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Design and Development of a Robotic Surgery Device and a Medical Simulator

by

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To Fabio: a perfect example of Love

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Abstract

The research theme of this investigation is driven by a strong clinical need for new and improved technology to help the modern surgeon. Since the beginning of the 21st century, the emergence of innovative technologies made further advances in minimal access surgery possible.

Surgical techniques have evolved rapidly, for example the introduction of minimally invasive surgery (MIS) and robotically-assisted MIS which have improved outcomes for patients with faster recovery, reduced post-operative pain and fewer scars. For such a reason, there is an increasing need to develop innovative engineering solutions to some of the challenges being faced as surgery evolves to help surgeons to achieve the best possible clinical outcome and also to develop solutions helping to reduce costs and improve quality. As a matter of fact, robotic surgery and medical simulator addressed the limitations of medical procedures, thus revolutionizing minimal access surgery.

First of all, with the introduction of robotics in the operating room, an evolutionary stage in the development of surgical technique was achieved to enhance the control and the visual field of the surgeon. It can be stated that this new approach was patient oriented as it brings several critical advantages for him: damage to healthy tissue is minimal; patients hospitalization is reduced to an average of 1.2 days; psychological impact of the procedure upon the patient is significantly lower; the risk of an unwanted infection is almost zero; using robotic systems the precision of the intervention is below one hundred of a millimetre; the risk of unwanted cuts (vessel sectioning, nerve damage, etc.) is minimal; the number of assistants in the operation room is reduced; 3D visual feedback.

Second, training with a surgical simulator offers several advantages. It is simi-

lar to a wet laboratory, human cost in the form of adverse outcomes for patients is minimized, and residents can practice in a relaxed learning environment at their own pace. Additionally, training on surgical simulators can be incorporated into a curriculum that is available to residents at any time.

Furthermore, the development of physical and cognitive surgical simulators offers an approach for learning which is different from the traditional apprenticeship model. Simulators cannot replace experienced surgical preceptors, but they are fast becoming an attractive and acceptable adjunct in surgical curricula. As the technology improves, the simulations will become more realistic, and the experience will become more valuable. Simulation programs will play a greater role in future surgical education.

For what concerns improving patient care and providing technology for healthcare professionals, there are many limitations and obstacles to overcome, before robotic surgery systems and medical simulators being able to be integrated into the medical field.

Motivated by the above observations, the goal of this research is to develop a new manipulator in order to improve such electromecanical limitation of the current surgery robotic systems and also to build a new surgery simulator to address some obstacles when doing some open surgery performances.

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Chapter 1

Introduction

1.1 Background: research motivation

Advances in surgery have focused on minimizing the invasiveness of surgical procedures, such that a significant paradigm shift has occurred for some procedures in which surgeons no longer directly touch or see the structures on which they operate. Advancements in video imaging, endoscope technology and instrumentation have made possible to convert many procedures in many surgical specialties from open surgeries to endoscopic ones. The use of computers and robotics promises to facilitate complex endoscopic procedures by virtue of voice control over the networked operating room, enhancement of dexterity to facilitate microscale operations, and development of simulator trainers to enhance the ability to learn new complex operations.

Robotic surgery and medical simulators have dramatically changed the procedures for the better and have much in common: both use a mechanized interface that provides visual patient reactions in response to the actions of the health care professional (although simulation also includes touch feedback); both use monitors to visualize the progression of the procedure; last, both use computer software applications through which the health care professional interacts. Both technologies are experiencing rapid adoption and are viewed as modalities that allow physicians to perform increasingly complex minimally invasive procedures while enhancing patient safety.

A review of the literature and industry developments allows us to conclude that medical simulators can be useful tools in determining a physicians understanding and use of best practices, management of patient complications, appropriate use of instruments and tools, and overall competence in performing procedures. Future use of these systems depends on their impact on patient safety, procedure completion time and cost efficiency. With that said, the sooner simulation training can be used to support developing technologies and procedures in order to get better results [1].

1.2 Problem Statement

Several medical simulators and surgery robotic systems have been developed for surgical operations. It is important to note that the various simulators available and surgical robots are still quite incomplete.

For instance, currently there are no surgical simulators designed for practing the technique necessary to perform an emergency cricothyrotomy with the following features:

– Usable in any part of the world

– Giving a good realtime feedback of surgeon performances

Moreover, there are no lighted manipulators helping the doctor to complete the robotic hysterectomy procedure using the Da Vinci robot.

Taking into account the observations listed above and being aware of research and innovation play a vital role in robotic surgery (for instance, medical simulators enhance the capabilities of surgeons performing open surgery and address the electromechanical limitations of current robotic systems), some solutions are developed in this research.

More in details, this thesis presents the advancement of a new low-cost simulator of the cricothyrotomy procedure and a new surgical uterine manipulator in order to address the above-mentioned problems. In particular, we present in this thesis:

An example to improve the open surgery performances:

- Cricothyrotomy simulator for procedural skill training: best choice in low resource environments

An example to address the electromechanical limitations:

- Lighted Uterine Manipulator

1.3 Contributions

The major contributions of this research are summarized below.

- Simulator for surgical training. A new low-cost, easily reproducible, cricothyrotomy simulator is designed and built.

- Method for measuring surgical performances. An innovative method of data collection for a good performance evaluation is developed and experimentally verified.

- Innovative method to assess competence. A new cheaper alternative in the assessment of surgical skills was designed and developed.

- Manipulator for use in hysterectomy procedures. A Lighted uterine manipulator is designed and built in order to improve patient safety.

1.4 Outline

This dissertation is organized in the following manner:

- The reminder of this chapter (1) introduces and illustrates the importance to develop innovative engineering solutions overcoming some limitations of the current surgical technologies: medical simulators and robotic surgical devices. Consequently an innovative surgical simulator and manipulator for robotic surgery are developed.

  Chapter 2 describes the state of the art in both contexts listed above and their current problems. Chapter 3 provides and discusses the method used to improve currently limitations and describes the innovations introduced. In Chapter 4 the analysis methods and the experimental results is discussed.

Finally, Chapter 5 makes the conclusions of the developed work and outlines possible future improvements.

Chapter 2

Background to the research problem: literature review

2.1 Introduction

Many trauma related surgical procedures cannot ethically be practiced by medical students or inexperienced doctors. Therefore, medical simulators that provide high anatomical and procedural fidelity are used. A very important specific procedure belonging to this category is:

- *Cricothyrotomy*, in which an emergency incision through the skin and cricothyroid membrane is made to secure a patient's airway during certain emergency situations, such as an airway obstructed by a foreign object or swelling and a patient who is not able to breathe adequately on his own [2], [3].

Moreover, the use of robotics is dramatically changing medicine. In the last years there has been a significant shift towards the robotic approach as the ergonomics and visualization of the robot offer significant advantages particularly when operating in the pelvis and when performing challenging procedures like:

- *Hysterectomy*, an operation to remove a women's uterus; different portions of the uterus, as well as other organs, may be removed at the same time [4].

2.2 Cricothyrotomy: anatomy and standard method

Cricothyrotomy is a critical procedure in emergency airway management and it remains one of the most important skills of the emergency physician. Many techniques of cricothyrotomy have been described in the literature. The accepted standard is an open technique that involves the use of a midline vertical incision, a dilator to open this incision, and the insertion of a tracheostomy tube [5], [6].

In particular, this procedure provides a temporary emergency airway making a cut in what is known as the cricothyroid membrane (Fig. 2.1), which is situated underneath the thyroid cartilage, or Adam's apple, and inserting a tube through the incision [7], [8], [9], (Fig. 2.2).

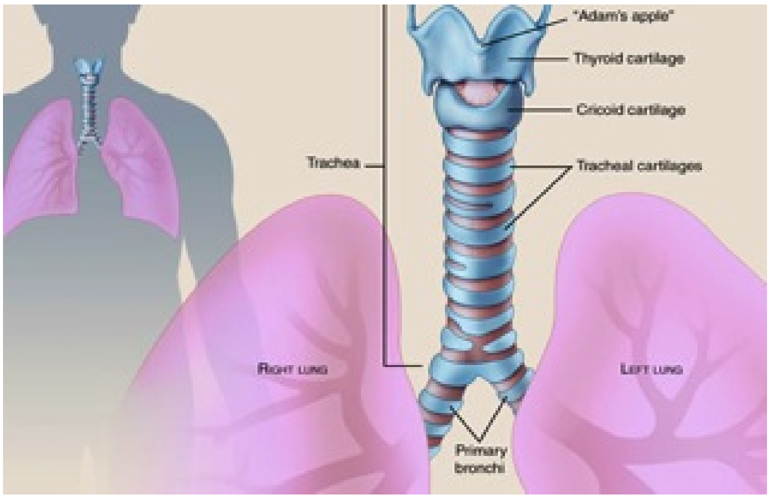


Figure 2.1: Thyroid anatomy

Cricothyrotomy may be carried out when there is a blockage higher up in the airway which is causing choking and preventing breathing [10]. In a life-threatening situation, a trained medical professional can use the technique to enable air to reach the lungs, keeping the person alive until admission to the hospital.

Emergency medical procedures become necessary when a person is unable to breathe unaided: for instance, if it is not possible to pass a tube through the mouth or nose down into the windpipe, or trachea, a cricothyrotomy may be carried out. It has the advantage of being a relatively quick and simple operation.

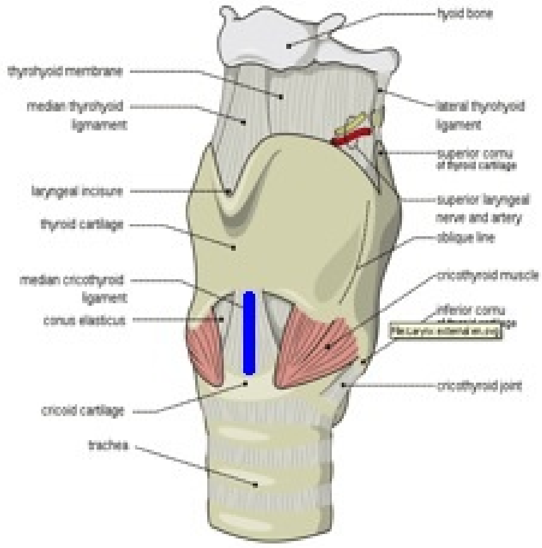


Figure 2.2: Landmarks for Cricothyrotomy. The incision is made in the cricothyroid membrane (blue line)

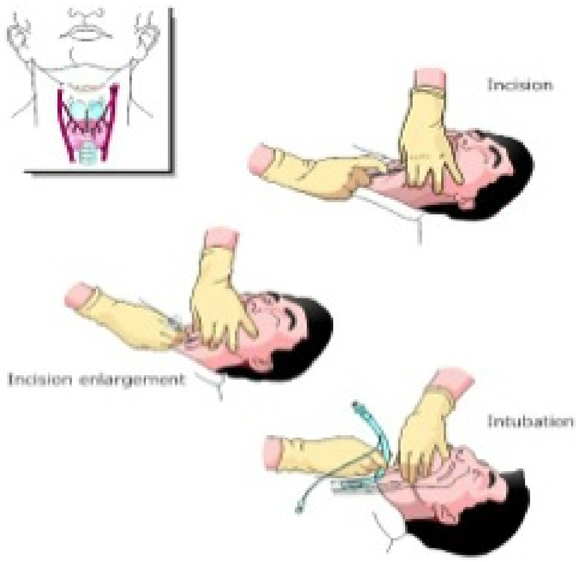


Figure 2.3: Cricothyrotomy procedure

This technique (Fig. 2.3), where an opening is cut into the trachea, is more difficult to perform and is associated with a greater number of complications. These types of surgical procedures are usually performed in life or death situations when there is no other option, and should be carried out by experienced practitioners [11].

A cricothyrotomy may be required if the airway becomes blocked. Blockage could be caused by a piece of food, bone fragments or teeth following serious injury to the head and neck, or swelling caused by an allergic reaction. The procedure may also be necessary in cases where the teeth are clenched shut or the area around the mouth is badly burned, making impossible to pass a normal breathing tube down into the trachea [12]. A surgical cricothyrotomy involves the use of a scalpel to make a larger incision in the cricothyroid membrane, into which a tube is inserted. The tube may be used to ventilate the person for at least 24 hours.

2.3 Medical simulators currently used for trainers

2.3.1 Mannequins

The use of mannequins in clinical simulations allows future and current physicians to practice on plastic first. The reality of mannequin-based simulations allows for virtual feedback using computers that regulate the mannequin's compressors, mimicking pulses and chest raising. These life-like mannequins simulate heart tones and other vital cues that when connected to monitors, provides real-time information to students. By practicing true clinical skills in a safe and regulated environment, future physicians learn permanent and excellent evaluation and treatment techniques [13], [14]. In such manikin-based training, students practice on plastic with life-like mannequins that simulate heart tones and other vital cues when connected to monitors, providing real-time information to students (Fig. 2.5, 2.4). They are designed for learning and practicing the techniques necessary to perform an emergency cricothyrotomy. Normally, the availability of cadaver material has determined the degree of procedural practice.

The kind of simulator offers palpable landmarks including the cricoid and thyroid cartilage. The prominentia laryngea is prominent on the hyperextended

Figure 2.4: Example of mannequin

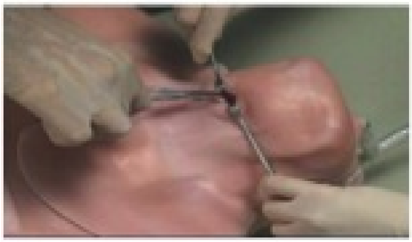


Figure 2.5: Using a mannequin during the cricothyrotomy procedure

neck. All landmarks are placed and allow for fast action. The trachea in this simulator is replaceable as the airway passes completely through from top to bottom. This allows checking the stylet and obdurator placement once the stab has been made. Complete with a full-size neck, ties can be used to hold the obdurator in a secure position.

2.3.2 Virtual Reality

Computer-based cricothyrotomy simulators using a hand-immersive platform with 3D graphics for the visuals and haptics for a sense of touch are currently available. In this simulators the touch is provided by two haptic devices, one per hand, to facilitate bimanual training. The hand-immersive platform helps preserve the surgeon's hand-eye coordination. The simulators incorporate a virtual patient with a model of the neck region (Fig. 2.6, 2.7). Different tissue types are encoded with different stiffness properties. Using the simulators, students can palpate the virtual patient and feel the thyroid and cricoid cartilage. The simulated surgical instruments can be controlled with either hand, based on the student's dominant handed. The virtual patient bleeds when an incision is made, and the student can feel resistance similar to an actual procedure. The haptic devices can also be used to change the orientation of the patient [15].

Figure 2.6: Simulator for virtual reality

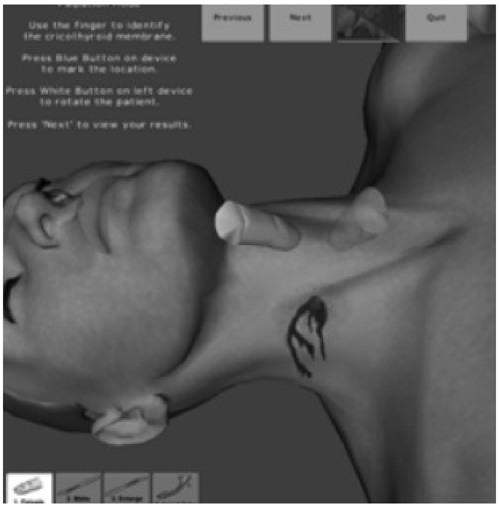


Figure 2.7: A virtual reality simulator during the cricothyrotomy procedure

The simulator has two modes, Mentor and Test. Mentor mode, which can display the underlying anatomy, guides the student through the procedure using on-screen instructions and immediate performance feedback. With the Test mode the user performs a cricothyrotomy without any of the Mentor mode guides. In this mode the user has a time limit for completing the procedure. Causing injury to the patient (e.g. making long/deep incisions) deteriorates the patient's state and decreases the amount of time provided to perform the task. A performance summary is generated in the end.

2.4 Overview: research question

Current simulators providing live feedback to the trainee are very expensive [16]. The amount of cases per doctor is further amplified in many developing countries, with many of these clinicians not being able to practice before being in the real life situation. High fidelity trauma simulators are in high demand in the developing world, while the training institutions do not have yet the means to acquire them. Therefore, a low cost and high fidelity cricothyrotomy simulator with a live feedback system is necessary.

Traditionally this procedure has been taught using animal models or human cadavers and is one of the skills routinely taught in the Advanced Trauma Life Support Course for doctors.

In the past several years high fidelity human patient simulators and trauma specific mannequins have become available for teaching students to perform the Cricothyrotomy procedure.

All of the methods described above have disadvantages. Animals do not have the same anatomy and there are ethical concerns with their use. Cadavers faithfully replicate human anatomy but can only be used once, do not bleed, and have fixed anatomy specific to that cadaver. Mannequins have variable realism and fixed anatomy specific to the model.

To address some of the limitations of currently available trainers, we have developed a new simulator combining the advantages of all the types listed above. Moreover, this thesis describes how the use of this simulator can enhance the training of medics in cricothyrotomy emergency.

2.5 Hysterectomy: anatomy and standard method

A hysterectomy is the surgical removal of a woman's uterus to treat a variety of diseases, disorders and conditions of the uterus and reproductive system [17]. It is the most common non-pregnancy-related major surgery performed on women in the United States, with one in three women having a hysterectomy by age 60. The uterus is a pear-shaped organ located in the lower abdominal (pelvic) area where a baby grows during pregnancy (Fig. 2.8, 2.9).

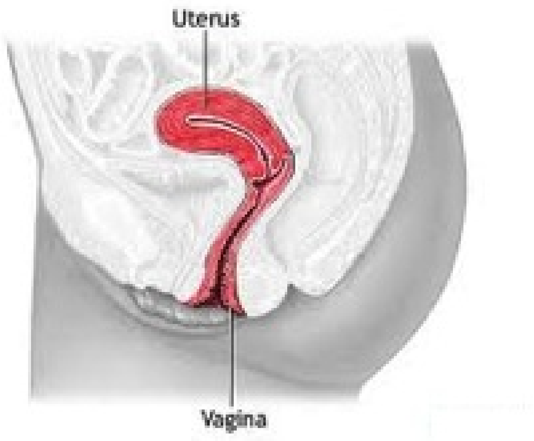


Figure 2.8: Uterus location

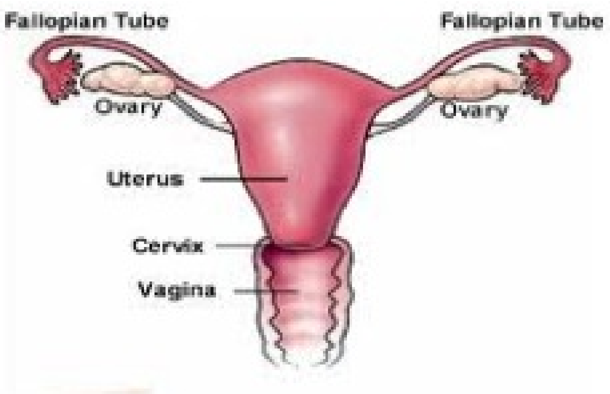


Figure 2.9: Uterus anatomy

Hysterectomy is a common but major surgery with significant risks and potential complications. Removing the uterus also means that a woman will no longer be able to be fertile and to bear children. This most common of all surgical procedures can also involve the removal of the fallopian tubes, ovaries and cervix to cure or alleviate a number of gynaecological complaints.

The majority of hysterectomies are performed when a woman is aged between 40-50, however many do occur before and after this age group. Women who have a hysterectomy that removes their ovaries, as well as other organs, will go through the menopause immediately (if they haven't already) following the operation regardless of their age, this is known as a surgical menopause [18], [19].

Women who have a hysterectomy that leaves one or both of their ovaries intact have a 50% chance of going through the menopause within five years of their operation, again regardless of their age.

Hysterectomies are most often done for the following reasons.

- Uterine fibroids: common, benign (noncancerous) tumors that grow in the muscle of the uterus. More hysterectomies are done because of fibroids than any other problem of the uterus. Sometimes fibroids cause heavy bleeding or pain [20].

- Endometriosis: another benign condition that affects the uterus. It is the second leading reason for hysterectomies. It occurs when endometrial tissue (the inside lining of the uterus) begins to grow on the outside of the uterus and on nearby organs. This condition may cause painful menstrual periods, abnormal vaginal bleeding and loss of fertility.

- Uterine prolapse: a benign condition in which the uterus moves from its usual place down into the vagina. Uterine prolapse is due to weak and stretched pelvic ligaments and tissues, and can lead to urinary problems, pelvic pressure or difficulty with bowl movements. Childbirth, obesity and loss of estrogen after menopause may contribute to this problem.

- Cancer: the reason for about 10 percent of all hysterectomies. Endometrial cancer, uterine sarcoma, cervical cancer, and cancer of the ovaries or fallopian tubes often require hysterectomy. Depending on the type and extent of cancer, other kinds of treatment such as radiation or hormonal therapy may be used as well.

- Hyperplasia: thought to come from too much estrogen and occurs when the lining of the uterus becomes too thick and causes abnormal bleeding.

Other reasons why hysterectomies are done include chronic pelvic pain, heavy bleeding and chronic pelvic inflammatory disease.

A hysterectomy can be done in various ways:

- Vaginal hysterectomy: the uterus and cervix are removed through the vagina. The uterus and cervix are pulled through a hole that is made in the top of the vagina. Surgical instruments are placed into the vagina to remove the uterus from ligaments that hold it in place. After the uterus has been removed, surgeons then remove the cervix. The incision at the top of the vagina is then closed with stitches.

Most surgeons will recommend this procedure because it is less invasive than an abdominal hysterectomy, and the patient recovers much faster. However, if the patient has many fibroids in her vagina it is not recommended. Sometimes, if there is a reason to remove the ovaries coming in through the abdomen may be better. For women who have never given birth the passage may be too narrow for this procedure.

- Abdominal hysterectomy: the uterus is removed through a cut in the abdomen. Abdominal hysterectomy requires longer healing time than vaginal, but it allows the surgeon to have a good look at the uterus and other organs during the operation. If the patient has tumors or suspected tumors the doctor will need to look around.

The technological innovation provided other procedures, such as laparoscopically or robotically:

- *Laparoscopy* is also known as keyhole surgery, band-aid surgery or minimally invasive surgery, and is used in many different types of surgical procedures, including hysterectomies [21], [22]. Between two to four small incisions less than half an inch wide are made in the abdomen, one usually in the belly button.

A needle goes into the first incision and fills the abdomen with CO2 (carbon dioxide) so that the abdomen is buoyed up and away from the organs, allowing for better viewing and maneuverability.

Also a long thin tube, called a laparoscope which has a video camera at the end so that the surgeon can see the organs, blood vessels, muscles, ligaments, and other tissue in fine detail, is inserted.

Various instruments are then inserted into the additional incisions to retract, cut, suture and staple. As incisions are much smaller with laparoscopic surgery there is less scarring, bleeding, and post-operative pain. Hospital stays are shorter compared to traditional surgery involving a much larger abdominal incision.

- *Robotic-assisted hysterectomy* : uses a robot, the most common one today is called the da Vinci Surgical System. It allows gynecologists to operate with amazing precision, vision and control [23].

  As with manual laparoscopy, small incisions are made in the abdomen, etc. However, the robot handles the laparoscope and instruments, while the surgeon sits looking into a screen, wearing glove-like devices which respond to finger movements and twists of the hands and wrists.

  Most surgeons agree that for complex hysterectomies, robot-assisted surgery is more effective and less invasive. The surgeon needs special training to be able to use this device.

When the tubes and ovaries have to be removed it used to be necessary to cut through the abdomen. Robotic procedure increases the possibility of doing this through the vagina. Patients usually need to have benign conditions that lead to hysterectomy and have a uterus that is not too large. Robotic-assisted hysterectomy are becoming more popular for patients with a uterine prolapse. Surgeons say that traditional vaginal hysterectomies give them less room to operate and no proper opportunity to look at the pelvic organs, while the camera at the end of the laparoscope allows him/her too see inside the abdomen [24].

2.6 A gold standard approach for hysterectomy: the daVinci Robot

Robotic surgery has also found a foothold within the field of gynecology, where minimally invasive procedures such as the laparoscopic hysterectomy have shown a faster recovery, shorter hospitalization, improved cosmesis, decreased blood loss and less postoperative pain.

In gynecologic, robotic assisted surgery provides a new tool for performing classically challenging surgeries such as hysterectomies.

Despite the proven benefits of minimally invasive surgery, the overwhelming majority of these procedures and others involving extensive suturing (eg, myomectomy and sacrocolpopexy) are still performed with a laparotomy. A large population based study of over 500,000 women undergoing hysterectomy in 2003 demonstrated that only 11.8% were performed laparoscopically, despite proven benefits supporting this technique.

This is again due to the steep learning curve for conventional laparoscopic surgery particularly for procedures requiring significant intracorporeal suturing.

The da Vinci surgical system is being heralded as a means of overcoming these obstacles while extending the benefits of minimally invasive surgery to more patients [25], [26].

In 2005, five years after its initial approval in the field of urology, the FDA approved the use of the da Vinci surgical system in gynecologic surgery. Since then, the surgical robot has been used in a number of gynecologic procedures including hysterectomy (with and without bilateral salpingo- oophorectomy).

When medication and non-invasive procedures are unable to relieve symptoms, surgery remains the accepted and most effective treatment for a range of gynecologic conditions. These include, but are not limited to, cervical and uterine cancer, uterine fibroids, endometriosis, uterine prolapse and menorrhagia or excessive bleeding.

Traditional open gynecologic surgery, using a large incision for accessing to the uterus and surrounding anatomy, has for many years been the standard approach to many gynecologic procedures (Fig. 2.10).

In addition, with open surgery can come significant pain, trauma, a long recovery process and threat to surrounding organs and nerves.

For women facing gynecologic surgery, the period of pain, discomfort and extended time away from normal daily activities that usually follow traditional surgery can understandably cause significant anxiety.

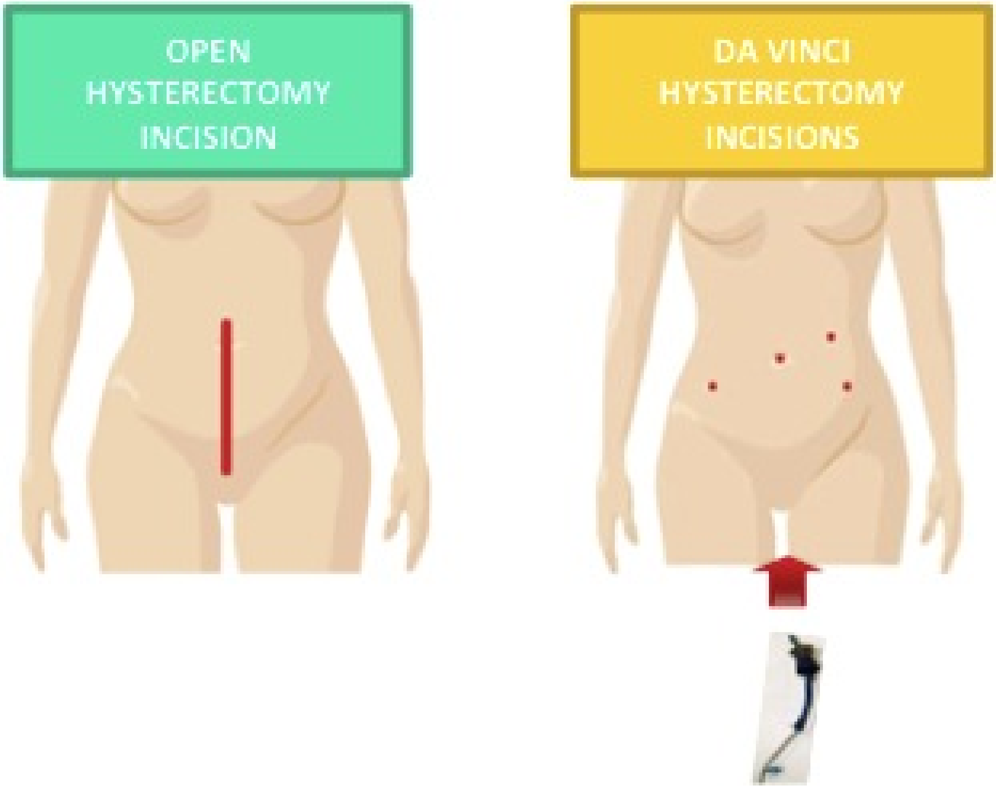


Figure 2.10: Open survery vs da Vinci Robot

Fortunately, less invasive options are available. Some gynecologic procedures enable surgeons to access the target anatomy using a vaginal approach, which may not require an external incision.

On the contrary, for complex hysterectomies and other gynecologic procedures, robot-assisted surgery with the da Vinci Surgical System may be the most effective, the least invasive treatment option.

Through tiny, 1-2 cm incisions, surgeons using the da Vinci System can operate with greater precision and control, minimizing the pain and risk associated with large incisions while increasing the likelihood of a fast recovery and excellent clinical outcomes.

The da Vinci is a state of the art robotic system designed to expand the surgeon's capabilities, providing patients with a minimally invasive option for many complex procedures.

The daVinci surgical system (Intuitive Surgical, Sunnyvale, CA) is comprised of 3 components:

1. The first component is the surgeon console where the surgeon sits away from the patient and uses a stereoscopic viewer with hand manipulators and foot pedals that allow control of the robot-assisted instruments within the patient (Fig. 2.11).

Figure 2.11: da Vinci Robot: surgeon console

2. The second component of the daVinci surgical system is the InSite vision system, which provides the 3-dimensional image through a 12-mm endoscope containing stereoscopic cameras and dual optical lenses (Fig. 2.12).

3. The third component of the daVinci surgical system is the patient-side cart with telerobotic arms and Endowrist instruments. Currently this system is available with either 3 or 4 robotic arms. One of the arms holds the laparoscope while the other 2 to 3 arms hold the various laparoscopic surgical instruments (Fig. 2.13).

These Endowrist instruments are unique because they have a mechanical wrist that replicates the full range of motion of the surgeons hand as controlled from

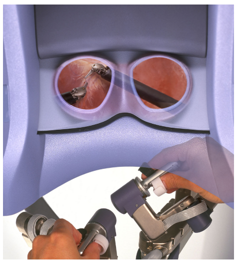


Figure 2.12: da Vinci Robot: InSite vision system

Figure 2.13: da Vinci Robot: patient-side cart

the surgeon console. Instruments move without the fulcrum effect seen with conventional laparoscopy: moving the hand to the right causes the instrument tip to move to the right, in contrast to the mirror-image motion required for conventional laparoscopy.

2.6.1 Operative technique

All patients were placed in low dorsal lithotomy position with arms padded and tucked at the side. The bladder was drained with a catheter and a uterine manipulator was placed.

Four ports were placed after pneumoperitoneum was obtained. The port for the endoscope was placed either at or above the umbilicus depending on the size of the uterus.

The accessory port was placed between the camera port and the right lower quadrant port. This port facilitated introduction of suture and suction/irrigation instruments.

Once all ports were in place, the surgical cart with 3 robotic arms was brought between the patient's legs and docked, meaning that each port was attached to the assigned robotic arm with the exception of the accessory port. Once the uterus and cervix were completely detached, they were delivered into the vagina. In particular, the uterine manipulator allows the surgeon to ligate the various blood vessels and ligaments so that the uterus can safely be removed through the vagina.

2.6.2 Current uterine manipulators

An integral part of da Vinci robotic hysterectomy is the placement of a uterine manipulator. Currently there are many uterine manipulators, some of them come in different lengths to adapt to uteri of different sizes.

Some have a cannula intended to perform such functions as chromotubation to test tubal patency. Such a cannula is not a necessary part of the uterine manipulators used for hysterectomy.

Some manipulators are reusable (eg, the Hulka clip, the Cohen cannula, and the Pelosi) [27], [28]; some are disposable (eg, VCare, the Endopath, and ZUMI Zinnanti); and some are partially disposable and partially reusable (eg, the RUMI), such that the tips are disposable but the handle is reusable (Fig. 2.14).

There are many uterine manipulators available, and they vary from one country to another and from one hospital to another.

The most commonly used manipulators include a sponge stick, the Hulka clamp, the Cohen cannula (Aesculap) (Fig. 2.15), the Pelosi (Apple Medical Corporation), the Zinnanti (Hayden Medical Inc), the RUMI System (CooperSurgical), the ZUMI (HNM Medical), UMI (U.A. Medical Products), the VCare (ConMed Endosurgery), the Endopath (Ethicon Endo-Surgery), the ClearView (Clinical Innovations), Valtchev (Conkin Surgical Instruments), and EZ Glide (B e H Surgical) (Fig. 2.16). The RUMI manipulator is often used with the KOH colpotomizer ring if total laparoscopic hysterectomy is to be performed [29].

2.6.2.1 Manipulator function

A uterine manipulator performs the following functions:

- Raises the uterus and brings it closer to the laparoscopic surgical instruments, facilitating the procedure
- Manipulates the uterus, thus stretching the side being operated upon
- Increases the distance between the uterus and the bladder, the ureters, and the rectum, thus reducing the chance of injury
- Could be used to pull the uterus vaginally after its complete detachment
- Facilitates identification of the uterovesical peritoneum, the cul-de-sac, and the vaginal cuff just below the cervical attachment
- Maintains the pneumoperitoneum following colpotomy.

2.6.2.2 Manipulator procedure

The uterine manipulator is placed after anesthesia is administered. A prophylactic antibiotic is given, and the patient is prepped and draped in the usual fashion.

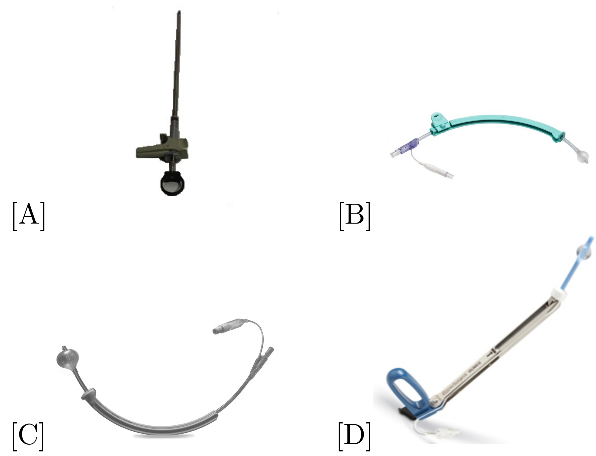


Figure 2.14: Current uterine manipulators: [A] Hulka, [B] Cohen Cannula, [C] Zumi, [D] Rumi

Figure 2.15: Current uterine manipulator: CohenCannula

Figure 2.16: Current uterine manipulator: EZ-Glide

A Foley catheter is then inserted and bimanual examination performed to assess the size and position of the uterus. A Pederson or vaginal speculum opened on the side or 1 or 2 Sims vaginal retractors are placed, and the cervix is visualized.

The cervix of a retroverted uterus, especially one fixed by dense adhesions to the culdesac, is often difficult to visualize. No attempt at insertion of the uterine manipulator should be made unless the cervix is clearly visualized and brought into the center of the vaginal speculum.

The anterior lip of the cervix is then grasped with a single-tooth tenaculum and the uterus sounded carefully to determine the length and the direction of the uterine cavity.

Among women with cervical stenosis, lachrymal duct dilators or small Pratt dilators might be needed before sounding.

If severe cervical stenosis is suspected preoperatively, an overnight insertion of a vaginal prostaglandin suppository might help soften the cervix and facilitate insertion of the uterine manipulator.

Depending on the type of the manipulator used, the manipulator might be hooked to the tenaculum (eg, the Pelosi) or the tenaculum removed before insertion of the manipulator (eg, the VCare or the RUMI).

Some manipulators are semidisposable, and the tip to be used will depend on the length of the uterine cavity (eg, the RUMI). Some others will need to be assembled immediately before insertion into the uterine cavity, and some disposable manipulators come assembled in different sizes.

When using the RUMI or the VCare, a number 0 Prolene stitch is often placed in the anterior lip of the cervix, passed through the cervical cap, and tied in order to maintain the cervical cap against the cervix and identify the vaginal fornices just below the cervix [30].

Some manipulators have intrauterine balloons that will need to be inflated at this time; other ones have a vaginal occluder which may be in the form of a balloon (eg, the RUMI) or a lockable sliding distal cup (eg, the VCare) (Fig. 2.17). After placement of the uterine manipulator, the robotic procedure is started.

Figure 2.17: Uterine manipulator: V-Care

In the United States, the two most commonly used uterine manipulators for the da Vinci robotic total laparoscopic hysterectomy have been the RUMI manipulator with the KOH colpotomizer ring and the VCare manipulator. Each of these manipulators comes in three different sizes. Changes in the forward cup polymers allow the VCare to be used with both electrosurgical and harmonic energy sources [31].

So, taking into account the observations just made, a new idea has been developed: to design a new version of an already existing manipulator, VCare, which has been built and tested at the University of Washington in Seattle, with the collaboration of the Medical Center. We will discuss about that more in details in the next chapters.

Chapter 3

Methodology: research design

3.1 New and useful surgical technologies: design and development

3.1.1 Introduction: the role of research in Robotic Surgery applications

Although the robotics firstly appeared as an entertainment form, its capabilities have continuously advanced from the first world's industrial robot to the surgical robotic systems which are today capable of performing many surgical maneuvers unaided. However, these surgical robots are not autonomous systems and had been developed to overcome the limitations of minimally invasive surgery. So, research plays a vital role in Robotic Surgery to enhance the capabilities of surgeons performing open surgery and to address the electromechanical limitations of current robotic systems. In this chapter we present:

- An example to improve the open surgery performances:
  - Cricothyrotomy simulator for procedural skill training : best choice in low resource environments
- An example to address the electromechanical limitations:
  - An innovative lighted Uterine Manipulator

3.2 Cricothyrotomy simulator

3.2.1 Introduction and motivation

Cricothyrotomy is one of only a few time-dependent life-saving interventions and it remains one of the most important skills of the emergency physician.

Although the 80% of American anesthesiology residency programs teach cricothyrotomy, the 60% consist of lectures only. Consequently, residents, often the first physicians on scene during resuscitations, have very little experience or confidence to perform this emergent intervention. Moreover, many people in the developing world live beyond the reach of medical first responders who are fully trained in airway restoration techniques. Under these circumstances, with airway obstruction, death is nearly assured.

In modern emergency medicine, the golden hour refers to the critical period of time between injury and medical treatment during which, medical care is most likely to save a persons life (Fig. 3.1). The critical period of time to restore ventilation after airway obstruction is even shorter and permanent brain damage occurs within minutes [32].

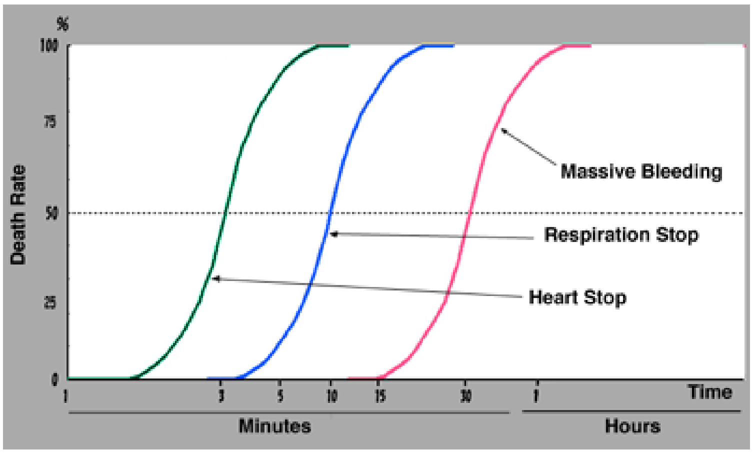


Figure 3.1: The golden hour concept

Prompt rescue breathing followed by intubation is the standard of care following the loss of self-sustained respiration. Modern airway protocols involve many techniques to restore ventilation including bag-mask-ventilation, placement of a laryngeal mask airway, intubation with or without Glidescope (Verathon, Bothell, WA), and ends with a surgical airway [33]. In cases where conservative measures fail or when contraindicated, the only methods remaining to re-establish ventilation may be surgical. In the developing world where technologies such as the Glidescope may not be available, accurate knowledge and training in the creation of a surgical airway may have a significant effect on patient outcomes [34], [35].

Although performing a cricothyrotomy seems relatively straightforward, studies have shown that those performed in the prehospital setting were mostly unsuccessful. A review of 54 emergency cricothyrotomies found that the majority of the procedures performed in the field were unsuccessful or resulted in complications. A military team identified gap areas in the training of cricothyrotomy in emergency situations; these included lack of anatomical knowledge including hands on palpation exercises, poor anatomy in medical mannequins, and non-standars techniques. An improved method of training needs to be provided for this rare, but life-saving procedure.

Most of the unsuccessful attempts were due to inaccurate placement, and perhaps incorrectly identifying anatomy. A study of physicians (mostly anesthesiologists) asked to identify the cricothyroid membrane did so correctly in only 10 out of 56 (18%) patients, using ultrasound as the gold standard. Elliot et al. [36] found similar rates (30%) of correctly identified anterior neck anatomy. If the anatomy is not properly identified, it is unlikely that the procedure will be successful. Further, a large review of emergency airway cases in the UK found that emergency cricothyrotomies performed by anesthesiologists were successful in only (36%) of instances.

Although many reports suggest that the success rate of surgical airway placement is low, publications from advanced centers with extensive training for airway protocols including simulation show that pre-hospital cricothyrotomy success rates can be as high as (91%). This data was gathered prospectively and found (3.2%) of airway cases required additional measures beyond endotracheal tube intubation, one of which was cricothyrotomy [37], [38]. Studies such as this suggest that with adequate training the success rate of cricothyrotomy can be dramatically improved.

Motivated by the above considerations, in collaboration with the Biorobotics

Lab at the University of Washington in Seattle, we developed a low cost simulator to teach resident physician about this emergency procedure. The new device is designed to help train people to safely perform this procedure and to assess their level of procedural skill with special attention to limited resources available in rural environments in the developing world.

3.3 The simulator

3.3.1 Design

We have developed a physical simulator of the cricothyrotomy procedure. It emphasizes the palpation and the correct identification of anterior cervical anatomy [39]. After having made a detailed study on the dimensions of the human trachea [40] [41], we were able to create a mock trachea by CAD (Fig. 3.2, 3.3, 3.4). We recreated an average of an adult trachea and we built the thyroid cartilage base and the cricoid cartilage components. Such components were printed on a Stratesys BST 768 3D printer out of ABS plastic.

The electronic part of the systems was representing by the Arduino Uno microcontroller board [42] based on the Atmel Amega 328 microprocessor (Fig. 3.6). Then, a 8x8 LED matrix-based display was mounted to the Arduino Uno (Fig. 3.7).

The medical instruments used for this operation (scalpel, hook and kelly forcepts) were connected by a wire to a pin of the microcontroller (Fig. 3.8).

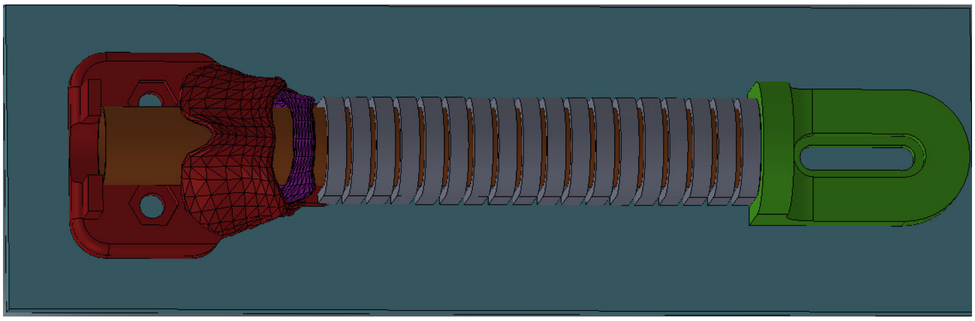


Figure 3.2: Simulator: front view

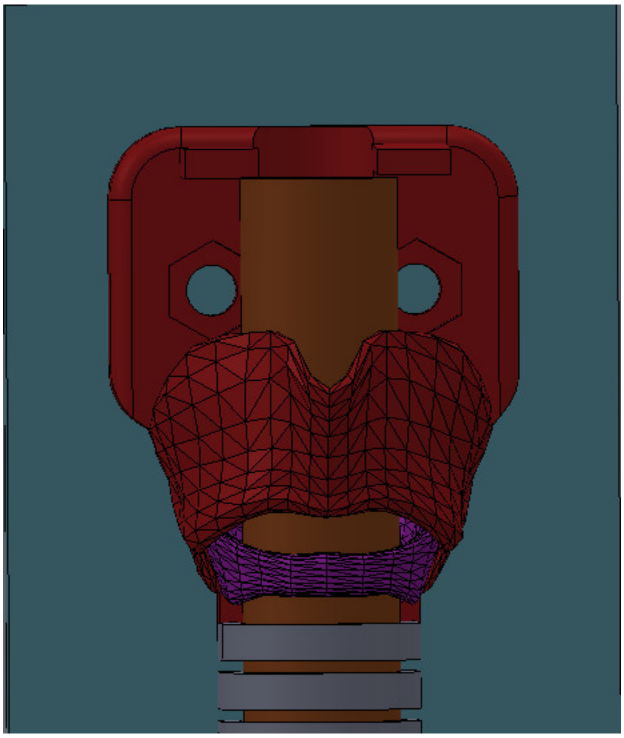


Figure 3.3: Front view of the simulator showing the thyroid and cricoid cartilage

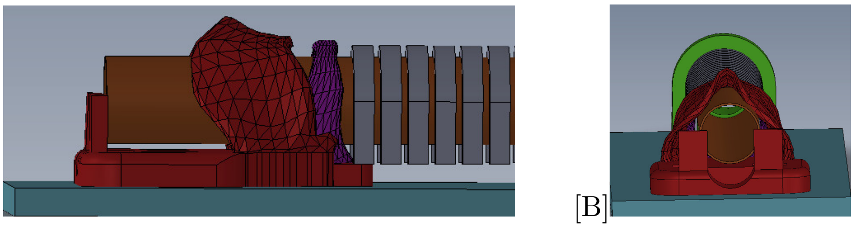
[A]  [B]

Figure 3.4: Simulator: top view

We also created a tracheal tube by CAD (Fig. 3.5) that we built on thin cardboard and then we covered it with a skin created by bicycle inner tube; we made such a choise after having noticed some very high similarity properties of this components with the human one at palpation.

We covered the trachea built with six stripes of alluminium foil which represents six different possible critical places that usually the doctor could cut. But only one of this six places is the correct place to be cut (PAD C shown in the

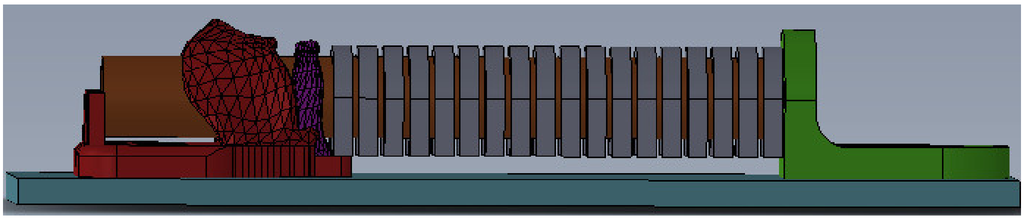


Figure 3.5: Simulator: side view

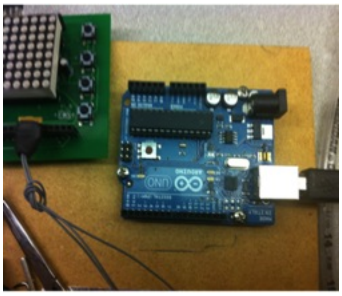


Figure 3.6: Arduino microcontroller

figure (Fig. 3.9)) and we want to help the doctor training him to cut the correct place and also to have real time feedback about which anatomical place he is cutting.

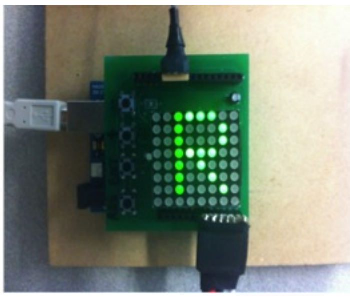


Figure 3.7: 8x8 LED matrix

The simulator's design is summarized by the following components:

- Low cost microcontroller (the Arduino microcontroller board) connected by wires to a mockup of the trachea
- Cricoid and thyroid cartilages are made of rigid plastic material

Figure 3.8: Medical instruments

[A] [B]

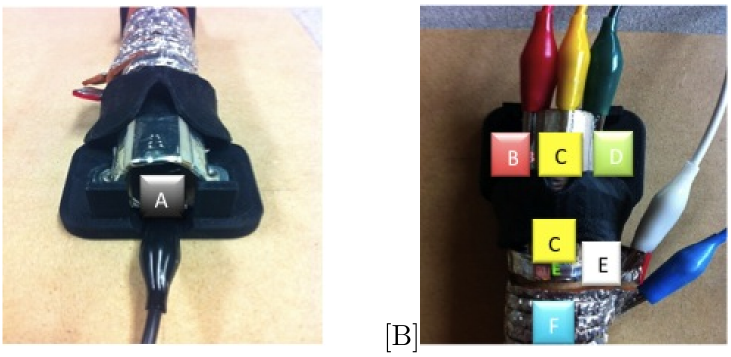


Figure 3.9: The six PADS

- The tracheal tube is made of thin cardboard
- Rings of cartilage are made from foam
- A simulated skin is provided by a piece of bicycle inner tube
- The instruments (scalpel, hook, and kelly forcepts) are connected by a wire to a pin of the microcontroller
- The defined surfaces in the anatomy are covered in aluminum foil which is electrically connected to other microcontroller pins

When a circuit is detected between the instrument and a patch of foil, the event is recorded by the microcontroller and labeled with the time in milliseconds until the event ends.

Traditional matrix scanning techniques are used by the microcontrollers software to detect connections between the instruments and the foil patches.

3.3.2 Simulator: cost analysis

The design of the simulator was optimized for materials that are low-cost and widely available, and for accurate anatomical landmarks.

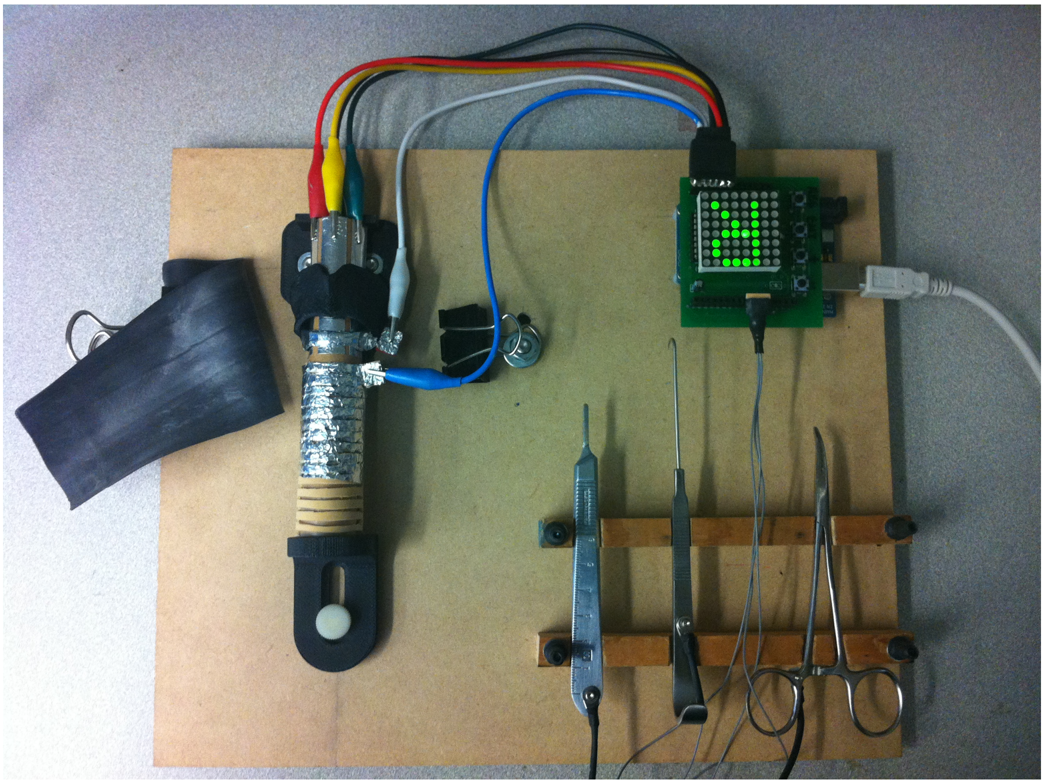


Figure 3.10: Cricothyrotomy procedure simulator showing the physical components

The cost estimate of the simulator components shown is around $30. This is a very low cost simulator, compared with the existing simulators that cost over

Cost Analysis	
Electronics (micro controller with PCB, wires)	$10
Board and reusable materials	$10
Disposable components	$1
Surgical tools:	
Kelly forceps	$1
Cricoid hook	$2
Scalpel handle with blade	$1
ET tube	$1
Total	$25 (reusable) $1 (disposable)

Table 3.1: Cost Analysis

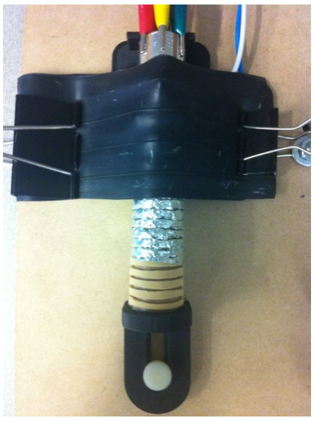
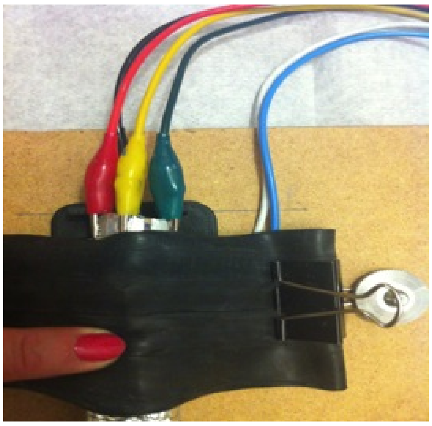
[A]

[B]


Figure 3.11: Simulator prototype: [A] The simulator showing a piece of elastomeric rubber covering the internal components of the simulator. [B] The rubber has similar properties to human skin and upon palpation anatomical landmarks are observable to the user.

thousand dollar. In details, we show a cost component analysis, as illustrated in table 3.1.

3.3.2.1 Simulator prototype

The system has three key parts on a wooden base:

1. plastic components representing cartilaginous structures

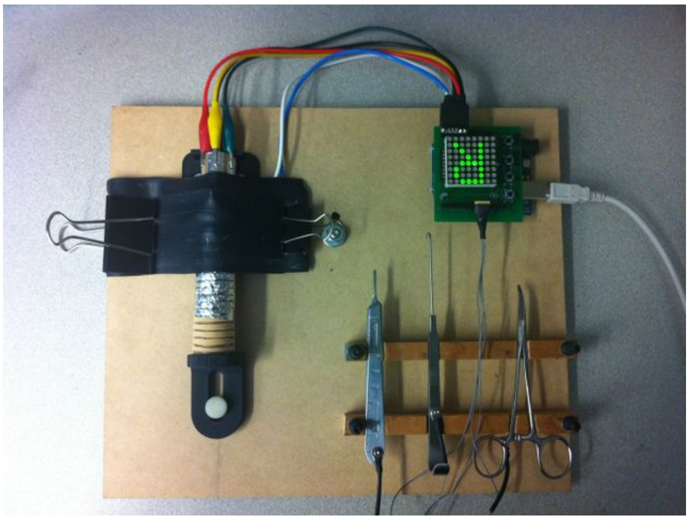


Figure 3.12: Simulator Prototype (held back)

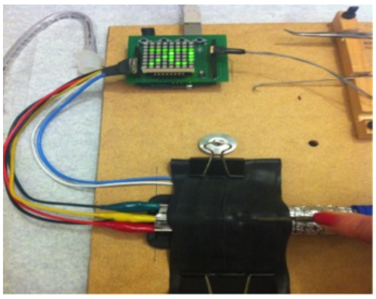
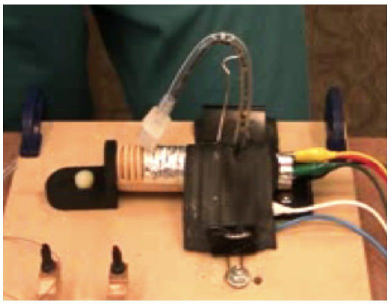
[A]  [B] 

Figure 3.13: Simulator prototype: [A] Many signals are generated when the scalpel touches one or more of the contact pads; [B] The placement of an Endotracheal Tube (ET).

2. electronics and software

3. replaceable simulated tracheal tube and skin

Our system uses electrically connected surgical tools and electrical contact pads to record the interactions between the provider and a patient mockup. Each contact between tool and tissue is electrically time-stamped and recording enables real-time feedback for training or automatic post-performance evaluation. Figures 3.10, 3.11, 3.12, 3.13 show the cricothyrotomy simulator prototype.

3.4 New uterine manipulator

3.4.1 Background of the invention

Each year there are millions hysterectomies performed in the world. In the US approximately one-third of hysterectomies are performed through a minimally invasive approach either laparoscopically or robotically [43], [44], [45]. Over the last 5 years there has been a significant shift towards the robotic approach as the ergonomics and visualization of the robot offer significant advantages when operating in the pelvis.

When doing a hysterectomy with the robot, a uterine manipulator is a device needed to put the uterus on tension and allow the surgeon to ligate the various blood vessels and ligaments so that the uterus can safely be removed through the vagina.

The uterine manipulation is also very important to keep the ureter and bladder out of harms way during the dissection of the blood vessels and ligament.

The standard uterine manipulator has a cuff that fits around the cervix. This cuff identifies the junction between the vagina and cervix, and the surgeon uses that cuff as an indicator of how far to dissect the bladder and where the surgeon will make a colpotomy (vaginal incision) that ultimately allows the surgeon to detach the uterus from the vagina.

Next, the uterus is delivered though the colpotomy and out from the vagina. Unfortunately there are some issues to solve. For instance, one of the main obstacles in doing this type of surgery is clearly identifying the junction between the vagina and the cervix and where exactly the colpotomy should be made. This is especially problematic when using a robot as there is no tactile feedback while doing robotic surgery.

In order to adress this research question, a new device was developed in collaboration with the University of Washington Medical Center (UWMC), where the robot has now allowed the gynecologic oncology service to do the majority of their endometrial and cervical cancer cases minimally invasively [46].

Previously, only 15% of the cases could be done through a minimally invasive approach. Many other gynecologic oncology services have reported similar changes in practice patterns. In addition the robot is used extensively in Europe

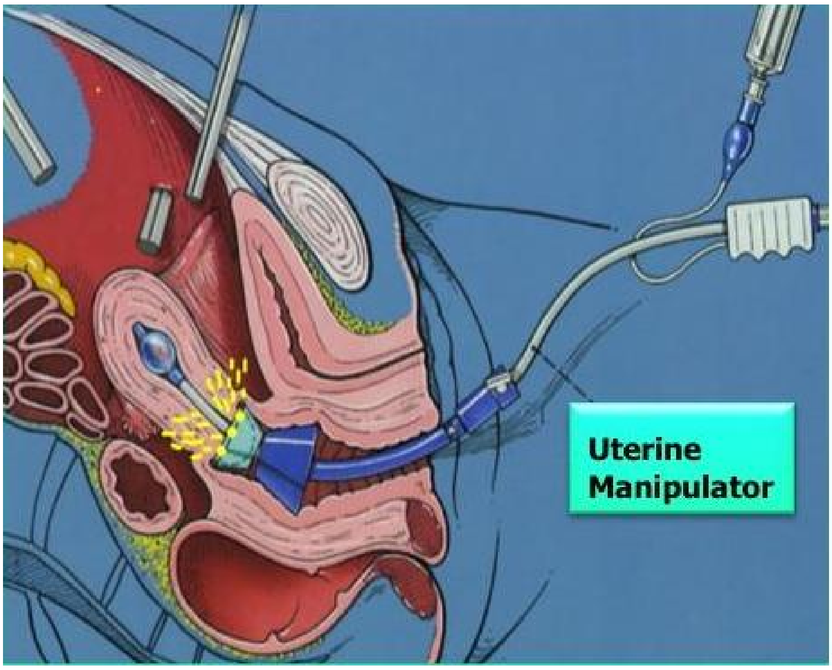


Figure 3.14: The main idea

and South America.

3.4.1.1 Manipulator design

Extensive investigations at the UWMC has led to the invention and development of this new technology for uterine manipulation to address this critical unmet clinical need in women's health care.

In order to address the previous issues, in this thesis, a solution to the problem was presented. The purpose is to create a new uterine manipulator to use during the robotically hysterectomy making possible that the anatomical part to be cut is easily localized and, consequently, the manipulator too. So, the main idea of the invention is to create a ligthed device which may be very useful to doctors making definitely easier the whole surgical procedure (Fig. 3.14).

Therefore, having an instrument that lights up and visually indicates the cervicovaginal junction and where the surgeon should make the vaginal incision would be a huge benefit.

Figure 3.15: Lighted uterine manipulator

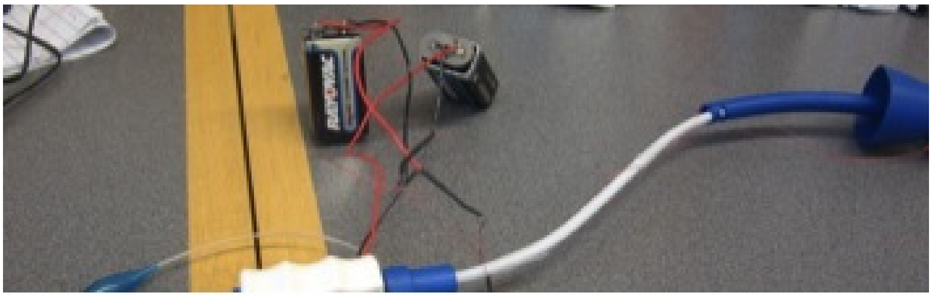


Figure 3.16: Proximal end of cervical manipulator with illumination batteries added

There are several reusable as well as disposable uterine manipulators on the market.

The manipulator that is most commonly used is a Conmed V-care: through our invention it is possible to make a lighted uterine manipulator for a similar cost. There would be a significant interest from surgeons due to improved patient safety and facilitation of surgery.

The invention has been prototyped by modification of Conmed V-care manipulator to include a ring of LEDs around the cervical cuff. The existing cervical

Figure 3.17: End-on view of cervical cap

cuff was removed from a Conmed V-care uterine manipulator and a new cuff was created by CAD and fabricated on a rapid prototyping machine.

Small wires, encapsulated within the cervical cuff, and extending down the shaft of the instrument power the LEDs through two 9 volt external batteries (Fig. 3.16).

When energized, a light from the LEDs is visible through the vaginal-uterine wall and identifies the location of the cuff to the surgeon viewing the uterus-vagina from the abdominal cavity (Fig. 3.17, 3.15).

The provision of light at the distal cervical cup is very important to transilluminate and better visualize tissues of the vaginal fornix area; an energized dissection means helping to dissect the uterus from the vagina.

When using commercially available alternative uterine manipulation products, it is frequently difficult to localize the vaginal fornices during the robotically hysterectomy.

During this critical dissection, many skilled and experienced surgeons have described the sense of getting lost deep in this pelvic anatomy.

With this invention, the uterine manipulator illuminated through the light of the distal cervical cup can make the identification of the cervical cup edges and the targeted fornices much easier.

These new devices may allow the surgical team to identify internal tissue structures, such as blood vessels, that lie within solid tissue planes. With this lighting option, important internal tissue elements can be differentiated through direct video imaging.

Currently there are no uterine manipulators that have a lighted cuff that would fit around the cervix. Finally, a lighted uterine manipulator would improve patient safety and would make the surgery easier for the surgeon.

Chapter 4

Experimental studies and results

The main aim of this section is to evaluate the performances and the innovation built; thus, we want to verify how well the system works and what the impact on the overall medical community would be.

4.1 The cricothyrotomy simulator: performance measurement

We present a system of medical procedure simulators coupled to a microprocessor for recording a medical procedure and assessing that performance for skill. It is capable of providing feedback for training, as well. The system will initially record the series of events, recorded data can be compressed and uploaded to a computer.

- Events are defined as the start and end times of contacts between specific instruments and surfaces on the anatomical model. Other types of events are defined in terms of readings from different sensor types.
- The events will be processed into a series of symbols (represented by ascii characters).

An excerpt from a data set of this form is shown below (Fig. 4.1, 4.2, 4.3).

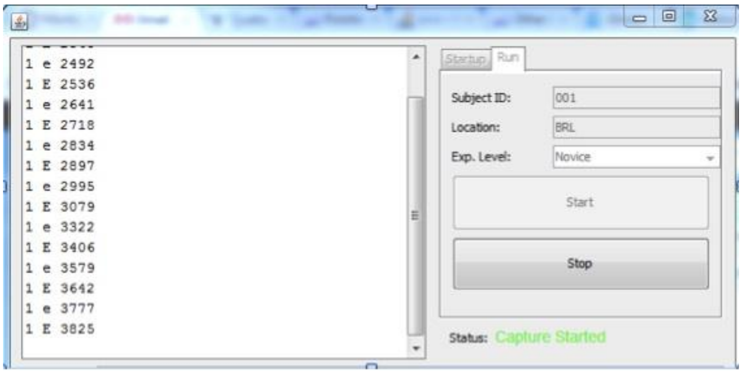


Figure 4.1: The user interface: beginning procedure

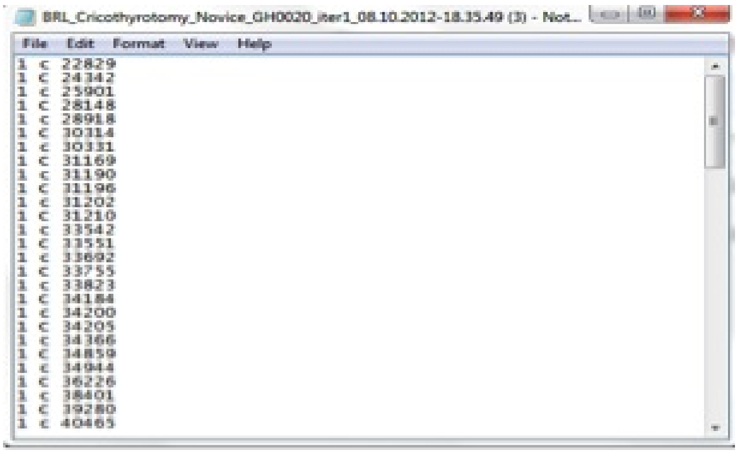


Figure 4.2: The user interface: recording data

- The first single digit number indicates the instrument
- The character indicates which foil patch is touched: upper-case for making contact and lower-case for breaking contact
- The last number is the time in milliseconds

The purpose of uploading score information is tracking user performances and skill certifications; anyway, other uses are possible.

Figure 4.3: The user interface: ending procedure

4.2 Procedure: study participants

The participants in this study consist of 29 residents (but the study will be conducted only on 20 subjects) selected from the University of Washington Department of Otolaryngology-Head and Neck surgery. The study participants' ages ranged from 27 to 53 years. Physicians had different levels of experience; specifically, there were novices, oto residents and experts.

After consenting to participate in the study, participants were shown a brief slide show discussing the procedure that culminated with a video tutorial published by the New England Journal of Medicine.

Participants donned nitrile gloves to assure anonymity and because incorrect tool contacts were occasionally registered when bare skin contacted the active tools. After watching the instructional video, each participant performs a procedure following the instructions below:

- Step 1: Immobilize the larynx and palpate the cricothyroid membrane - Stand at the patient's right side if you are right-handed, or at the patient's left side if you are left-handed. Immobilize the larynx with the nondominant hand and perform the procedure with the dominant hand.

- Step 2: Incise the skin vertically - After palpating the cricothyroid membrane, make a midline, vertical incision 3 to 5 cm long through the skin overlying the membrane. The midline skin incision avoids vascular structures located laterally. The vertical orientation also enables extension of the incision superiorly or inferiorly should the initial location be too high or too low or provide inadequate access to the cricothyroid membrane. Such extension cannot be performed with a horizontal skin incision.

- Step 3: Incise the cricothyroid membrane horizontally - Make a 1 cm horizontal incision in the cricothyroid membrane over the caudad part of the membrane to avoid the vasculature running across the cephalad portion. Make the incision with care; excessive force can lead to injury of the posterior wall of the trachea. Aim the scalpel in a caudad direction to avoid the vocal cords.

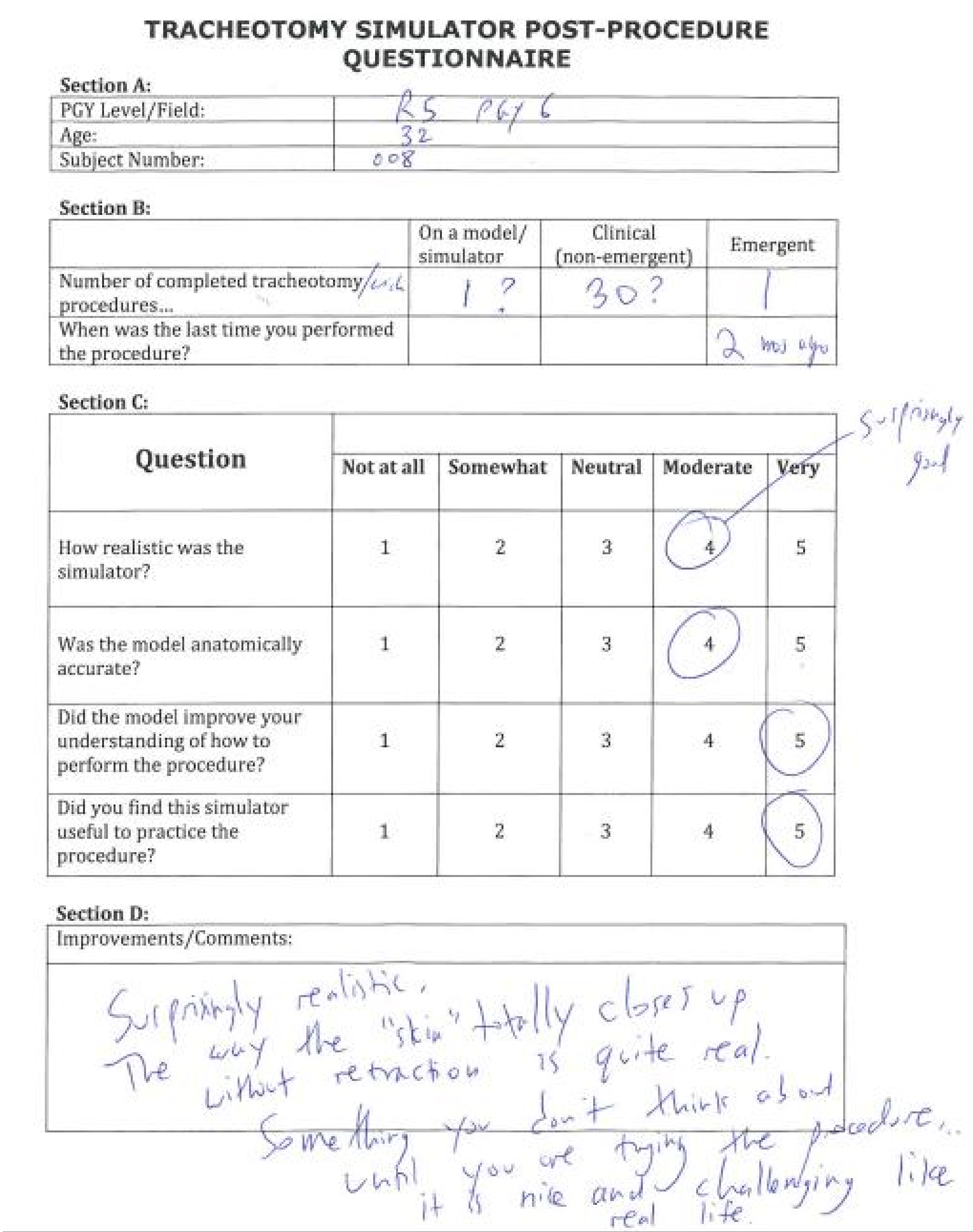
- Step 4: Insert the tracheal hook - Place the tracheal hook under the thyroid cartilage.

- Step 5: Insert the dilator and open it to enlarge the incision vertically - Squeeze the handles of the dilator to open its jaws. The membrane is naturally wider in the horizontal direction, which makes the vertical direction the hardest to dilate. Leave the dilator in until the tube is placed; the thyroid and cricoid cartilages will spring back into place if the dilator is removed.

- Step 6: Insert the tracheostomy tube - After dilating the opening, rotate the dilator 90 degrees so that the handles are pointing towards the patient's feet and insert the tube. If the dilator remains in its original horizontal position, its inferior blade will prevent the tube from passing into the trachea. Once past the blades, advance the tube into the trachea. Remove the tracheal hook and dilator.

Simultaneously, all the data were recorded (movement of the instruments, the response of the simulator), procedures were also video recorded for analysis.

Next, each subject was asked to answer four subjective questions about the simulator, in order to measure the subjective impressions, listed in table below and using a Likert scale (Fig. 4.4).



TRACHEOTOMY SIMULATOR POST-PROCEDURE QUESTIONNAIRE

Section A:

PGY Level/Field:	RS PGY 6
Age:	32
Subject Number:	008

Section B:

	On a model/ simulator	Clinical (non-emergent)	Emergent
Number of completed tracheotomy/cric procedures...	1 ?	30 ?	1
When was the last time you performed the procedure?			2 mos ago

Section C:

Question	Not at all	Somewhat	Neutral	Moderate	Very
How realistic was the simulator?	1	2	3	4	5
Was the model anatomically accurate?	1	2	3	4	5
Did the model improve your understanding of how to perform the procedure?	1	2	3	4	5
Did you find this simulator useful to practice the procedure?	1	2	3	4	5

Surprisingly good

Section D:

Improvements/Comments:

Surprisingly realistic, The way the "skin" totally closes up without retraction is quite real. Something you don't think about until you are trying the procedure... it is nice and challenging like real life.

Figure 4.4: Assigned post-procedure questionnaire

4.3 Experimental results

4.3.1 Graphic results

The experimental analysis has been made through the Matlab tool, which allowed us to represent all the data recorded and to get a trend on how the surgical procedure is going on. More in details, a specific and innovative way of representing such kind of data has been designed and used for the evaluations.

As we can see in the figures

- The normalized elapsed times
- The PADs touched/untouched
- The three different medical instuments used

The defined protocol has the following features:

- On X-axes the elapsed time normalized to 100 seconds is represented
- On Y-axes, we defined one different level for each PAD: so, we have six levels, identified by A-F letters
- For each PAD, we specify three more levels, each one corresponding to a particular instrument: more in specific, we have:
  - Level 1, Scalpel, identified by blue colour
  - Level 2, Kelly forceps, identified by red colour
  - Level 3, Hook, identified by green colour

This kind of data representation is very useful, because it allows us to easily understand the performance quality of each subject. So, also considering that Pad C represents the correct shared zone, a good performance for us should match a specific pattern, which is related to a correct sequence of instruments to be touched.

Such a ordered correct sequence of touched instruments is: Scalpel-Kelly Forcepts-Hook (Blue-Red-Green) , as we can see it the figure 4.5, where a very good performance made by an expert is represented.

On the contrary, the following conditions verified (Fig. 4.6, 4.7)

- A Pad different from PAD C is touched
- There are no correct sequences

represent the worst cases for us.

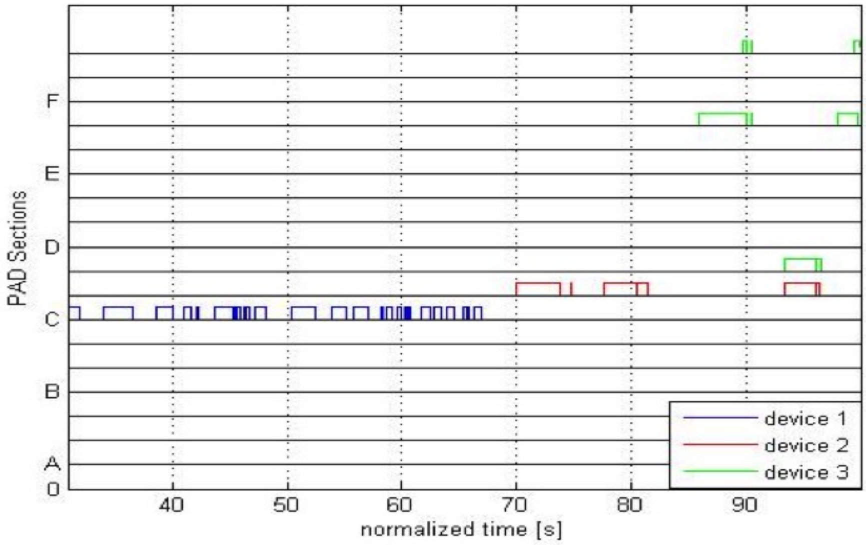


Figure 4.5: example of an expert performance

4.3.2 Objective Structured Assessment of Technical Skills (OSATS) Analysis

4.3.2.1 The golden standard evaluation: OSATS method

Assessment tools have been developed to evaluate surgical skills. Undoubtedly one of the most significant advancements in this type of evaluation has been the introduction and validation of the expert-based OSATS (Objective Structured Assessment of Technical Skills) developed at the University of Toronto. OSATS assesses discrete domains of surgical competence and are being increasingly used in surgical residency programs [47], [48].

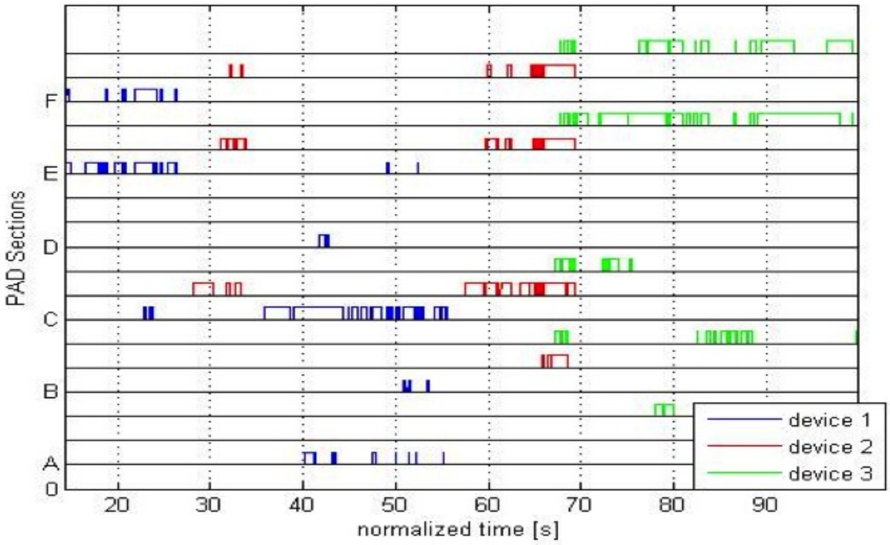


Figure 4.6: The worst case: first example

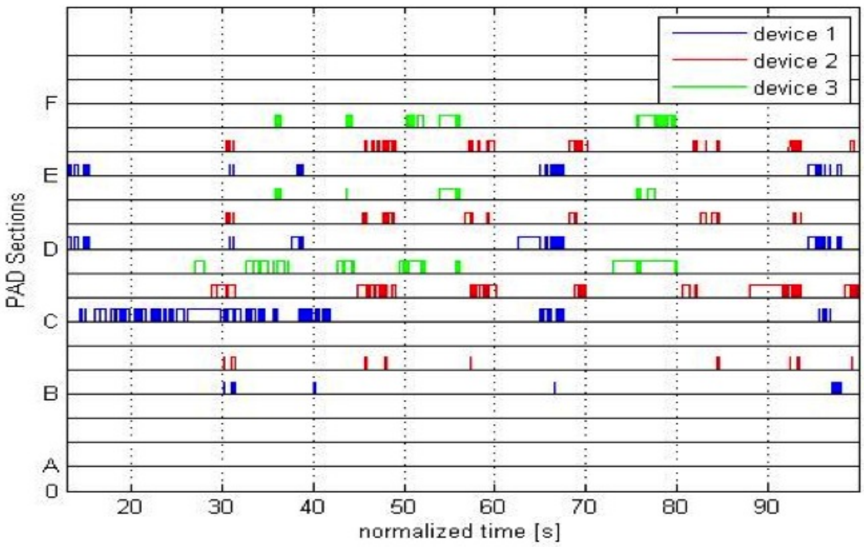


Figure 4.7: The worst case: second example

In OSATS original form, a surgeons performance of a number of standardized surgical tasks is subjectively assessed by expert colleagues, an evaluative method valued for its consistency. OSATS relates information about whether all crucial movement components were executed, how movements were performed (general impression), and the quality of the final product [49]. The criteria come from skill task or procedure specific checklists and global rating scales. The checklists are detailed, dichotomous evaluation instruments, whereby one mark is given if the item is performed correctly and no mark is given if the item is performed incorrectly or not performed. The global rating scales consist of multiple items, each rated on a behaviorally anchored scale. Specifically, these scales consist of a validated set of seven dimensions that describe surgical performance characteristics common to all procedures. Each dimension is rated from one to five with the extremes and the midpoints anchored by descriptions. The dimensions include: respect for tissue, time, and motion; instrument handling; flow of operation; use of assistants; knowledge of specific procedure; and performance overall (Fig. 4.10).

Studies on the validity and reliability aspects of OSATS have shown that both are high and deem this method acceptable for summative evaluation purposes.

Construct validity has been shown by demonstrating systematic growth in each year of training in regard to residents at differing levels of training. The fact that OSATS evaluates the actual performance of trainees gives it face validity. OSATS have been successfully administrated at several sites yielding very similar results, a phenomenon known as external validity. In addition to its assessment-related attributes, OSATS can be used an educational tool. It has been observed that periodically administrated tests can be used to track an individual residents training and offer valuable feedback about technical performance shortcomings in comparison to training level.

Thus, for these reasons, an OSATS analysis was performed. More in specific, three experts graded the recorded procedures by completing an Objective Structured Assessment of Technical Skills survey.

This validation study examines 20 subjects of varying skill levels using the simulator, and then graded using OSATS. These grades were compared to training level and task time.

The different training levels (in our case Novice, Junior Oto Resident and

Expert) were correlated to OSATS scores. Thus, we obtained the graphic shown in figure 4.8. It is possible to note, as illustraded in the mentioned pictures, the following features:

- On X-axes the training level is represented
- On Y-axes the OSATS score values are displayed

Consequently, a boxplot of technical skills about cricothyrotomy procedure was made. The plot elements and the statistics they represent are as follows:

- The maximum score on Y axes is 30
- The heavy and horizontal line within each box represents the median value
- The length of the box represents the interquartile range (the distance between the 25th and the 75th percentiles)
- The vertical lines issuing from the box extend to the minimum and maximum values of the analysis variable

The OSATS score distributions related to the three training levels are different. As we can see in figure 4.8, the average training level for experts is defintely the highest and the distribution is symmetric as well. For what concerns Junior Oto Resident's performances, the average training level is comprehensibly lower that experts' and higher than novices': by the way, its distribution is also less symmetric than the experts'. Finally, the average training level for novices' is much lower than the others, and also its distribution is less symmetric than the other ones.

Starting from these results, it is shown how important is to have a great experience in this particular medical procedure and also how important is to make some training with a simulator to became an expert.

Furthermore, another study was performed to correlate the OSATS data with task time (Fig. 4.9). The elements are plotted as follows:

- The procedure elapsed time in minutes is displayed on X-axes
- An average of the OSATS scores is represented on Y-axes

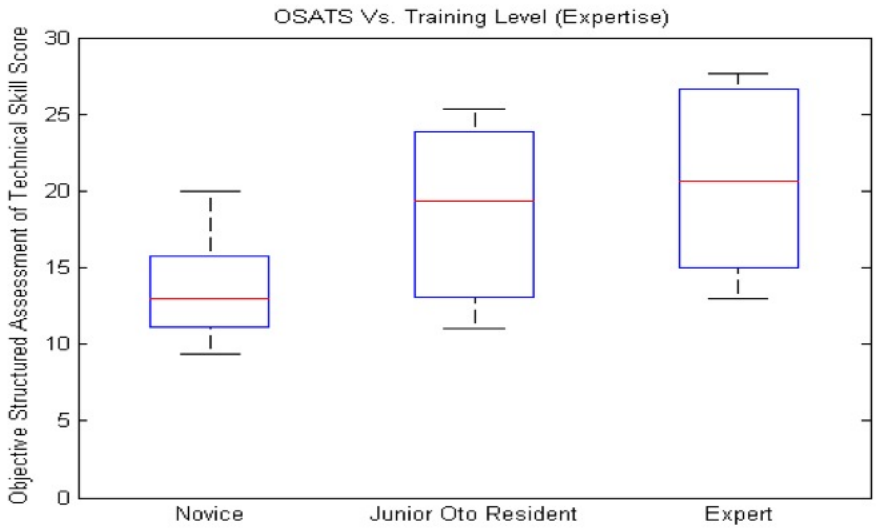


Figure 4.8: OSATS vs training level

- The maximum score on Y axes is 30

As it is possible to see in the figure 4.9, the minimum time to perform the procedure is around 50 seconds, while the maximum time is around 5 minutes. The distribution of data values is represented by the mathematical model below:

$$y = -93.485x + 28.934 \tag{4.1}$$

where we can also find the coefficient of determination, denoted R^2, used to describe how well a regression line fits a set of data. This coefficient is equal to:

$$R^2 = 0,7739 \tag{4.2}$$

The coefficient of determination (R^2) is most often seen as a number between 0 and 1. In particular, in this case, our R^2 is near to the value 1 and this indicates that our regression line fits the data well. Moreover, it tells us that the mathematical model is a perfect correlation of the two variables X and Y.

Thus, it is possible to note by this graphic (Fig. 4.9), that physicians who have performed the procedure in a smaller time got highest scores than the other physicians that have completed the operation in a higher time. In addition, most of the physicians that have performed the procedure in very limited times were experts. That highlights once again the key role of the experience on this surgery procedure.

In summary, the obtained results emphasise the importance to have experience on this surgery procedure and, in particular, to make simulations as well [50].

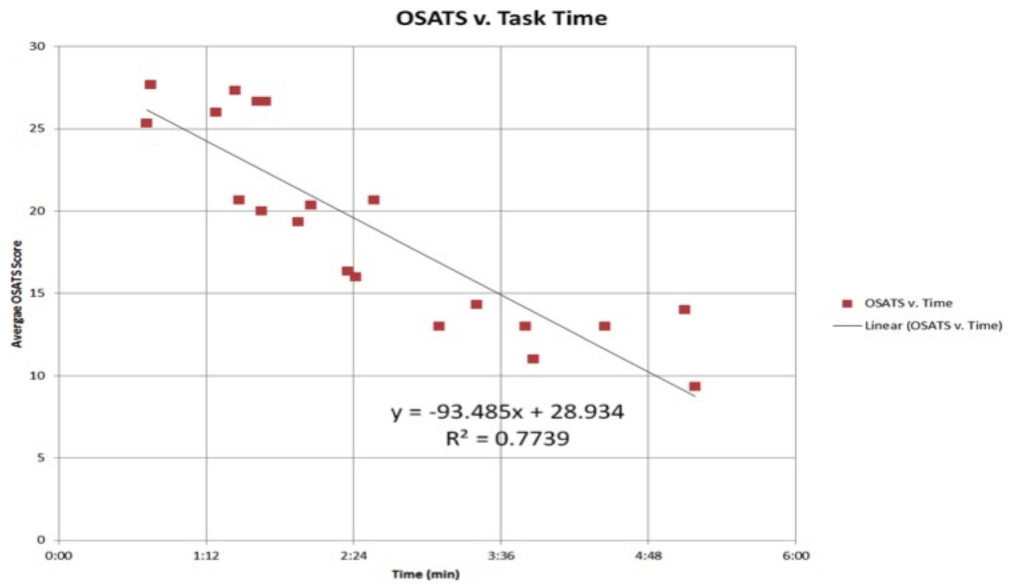


Figure 4.9: OSATS vs task time

Moreover, by comparing data from the experts to the novices, we have identified few essential parameters of proficiency for this procedure. These parameters include:

- Time to spot the correct zone on trachea
- Sequence of using instruments in the procedure
- Duration of procedure

4.3.3 Post procedure questionnaire: graphical results

After having collected the data of the 20 subjects that performed the procedure, we gave them a questionnaire, in order to get a feedback about the quality of the developed simulator. In particular, the aim of the survey consists of measuring efficiency, user satisfaction and perception of the simulator; moreover, we would also like to address quality and innovative performances in the future. The example of the survey is shown in the figure 4.11.

The survey data showed the majority of participants answered *moderate* or *very* on questions related to (1) anatomical accuracy (85%), (2) realism (50%), (3) improved understanding of procedure (65%) and (4) useful for practice (85%).

In conclusion, this study of 20 subjects demonstrated that the developed simulator was realistic, anatomically accurate and useful for practice and improving procedure knowledge.

4.4 A new and inexpensive method to assess competence

Experts in the field of surgical procedures complete OSATS (objective structured assessment of technical skills) to evaluate the physicians' ability. This golden standard method used in surgical residencies is very efficient and gives us a relevant feedback about the correlations of different parameters, such as task time and level of training. Nevertheless, it is also very expensive and time consuming.

This would help us to identify a possible cheaper alternative in the assessment of surgical skills. Consequently, subjects may be tested on a less expensive and time-consuming method.

Thus, we have found a solution to this problem consisting in an inexpensive microchip which could help to evaluate competence in this procedure, and to provide the same results as a gold standard (OSATS).

On the basis of the above observations, in collaboration with the department of the computer science at the University of the Washington, we developed a Mobile Crycothyrotomy Simulator.

This mobile application consists of a mobile phone connected to simple sensors;

it can be used to train healthcare professionals on the life saving procedures of the cricothyrotomy. This solution has a good balance of software and electronics applied to a critical problem and might be also a nice complement to streamline the communication part of the earlier shown cricothyrotomy prototype based on Arduino.

More specifically, a quick overview of the idea of the components we are developing on the Android side for the cricothyrotomy application, specifies:

- an ODK Sensors (part of the Open Data Kits [51], [52], [53] modular set of tools that helps to simplify sensing application development by creating a single interface that can virtually control any kind of sensor (either external or built-in)); the driver is able to process sensor data it receives from the custom board (4.12)
- a user application which researchers and physicians will interact with

There has been used a custom board (foneastra), based on the popular Arduino Mini platform (Fig. 4.12). It is a small, low-cost add-on device that plugs into cheap, non-programmable mobile phones and transforms them into networked sensing nodes. This device hosts application specific sensors and software, and leverages the connected mobile phone to communicate with backend servers or other mobile phones [54]. This system enables a variety of mobile applications in domains ranging from healthcare to remote monitoring to participatory sensing [55] [56], [57], [58].

We have thought about this kind of solution for the following reasons:

- mobile phones are the de-facto computing device in most of the world
- sensor networks are difficult to set up and manage

Thus, our solution allows:

- To extend phone capabilities via a lowcost, programmable hardware add-on
- To support for application-specific sensing and computation
- To leverage phone as modem for communication and for I/O with user

This custom board can interface with mobile devices over wired (UART) or wireless (Bluetooth) communication channels. Being battery-powered, it can operate autonomously and support the cricothyrotomy applications, in which a mobile device collects sensed data by connecting to the board intermittently. When connected to a mobile device that acts as a USB Host (i.e., can source power on the USB port), the board can be powered by the mobile device itself, and does not require a battery [59].

The board acts as an interfacing board for sensors that only have low-level, analog or digital (e.g., I2C, SPI) communication interfaces; it also has an on-board SD memory socket, a real time clock (for autonomous data collection), a few LEDs and an audio buzzer.

Thus, a new plataform with the trachea mockup, the tracheatomy medical instrumentation tools and the new custom board were created instead of developing a mobile phone interface (Fig. 4.13).

The board was also connected to the trachea mockup and to the different medical instruments. Moreover, an Android smart phone (Nexus 7) was used to implement the mobile application (Fig. 4.14, Fig. 4.15). This Android side has a working system that can display which pad is being touched and to record the data as well. In addition, a tutorial with a video clip about the way to perform a good cricothyrotomy procedure can be displayed on this smart phone. A detailed web interface showing error messages and numerous real-time information about the procedure can help the user on the navigations on the cricothyrotomy mobile application (Fig. 4.16).

Furthermore, a questionnaire was created to get a first feedback about the physician's user (Fig. 4.17). This application is still in progress and needs to get feedbacks from quality questionnaires and experimentation outcomes. However, the simulator created also combined with this mobile application, can help the physicians to correctly perform the procedure and get directly feedback about their performance.

Finally, the whole system is completely usable in each part of the word. All its components are made with very low cost materials; moreover, adding the microchip described above to the system, it is also possible to evaluate the users' competence in performing the procedure in a way that is very cheaper than the

OSATS method.

4.5 The lighted uterine manipulator: a preliminary performance measurement

It is very important to evaluate how well the manipulator will work in real applications and what the impact on the overall medical community would be.

In order to achive this goal we have showed our built manipulator to numerous medical doctors of the University of Washington Medical Center: all of them gave us a very positive feedback about it, as the manipulator perfectly fits their needs.

Considering that our manipulator is an upgrade version of an already existing commercial one (even if the updates are definitely essential...), we do not need a very detailed experimentation; by the way, we are still testing it on cadavers and, if results would be promising, we plan of applying this simulator on humans.

So, such an experimental work is still in progress, but it seems like the preliminary results are very good.

GLOBAL RATING EVALUATION OF PERFORMANCE

Please circle the number corresponding to the candidate's performance regardless of their level of training

Respect for tissue

1	2	3	4	5
Frequently used unnecessary force on tissue or cause damage by inappropriate instrument use		Careful handling of tissue but occasionally caused inadvertent damage		Consistently handled appropriately with minimal damage to tissue

Time and motion

1	2	3	4	5
Many unnecessary moves		Efficient time & motion but some unnecessary moves		Clear economy of movement and maximum efficiency

Instrument handling

1	2	3	4	5
Repeatedly makes awkward or tentative moves with instruments through inappropriate use		Competent use of instruments but occasionally appeared stiff or awkward		Fluid movements with instruments and no stiffness or awkwardness

Suture handling

1	2	3	4	5
Awkward and unsure with repeated entanglement, poor knot tying and inability to maintain tension		Careful and slow with majority of knots placed correctly with appropriate tension		Excellent suture control with correct placement of knots and correct tension

Flow of operation

1	2	3	4	5
Frequently stopped operating and seemed unsure of next move		Demonstrated some forward planning and reasonable progression of procedure		Obviously planned operation with efficiency from one move to another

Knowledge of procedure

1	2	3	4	5
Insufficient knowledge Looked unsure and hesitant		Knew all important steps of operation		Demonstrated familiarity with all steps of operation

Overall performance

1	2	3	4	5
Very poor		Competent		Clearly superior

Quality of final product

1	2	3	4	5
Very poor		Competent		Clearly superior

Figure 4.10: OSATS Global assessment form: to assess physician competence in a surgical procedure

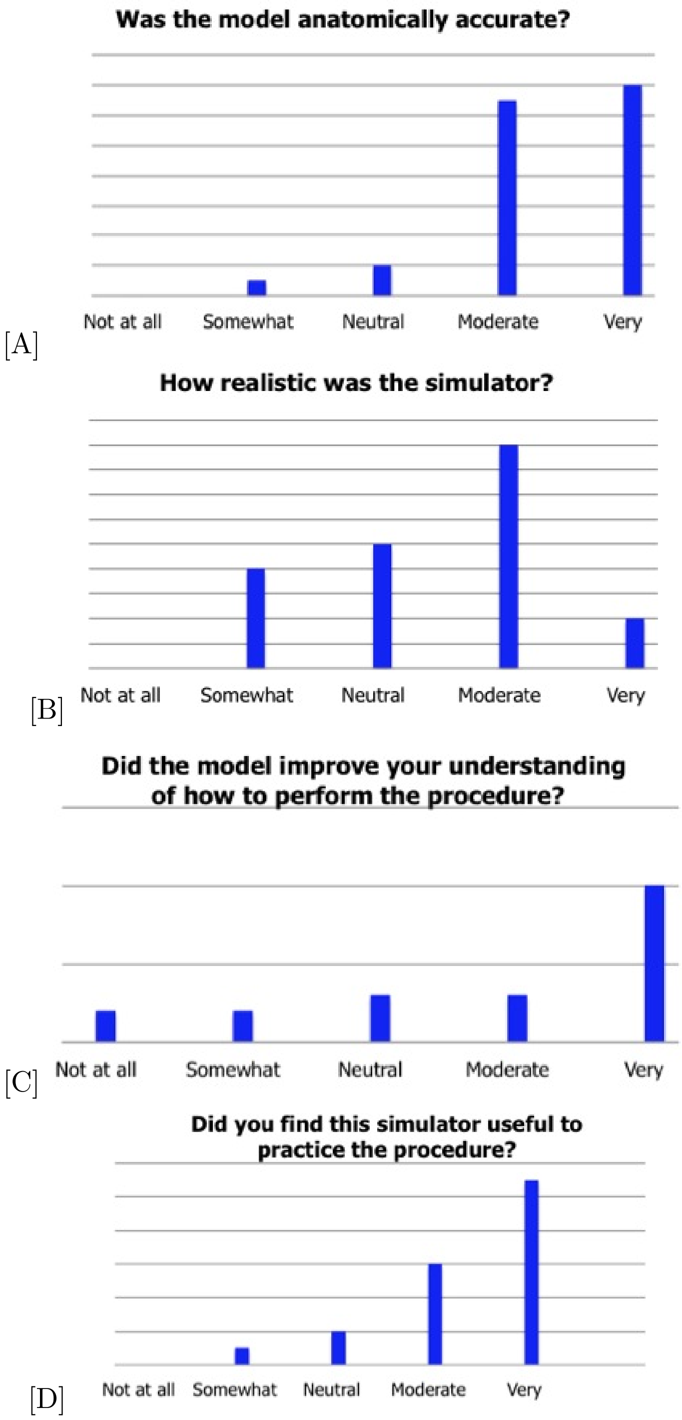


Figure 4.11: The survey results

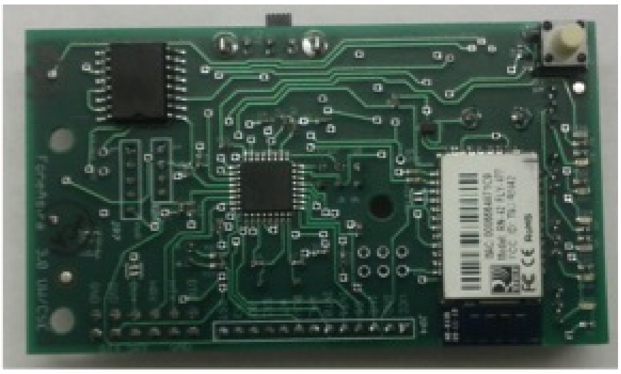


Figure 4.12: The custom board used for mobile applications

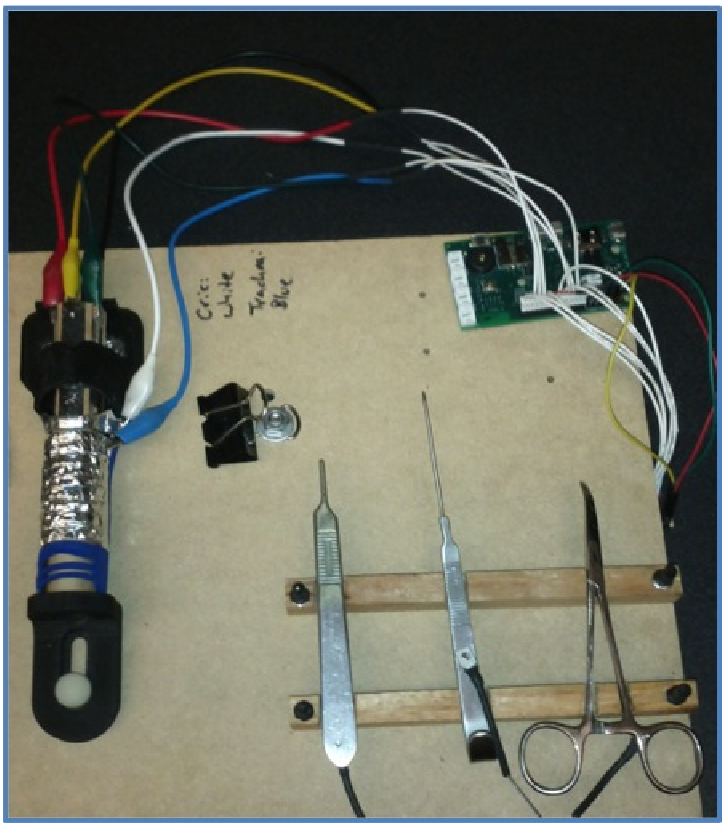


Figure 4.13: The simulator with the custom board

Figure 4.14: The customized user interface for mobile phones created

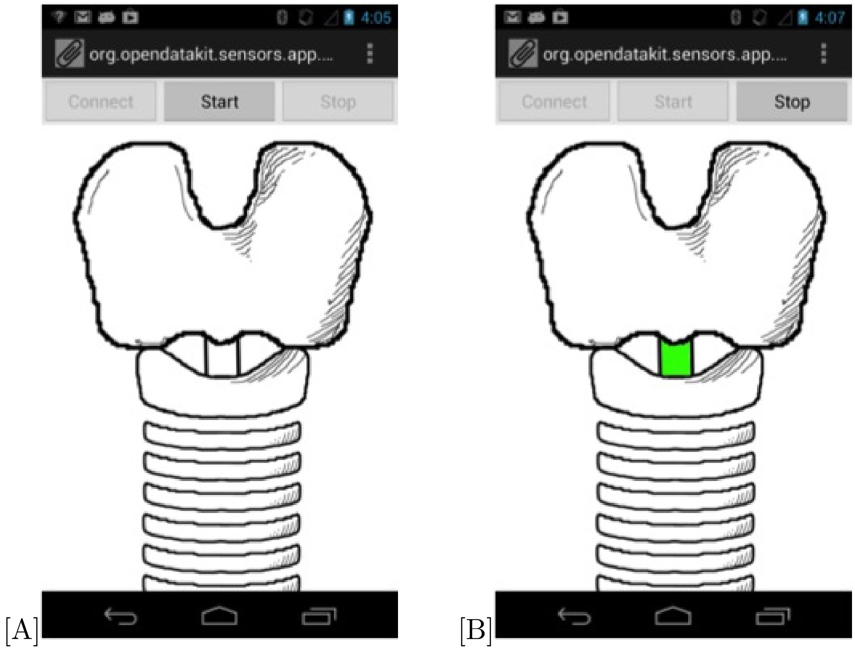
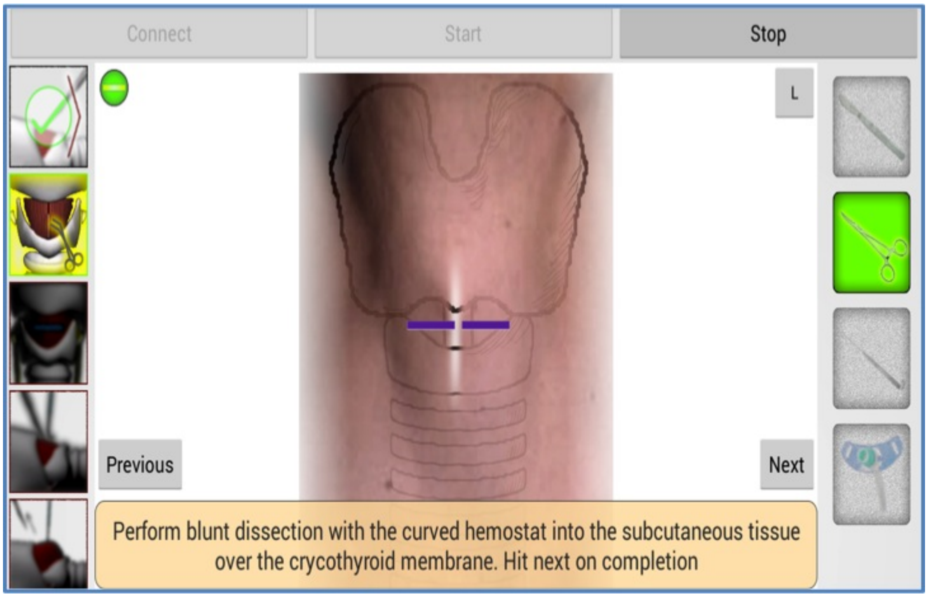
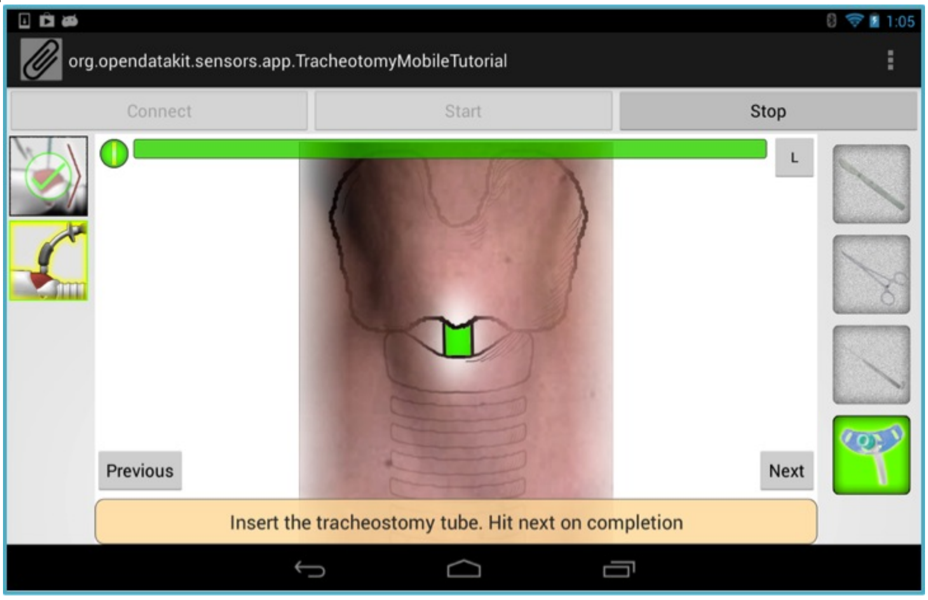


Figure 4.15: Mobile phone interface: [A] starting tutorial; [B] ending tutorial



[A]



[B]

Figure 4.16: The android application created for the mobile training tool interface: [A] example of a blunt dissection with the curved hemostat; [B] example of tracheostomy tube insertion.

Subject Number: ___

ODKSensor Tracheotomy Simulator Usability Questionnaire

Section A:

PGY Level/Field: ________________ Age: _____ Handedness: R / L / A

Section B:

	On a model/simulator	Clinical (non-emergent)	Emergent
Number of completed tracheotomy procedures? (Approximate)			
Last time you performed the procedure? (Days, weeks, years, never)			

Section C:

Please select a rank for each of the following questions (1 being poor, 4 being excellent).

General Questions	**1 (Poor)**	**2 (Bad)**	**3 (Good)**	**4 (Excellent)**
How familiar are you with Android smart phone?	☐	☐	☐	☐
How do you feel about the mobile application as a whole?	☐	☐	☐	☐
How do you feel about the navigations of the mobile application?	☐	☐	☐	☐
Tutorial Mode Questions	**1**	**2**	**3**	**4**
How representative is the Cricothyroid display to the simulator?	☐	☐	☐	☐
How do you feel about the instructions on the bottom of the display?	☐	☐	☐	☐
How do you feel about the error messages on the top of the display?	☐	☐	☐	☐
How do you feel about the progress bar on the right of the display?	☐	☐	☐	☐
How helpful were the video clips?	☐	☐	☐	☐

Figure 4.17: ODKSensor tracheotomy simulator usability questionnaire

Chapter 5

Conclusions

The goal of this thesis is to develop new technologies in surgery in order to improve the current limitations. Consequently, with the purpose to resolve some issues in surgical cricothyrotomy and in robotic hysterectomy, respectively, an innovative surgical simulator was developed and a new uterine manipulator was built.

This chapter concludes the thesis by providing a summary of results obtained in the preceding chapters and suggestions of areas for future research.

5.1 Summary of contributions

The focus of this thesis is to overcome some limitations on open surgery and surgery robotics as well. An original *cricothyrotomy simulator* and a new *surgical robotic manipulator* built for hysterectomy were presented.

- *A cricothyrotomy simulator* for use in a low-resource environment was designed and produced. It collects data that can be used for performance evaluation and instruction. The device was designed to help training people to safely perform this procedure and to assess their level of procedural skill with special attention to limited resources available in rural environments in the developing world. It emphasizes the palpation and the correct identification of anterior cervical anatomy. Our system uses electrically connected surgical tools and electrical contact pads to record the interactions between the provider and a patient mockup. Each contact between tool and tissue is electrically time-stamped; the recording enables real-time feedback for training or automatic post-performance evaluation. This validation study examines 20 subjects of varying skill levels using the simulator, and then graded using OSATS. The study implemented, demonstrated that it was realistic, anatomically accurate, and useful for practice and improving procedure knowledge.

The simulator was designed to be built in low-resource environments using common tools and available materials. This surgical procedure simulator is powerful and precise and it is coupled to a microprocessor enabling:

  - recording a medical procedure and assessing that performance for skill
  - providing handson skills training with immediate feedback

The model is a training and assessment tool for cricothyrotomy, but it also provides an opportunity to educate users on the entire airway management algorithm, in which cricothyrotomy is the last resort.

In addition, a mobile phone interface was created and added to the simulator. It has permitted to obtained a possible cheaper alternative in the assessment of surgical skills. Thus, physicians may be tested on less expensive and time-consuming method.

- Moreover, an innovative design for an *uterine manipulator* used for robotic hysterectomy was proposed. One of the main obstacles in doing this type of surgery is clearly identifying the junction where exactly the colpotomy should be made. This is especially problematic when using a robot; therefore, an innovative manipulator that lights up and visually indicates the cervicovaginal junction and where the surgeon should make the vaginal incision was invented. This lighted uterine manipulator

  - would improve patient safety
  - would make the surgery easier for the surgeon

This innovation would cause a huge benefit for the entire medical community; currently, there are no uterine manipulators with a lighted cuff that would fit around the cervix.

5.2 Avenues for future research

In reflecting on the research questions addressed, we observed several interesting research topics. These would allow us to further evaluate and expand the findings of this thesis.

Future work in relation to the *cricothyrotomy simulator* will explore creating post-performance evaluation algorithms that will be validated against traditional human-graded cricothyrotomy procedure certification assessments.

The next step would be to create a website with the instructions to build the system, the models, and the training and assessment curriculum; then, we would also like to go ahead in this direction, designing a mobile training curriculum (as we already doing - see 4.4 section). It would be also interesting to provide:

- A validation of the simulator in developing world
- An incorporation into airway algorithm teaching
- An impact assessment in patient survival rates

Finally we will perform wider validation studies and create simulators for different procedures using the same base of technology.

For what concerns the *surgical robotic manipulator*, a detailed experimentation on cadavers (already started) and then on real applications is necessary.

In order to address this issue, a specific experimental protocol has been just designed: thus, we have just required some apposite permissions to medical doctors, who gave us a very positive feedback.

So, we are waiting for the experimentation on cadavers completed and for some official permission agreements to go on with the next steps.

Finally, it is hoped that the work presented in this thesis will provide a solid foundation for research in the field of new surgical technology as robotic surgery and simulation.

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