KEY DESIGN FEATURES TO IMPROVE THE SAFETY OF SURGICAL ROBOTIC SYSTEMS AND EVALUATION AND IMPROVEMENT OF A SURGICAL-ASSISTANT TEST-BED ROBOTIC SYSTEM

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To my Family

ABSTRACT

The significance of the robots in the medical field have been increasing rapidly. Humans and robots working together increases the strengths and decreases the limitations of surgical operations. Human life makes safety the most important problem for medical robots, for which there are no universal standards. This thesis presents detailed design methods for increasing medical robots' safety by considering issues of sterilization, robot's size, operating room placement of the robot, the robot mechanics, selection of the electromechanical components, drive mechanism, stiffness, sensor redundancy, software application, and hazard identification and analysis. The proposed safety design concepts were applied a surgery robot named MISA (Minimally Invasive Surgery Assistant) and the outcomes are discussed.

This thesis presents the architecture of a surgical robotic system designed to assist minimally invasive surgeries. The design, mechanism, electronic components, kinematics and control of an example robot MISA are discussed. The system includes a 5 DoF robotic arm and surgical scissor as an end effector.

As far as all the information about required safety concepts is concerned, this thesis can be considered as a guideline to design more safe surgical and medical robotic systems.

ÖZETÇE

Medikal alanlarda kullanılan robotların önemi gün geçtikçe artmaktadır. Insanların ve robotların beraber çalışmasıyla cerrahi operasyonların yapılabilirliği artarken karşılaşılan limitler de azalmaktadır. Insan hayatı güvenlik konusunu en önemli sorun haline getirmesine rağmen sağlık robotları hakkında evrensel bir standart bulunmamaktadır. Bu tez, sterilizasyon, robot boyutları, robotun ameliyathanedeki yerleşim şekli, robot mekaniği, robotun elektromekanik aksamlarının seçimi, robotun çalıştırma mekanizması, robotun katılığı,sensör artıklığı, yazılım uygulamaları, risk tanımlama ve risk analizi konularını ele alarak medikal robotların gvenliğini artırmak için detaylı tasarım yöntemlerini göstermektedir. önerilen güvenli robot tasarım konseptleri MISA(ENG: Minimally Invasive Surgery Assistant - TR: Laparoskopik Cerrahi Asistanı) Robotu'na uygulanmıştır ve bu uygulamanın sonuçları tartışılmıştır.

Bu tez laparoskopik cerrahiye yardımcı olacak bir ameliyat robotunun tasarımını anlatmaktadır. Ayrıca, örnek model robot MISA'nın tasarımı, mekanizması, elektonik aksamları, kinematiği ve denetimi incelenmektedir. Bu robotik sistem, 5 serbeslik dereceli robot kolu ve cerrahi makas içermektedir.

Gerekli güvenlik konseptleriyle ilgili bilgiler göz önüne alındığında bu tezin daha güvenli ameliyat ve sağlık robotu tasarımı için bir yol gösterici olduğu söylenebilir.

ACKNOWLEDGEMENTS

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CHAPTER I

INTRODUCTION

Over the last few years, the role and importance of robots have increased in medical services through significant improvements in relevant technology. It is possible to apply industrial robots' mechanical design concepts, kinematics, control algorithms, and programming to medical robots. However, robots have limitations besides their strengths. The differences between humans and robots should be taken into consideration to assess the benefits of using robots in surgeries. For instance, robots might not be as good as humans in decision-making when an issue arises during a surgery. Therefore, it might be risky to completely replace the surgeons with robots due to safety problems.

Robotic systems should have extended version of human capabilities, and not take the humans place [24]. The most appropriate help for surgeons, who mostly use their hands during the operation, is to provide physical guiding assistance by a medical robot [25]. To be good assistants robots should be developed considering safety issues and patients satisfaction after the surgery.

Safety as a bedrock problem of the human and robot collaboration needs to be required for every robotic surgery system. To be able to do this, there need to be some safety standards. Currently, there are no universal, specific, and detailed standards for certifying a robotic surgery system's safety. The way safety is framed for industrial robots is different from the way it should be framed for a surgery robot, therefore industrial robot safety procedures are not necessarily transferable to the operating room (OR). For instance, safety in the case of industrial robots is achieved by hindering humans from direct contact with the robot, while surgeons and patients need to be in contact with medical robots. The main aim of industrial robots is production and safety measures are developed accordingly, whereas the main concern is human life for medical robots, therefore the safety should be considered accordingly [26].

No system can guarantee absolute safety and this creates a big concern for medical robots. However, the existent systems are in need of at least some basic standards to address the safety issues to make the medical robots more practical, safe and accurate. This thesis provides detailed information about the design aspects of a safe surgical robotic system and reports the results of their application on a test bed system, the MISA (Minimally Invasive Surgery Assistant). The design of the robot was improved according to the proposed safety guidelines and it was possible to generate a safer medical robot.

1.1 Safety Parameters

The aim of engineering has always been developing a need-based design using available resources. The best options are adopted during the design optimization process, which should contain variables that specify the alternatives of the design, selected criteria to designate the variables of the design, constraints, and limitations of the design, and the variables of the design which satisfy the limitations and constraints [4]. During the design process, it is essential to keep in mind the safety maintenance since the designed parts always interact with people and the environment. In this section, the concepts of sterilization, training for robotic assisted systems and patient safety, placement of the robots in the ORs, mechanism and design alternatives of the system, and software applications are addressed and explained to improve the safety of a medical robot.

1.2 MISA (Minimally Invasive Surgery Assistant)

Minimally Invasive Surgery (MIS) has been becoming a common procedure in recent years. This surgery type, that requires small incisions, has significant advantages such as shorter recovery time and reduced risk of trauma for patients when it is compared with the open surgery. On the other hand, MIS has some disadvantages like having low manipulability and small view angle. These drawbacks can be compensated by using an assistant robot in laparoscopic surgeries[27].

MISA (Minimally Invasive Surgery Assistant), is a 5 DoF surgery robot that is designed to assist MIS. MIS operations are not applied by MISA itself. MISA can be considered as an additional hand for the operators to implement small incisions, to hold a camera or other surgical equipment. The base of the robot is produced from light weight aluminum sigma profiles to have a light and cost-effective body structure. Thanks to the casters, it can be moved and stored to desired positions easily in the operating rooms. It can be placed anywhere in ORs simply since it has an advantage of being small compared to the other medical robotic systems[28]. Locking mechanism of the casters aid to keep the robot position stable and secure during the surgical operation. The robot arm of MISA is produced by ABS filament with an usage of 3D printer to have a fast prototype of this experimental robot. Since ABS is cheaper, easy accessible and relatively durable, it is decided to generate MISA by using this material. It is important to note here that ABS is not a sterile material and this design is still in development process to implement safer surgical operations. Figure 1 demonstrates the CAD model of the robot.

Safety of the medical and surgical robots is a huge theme to discuss and no system can reach an absolute safety. However, it is achievable to improve the safety of the robotic systems by considering a couple of design parameters as discussed in this thesis. MISA can be considered as an example surgical robot prototype of a relatively safe, budget friendly, light weight, small and portable surgical operation assistant that is generated by using safety design parameters.

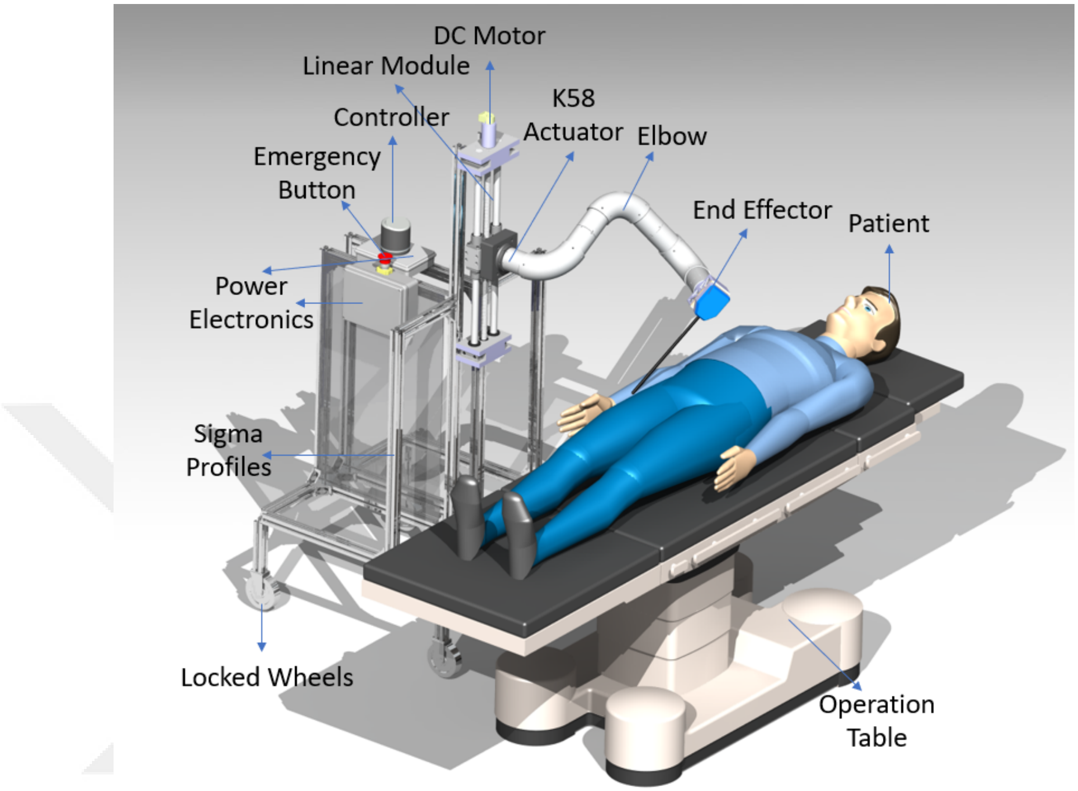


Figure 1: MISA as a laparoscopic surgery assistant, with operation table and patient.

1.3 Thesis Outline

This thesis is organized as follows. The improvements and suggestions to design safer medical robots are discussed in Chapter 2. The concepts of sterilization, patient safety, robot size and placement, robot mechanics, sensors, drive mechanism and stiffness, software applications and risk analysis are explained in detail. In Chapter 3, these safer design concepts are implemented on a test bed system and the design of a prototype surgery robot is finalized.

CHAPTER II

SAFETY PARAMETERS FOR MEDICAL ROBOTIC SYSTEMS

Safety is an essential concern for medical robotic systems since they have influences on living creatures. To improve and ensure the safety of a robotic system, there are some safer design concepts that need to be considered such as sterilization, training for robotic systems and patient safety, size and placement of the robot, robot mechanics design and selection of electromechanical components, sensor redundancy, drive mechanism, stiffness, and software applications

2.1 Sterilization

Sterilization is making an item microorganism- and spore-free and it is an international standard to use sterile materials in surgeries [29]. Therefore, every part of a medical robot that comes in contact with a patient's body should be sterilized or covered by sterile drapes. It is convenient to design single-use-components, which need to be sterilized only once, as the safest and most hygienic solution. It eliminates the risk of contamination. If there is no chance to replace the parts for each surgical session, it is recommended to design the robots end effector removable and sterilizable. However, possibility of any sterilization problem creates risks for the environment. If the end effector has sensors and motors, gas or soak sterilization could be used [28, 25, 30]. For other parts of the robot, a bag that can be sterilized recurrently can be used as a cover. For any medical situation, safety and hygiene are more significant factors than cost effect. Thus, to have an end effector single used and cheaper would be the best option in terms of safety.

Figure 2: Heat method of sterilization [2]

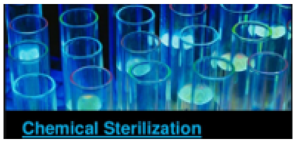


Figure 3: Chemical sterilization [3]

Figure 4: Sterile drape [4]

Figure 5: Gas sterilizer [5]

2.2 Training for Robotic Assisted Systems and Patient Safety

The pressure on the hospitals has been increased to fulfill the patient demand and satisfaction. According to Agency of Healthcare Research and Quality (AHRQ), the idea of having surgery by a robot is catchy and exciting for patients. As a result, it affects the growth of robotics in the medical field. Moreover, hospitals see this demand as a marketing strategy [31]. Although robotic surgery seems so fascinating, it has some disadvantages such as patient safety and selection of training period for operators. Training can be considered as a risk factor since there is no universal and standard procedure for robotic surgery applications. Even though there are some advises of professional organizations, a standard that covers all procedures needs to be defined for this new technological application. To prevent risks and improve the patient safety, implementation of training and providing certification should become the responsibility of individual healthcare organizations. However, it may not be enough to prepare operators/surgeons totally to implement complex robotic system applications successfully. A license program can be generated and applied to operators using robotic systems. Additionally, some specific standards for clinical training, inspection, competency and accreditation need to be defined by the healthcare organizations, to guarantee that the operators and the whole team ready to implement robotic assistant system operations [31]. The training that focuses on competency more than time and quantity, involves level-based learning objectives and assessment, includes simulations and requires minimum criteria to indicate competency is more educational and helpful for the operators. According to the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and Minimally Invasive Robotics Association (MIRA), the practical experience, having knowledge on standard operating procedures and emergency protocols, risk detection and evaluation are the key elements that a surgeon should have. According to the FDA survey, it is stated that surgeons that have experience about robotic operations, need to perform several robotic operations to become proficient. In some cases, the surgery type can be changed. Therefore, the operators and the medical team should be ready to any conversation between robotic surgery to open surgery in necessary conditions. To make the whole surgical team prepared to perform safe and effective robotic operations, can be achieved by a training program, includes simulations. Moreover, surgeons should become too specialized at using foot pedals, cameras and instruments, complying with the robotic arm movements, having basic skills, and being familiar with the medical procedures. Organizations should generate an evaluation criteria for robotic operations proficiency maintenance in the long run, includes continuous training and education, performance observation, and re-accreditation [31]

Patient selection and informing patients about the robotic procedures are two key elements for patient safety. Patients should be aware of that every patient may not be an ideal candidate for robotic applications. The outcome of the robotic operations is influenced by health conditions of the patient such as diabetes, patient's history of other surgeries, cardiac diseases and obesity. To reduce the risks, operators and organizations should also generate a guideline for patient selection. The guideline can be helpful for clinical decision making and handling the expectations of the patients about robotic operations. Last but not the least, the patient should be informed and educated about the robotic operation by the surgeons. This education involves the information about the surgical operation and its implementation, the experience of the operators with robotic surgery, alternative treatment options and comparison of these alternatives with robotic implementation and potential risks related to surgery itself and the robotic application failures such as system errors, unexpected equipment motions, broken components, electrical problems, and imaging errors [31].

2.3 Size of the Robot and Its Operating Room Placement

Surgical robots should be coherent with the OR. The size of the robot is significant since the ORs have limited space. When a surgical robot is placed in the OR, the room is reserved for only this robot and its medical operations need to maintain the sterile conditions. There are some placement options for the robot, which are, mounting to the operating table, placement on the floor next to the patient, mounting to the ceiling, or placing the robot on the patient. All options have certain drawbacks, therefore none of them can be considered as the ideal option [32]. The most commonly used methods are mounting the robot to the operating table and placing the robot next to the operating table. The operating table attachment is appropriate only when the table can move freely. In some operations, the table orientation might be changed for easier access to the surgical site. If the robot is table mounted and heavy, this might hinder the operation. ZEUS Robotic Surgical System and Raven are examples of operating table mounted surgical robots [33, 28]. Although floor-attached robots allow for higher payloads, they need more space in the OR. da Vinci Surgical System, ROBODOC, NeuroArm, and RIO Robotic Arm Interactive Orthopedic System are such robots designed as patient side systems [34, 35, 36, 37]. Ceiling mount surgical systems, such as HISAR [7], allow the robot to move freely, but they need an exclusive OR in the hospital. Robotic systems that are placed on the patient, such as SPRINT and Light Puncture Robot [38],[39], can adapt to the motion of the patient, however, it causes stability, weight and access problems.

Figure 6: Floor attached surgery robot: Da Vinci Surgery Robot [6]

2.4 Robot Mechanics Design & Selection of Electromechanical Components

2.4.1 Power Specifications

For patient safety, it is important to specify the maximum safe propulsion force, the contact pressure, the minimum required speed and power, maximum reached safe temperature, and length of travel [40]. Force-controlled robots that use series elastic actuators (SEAs) are better options to use since they offer more safety features and good collaboration with the operators. The series elasticity of these actuators makes it possible to gain the lost qualities caused by the gears, and increase the stability of the force control [41]. Their relatively higher cost is the only drawback of the SEAs.

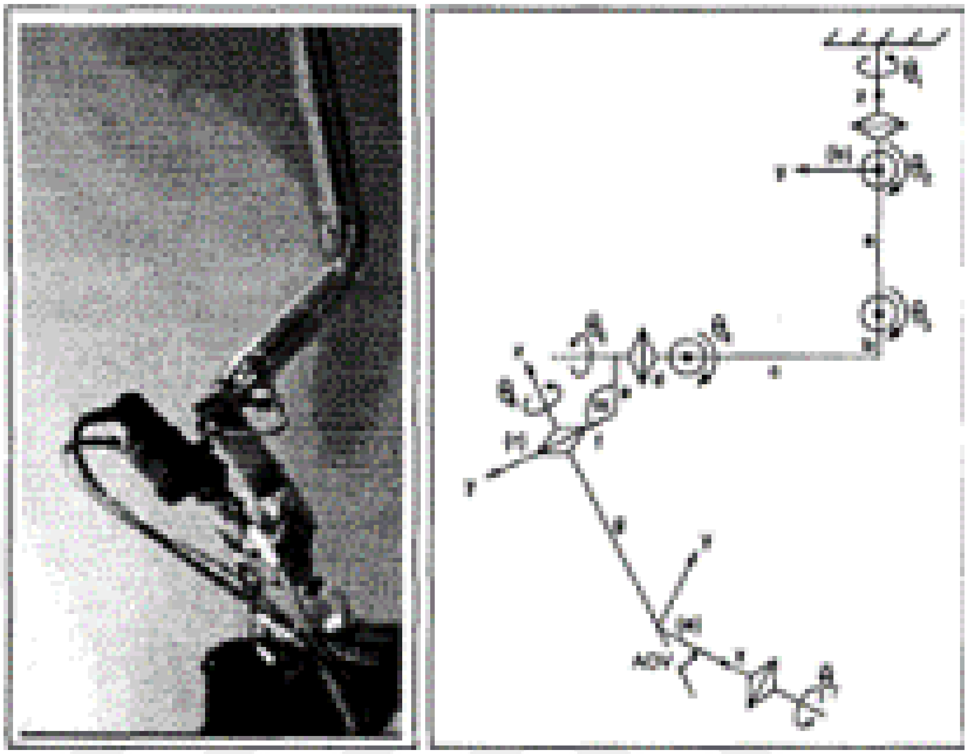


Figure 7: Ceiling mount surgical system: HISAR [7]

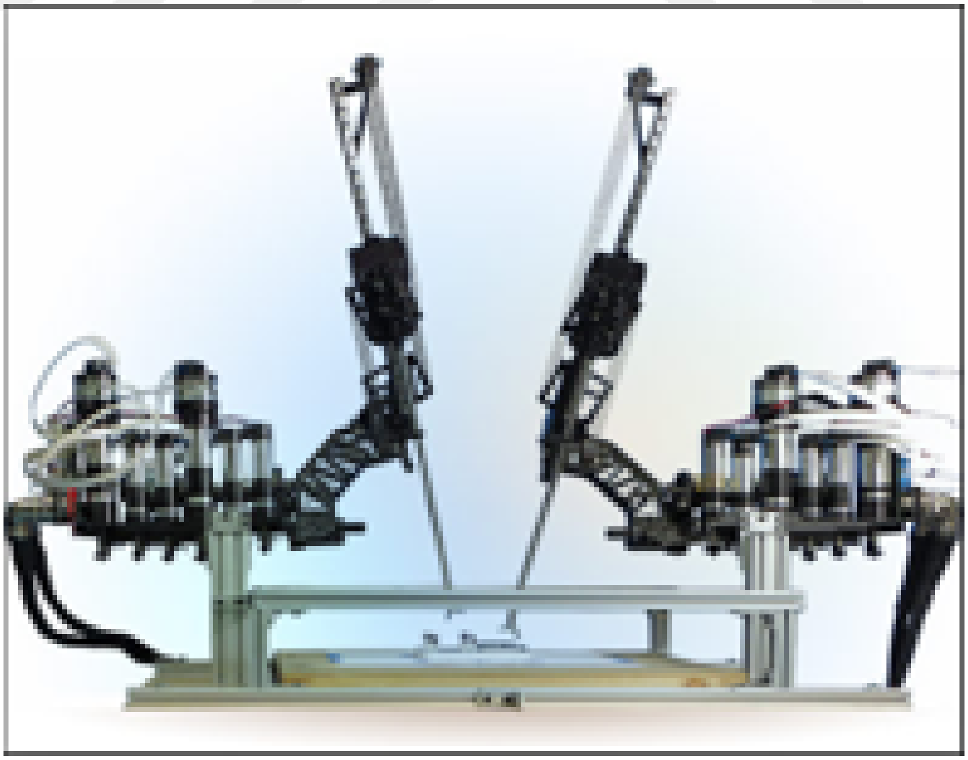


Figure 8: Operating table mounted surgical robot: Raven. [8]

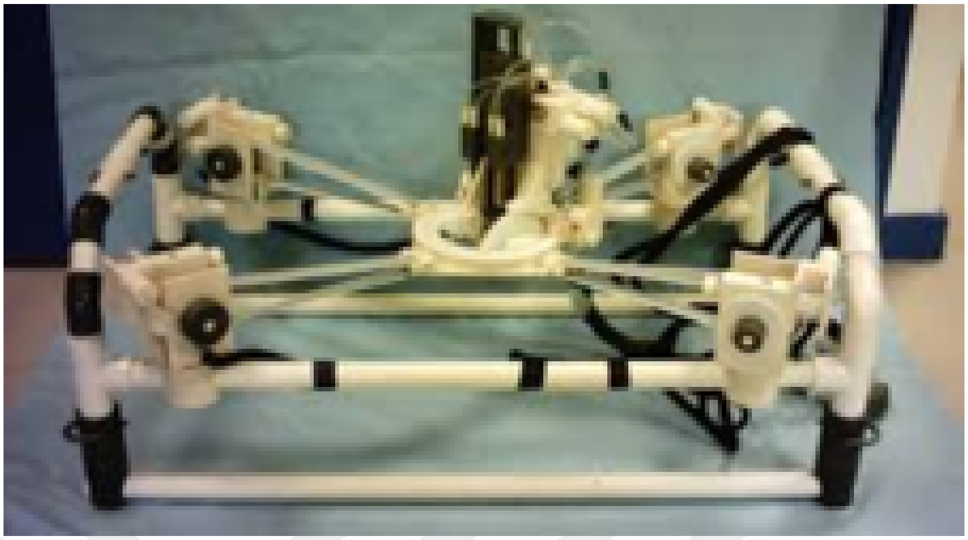


Figure 9: Light Puncture Robot as an example of patient attached surgery robot. [9]

2.4.2 Head injury criterion

Injury risks associated with a robotic system during its interactions can be estimated with an approved risk criterion. Head injury criterion (HIC)[42] for measuring the robotic system safety is one of them. HIC is based on two quantities: effective arm inertia and interface stiffness [43]. Building lightweight and low-inertia manipulators can provide safer and more ergonomic experience to users compared to the larger and heavier ones for medical purposes [32]. Hence obtaining reduced size and lightweight manipulators are of significant importance. For an industrial robot that is interacting with a human, there is a basic safety requirement, restricted by ISO-10218. According to this requirement, a tool center point and flange ratio velocity of a robot should be less or equal to 0.25 m/s, the maximum dynamic power should not exceed 80W or the static force should be maximum 150N [44].

2.4.3 Electronics

The robot should comply with the basic medical electrical equipment standards followed by the industry, such as IEC 60601 [45]. According to these standards, every medical device touching the patient should have proper electrical isolation. Extra care should be given to select the electrical equipment.

It is also reasonable to choose miniature brushless motors for simple and lightweight systems. Systems should operate with low speed since it decreases the overheating and provides a faster stop response [25]. These motors reduce the total weight of the system which makes the system more reliable. Since the number problematic points are decreased, the requirement of any lubrication or maintenance method is annihilated, and the problems of actuation cables such as stretching, are solved. Also, the collision risk between the manipulators is eliminated. Thus, the system's safety can be increased by the decreased motor torque necessities in the manipulators [28].

2.4.4 Kinematic Configuration with respect to the Surgery Type

There are two main types of a surgery: open (traditional) and laparoscopic. For an open surgery, an 8-10 cm incision needs to be open. On the other hand, multiple small incisions are sufficient to perform laparoscopic surgeries. Single-port surgery is the type of a laparoscopic surgery that is performed through a single incision. To enable single port surgery, using a Remote center of motion (RCM) mechanism is the main design option. This mechanism is able to inhibit possible damages, created by the surgery robot, to tissues [46]. It has two advantages that are allowing translational actuators to be disabled as long as only pivoting motions are necessary and allowing to size the actuators and gear ratios properly for their individual motions. Therefore, control of the system and safety can be simplified [32]. For the traditional surgeries, RCM is not required to use as it would increase the complexity of the robot.

2.5 Sensor Redundancy, Drive Mechanism and Stiffness

Sensor usage is critical to observe and control the precise positioning tasks. The position, speed and current data about the process are gathered by sensors and localizers, to implement a safer operation. Furthermore, the selection of the drive mechanism also has influence on the quality of the processes.

2.5.1 Sensors and Switches

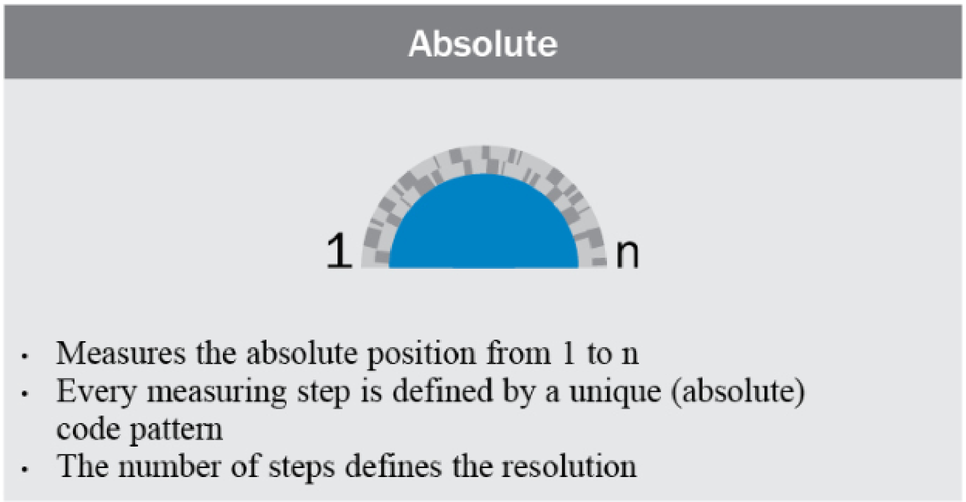
Localizers such as optical tracking, magnetic tracking, or medical imaging systems, such as ultrasound and X-ray, can be used for positioning. Measurement uncertainty could be reduced by using internal and external sensors together [30]. Emergency power off switch buttons must added to the system to cut the power supplied to the motors. More than one button could be used to provide accessibility from various positions. Magnetic and mechanical locks for limiting the joint motion, brakes, and position feedback can also be added to the system.

2.5.2 Position Sensor Selection for Closed-loop Control

During precise positioning tasks, it is necessary to observe and control the activity, and the moving speed before the interaction between the manipulator, and the patient should be low. To achieve these, it is essential to use rotational position sensors, which can be added to the design [26]. Encoders, hall effect sensors and potentiometers are commonly used position sensors in robotic systems to collect the position, speed, and current data. Hall effect sensors are small in size, low cost, easy to use, and durable making them a convenient choice [47]. Potentiometers are also simple to use, easy to reach, relatively inexpensive, and lightweight [48].

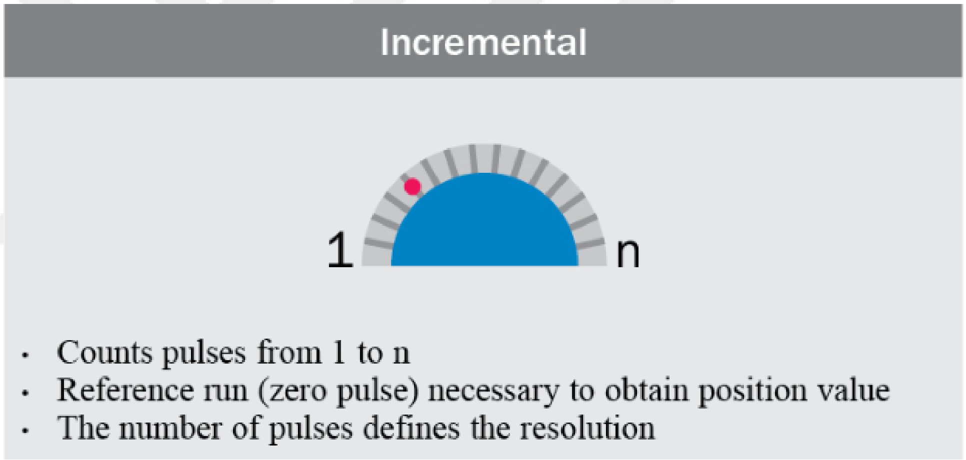
There are two types of encoders: absolute and incremental, Figure 10 and 11. Their size and resolution features are different from each other. Absolute encoders have potential to give unique position information by analyzing the position data from the moment they are turned on. Every position in the system has a unique code. They can ensure that accurate positioning is maintained in cases of power interruptions. Absolute encoders can be more effective and suitable for precise applications but they are larger than incremental encoders.

Incremental encoder's output signal is in tick counts for a specific amount of shaft



- Measures the absolute position from 1 to n
- Every measuring step is defined by a unique (absolute) code pattern
- The number of steps defines the resolution

Figure 10: Absolute encoder working principle. [10]



- Counts pulses from 1 to n
- Reference run (zero pulse) necessary to obtain position value
- The number of pulses defines the resolution

Figure 11: Incremental encoder working principle. [10]

rotation. No matter what the initial position of the shaft is, they start to count from zero when the encoder is turned on. In the case of an encoder failure, the system measures a permanent steady state error. Thus, the system tries to decrease this error by continuing to drive the motor [30]. This situation may cause fatality and also damage the robot. To correct encoder failures, a second encoder can be added to the system for redundancy. It is appropriate to use absolute and incremental encoders together to make up for each others' deficiencies.

2.5.3 Guidance Systems

Obtaining the information about the changes of an objects position, velocity or acceleration, namely guidance is another important aspect of robotic surgery systems. Since every human has a different anatomy, there cannot be a standard design and orientation of the surgical components. Thus, it is required to specify both the orientation and the position of the patient's body at every stage of the operation [49].

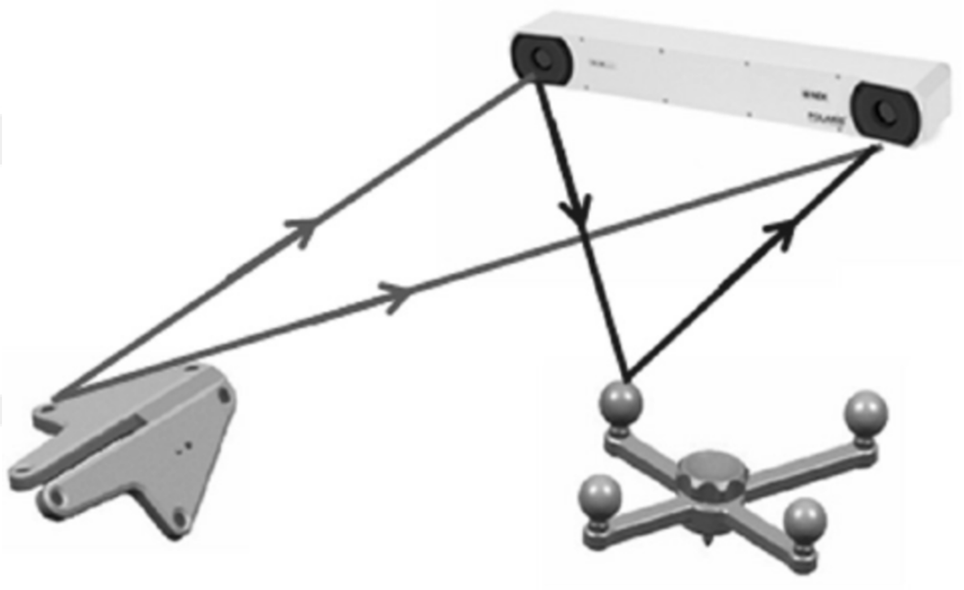


Figure 12: Polaris NDI Tracking Navigation System. [11]

Imaging methods can be used for guidance in most surgical operations, which makes it possible to get the 3D position of the target tissue and to guide the end effector simultaneously to make the operations more risk-free [50]. Image guiding systems are classified into three categories: Passive systems (Navigators, Aiming Systems), Semi-active systems (Laser guided alignment, Figure 13, Mechanical guide) and Active systems [25]. In passive systems, the surgeon can reach the information about the surgical tools position according to the anatomical data or a pre-planned strategy and he/she has complete control over all surgical actions. Active systems are autonomous. For instance, they can drill a bone with no help from the surgeon.

In semi-active systems, the surgeon collaborates with the system [51].

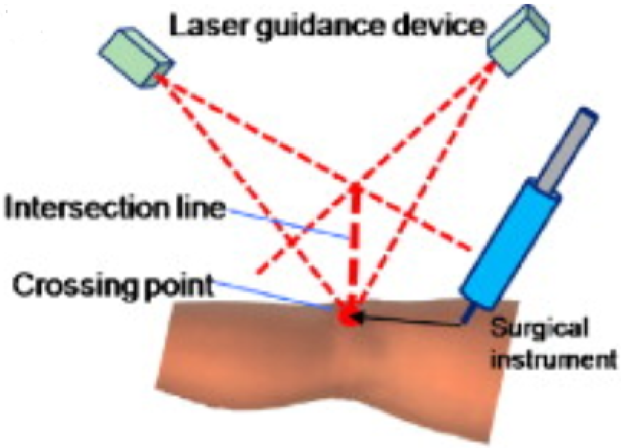


Figure 13: Laser guidance system with a surgical instrument. [12]

Passive and active tracking devices could be used together to place the active volume at the correct location on the patient. It is suggested to use a passive arm with a locking mechanism [32]. The most common alternative for tracking process is optical tracking as it provides higher accuracy, foreseeable efficiency, and indifference to discrepancies in the environment. However, it is hard to use optical trackers on human body since they need a distinct and clear vision between the tracked parts and the camera. Also, it is difficult to transfer information from the sensor to the robot, and integrate the navigation and visualize the tissue with the robotic system. Another option for tracking technology is electromagnetic tracking, Figure 14, but they offer less accuracy than optical trackers and require non-ferrous metal environment. [30].

2.5.4 Open Sources

There are also open source software applications that can be reached easily, such as Visualization Tool Kit (VTK), 3D Slicer and Insight Segmentation&Registration Tool Kit. All of them are software systems to obtain 3D computer graphics, medical

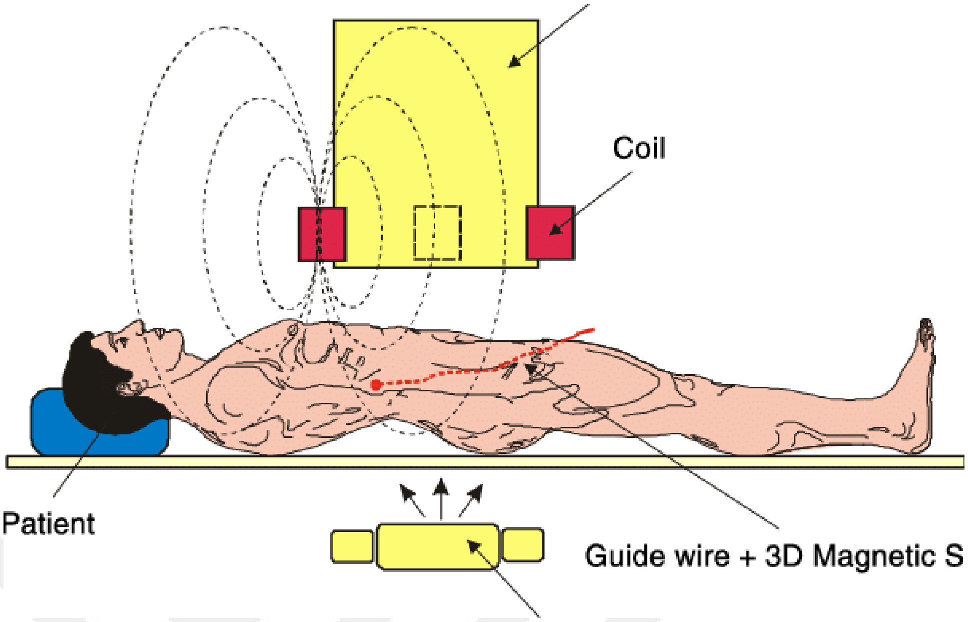


Figure 14: Electromagnetic tracking system with a patient. [13]

image processing, and image screening [52, 53, 54]. Other alternatives for computer assistance are Image Guided Surgery Tool Kit (IGSTK), Surgical Assistant Work Situation (SAW) and Computer Integrated Surgical Systems&Technology (CISST) [30].

2.5.5 Drive Mechanism

There are two alternatives to medical robots' drive mechanism such as using low back-drivability and high stiffness at the same time or having a back-drivable system with direct drive or lightly geared actuation. There are some benefits of using back-drivable systems. They make it possible to pull out the surgical tool manually in cases of power loss. These systems allow forces applied to the end effector by the tissue to be reflected the actuators which make their control easier. Unfortunately, it is hard to obtain high precision with these systems. Providing there is a power loss, the mechanism might drop on the patient. It is also possible to experience unwanted accelerations that create control failures. Therefore, it is recommended to use high ratio, non-drivable transmissions that provide high accuracy and good load carrying

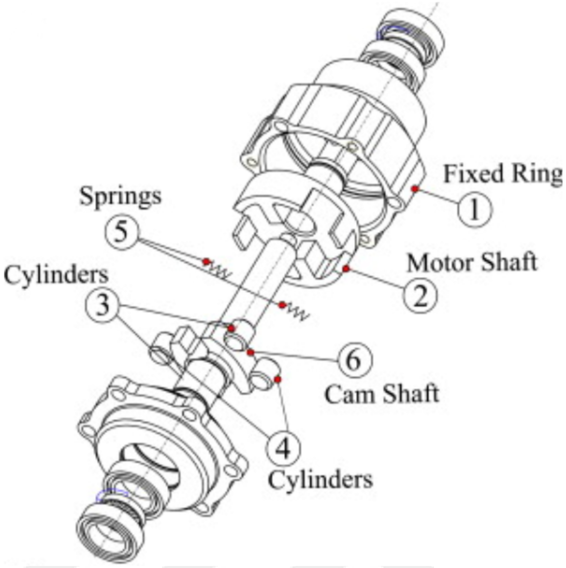


Figure 15: Non-back-drivable mechanism exploded view. [14]

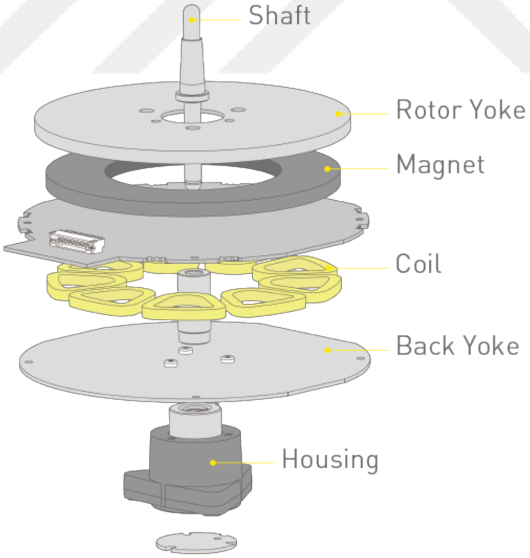


Figure 16: Direct drive turnable system. [15]

abilities with low power actuators. Accuracy can be influenced negatively by the mechanical backlash and high transmission ratios. To overcome rotational backlash, harmonic drives, Figure 17, can be used.

Other options are using a ball screw mechanism, Figure 18, cable-belt drive, spur

Figure 17: Harmonic drive mechanism components. [16]

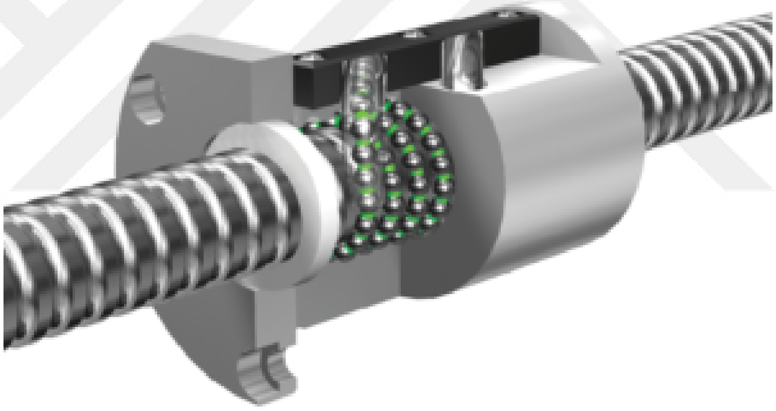


Figure 18: Ball screw mechanism. [17]

& beveled gears, and worm gears. Another significant safety property is passive gravity balance. If there is a power failure, non-backdrivable and locked mechanisms are safer to use, however, they are not safe in cases of controller failures. A redundant mechanism design can increase both the safety and the complexity of the system [32].

2.6 Software Applications

2.6.1 Software Safety in General

The general system safety plan should include every documented category of the safety program since safety is the integration of the improvements and applications. The following tasks can be carried out to increase the software safety [55]:

- Tracking the detected system hazards to the interface of software-hardware.
- Proving the consistency of the safety of the software application limitations with the specifications of the software necessities.
- Improving the criteria for the software design by testing the requirements.
- Generating a code including the limitations and safety requirements.
- Specifying the parts of the software for critical processes and components.
- Having software test plans, procedures, and analysis.
- Having a tracking system for checking the sufficiency of the software about fulfilling the safety requirements.
- Implementing any special safety analysis such as FTA or FMEA, demonstrating the results of the tests for safety problems, and having listed cautions and warnings about the design.

System and software safety tasks should be described together because the software safety is also an essential part of the overall design safety applications.

2.6.2 User Interface

User interference is significant since a robot is a complex system and the users of the surgical robots may not be engineers or have prior experience. Each medical robot has special requirements for operation. The instructions of the whole operation should be easily followed by the users. The user interference should prevent mistakes, give warnings for important actions, report and detect the system errors and conditions.

2.7 Methods for Hazard Identification & Analyses

To ensure the safety, the system should be safe in both software and hardware components. Physical boundaries should be modeled and controlled by a software. There is no specific systematic model for solving safety issues of surgical robots. One of the methods explained below can be used to reduce risks during the surgery.

2.7.1 Hazard Identification and Safety Insurance Control (HISIC)

HISIC (Hazard Identification and Safety Insurance Control) is a systematic methodology for analyzing and controlling the safety of medical robotic systems. There are many factors that create safety issues such as human error and system error. Every robotic system should have basic safety necessities.

HISIC consists of seven components: (1) HI (Hazard Identification), (2) SIC (Safety Insurance Control), (3) SCL (Safety Critical Limits), (4) MC (Monitoring and Control), (5) VV (Verification and Validation), (6) System Log, and (7) Documentation [26]. These are implemented in every phase of the software development. Each layer of the robot should be tested one by one according to their applications and own purposes following the HISIC plan. Tests could contain normal, extremes and exceptional situations. Unfortunately, it is hard to understand and implement the formal languages and analysis techniques by engineers. A solution to this problem can be using the UML (Unified Modelling Language), which creates a standard in system and software modeling and is suitable for robotic systems [56].

2.7.2 Hazard Analysis

An appropriate safe robot design could also include an analysis of hazard or risk [30]. There are three steps that are presenting general concepts of the risk management, defining the system with the consideration of the human factor and risk assessment. Analytic methods for risk assessment such as “Failure Modes Effects and Critically Analysis (FMECA)” and “Fault Tree Analysis (FTA)” are commonly used. FMECA can be described as the extended version of FMEA. The qualitative information about the system is obtained by FMEA. Then, FMECA is applied to rank the failure modes, that FMEA specified, according to their order of importance. In other words, to implement FMECA, an FMEA should be performed first.

The FMECA method, which uses tables to demonstrate the information about risks, hazards, and failures, makes bottom-up analyses that specify and follows the possible components of failure and interprets the influences of them on the system. The severity, occurrence, and detectability, whose multiplication aid to find a risk priority number (RPN), are the key numerical parameters of the FMECA [57]. The RPN determines the requirement of an additional control method. Equation (1) shows how the RPN is calculated. The components of the FMECA is specified on a 10 point scale. RPN can be in the range of 1 and 1000. The most important factor of RPN to be considered is the severity number. The occurrence comes next. The final component of the FMECA to take into consideration is the detection factor [57].

$$Severity \times Occurrence \times Detection = RPN \tag{1}$$

The FTA method is a top-down analysis method and is used for determining the effects of the failure after the failure event [30]. Hazard and Operability Analysis (HAZOP) is another technique for eliminating the risks and developing the safety of the system [55].

2.7.3 Risk Management

Risk management consists of risk analysis, risk evaluation, and risk control. Risk analysis can be described as the key point for risk management. Describing the system and its boundaries is the first step to risk analysis. The function allocation and task analysis are fundamental activities of human factor engineering. Furthermore, business modeling makes the understanding of the work and communication between doctors and engineers easier. It is hard to model the workspace as it is the human body. The specification of the boundaries of the system is also a main step of the analysis [56]. Human factor should also be considered, it is an incomplete and very important field in safety [56]. There will always be some risk involved, no matter how big the magnitude. In the case of a robot failure, surgical robots can be removed from the cite, and the operation can be completed manually with the elimination of the risk to the patient [58].

CHAPTER III

DESIGN OF A SAFER SURGERY ROBOT

The primary aim of this chapter is to show how an existing system's safety can be improved by implementing the proposed safety concepts. The preliminary design of a medical robot is changed to obtain a safer system by considering the mechanism, electromechanical components, arm design, joint configuration and software.

3.1 Preliminary Design

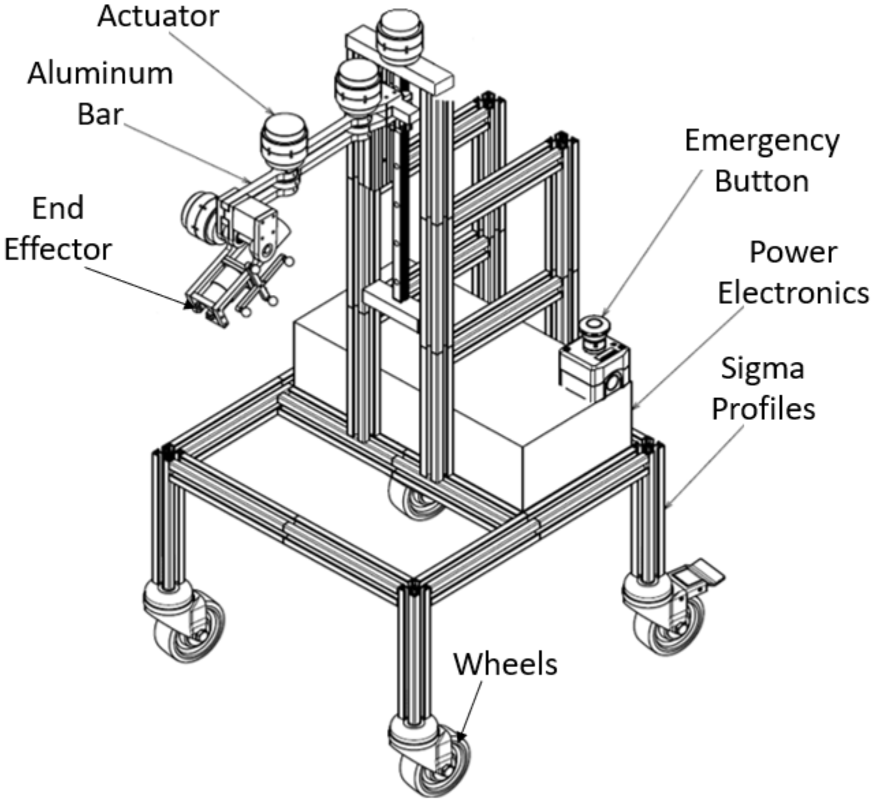


Figure 19: Preliminary design of the surgical robot with Al bars.

The preliminary design of the medical robot is altered according to the safety design aspects. The main goal of these design changes is to have a safer, low-cost, lightweight and multipurpose surgery robot with a smaller footprint. Finally, the design becomes MISA that assists minimally invasive surgeries. The preliminary design is a prototype 5 DoF surgery robot that is designed to perform medical operations. The base and the links of the robot are made from light weight material. Figure 19 demonstrates the CAD model of the previous work. It has 5 actuators and a linear module to alter the height of the robot according the operation table and surgery type. Wheels, attached to the sigma profiles, are added to the system to achieve mobility. The joints are make prismatic, roll, yaw and pitch motions. The robot arm consists of light weight aluminum bars because of the cost advantage. The actuators are attached that bars externally. The preliminary design can be considered as a fast prototype to cover an experimental necessity. The preliminary design structure is inspired from the existing surgery robots in the market such as DaVinci Surgery Robot.

3.2 One Step Closer to a Safer Design: MISA

3.2.1 Mechanism and Electromechanical Components of MISA

MISA uses 1 DC motor and 4 Kinova K-58 actuators [18] to have 5 DoF. The DC motor activates the linear module to have a vertical motion. It is decided to use Kinova actuators as an series elastic actuators (SEA), in the MISA design since they offer reduced peak gear forces, simple and stable force control, lighter weight and more energy efficiency [41]. Kinova actuators are responsible from roll, pitch, and yaw motions of the joints. The usage of the Kinova K-58 actuators makes the system lighter. Additionally, the internal sensors to detect and analyze risks such as F/T sensor, in K-58 actuators are added to the system automatically. Thus, the force control becomes more stable and easy. Figure 20 shows the Kinova K-58 actuator.

Figure 20: Kinova K58 Actuator for simple and stable force control, reduced peak gear forces, lighter weight, and more energy effiency.[18]

3.2.2 Sterilization

During the operation, the electrical box, the base of the robot and the robot arm will be covered by a sterile drape before each application. Figure 21 represents how a sterile drape implemented on a robotic arm. It is the most cost-effective and easy way to meet sterilization requirements. Also, the end effector of the robot are detachable, which makes their sterilization simpler.

3.2.3 End Effector of MISA

The end effector of MISA can be changed according to the type of laparoscopic surgery. The link connected to the last actuator, provides an opportunity to alter the end effector easily. In this thesis, Intuitive Surgical Endowrist Round Tip Scissor is the active end effector in robot kinematics and control of MISA and the end effector can be seen in Figure 22. The scissor's task is to open small incisions on the patient

Figure 21: Sterile drape installation on a robotic arm.[19]

by reducing the risk of hand tremor.

3.2.4 Size and Placement of MISA

ORs must have a minimum space that fulfills the demands of the medical employees and medical equipment used in the room. Therefore, the minimum space for inpatient surgical applications must be approximately 37 m^2 for traditional procedures and 56 m^2 for applications that need more personnel and equipment [59]. Current robot-assisted surgery systems have a disadvantage of being very large. It is hard to place these huge and cumbersome robotic systems in already crowded operating theatres. Thus, it is suggested to minimize the robots' dimensions to fit the room [60]. Unfortunately, once these robotic systems are placed in the operating theatres, the ORs cannot be used for other non-robotic operations. Therefore, hospitals try to operate more using the robotic system to cover the high initial cost. For instance, the da Vinci Robot requires approximately 9.5% of an ideal operating theatre. They can be difficult to fit into a standard surgery room. Another example can be the ZEUS surgical system. It has relatively a smaller footprint because it is a table mounted system, but the large manipulator bases limit the access of the surgical personnel to the patient. In addition, collisions during the surgery can occur if the system's motions are not planned in detail [28].

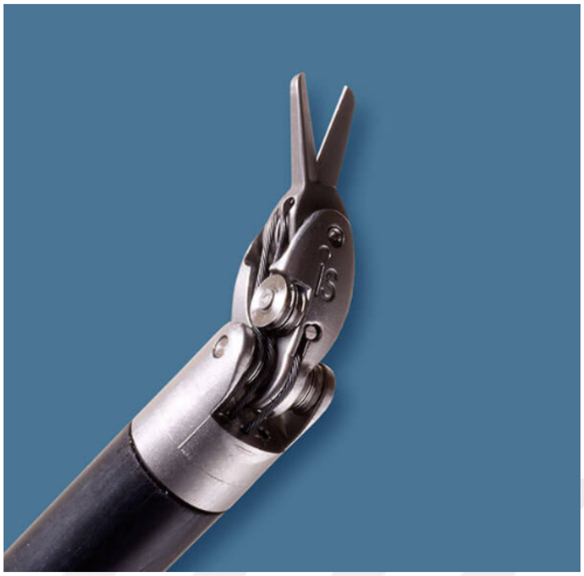


Figure 22: Different end effectors can be attached to MISA. The Endowrist Round Tip Scissor as an example end effector [20]

The space that the MISA requires is 2.16% of an ideal OR. When the other robots' space requirements are taken into consideration, the MISA has an important advantage of being small. Thanks to its smaller size, lighter weight, and less complex system, it is easier to have full access to the patient during the operations. The manipulator can be placed in the required positions easily. Additionally, the system's storage is less problematic. Simpler systems allow for individual manipulators' addition to or removal from the system during the surgical applications [28].

The base of the MISA is made from aluminum profiles to prevent bending and decrease the cost. This base makes the robot portable. Therefore, it does not need to be mounted on the table, and it can be rolled on its wheels and used in different ORs. The MISA's height is 1.40 m which provide an opportunity to the surgeon to position the end effector of the robot according to the patient in an easier way. The storage of the robot is also not problematic due to its small footprint and wheels.

3.2.5 MISA's Robotic Arm Design and Design Analysis

As mentioned in the 'Preliminary Design' section, there are two different design alternatives for robot links: light weight aluminum bars and ABS filament pipes. Figure 23 shows the design options for the robot arm. In the preliminary design, the links are made from aluminum bars. Providing that a problem with the actuators occurred, the time period to solve the problem is shorter as K-58 actuators are connected to these bars externally. On the other hand, metal bars make the system heavier and not allow the system to have different joint configurations. During the design improvement, the structure of the links has been altered and become pipes at first. However, to have Al pipes would make the system heavier. Also, it is harder, more expensive and time consuming to produce Al pipes with respect to the actuators' specific outer diameter. Therefore, ABS filament has been chosen as a second option. The second alternative for the link design is pipe design. ABS pipes make the arm lighter. Moreover, this design has elbows in the structure which allows to alter the joint configuration of the robot arm easily. K-58 actuators are located inside the pipes which increases the intervention time but makes the system more protected from the environmental effects. It is decided to use ABS filament and 3D printer for the production of the pipes to obtain desired dimensions. Figure 24 and 25 indicates the displacement analysis for aluminum bars and ABS pipes under force application. According the analysis, the displacement of the aluminum bars are 10 times greater than the displacement of the ABS pipes for the same conditions. Therefore, for having a lighter and more stable system, the robot links of MISA are decided to be ABS pipes.

3.2.6 Kinematics and Control of MISA

3.2.6.1 Forward Kinematics

Equation 2 shows the MISA's end effector position without the Endowrist attachment. In the equations, "c" symbolizes cosine function and "s" symbolized sine function.

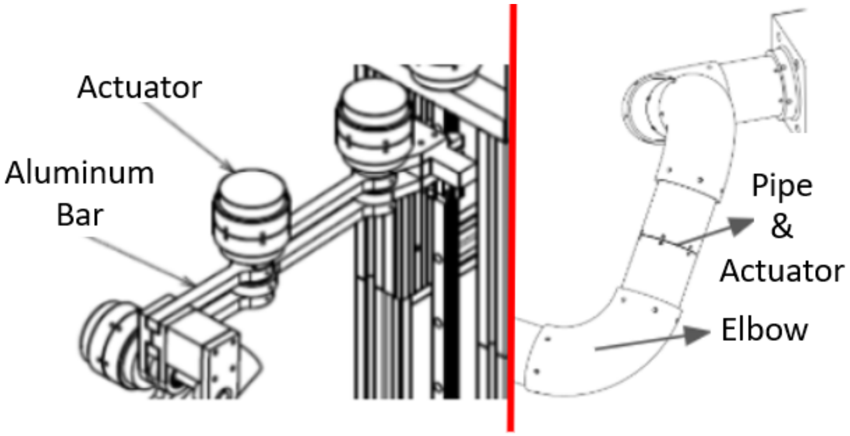


Figure 23: There are two options for MISA robot arm design: Aluminum Bar Design and ABS Pipe Design.

Table 1: Comparison of Design Alternatives for MISA Robot Arm

Al Bar Design	ABS Pipe Design
1. Time period to solve any harness problem is shorter.	1. It is longer since it has a closed structure.
2. Metal bars makes the system heavier.	2. The arm is lighter thanks to the ABS pipes.
3. No chance to change the joint configuration.	3. The structure allows to have different joint configurations.
4. Displacement under the same load is greater.	4. Displacement under the same load is smaller.
5. Link weight is 0.292 kg.	5. Link weight is 0.172 kg.
6. 4 DoF without the end effector.	6. 5 DoF without the end effector.
7. Workspace volume is 0.0119 m^3.	7. Workspace volume is 0.0659 m^3.

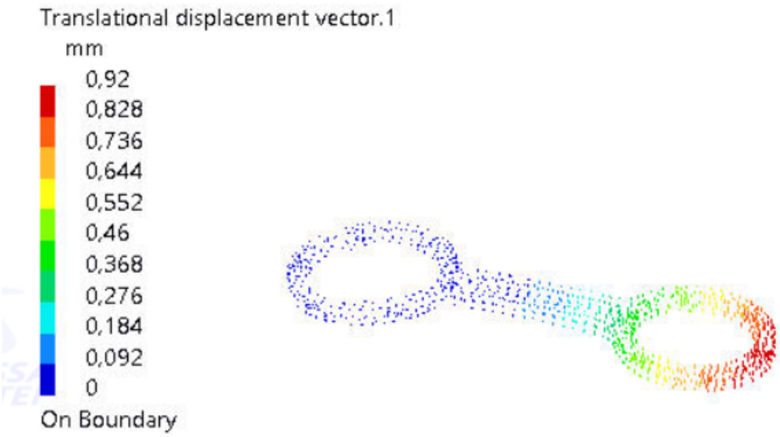


Figure 24: The displacement analysis for aluminum bars.

x_0, is the x-axis length up to the first K-58 actuator, l_0 is the length of the sigma base, l_1 is the length of the linear module, h_1 is the length of the distance traveled by the

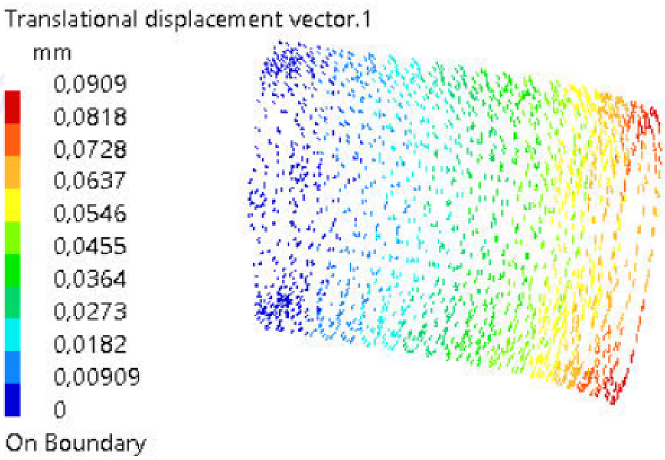


Figure 25: The displacement analysis for ABS pipe design.

linear module, l_2 is the x-axis length of the roll joint after the first K-58 actuator, l_3 is the x-axis length of the first elbow, l_4 is the z-axis length of the first elbow, l_5 and l_6 are the z-axis length of the yaw joint, l_7 is the z-axis length of the second elbow, l_8 is the y-axis length of the second elbow, l_9 and l_{10} are the length of the pitch joint on y-axis, l_{11} is the y-axis length of the third elbow, l_{12} is the x-axis length of the third elbow, l_{13} and l_{14} are the length of the roll joint on the x-direction. q_1 represents the roll joint angle,q_2 represents the yaw joint angle, q_3 represents the pitch joint angle and q_4 symbolizes the roll joint angle.

Equation 3 indicates the position vector of the Endowrist attachment. The end effector's position with the Endowrist attachment, can be found by using Equation 4. The transformation matrix of the robot arm with the Endowrist attachment, T_{EndEff}, can be calculated from Equation 5. Endowrist is not able to control roll, yaw and pitch motions directly. Therefore, the transformation matrix in the Equation 5 is used to make the actuators of the Endowrist to do pitch, yaw and roll motions. k_{pn}, k_{yn}, k_{rn} symbols in the matrix, are the constants and their values range from 0 to 1. The constants specify the ratios of pitch, yaw and roll movements for the n^{th} motor, respectively. The value of k_{p1} is 0.67 and the value of k_{y2} is set as 1 for the first motor. In other words, when the first motor makes a turn, it makes 1 unit yaw and 0.67 unit pitch motion. The values indicated as $m_{noffset}$, are the servo motor offset constants that used in the Endowrist attachment. These offset constants specify the current position of the servo motors. To clarify, it determines how far the current position of the servo motors from the target position. The constants, defined as r, p, y, symbolize the roll, pitch, yaw joint angles and the rotation angle of the motors are shown as m_n [61]. Finally, the constants used for the Endowrist motor control of MISA can be seen from Table 2.

$$\begin{bmatrix} x_e \\ y_e \\ z_e \end{bmatrix} = \begin{bmatrix} l_2 + l_3 + c(q_2)(l_{12} + l_{13}) - s(q_2)(l_{10} + l_{11}) + l_{14}c(q_2)c(q_3) \\ \\ \begin{array}{c} l_4 + l_5 + l_{14}(s(q_1)s(q_3) + c(q_1)cos(q_3)s(q_2)) + \\ c(q_1)(l_8 + l_9) - s(q_1)(l_6 + l_7) + c(q_1)c(q_2)(l_{10} + l_{11}) + \\ c(q_1)s(q_2)(l_{12} + l_{13}) \end{array} \\ \\ \begin{array}{c} l_0 - h_1 + l_1 + c(q_1)(l_6 + l_7) + s(q_1)(l_8 + l_9) + \\ c(q_2)s(q_1)(l_{10} + l_{11}) + s(q_1)s(q_2)(l_{12} + l_{13}) - \\ l_{14}c(q_1)s(q_3) + l_{14}c(q_3)s(q_1)s(q_2) \end{array} \end{bmatrix} \tag{2}$$

$$\begin{bmatrix} 0 & k_{p1} & k_{y1} & m_{1_{offset}} \\ 0 & k_{p2} & k_{y2} & m_{2_{offset}} \\ k_r & 0 & 0 & m_{3_{offset}} \\ 0 & k_{p3} & 0 & m_{4_{offset}} \end{bmatrix} \begin{bmatrix} r \\ p \\ y \\ 1 \end{bmatrix} = \begin{bmatrix} m_1 \\ m_2 \\ m_3 \\ m_4 \end{bmatrix} \tag{3}$$

$$\begin{bmatrix} x_{EndEff} \\ y_{EndEff} \\ z_{EndEff} \end{bmatrix} = \begin{bmatrix} T_{EndEff}(1,4) \\ T_{EndEff}(2,4) \\ T_{EndEff}(3,4) \end{bmatrix} \tag{4}$$

$$T_{EndEff} = T_e \times T_{endo} \tag{5}$$

Table 2: Endowrist Motor Control Constants [1]

Variable	n=1	n=2	n=3	n=4
k_{pn}	0.67	0.67	1	-
k_{yn}	0.67	1	-	-
k_{rn}	0.75	-	-	-
$m_{noffset}$	-21.85	-52.63	-20.67	-8.7

3.2.6.2 Work-space and Manipulability

Thanks to the elbows in MISA's design, different joint configurations can be obtained. In an ideal scenario, robot arm needs to have at least 3 DoFs to implement MIS. Furthermore, it is desired to have the capability of doing prismatic and pitch movements in the configuration at the same time since they are the most significant ones [62]. Joint configurations have influences on the surgical operation's success since the robot arm is used to hold several medical equipment along with different tissues. Thus, it is required to find the most optimal configuration to use the robotic arm in different operations in a non-problematic way by maximizing the workspace and obtaining highest manipulability. Different configurations are compared to each other with respect to workspace and manipulability to find the most optimal configuration for the robot arm. According to the comparison, it can be said that Prismatic-Roll-Yaw-Pitch-Roll configuration is the most optimal configuration as it has the highest workspace volume and manipulability. The configuration has a 0.0659 m^3 workspace volume with 261.72 manipulability measure. The workspace volume can be seen from Figure 26. Figure 27 shows the manipulability ellipsoids for the most optimal configuration [21].

3.2.6.3 Inverse Kinematics

The aim of the inverse kinematics is calculating the joint angles that are necessary to move the end effector in a desired axis with infinitely small steps. Thus, the required torques are specified to aid the control of the actuators. Jacobian method

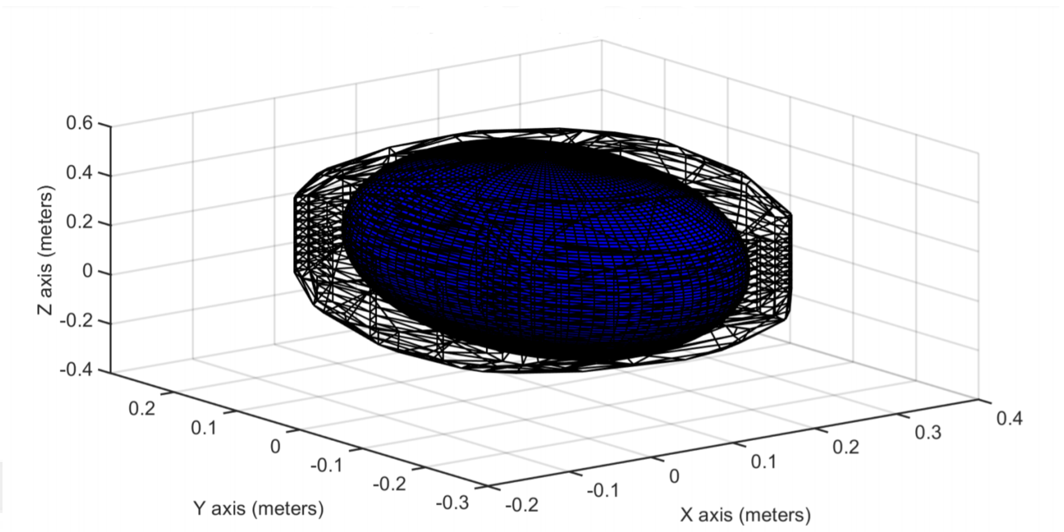


Figure 26: Workspace of Prismatic-Roll-Yaw-Pitch-Roll Configuration [21]

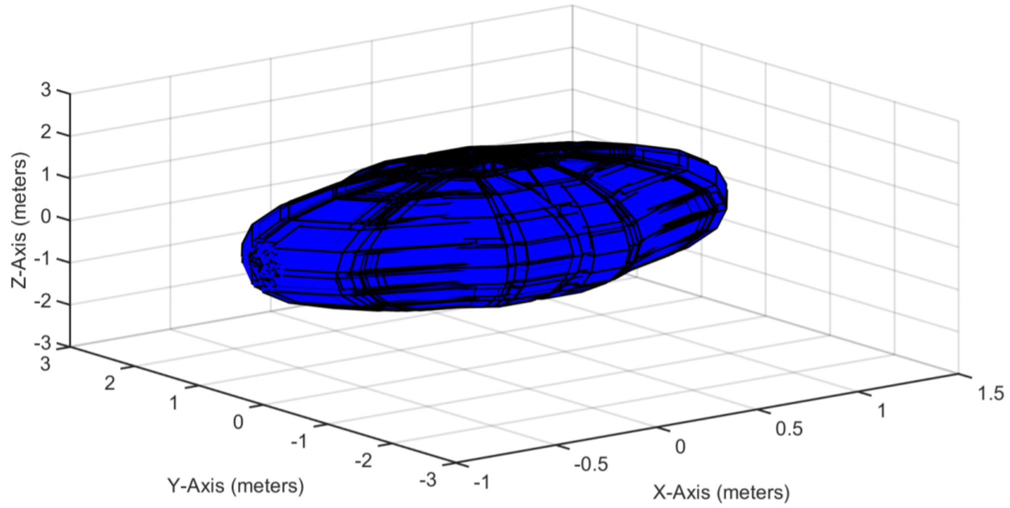


Figure 27: Manipulability Ellipsoids for Prismatic-Roll-Yaw-Pitch-Roll Configuration [21]

is used to calculate the inverse kinematics of MISA. The partial derivative of the end effector position, calculated by inverse kinematics, is taken with respect to each joint to generate Jacobian matrix [63]. The Jacobian matrix, Equation 6, defines the velocity and direction of the end effector when the joint angles are changed. Equation 9 indicates the instant joint angle change (Δq), which equals to the multiplication of the inverse Jacobian matrix and the position change (Δx). This equation calculates the required joint angle change to achieve desired positions in required axes. (Δq) is calculated by using Equation 8.

$$\mathbf{J} = \begin{bmatrix} \frac{\partial x_1}{\partial q_1} & \frac{\partial x_1}{\partial q_2} & \frac{\partial x_1}{\partial q_3} & \cdots & \frac{\partial x_1}{\partial q_n} \\ \frac{\partial x_2}{\partial q_1} & \frac{\partial x_2}{\partial q_2} & \frac{\partial x_2}{\partial q_3} & \cdots & \frac{\partial x_2}{\partial q_n} \\ \cdots & \cdots & \cdots & \cdots & \cdots \\ \frac{\partial x_n}{\partial q_1} & \frac{\partial x_n}{\partial q_2} & \frac{\partial x_n}{\partial q_3} & \cdots & \frac{\partial x_n}{\partial q_n} \end{bmatrix} \tag{6}$$

$$J = \frac{\partial x}{\partial q} \tag{7}$$

$$J^{-1}\Delta x = \Delta q \tag{8}$$

$$q_{t+1} = q_t + J^{-1}\Delta x_{t+1} \tag{9}$$

MATLAB R2018.A and MATLAB's Symbolic Toolbox are used for inverse kinematic calculations. Inverse kinematics calculations are taken more time than forward kinematics calculation by using this software. Since for inverse kinematics calculations, Jacobian matrix needs to be inverted. Therefore, the duration of the symbolic inverse kinematics calculations become longer as long as the inverse kinematics' equations become more complex. To make the process shorter, only the Jacobian matrix is calculated symbolically. Then, its inverse is numerically calculated because it takes less time to calculate inverse numerically than to calculate it symbolically.

3.2.6.4 Motor Drivers

An ESCON 70/10 Controller (Maxon Motor), Figure 28, is used to control the DC Motor and a Kinova Controller, Figure 29, is used for controlling the Kinova K-58 actuators. The Kinova controller has force, angular and cartesian control modes. It is easier to detect collision since the Kinova controller has torque control modes which monitors the torque values. Kinova K-58 actuators are also able to controlled by only one controller (This feature allows to control maximum four actuators at the same time). All K-58 actuators are connected to each other by a flat cable, in series. Then, the first actuator is connected to the Kinova controller, Figure 29, and the controller manipulates the Kinova actuators separately.

Figure 28: ESCON 70/10 Controller for the DC motor. [22]

Figure 29: Kinova Controller for the K-58 actuators. [23]

3.2.6.5 Hazard Identification and Analysis

To enhance the safety of the robots, at least one of the hazard identification and analysis method needs to be implemented to the system. Table 3 demonstrates the

Table 3: A risk calculation of MISA by FMECA.
∗ The most important failure mode is breaking of the drill since no matter the magnitude of its RPN value, the failure's severity is the highest among all.

Item	Failure Mode	Severity	Occurrence	Detection	RPN
End Effector	Break	10*	2	2	40
Robot Base	Break/Move	7	1	2	14
Power	Power Supply Failure/Power Cable Failure	6	2	1	12
Links	Break	9	2	1	18
Motors	Burn/Detach	7	2	3	42
Encoder	Fail	9	5	2	90
Tracker	No Response	6	3	3	54
Path Planning	Wrong Target	2	2	2	6

risk assessment of MISA by using FMECA method. For this surgical system, the failure modes can be breaking of the end effector inside the patient, breaking or movement of the robot base from its initial position, failure of the power supply or the power cables, breaking of the links during the operation, burning or detaching the actuators, failure of the encoders, getting no response from the tracker system or having a wrong target due to the path planning failure. According to this FMECA analysis, the most significant failure might be the breaking of the drill, because the severity of this failure is the highest, independent of its RPN magnitude. Encoder failure has the next highest risk since its severity and RPN values are greater than the other failure modes. The failure modes in the table are absolutely unacceptable for the safe maintenance of a medical robot. Therefore, it is an important requirement to apply a software control mechanism to the surgical system.

3.2.7 MISA Software

3.2.7.1 Operating System and Programming Language

Controller of the Kinova K-58 actuators used in the robotic arm of the system, is designed to work with Windows, Ubuntu and Robot Operating System (ROS). The application programming interface (API) is only compatible with C++ language. Therefore, whole system is installed in Ubuntu 16.04 operating system and ROS works as a core in the software of MISA. This Ubuntu version offers long term support which provides longer access to existing documents and drivers. C++ is used for the interaction with motor controller. Phyton, that is easier to debug, is used for creating other control software. It is preferred to use ROS-kinetic version as it is the most compatible ROS version for the motor controller. Thus, the communication problem between ROS C++ and Phyton is eliminated.

3.2.7.2 Flow Diagram

The flow diagram of MISA is created for the operator to use the robot in the safest way. Figure 30 indicates the flow diagram for MISA. This diagram analyzes control mechanism of the system by including security protocols. The flow diagram is initiated by the feedback that obtained from the 3D monitor, given to the end effector's position or the controller commands from the operator. The joint angles for reaching the desired position are calculated by the equations of forward and inverse kinematics. Then, the system plans a path according to the calculated joint angles and the path is transferred to the 3D monitoring software. The 3D monitoring software specifies a set of position patterns for the robotic arm and detects the risk of collision for each pattern. As long as a collision detected, a warning message is sent to the operator via the user interface and new position input is asked. If there is no risk of collision, the torque values required to move the arm are calculated. The path is going to be followed is shown in the monitor and wait for the operator's confirmation before starting the motion. To get confirmation from the operator is optional and it increases control and detection capability of the system. This feature can be closed to make the system faster. The offline feedback of the collision detection before starting the motion, is very significant to use MISA in a safer way. The purpose of this step is preventing the collision in the real environment before the collision takes place in the virtual environment. It warns the operator about the potential dangers visually, without moving the robot arm by using the 3D monitor.

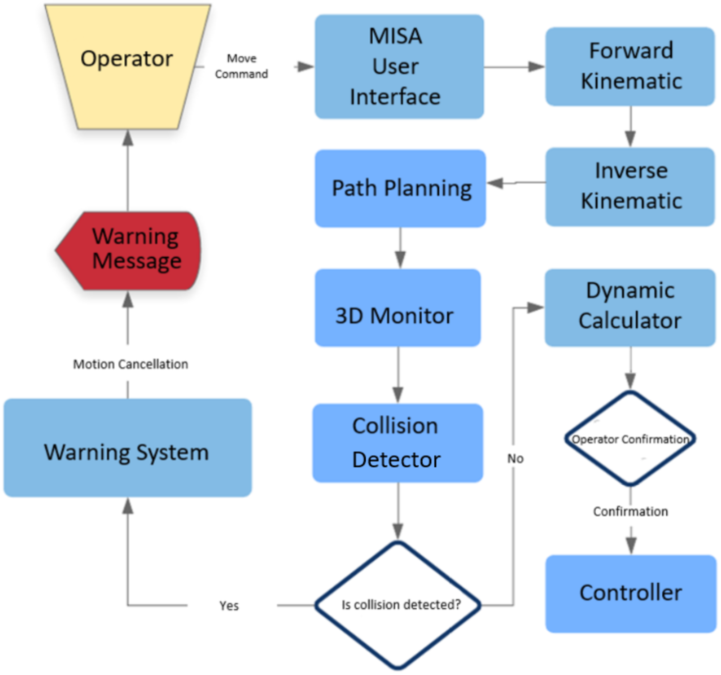


Figure 30: Flow Diagram for MISA

3.2.7.3 3D Monitoring

Monitoring and planning are developed in the ROS platform. RVIZ and MoveIt softwares are used for 3D monitoring of the robot arm. RVIZ is only used to view the 3D model of the robot arm while MoveIt is used to plan the simulation path. Figure 31 demonstrates an example of 3D Monitoring by using the related softwares. The opaque model in the figure shows the current situation of the robot arm, the transparent model indicates the planned path of the robot arm and white and transparent model indicates the target position. The macro used to visualize the robot arm is United Robot Description Format (URDF) which known as description language in ROS platform. To generate URDF macro, model files of the robot parts, position of these parts and orientation vectors are used. All the robot parts are generated and added to the computer space in order. Every generated part are attached end to end and the assembly process of the robot is transferred to the computer environment.

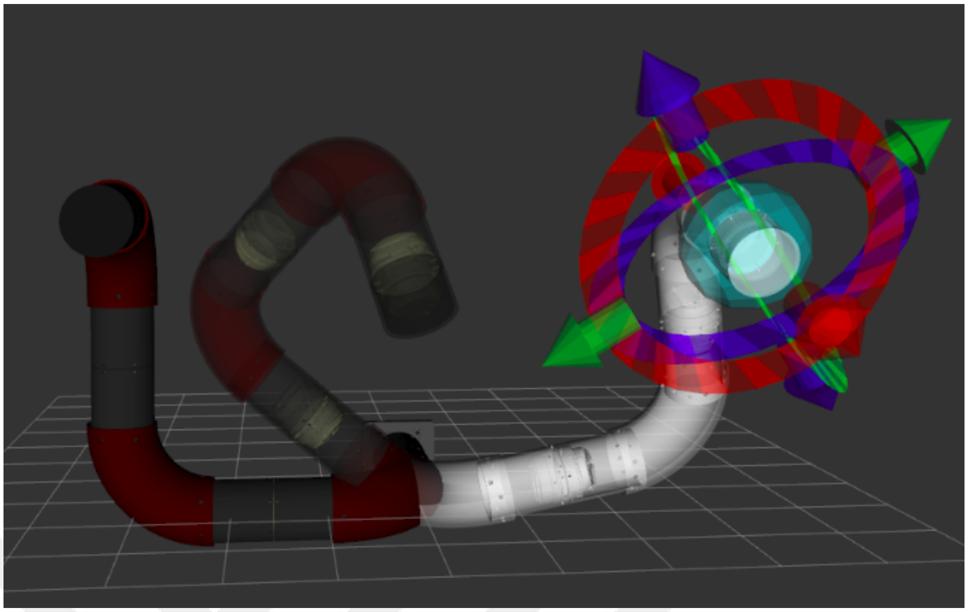


Figure 31: MoveIt to simulate the motions of the robot.

3.2.7.4 MISA Software and User Machine Interface Design

The software of the MISA will have four main components: low-level control, and high-level control layer that includes forward&inverse kinematics and trajectory generation, teleoperation, and application. The user interface will inform the user with basic warnings about the robot's state while preventing time delays. Any code and irrelevant information are not displayed to keep the messages lean. Exceptional conditions on time-dependent information could also be presented for drawing the attention without clutter. Memory load of the user could be minimized by having objects, options, and operational steps visible. Therefore, the possibility to forget any operational step during the surgery would be reduced. In an unwanted situation, the system should warn the user and point the "emergency exit" clearly [64], [65]. When the emergency button is pushed, the robot will go to a safe position. The usability of the user interface should be evaluated by the surgeons. Tests should be performed in medical robots' natural environment, such as at hospitals to evaluate the system more realistically.

3.2.8 Summary

Figure 32: MISA manufactured by using ABS material and 3D printer.

MISA, Figure 32 and 33, is designed and produced to become the third hand of the operator in MIS procedures by holding different type of medical equipment such as scissors, cameras, graspers and needles. Owing to the MISA's design, the requirement for an additional medical personnel in the operating room is eliminated since there is already an assistant near to the operator. Due to the design aspects in this thesis, a long road has been completed to improve the robotic arm design: Actuators with sensors have been selected to simple and stable control by minimizing the weight and complexity. According to the sterilization requirements, the most practical and cost effective option is covering the robotic arm by a sterile drape. End effector connection of the arm is designed to allow the user to alter the effector with respect to the surgery type and his multi-functionality helps to decrease the total cost. Furthermore, to make the robot mobile, wheels with lock mechanism are added the base, which is generated from Al sigma profiles to protect lighter weight of the total system. ABS material pipes are used to obtain desired dimensions with a lighter weight and the robot arm become more secured against the environmental effects. The pipe structure also allows to change the robot configuration. The most optimal configuration is specified according to the maximum workspace and manipulability. Hazard identification analysis is another important concept to apply for being aware of the possible risks and more prepared to eliminate the failures. Last but not the least, to have software control mechanism and user-friendly interface for the surgical system cannot be skipped as it is the first and the most essential communication element between the robot and operators.

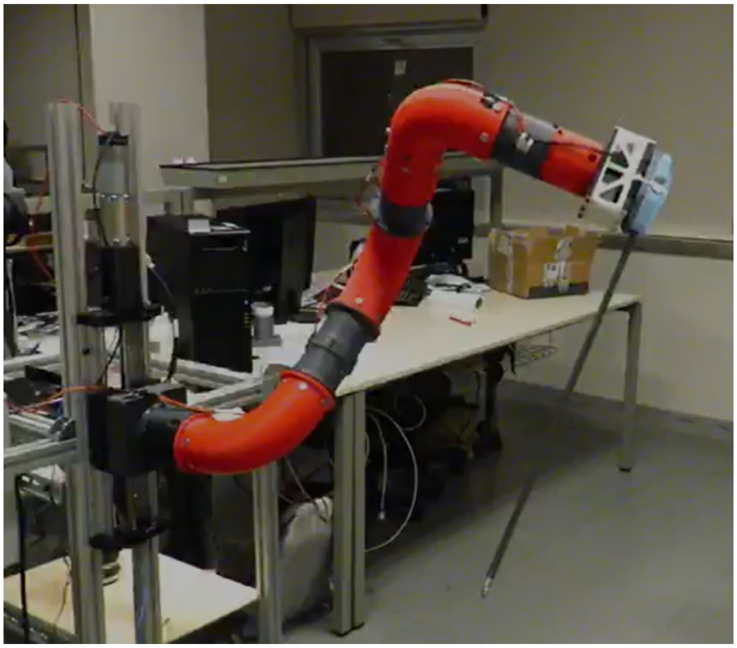


Figure 33: MISA with the End Effector.

CHAPTER IV

CONCLUSION

When the treatment techniques and technological improvements over the last decades in the medical field are taken into consideration, it can be said that the significance and role of the robotic applications in the healthcare systems, have been dramatically increased. Thus, taking care of a living being makes the safety the most important concept to discuss. However, there is no specific and universal standard to make sure the safety in medical and surgical operations. The main aim of this thesis is to fill that gap and improve the safety of robots in the medical field. During the design period of a medical robot, sterilization, size, placement, mechanics and mechanism, electrical components, software applications and risk analysis need to be considered to have a safer robot.

To put all the design aspects proposed in this thesis in a nut shell, it is not hard to generate a safer, cost effective, lightweight, small, portable and multi-purpose robot such as MISA by following the design concepts in this thesis:

- Since the medical systems work with living creature, it is important to meet sterile requirements with different types of sterilization such as heat method of sterilization, chemical sterilization, sterile drape or gas sterilizer.

- Training for RAS can be considered as a risk factor as there is no enough standard for this type of operations. To generate a certification system should be a responsibility of healthcare organizations to create experience and awareness among the operators for patient safety.

- As the operating rooms have limited space and need to maintain the sterile conditions, it is important to design portable, easy-stored, and small robotic system.

- To ensure the patient safety, the force, pressure, speed, power, temperature and length of travel need to be specified.
- To obtain reduced size, lightweight and low-inertia manipulators is key element to meet HIC requirements.
- The basic medical electrical equipment standards need to be implemented on the robot.
- It is important to specify the robot configuration with respect to the surgery type to achieve maximum workspace and manipulability at the same time.
- To gather precise position data, sensors and guidance systems need to be used.
- High-ratio and non-backdrivable transmissions offer higher accuracy and better load carrying.
- Since the user interface of the robot is the main communication element between the operator and the system, it is significant to have easy followed, alerter and assistive interface.
- To apply any special safety analysis such as FTA or FMEA, demonstrating the results of the tests for safety problems, and having listed cautions and warnings about the design.

It is really significant to note that safety is a broad concept and there is no guarantee to have a 100 % safe robot. There might be other design aspects that not be discussed in this thesis. This thesis can be considered as a guideline and the first step to improve safety of the medical and surgical robots.

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