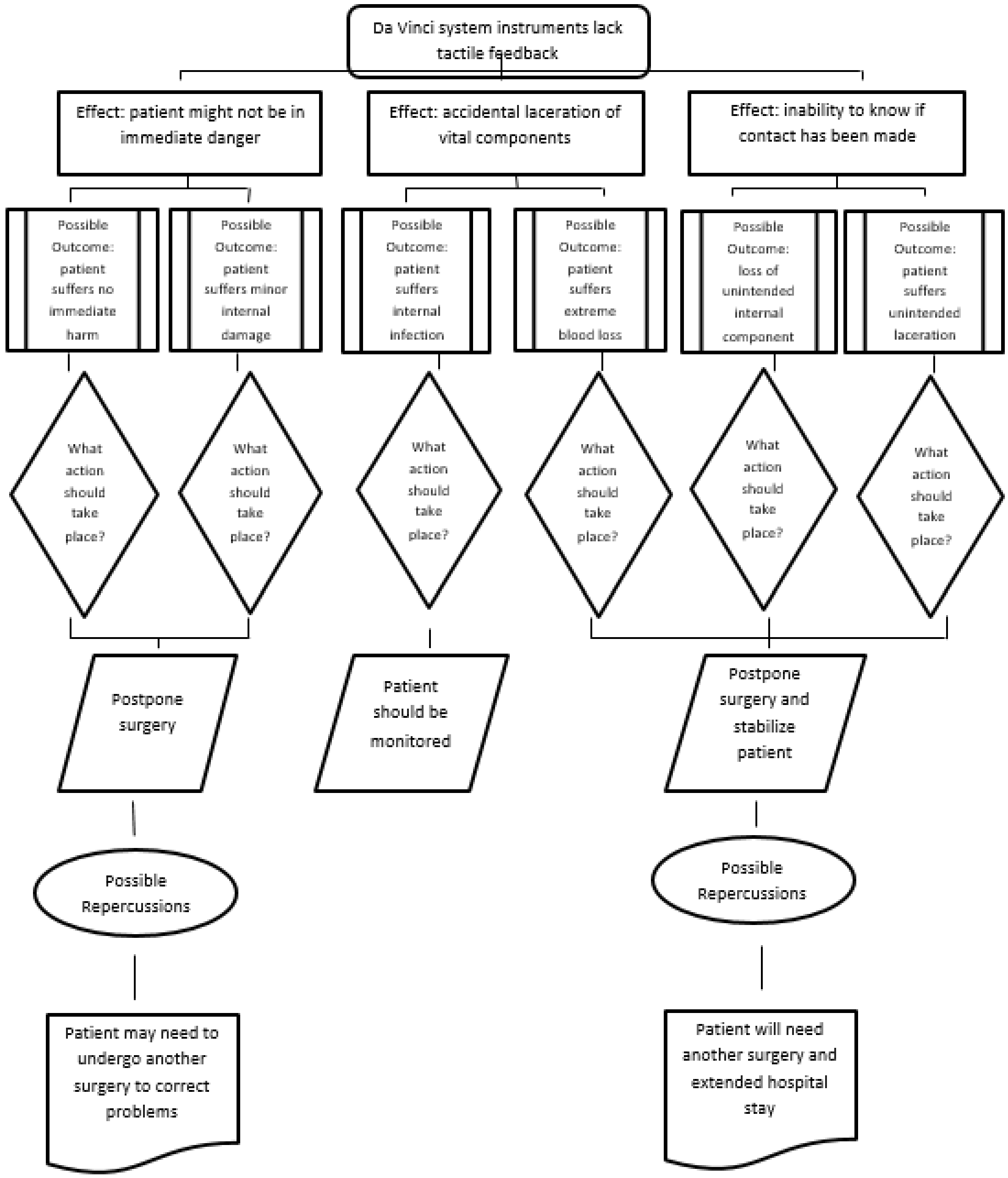


Figure 2: Graph of Factors Attributed to Reported Failures

Failure Analysis

Table II: Failure Modes Effect Analysis of Da Vinci Surgical System



A high source of failure for the robot-assisted hysterectomy procedure is the lack of tactile feedback. There are three plausible results that could come out of this failure: patient might not be in immediate danger, accidental laceration of vital component, and inability to know if contact has been made. In the first result, patient might not be in immediate danger, two outcomes could exist, patient suffers no immediate harm and patient suffers minor internal damage. In both cases the surgery should be postponed. There is the possibility that the patient may need to undergo another surgery to correct the original problems. If another surgery was necessary it would cost the hospital unneeded costs and create the risk for the surgeon and hospital of legal involvement.

The second result, accidental laceration of a vital component also has two outcomes. The first possible outcome is that the patient suffers an internal infection. The patient would then need to be monitored until they return to stability. The other outcome is that the patient suffers extreme blood loss. This outcome ties directly into the outcomes of the third result. The third result is the inability to know if contact has been made with tissue. The outcomes of this are the loss of an unintended internal component and the patient suffers unintended laceration. All three outcomes would require the surgery to be postponed and immediate stabilization of the patient. There would be repercussions of a possible other surgery and an extended hospital stay. These repercussion would also result in the hospital losing money and the hospital and surgeon risking the possibility of legal involvement.

Recommendations

Robot-assisted hysterectomy and robot surgery as a whole is a growing area of medicine. In order for the robot-assisted hysterectomy become a common and accepted procedure improvements to the safety have to be obtained. Providing a greater and more intensive training program for the surgeons using the da Vinci surgical system would allow the surgeons to be much more comfortable with the procedure. The level of comfort that the surgeons has with a procedure can have a direct correlation with the level at which the surgery is performed. A longer and interactive training with ample opportunities to experience every aspect of the procedure multiple times would benefit the surgeon, patient, and hospital. It seems logical to assume that the company has been actively involved in making modifications to the robot system to aviate the problems to ensure safety efficiency.

The lack of tactile feedback plays a major role in the high failure rate. To adjust for this, sensors should be placed on the end of the four robotic arms that warn the surgeon at the surgeon's console that they are approaching tissue. A prominent concern for both the critics and surgeons is the ability to feel. Without any means of force feedback the surgeon relies solely on vision to approximate the tension, for example by looking at the stretch of a suture. Feedback is an issue from both the doctor performing surgery and the robotic system itself. With the addition of the sensors, the robotic system is able to relay some force feedback sensations throughout the procedure, allowing the surgeon to feel material inside the patient. The force feedback is able to provide a viable alternate for tactile sensation. With advances in microelectromechanical systems and nanotechnology as well as materials it is possible to have sensors printed on the robotic claw in order to have information on the pressure and other characteristics to the surgeon performing the operation This advancement is not available for clinical use at the present time. A lot of work needs to be done followed by validation for haptic feedback clinical trials to take place. It is expected to be included in the present system in a few years.

Many advancements and future application of robot-assisted gynecological procedures can be made. The same technology used in robot-assisted hysterectomy can be used to create robot-assisted caesarean section. Creating a systematic and more precise form of caesarean section could save lives and allow mothers to recover at a much quicker rate.

Another application of the technology used in robot-assisted hysterectomy can be applied in military scenarios. A mobile robot with the same capabilities and tactile components of the robot-assisted hysterectomy device can go onto the battle field and get a soldier to stability without risking the lives of other military professionals. This idea could also be applied to any natural or terror disasters, for example the Boston marathon tragedy. In a time of chaos and confusion it would be beneficial to everyone involved to have a robot that can go into unsafe conditions under the control of a doctor, located at an alternate location, and stabilize and save victims lives by returning them to safety.

Conclusion

Robot-assisted hysterectomy has become a common application of robot-assisted surgery. The procedure has allowed surgeons to create a less invasive, more stable, and safer surgical environment while still providing an acceptable level of care. Improving the safety of robot-assisted hysterectomy through adding tactile feedback, performing rigorous design reviews, thorough testing of the robot-assisted system with phantoms, giving surgeons more training, and putting greater of a focus on fault prevention of gynecological procedures will result in greater safety and success rate of an advanced procedure and a more accepting patient community resulting in positive outcomes.

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