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SY-MIS Project: Biomedical Design of Endo-Robotic and Laparoscopic Training System for Surgery on the Earth and Space

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Abstract

Despite the location (Earth or Space), surgical simulation is a vital part of improving technical skills and ensuring patients' safety in the real procedure. The purpose of this study is to describe the Space System for Minimally Invasive Surgery (SY-MIS©) project, which started in 2016 under the supervision of the Center for Space Systems (C-SET). The process connects the best features of the following machines: Biomedik Surgeon, Space Biosurgeon, SP-LAP 1, and SP-LAP 2, which were defined using the VDI 2221 guidelines. This research uses methods based on 3 standards: i) Biomedical design: ISO 9001-13485 / FDA 21 CFR 820.30 / ASTM F1744-96(2016); ii) Aerospace human factors: HF-STD-001; iii) Mechatronics design: VDI 2206. The results depict the conceptual biomedical design of a novel training system named Surgical Engineering and Mechatronic System (SETY©), which integrates the use of 2 laparoscopic tools and 2 anthropomorphic mini-robotic arms (6 DOF). It has been validated by the Evaluation of Technical Criteria, getting a total score of 90% related to clinical assessment, machine adaptability, and robustness. The novelty of the research lies in the introduction of a new procedure that covers the simultaneous use of laparoscopic and robotic systems, named Hybrid Cyber-Physical Surgery (HYS©). In conclusion, the development of SY-MIS© promotes the use of advanced technologies to improve surgical procedures and human-machine medical cooperation for the next frontier of habitability on other planets.

Keywords:

Engineering Design;
Biomedical Technologies;
Medical Mechatronics;
Surgical Robotics;
Aerospace Medicine.

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1- Introduction

Surgery on the Earth has been reflecting important robotic milestones. Starting in the late 1980s, ROBODOC and PREBOT proposed the idea of using augmented reality (AR) through novel mechanical devices for guidance in surgical procedures [1]. At the beginning of the 1990s, the Food and Drug Administration (FDA) approved the first product designed to hold an endoscopic camera during surgery: the Automated Endoscopic System for Optimal Positioning (AESOP) [2]. By 2001, the FDA had cleared the Zeus Robotic Surgical System, which was initially created to carry out the first robotic coronary artery bypass graft (CABG) surgery back in 1998 [2]. In the 2000s, the Da Vinci system was created as a console for surgeons to remotely control robotic arms connected to the patient while navigating through anatomy with a high-quality magnified three-dimensional view [3, 4]. This device offers advanced dexterity due to the increased degrees of freedom of the "EndoWrist" system; it also provides enhanced motion for tremor filtration and the removal of the fulcrum effect. Furthermore, the possibility of connecting dual consoles for training is an essential and simple asset to surgical education. Given these wide varieties of assisted surgical procedures and the tight association between postoperative complications and fine surgical skills [5, 6], several computer-based trainers were created to decrease intraoperative errors and shorten operative time [7–11]. Spiliotis et al. [12] published a systematic review of all randomized clinical trials that assess the effectiveness of transferring simulation training skills to the real operating room. The simulation provided superior surgical performance measured in operation time, accuracy, and intraoperative and postoperative complications.

On the other hand, regarding surgical treatments in Space, the development of new medical devices with easy-to-learn platforms and the availability of remote control prompted organizations like NASA to introduce the concept of "telerobotics" in the early 1970s. This was an effort to use robots remotely controlled from Earth to provide medical care to astronauts on space missions. In 1984, his ARTHROBOT was developed to perform the first robotic assistant intervention at the University of British Columbia Hospital. In 1993, the first long-range remote robotics experiment took place between NASA (JPL, Pasadena, CA) and Milan (Italy) [2]. In 2006, one of the first microgravity surgical procedures in humans was performed aboard an Airbus A-300 (zero-gravity aircraft). The biggest challenge was miscommunication due to transmission delays between the Earth and the Moon. In 2006, the 9th NEEMO project led a team to build a mobile M7 surgical robot to perform abdominal surgery on a patient simulator with a 3-second earth-moon communication delay via microwave and satellite links. In 2007, as part of the 12th NEEMO project, the feasibility of telesurgery using the Raven robot and his M7 robot was measured [13, 14]. Staff performed zero-gravity stitches under the guidance of Seattle, Washington. The robot was controlled over a commercial internet connection and achieved delays of up to 1 second [2]. Under these circumstances, the North Atlantic Treaty Organization (NATO) decided to complement these devices with onboard healthcare personnel. Nowadays, NATO recognizes "flight surgeons" as physicians with specialized training in aerospace medicine, air environments, risk management, and safety aviation programs.

Regardless of the location (the Earth or Space), the importance of surgical simulation is evident in order to become technically proficient and decrease adverse events. In space medicine, the collaboration also includes non-surgeon astronauts. A hierarchical task analysis model (HTAM) was created with the intention of following the roles and actions of surgeons, surgical assistants, and anesthesiologists using the minimum required equipment [15]. In this model, teleoperated surgical robots have the potential to shape the future of extreme health care both in Space and on Earth [16]. Accurate prediction of surgical demands during space flight missions is extremely challenging [17]. In fact, current protocols contemplate emergency repatriation of crew members as the general approach for serious medical and surgical emergencies [18]. Even a precise diagnosis is difficult given the limited resources; only ultrasound has proven to be effective in these conditions [18, 19]. Given the importance of training in laparoscopic and robotic surgery to meet these demands, simulation technology appeared as a tool for surgeons to enhance their technical and non-technical laparoscopic and robotic skills. The use of simulation technology has increased over the last few years and now has become essential for surgical training [20, 21], including space surgery clinical-fellowships [22]. In addition, laparoscopic training models such as the Ergo-Lap, the LapaRobot, and the EoSim Box were home-made to decrease costs and even showed similar results in Likert Scale questionnaires compared to those obtained by using sophisticated trainers. Likewise, with the steady increase in the use of robotic platforms in different surgical specialties during the last 15 years, the creation of robotic simulators such as dV-Trainer, Da Vinci Si Surgeon Console, RoSS, and RobotiX Mentor have been an essential part of surgical training.

Therefore, the motivation of this study can be summarized in the proposal of the project Space System for Minimally Invasive Surgery (SY-MIS©), shown in Appendix I-Figure A-1, and the introduction of a new terminology: Hybrid Cyber-Physical Surgery (HYS©) procedure. The rest of the paper is structured as follows: Section 2 depicts the methodology applied to the project phases of biomedical research development. Section 3 introduces the new proposed system and shows the main results. Then, the discussions and descriptions of other surgical simulators are explained in Section 4. After that, Section 5 states the promising future works. Finally, the manuscript ends with conclusions.

2- Methodology for Project Research and Development

Space human medicine and human factors mainly explore 4 categories of "Health & Bio Tech": a) Diagnostic Imaging; b) Pharmacological and Surgical treatment; c) Medical Robotics; and d) Clinical Safety and Human Physiology. Therefore, under the supervision of the Center for Space Systems (C-SET), the project called Space System for Minimally Invasive Surgery (SY-MIS©) is under development, which started in 2016 to develop a mechatronic platform for surgical training to be used as a tool for skill enhancement by professionals who want to acquire abilities to perform space surgery in future exploration missions. Additionally, it can be used by healthcare students/professionals at universities/institutions, and surgeons working in remote areas.

Therefore, the application of this project has 2 main fields, Earth and Space; and is based on the Sustainable Development Goals (SDG) of the United Nations (UN), specifically, Goal #3 Good and Well-Being. This section aims to show and explain the designs and prototypes of each phase that covers the SY-MIS© project until 2022 (Appendix I-Figure A-1), which are the base of the novel system "SETY©" introduced in the "novel biomedical design and results" section. Thus, following the guideline VDI 2221 [23], the project methodology covers a series of steps (shown in Figure 1), starting with the development of Phase 1: Biomedik Surgeon System, which begins with task clarification and identification and then ends with validation and tests. After the next phase is considered, in this case, Phase 2: Space Biosurgeon System, the loop iteration is repeated until the input must be SETY©.

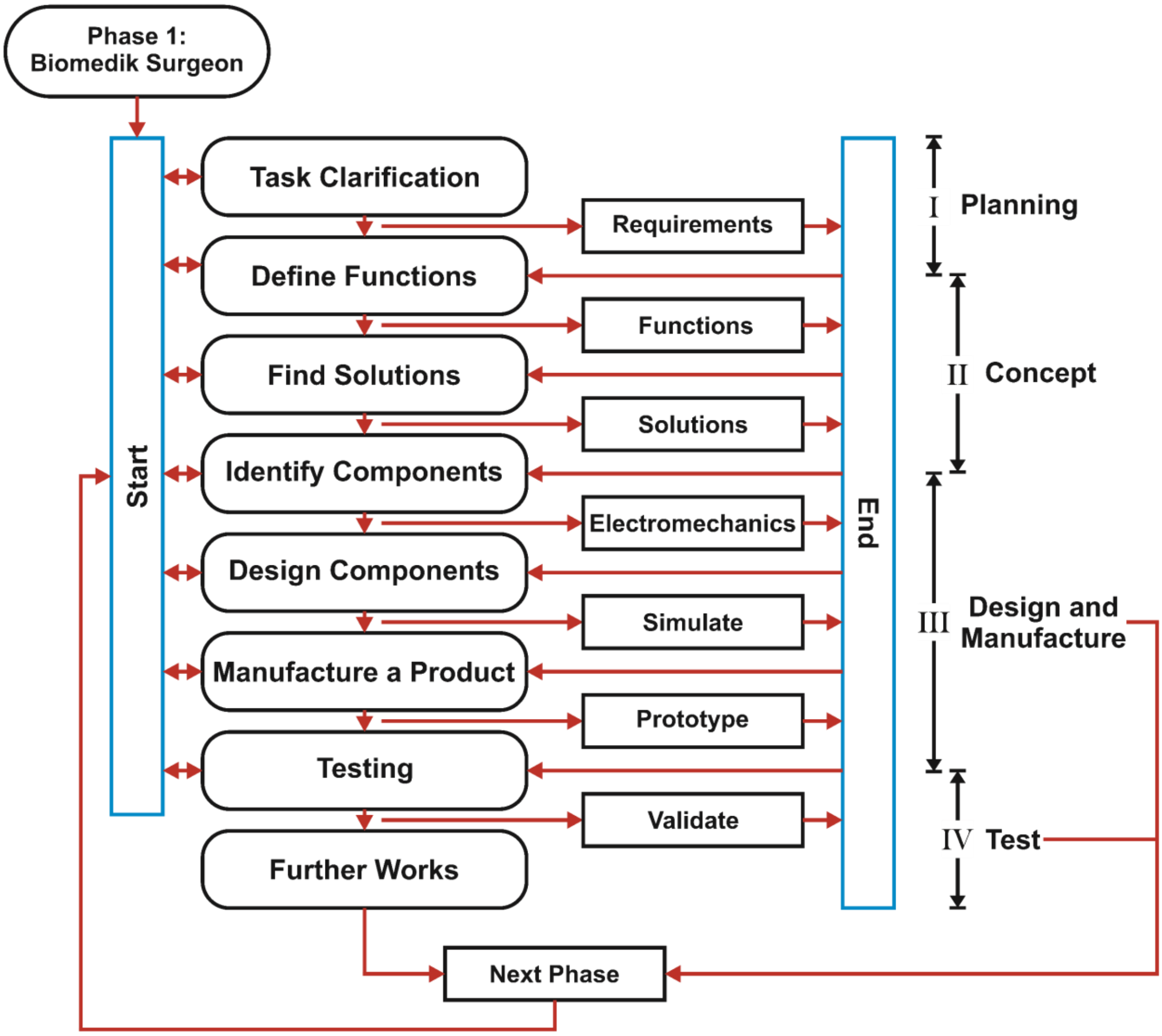


Figure 1. **Flowchart of Project Management**

2-1- Phase 1: Biomedik Surgeon

The first version prototype (Figure 2) proposes the application of a teleoperated ergonomic remote control to convey movement to an anthropomorphic robotic arm. Additionally, a Micro Camera is utilized for real-time image transmission and is implemented at the effector of the robot. The main objective of this research is to evaluate surgical performance and biomedical applications and to train medical students in Peru to develop surgical skills using various medical robotics concepts to prepare them to become more skilled doctors in performing robotic-assisted surgeries [24].

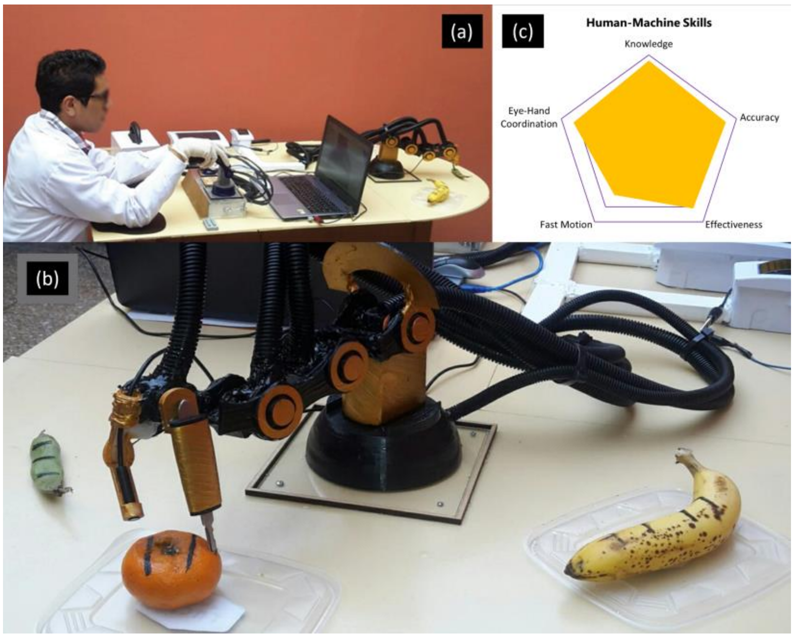


Figure 2. **a) Performance testing b) Robotic System making an incision on fruit skin c) Human-Machine skills**

The principal focus of the design (Figure 3a) is effectively integrating all the components of surgical robots to replicate the performance of surgeons. In addition, an in-depth analysis of the biomechanics and ergonomics of the hand was carried out to adapt the ergonomic joysticks to the surgeon's hands. The process of building is shown in Figure 3b. The steps considered were: analysis, the conception of ideas, prototyping, and testing, which allowed defining the project in three sections: Surgeon Control Box, which is the system that is responsible for transmitting the movement to the robotic arm; Robot-Patient Platform, which is the anthroponomic robotic arm that mimics the actions of the surgeon having a range of motion of 70°; and Vision Module, which is responsible for displaying in real time the action performed by the robotic end-effector. The operation is based on the principle that the movement of the angle exerted by the joystick is propagated to a joint of the robot, performing the move and efficiently achieving data transmission and programmed control. It has been possible to design and implement this research, which is categorized in the field of Medical Robotics and surgical practice, specifically in the category of minimally invasive and teleoperated surgical robots, which is centered on three fundamental principles of International Surgical Innovation: simplified sophisticated technology, an innovative low-cost business model, and precise economic value, which were established by the Center for Medical Innovation, USA.

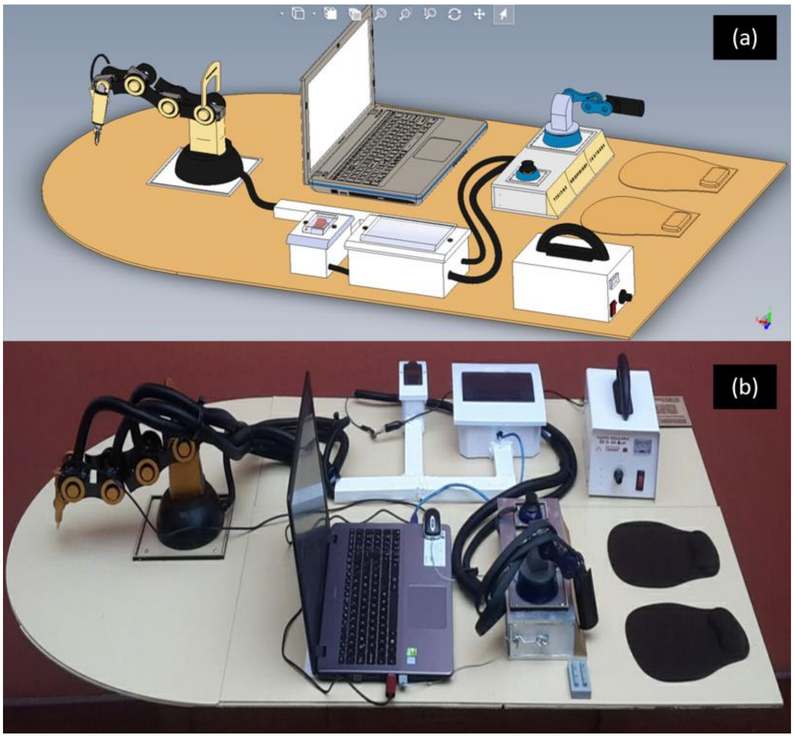


Figure 3. **a) 3D Design on E-Drawings software; b) Final Prototype**

The test and validation step were performed using the robotic arm, where the incision procedure was evaluated, being applied to banana, mandarin, and broad beans because each of them has a different shell thickness. So, as a result of the integration between the human (user) with the machine, the skills and features were quantified: knowledge (top score), accuracy, eye-hand coordination, fast motion (lower score), effectiveness represented by translating 3D movements with 2D instructions, and instrument manipulation control, which are shown in Figure 2c. The evaluation was based on 120 attempts, indicating the matching points (on the chart) as an average count of 200 people (engineering and medical students, healthcare professionals). Biomedik Surgeon is the first surgical robotic system made in Peru for training and simulation focused on the field of medicine. Also, it is an affordable system, obtaining a 97% acceptance rate, showing a high percentage of interest from the medical community. The training and simulation tests at Ricardo Palma University were successfully accredited by the Scientific Society of Medical Students of the Faculty of Human Medicine, "Manuel Huamán Guerrero", and by the Surgical Engineering Society (SES).

2-2- Phase 2: Space Biosurgeon

The main objective of this project is to show an alternative to providing mechatronic support for advanced laparoscopic surgical procedures applied to General and Gastrointestinal Surgery. Therefore, the project's contribution marks the start of a promising advancement in robotic surgery, which entails designing a technological system for surgical applications by integrating principles from mechatronics engineering and space human medical sciences. It aims to ensure safety, efficiency, and a smooth learning curve. Furthermore, the study proposes the utilization of the robot within the Operating Room of a specialized hospital in Spain [25].

Robotic technology has revolutionized surgical procedures, offering less invasive approaches and enhancing surgeon performance. Because of the variety of surgical applications and operating room conditions, the investigation proposed a mechatronic system dedicated to teleoperated surgical procedures, specifically aiming to pioneer robot-assisted gastrointestinal surgery. The design of the Surgical Robotic System focuses on accomplishing four primary objectives: natural eye-hand-instrument alignment; enhancing surgical motor dexterity while minimizing invasiveness; improving surgical ergonomics; feasibility; safety; and risk mitigation.

The Space Biosurgeon (Figure 4), an innovative medical robotic device, has been designed for application in Single Port Surgery. It consists of three robotic arms: one is dedicated to intra-abdominal procedures involving Micro-instruments and a camera, and the other two are used for surgical incision approaches using a surgical scalpel and scissors. The conceptual design includes the development of two surgical stations, as shown in Figure 4. One of the stations, called SurgiConsole, serves as the control center where the surgeon sits to command the robotic arms and surgical instruments and has two components: SurgiControl and SurgiPedals. Another station is SurgiPlatform, where the surgery takes place and is equipped with four robotic arms. It incorporates SurgiTable, SurgiCamera, and four SurgiArms. (Figure 5) [25].

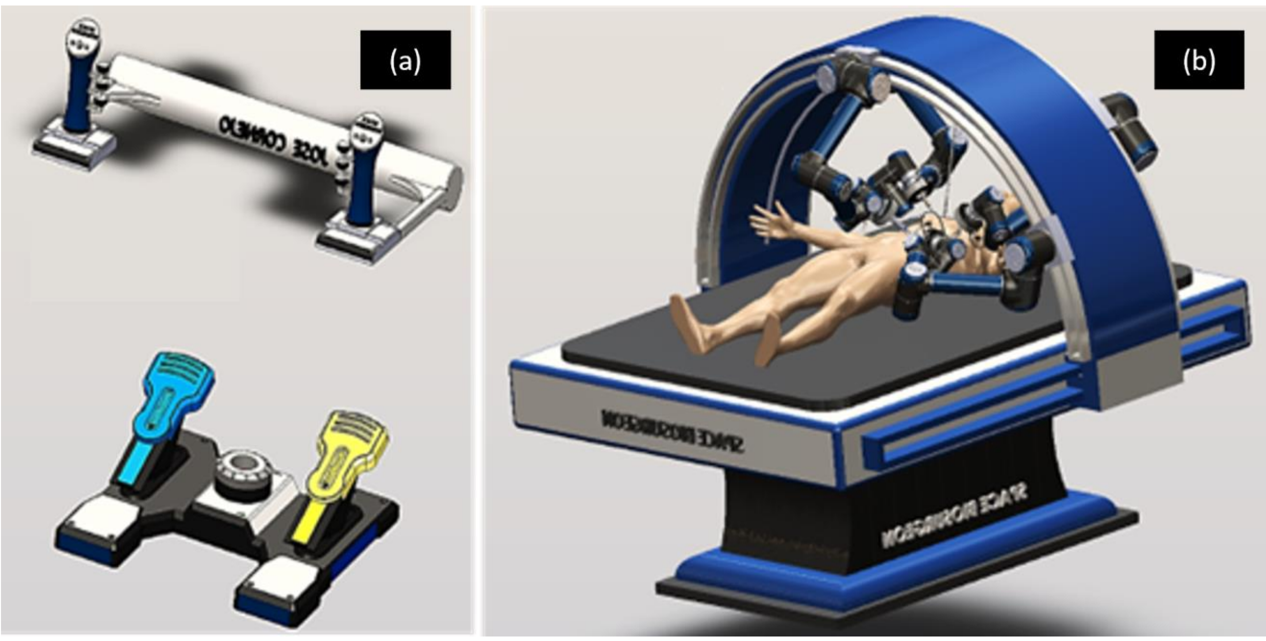


Figure 4. 3D Design of Biomedik Surgeon: a) Remote Console. b) Surgical Platform

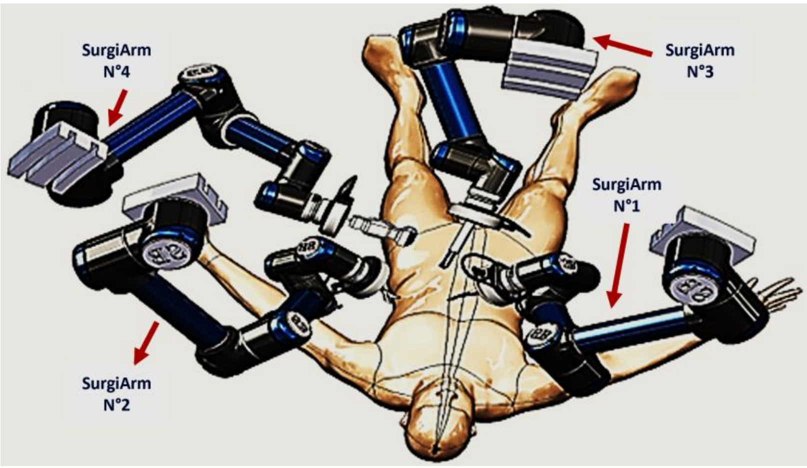


Figure 5. SurgiArms located on anatomical sides of the body

The surgeon assumes control of the SurgiConsole using two master controllers and foot pedals, which allow for manipulation of the system's semi-automated tasks. It is also capable of commanding the SurgiPlatform, which consists of two robotic arms dedicated to the Surgical Incision approach: one for Single Port Surgery (SPS) and another for Aerospace Medicine applications by teleoperation. The design of the system enables an effective anatomical triangulation for General and Gastrointestinal Surgery. The research focuses on 3D design in Solidworks and conducts Forward Kinematic analysis and simulation in Matlab. Furthermore, a study has been conducted to explore the technical and biomedical characteristics that enhance the surgeon's skills.

This investigation focuses on applying the fundamentals of HTA (Health Technology Assessment) in surgery, aiming to develop a culture of innovation in biomechatronics and clinical practice. Its objective is to drive advancements in General and Gastrointestinal Surgery; it proposes the design of a futuristic teleoperated Surgical Robotic System prototype that combines the efficiency of robots used in microsurgery with the precise accuracy of aerospace medicine technology. This integration aims to enable less invasive surgical procedures, thereby reducing risks for patients during the postoperative period. Notably, this prototype is considered the first of its kind in Latin America. In addition, Space Biosurgeon has been awarded second place during the period of Representative Documents by Scopus on the topic: Weightlessness; Aerospace Medicine; Space Flight (T.30830) [25].

2-3- Phase 3: SP-LAP

2-3-1- SP-LAP 1

The main objective of the system is to leverage remote teleguidance and telemonitoring to ensure precise, maneuverable, and high-quality surgical training. To achieve this, a prototype called SP-LAP (Space Laparoscopy); has been proposed, which is a medical robot. It is essentially a Surgical Laparoscopic Simulation Platform integrated with a multi-degree of freedom (multi-DOF) system, as shown in Figure 6. The platform was proposed to be tested at the Mars Desert Research Station (MDRS) and will utilize real-time communication to enable tele-assistance and training from remote medical teams to on-site non-medical analog astronauts. The training will employ Objective Structured Assessment of Technical Skill (OSAT) surgical procedures [26].

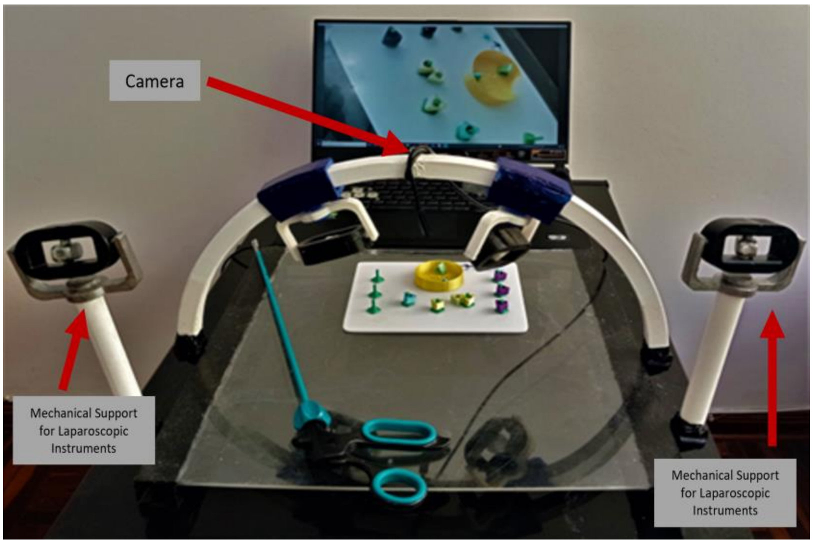


Figure 6. 3D Printed Prototype

Enhancing the skills of medical students performing surgery in space necessitates remote guidance from expert physicians. As a result, advances in telemedicine applications are crucial for developing space medicine technologies for future exploration missions. In this context, the project evaluates three essential clinical aspects based on surgical training: identifying what should be trained, determining the most effective training methods, and establishing them for assessing the training outcomes. Additionally, the evaluation focuses on adapting behavioral levels, including knowledge-based, rule-based, and skill-based behaviors, to ensure superior quality and optimal development of surgical training.

Some components of this prototype have been considered to be manufactured by 3D printing, because of the easy and low cost of this option. Also, it is indicated on the technical drawings that the materials to be used are Polylactic acid (PLA). The system is composed of multi-DOF, as shown in Figure 7-a, to enhance triangulation, precision, and accessibility. The general characteristics of the system are a length of 40 cm, a height of 22 cm, a width of 31 cm, 800 g, and a total of 11 DOF, based on the ergonomics of human arm kinematics, which allow replication of the same actions performed by a surgeon. These DOFs are divided into two principal mechanisms and have an objective to achieve. One of the mechanisms is the ELBOW/Shoulder Mechanism, consisting of 2 pieces and 3 DOF. The other is the Hand/Wrist-Instrument Mechanism, which consists of 10 parts and 8 DOF. One of the essential pieces for this project is Piece 6, which is designed to be manufactured by 3D printing and coupled with a surgical instrument such as a toothed/paddle grasper, needle holder, and hook/micro scissors that have a maximum diameter of 1.1 cm. Those elements enable precise and effective remote telemonitoring to be carried out [26, 27].

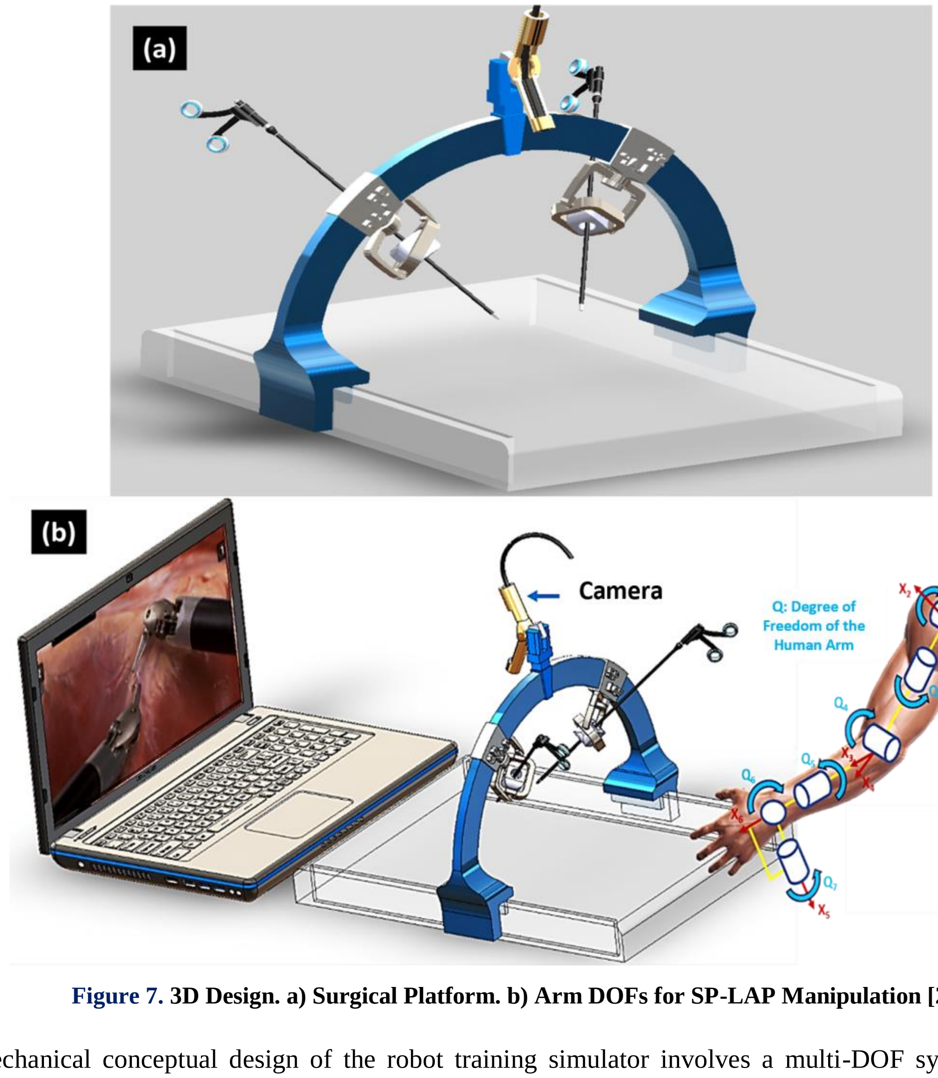


Figure 7. **3D Design. a) Surgical Platform. b) Arm DOFs for SP-LAP Manipulation [26]**

The mechanical conceptual design of the robot training simulator involves a multi-DOF system. It enables the exploration of new surgical techniques and approaches under the guidance of a medical expert while considering the ergonomics of human arm kinematics. It is worth noting that each human arm typically utilizes 5 DOFs out of a total of 7 DOFs (Figure 7-b). The chosen system serves to evaluate surgical performance, as illustrated in Figure 8, and is intended for the development of technical-clinical validation tests at the Mars Analog Desert. The proposed technology aims to be capable of remote teleguidance and telemonitoring, ensuring precision, maneuverability, and high-quality surgical training. In addition, this system has been awarded first place during the period of Representative Documents by Scopus in the topic: Weightlessness; Aerospace Medicine; Space Flight (T.30830).

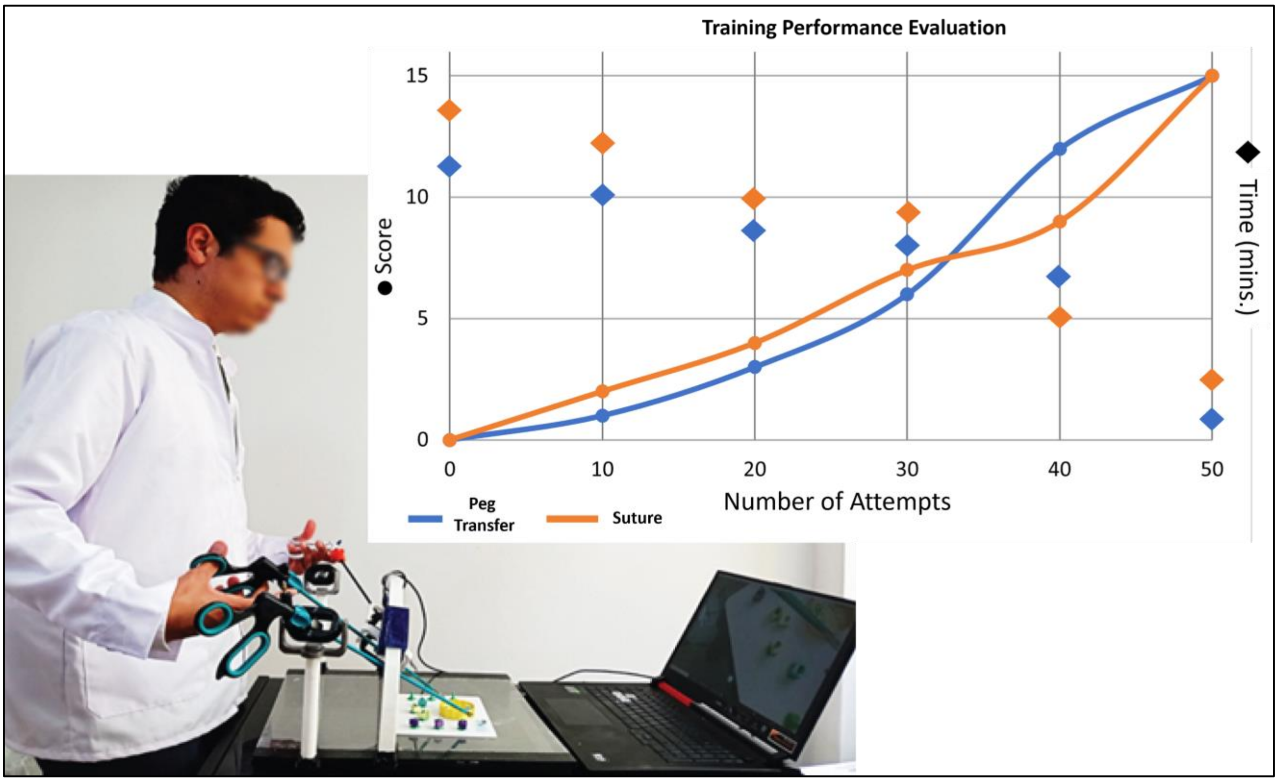


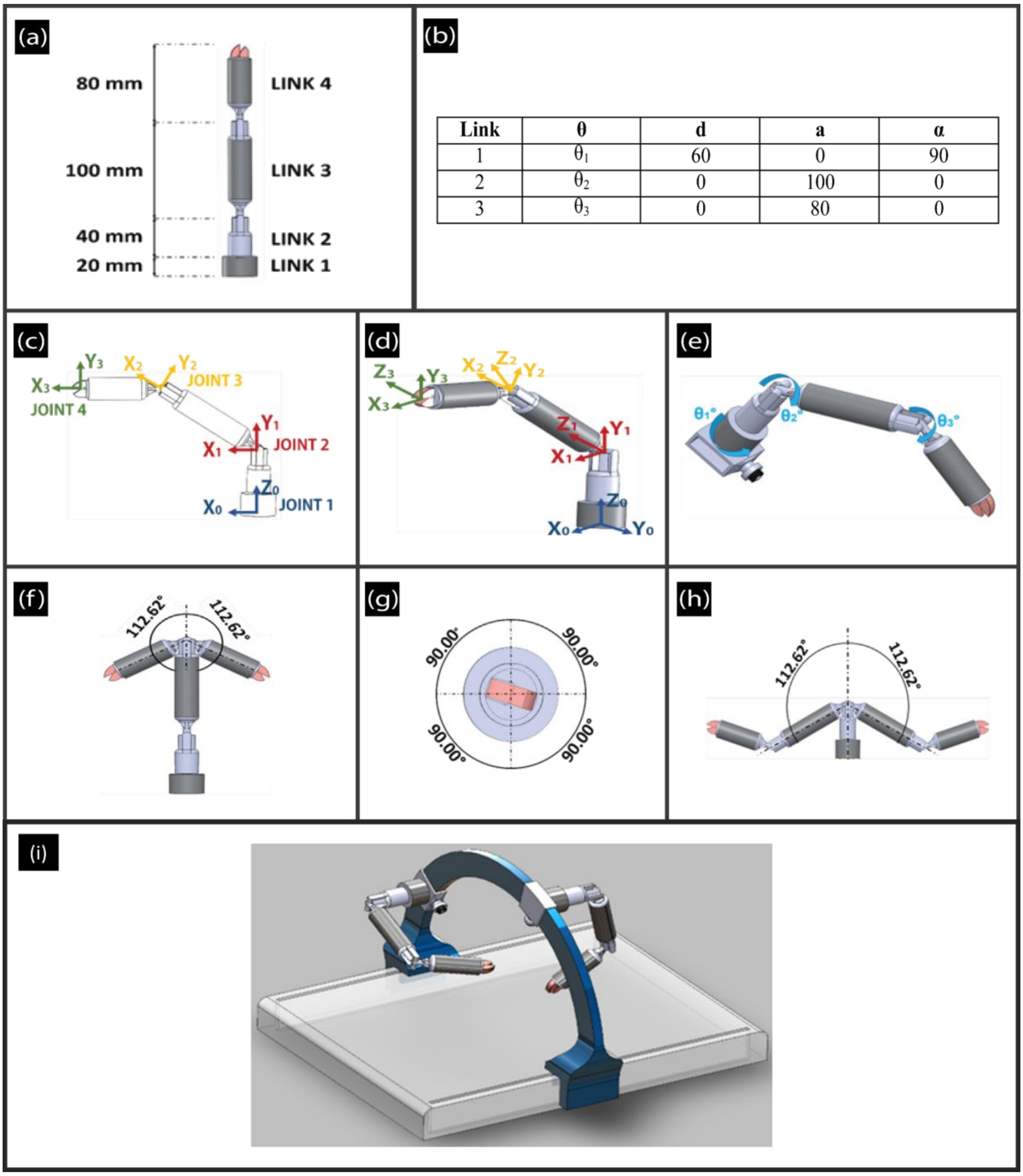
Figure 7. Performance Testing

The test and validation step was performed using the laparoscopic instruments, where 2 procedures were evaluated: Peg transfer and Suture, both considered 15 points as the maximum score, which means that the activity was completed. In Figure 8, it is observed that both learning curves were exponentially positive, having Peg transfer as the task that resulted easier to learn than Suture; in addition, it is shown that Peg transfer can be finished in 1.7 minutes, meanwhile, the suture task was finished in 2.6 minutes. The evaluation was based on 50 attempts, indicating the matching points (on the chart) as an average count of 100 people.

2-3-2- SP-LAP 2

It was designed to improve robotic skills, taking advantage of the precise and multi-DOF nature of the mechanical design. The project utilizes remote control haptic manipulation to amplify the natural alignment of the eye, hand, and instruments, enhance motor skills, minimize invasiveness, improve ergonomics, ensure feasibility and safety, and reduce patient risks (Figure 9) [28]. Due to the need to optimize surgical techniques to promote life support and medical treatment systems during space exploration, importantly, with remote capabilities, it is essential to develop innovative systems to be able to guarantee optimum medical and surgical care. Thus, the investigation states a ground-breaking design based on two robotic arms to be implemented in the platform of the robot, taking the places of the devices for accurate triangulation of surgical instruments. In Figure 9, it is shown the anthropomorphic robotic arm (length: 24 cm) [29], which has 4 DOF that are represented in kinematic parameters organized on the denavit-hartenberg table [30], also has 4 links and 3 joints.

It is implemented with the multi-DOF system and provides a total of 9 DOF, enabling the application of innovative surgical techniques and approaches while considering ergonomic considerations during surgical triangulation. To ensure accuracy and excellence in surgical training, this technology proposes to use haptic remote control [28]. The manipulator is designed in SolidWorks to develop the analysis and validation of the mechanism (Aluminum is selected as a material) and minimize possible failures, determining the maximum DOF angle of each joint by design simulation. It is a design approach that has been refined over the years and recognized in different conferences such as the IEEE International Conference on Control of Dynamical and Aerospace Systems (2019), IEEE ANDESCON (2020), and IEEE 3rd Eurasia Conference on Biomedical Engineering. This prototype proposes a physical and mathematical analysis favorable for its development, working on perfecting new surgical techniques, and considering the ergonomics principles when performing triangulation.



Link	θ	d	a	α
1	θ_1	60	0	90
2	θ_2	0	100	0
3	θ_3	0	80	0

Figure 8. a) Robotic arm, b) Denavit-hartenberg parameters, c) Coordinate System – frontal view, d) Coordinate System–isometric view, e) Joint angles – 3 DOF, f) Joint 3 – angle motion analysis, g) Joint 1 - angle motion analysis, h) Joint 2 - angle motion analysis, i) SP-LAP 2 system design.

3- Novel Biomedical Design and Results

Correspondingly to the SY-MIS© project versions in Section 3 and detailed in Appendix I – Figure A-1, an updated medical approach is proposed, which is called Hybrid Cyber-Physical Surgery (HYS ©), it consists of the simultaneous use of laparoscopic devices and robotic systems in order to get better outcomes during the procedure, combining the accuracy of robotic arms with the high flexibility of human motion. Therefore, a novel surgical training platform has been developed and named: Surgical Engineering and Mechatronic System (SETY ©), which is designed following the standards from 3 blocks: i) Biomedical design: ISO 9001-13485 [31] / FDA 21 CFR 820.30 [32] / ASTM F1744-96(2016) [33]; ii) Aerospace human factors design: HF-STD-001 [34]; iii) Mechatronics design: VDI 2206 [35].

SETY © platform is designed to achieve 2 main objectives related to training and enhancing skills related to eye-hand coordination, 3D movements with 2D guidance (which is planned to be updated with a virtual reality system), and control of instruments, to be used by: i) Healthcare and allied professionals; ii) Official and analog Astronauts. In addition, the access for learning can be at: i) Medical and training centers; ii) Remote or extreme environmental conditions areas; iii) Space surgery hybrid operating rooms.

According to VDI 2206, there is a standard for systems development (Figure 10), which has been applied in SY-MIS© project, and it covers 4 stages: i) Requirements, where are 2 procedures that have been analyzed, Endo-Robotic Surgery (E-RS) and Laparoscopic Surgery (LS); ii) Systems Design and Simulation, which starts with Biomedical (BM) study, followed by Mechatronics (MT) and Robotics (ROB) research; iii) System Implementation and Prototyping, where Mechanics (MEC), Electrical-Electronics (E-E), and Software and Computer (S-C) fundamentals are developed independently; iv) System Integration and Clinical Study, where the technologies are combined resulted in a functional platform and then it is validated by Medical Students (MD-STD), Medical Doctors (MD), Flight Surgeons (FS); v) Product Usage, which determines the location where the platform is used, for example, Education Centers (ED-C) and Medical Centers (M-C). Furthermore, the verification process is applied during each stage. Note that this manuscript describes until the Biomedical System Design (BM) stage.

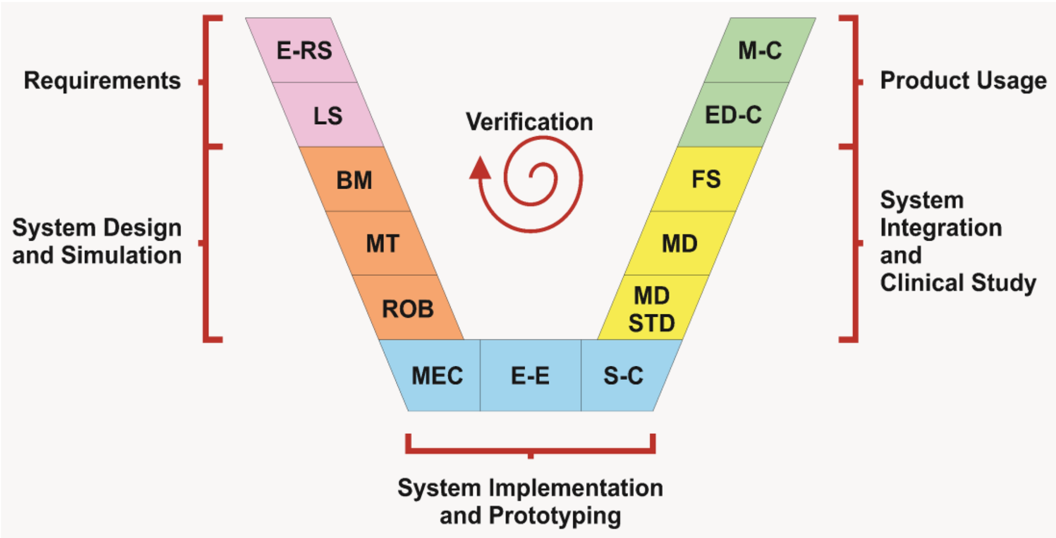


Figure 10. Development stages for SETY© platform following VDI 2206 standard. Legend: Endo-Robotic Surgery (E-RS), Laparoscopic Surgery (LS); Biomedical (BM), Mechatronics (MT) and Robotics (ROB) research; Mechanics (MEC), Electrical-Electronics (E-E), and Software and Computer (S-C) principles; Medical Students (MD-STD), Medical Doctors (MD), Flight Surgeons (FS); Education Centers (ED-C), Medical Centers (M-C).

a) First Stage

Starting with the requirements, the main medical considerations (Figure 11) that address our proposal lie in the fact that the body suffers morpho-physiological changes [36, 37] caused by: “trauma” such as hemopneumothorax, airway obstruction, and bone fractures; also, by: “non-trauma” such as gallstone cholecystitis and urolithiasis. Those health conditions sometimes have to be treated using a surgical procedure, where, due to microgravity it is crucial to perform the best management procedures for bleeding control [38], for this reason, it is expected to be used for 2 types of surgeries in order to be the less invasive [39]: i) Natural Orifice Transluminal Endoscopic Surgery (NOTES), which is an operation that uses a computer system to help guide the surgical tools, which are passed through the mouth to access the mouth and throat; and ii) Single Port Surgery (SPS), which is an operation using one single entry point. Therefore, the SETY© Platform is able to be used for training future medical astronauts with endoscopic tools and robotic arms. In addition, laparoscopic instruments can be used for tissue grasping [40].

In addition, the SY-MIS© project is the first of its type. The purpose of using it for space applications is due to the need for training for medical unexpected events [41]. During space travel, human physiology experiences unique changes affecting blood pressure regulation, cardiac output, the distribution of body fluids, bone demineralization, and muscle atrophy. Therefore, astronauts might be more prone to trauma, and also susceptible to conditions like appendicitis, acute gallbladder disease, and unexpected cancer presentation as the most common causes of surgery [42]. Crew members undergo extensive testing when they are selected, but even healthy people can develop surgical emergencies, which can be exacerbated. For example, scientists successfully repaired a rat's tail in zero gravity and performed laparoscopy [43], a minimally invasive surgical procedure used to examine and repair abdominal organs [44], on the animal [45, 46].

One problem with open surgery was that the viscera floated and obstructed the view of the surgical field, so astronauts should opt for minimally invasive surgery (MIS), which is performed inside the patient's lumen through a small incision using a camera and instruments. In 2017, a laparoscopy [47] was performed on a prosthetic abdomen during a parabolic "weightless flight" [48] and surgeons successfully stopped traumatic bleeding. Robotic surgery is another option being routinely used on Earth and tested for space. NASA's NEEMO 7 series of missions at the Aquarius underwater habitat (Florida Keys) show a successful robotic surgery controlled by another lab to remove fake gallbladder and kidney stones from a cadaveric model [49].

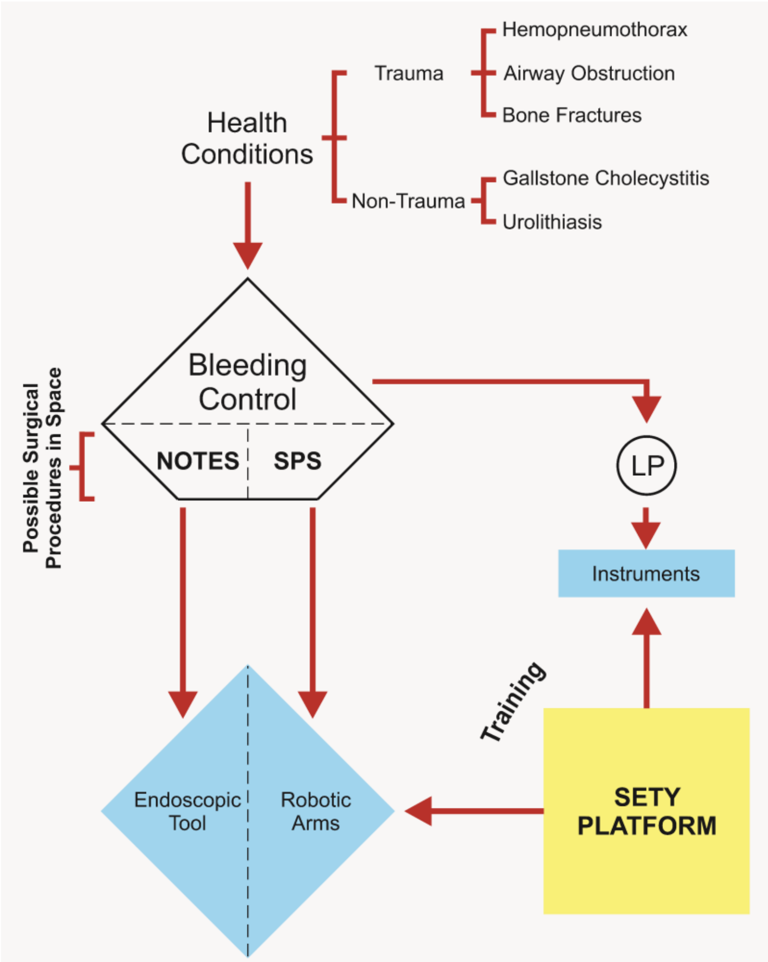


Figure 11. **Surgical procedures training using SETY© to manage health conditions in space. Legend: Natural Orifice Transluminal Endoscopic Surgery (NOTES); Single Port Surgery (SPS); Laparoscopic (LP)**

b) Second Stage

To develop the biomedical design, there are 3 main features to take into account, which are: i) Clinical assessment, ii) Machine adaptability, iii) Robustness, because those fulfill the expectations of the users in order to ensure the best performance of the system. Then, the selection of design concepts was performed based on the preliminary prototypes explained in section 3, so now, 2 possible training platforms are evaluated, as shown in Table 1: one is about the use of 1 robotic arm + 1 laparoscopic tool, and the other is about the integration of 2 robotics arms + 2 laparoscopic tools. After analyzing them, it has been validated that solution 2 is the most optimal, since it achieved a score of 90% compared with 76.7% of solution 1.

Table 1. **Evaluation of Technical Criteria**

Best Design Selection				
			Solutions	
Features	**Criteria**	**Importance (%)**	**Solution 1: 1 Robotic Arm + 1 Laparoscopic Tool**	**Solution 2: 2 Robotic Arms + 2 Laparoscopic Tools**
Clinical Assessment	Medical Function	20%	2	3
	Safety	10%	2	2
	Easy of Operation	10%	2	3
Machine Adaptability	Modular Mechanisms	20%	2	3
	Easy of Assembly Components	10%	3	3
	Easy Access of Maintenance	10%	3	2
Robustness	Stability	10%	2	3
	Lightweight	10%	3	2
	TOTAL	**100%**	2.3	2.7
	Unit Score		**76.7%**	**90%**

Note: Solution Score – 1= Average, 2=Good, 3= Excellent

Finally, the conceptual design of SETY© (Figure 12) is composed of 2 vertical supports for laparoscopic device placement, those supports have 3 DOF mechanisms which were inspired by the clinostat (machine for gravitational experiments) [50] – Figure 13-a, in order to facilitate the yaw, pitch, and roll motion. The performance usage protocol is described as: one person is able to move the 2 robotic arms using teleguidance from a remote control, while another person can use the laparoscopic instruments. On the other hand, there are 2 robotic arms (6 DOF each) with interchangeable end effectors – Figure 13-b, in addition, between them, micro-cameras are located. Then, the robotic arms are able to move along the arc structure, in addition, the arc can perform a linear motion through the base.

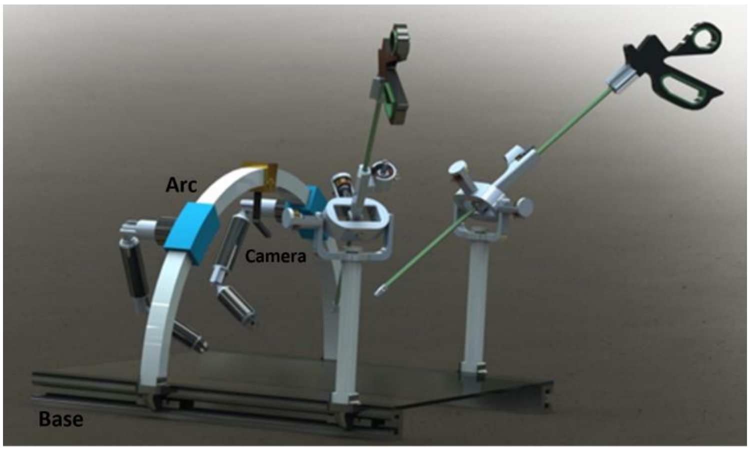


Figure 12. 3D Design of SETY©.

Regarding the mechanisms, the robotic arms are composed of active joints (6 DOF) [51], meanwhile, laparoscopic support has passive joints (3 DOF) [52], therefore, the combination of sensors and actuators is shown in Table 2. Additionally, the platform has 3 DOF, 1 for lineal displacement of the arc along the base, and 2 for rotational motion of the robotic arms around the arc, besides there is an integrated micro-camera for real-time visualization of the procedure.

Table 2. Basic Electromechanical Requirements

	Robotic Arm		Laparoscopic Support		Platform	
	Name	Number	Name	Number	Name	Number
Sensor	Encoder	6	Gyroscope	3	Encoder	3
	Torque	6	Encoder/ Potentiometer	3	Camera	1
Actuator	Motor	6	-	-	Motor	3

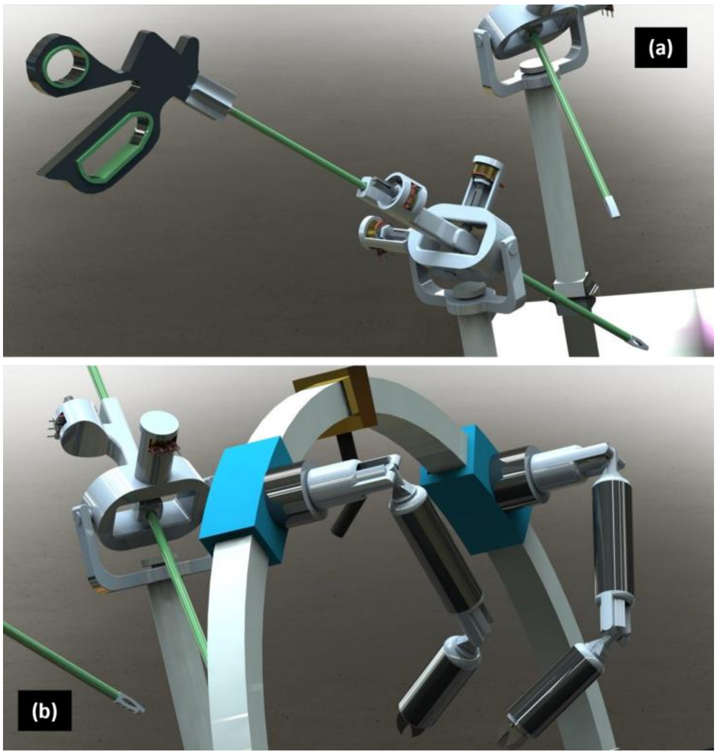


Figure 13. Zoom view of a) Laparoscopic Support and Devices, b) Dual robotic arms

4- Discussion

This section shows a comparative analysis of each system developed as part of the SY-MIS © project, based on the description of 2 main fields: machine components and skills evaluation (Table 3). The first one mentioned depicts that there are 3 systems composed of only robotic arms – Biomedik Surgeon (1), Space Biosurgeon (4), and SP-LAP 2 (2), but SP-LAP 1 contains only laparoscopic supports, meanwhile, SETY © has a combination of both components which will give it a better performance during manipulation tasks. In addition, all systems have an integrated camera with the aim of reproducing a real-time visualization of the operating field. The second one is related to the systems that have been tested, thus, scores are assigned for quantifying the acquired knowledge, accuracy, effectiveness, and fast motion. Therefore, it is observed that according to an overall average, SP-LAP 1 (acquired knowledge: top score 4.7 out of 5) evidenced better physical experience than Biomedik Surgeon (eye-hand coordination: top score 4.8 out of 5), although SP-LAP 1 trains laparoscopic dexterity (peg transfer and suture) - tested by 200 people, and Biomedik Surgeon instructs for robotic motion (incision) – tested by 100 people.

Table 3. Systems developed during SY-MIS Project

		Biomedik Surgeon	Space Biosurgeon	SP-LAP		SETY
				SP-LAP 1	SP-LAP 2	
Machine Components	*1 robotic arm*	x				
	2 robotic arms				x	x
	4 robotic arms		x			
	Laparoscopic supports			x		x
	Camera	x	x	x	x	x
Skills Evaluation (Score 0-5)	*Knowledge*	4.7		4.5		
	Accuracy	4.4		4.7		
	Effectiveness	4.1	--	4.3	--	Test scheduled at the end of 2024
	Fast motion	3.2		4.6		
	Eye-hand coordination	4.3		4.8		

Constant training in traditional laparoscopic and robotic procedures is essential for improving surgical skills. These new devices require constant practice because granular and precise movements are needed for minimally invasive surgery. In this context, different simulators have been created to help surgeons acquire the dexterity necessary to master these new tools [53]. There are three main types of laparoscopic surgical training systems: biological, box trainers, and virtual simulators [54]. However, the high cost of commercially used simulators limits its availability. For this reason, many low-cost homemade simulators have been created as a solution to this demand. Different studies compared commercial laparoscopic trainers with homemade models confirming a non-inferior utility for practicing surgical skills [53]. Most of these models consist of either a mirror-based or a webcam-based laparoscopic simulator. Mirror-based laparoscopic simulators consist of two parallel mirrors at a 45° angle inside a small plastic box. Holes are made to fit a central light on the top and two trocars on each side. On the other hand, the webcam-based laparoscopic simulator would use the same plastic box with 3 additional orifices to fit additional trocars and a webcam with an HD camera for better visualization [53]. Following these principles, several models have been presented broadly across literature, as shown in Appendix II - Table A-1.

Ergo-Lap is a homemade inexpensive and portable simulator that includes a static or mobile camera intended to provide high precision for practice. This device is particularly useful given its similar design to real human cavity dimensions and the possibility of participating in an online competition from two different locations by using an internet connection [53-55]. Other homemade laparoscopic simulators as described by Alfa-Wali et al. and Wong et al. which offered the same tasks as more sophisticated simulators showed to be feasible to use at home and helpful in developing hand-eye coordination [52, 53]. The LapaRobot is another robotic platform for laparoscopic skill training. It is characterized by the ability to teleoperate, adapt easily to any surgical instrument, and incorporate all degrees of freedom (DOF). The system consists of four sub-assembly mechanisms: a spherical mechanism, a rotational tool, an insertion mechanism, and a grasping device [54]. On the other hand, the EoSim Box laparoscopic simulator is a box training system with a standard configuration connected to a laptop. The available tasks include passing a shoelace through five rings, cutting remarked lines, and suturing fabric borders. The Fundamentals of Laparoscopic Surgery (FLS) is a similar simulator that uses a standard configuration connected to a TV and Karl Storz KOH needle holders and graspers. FLS allows peg transfer, circle cutting, and suturing [20].

Moreover, laparoscopic surgery has been optimized by robotic-assisted procedures over the past decade [56], making it essential for simulator devices to adapt to these new conditions. Robotic consoles have a training feature with enhanced virtual reality to simulate actual procedures and allow physicians to improve psychomotor and procedural skills. The dV-Trainer (Mimic, Seattle, WA, USA), introduced in 2007, was the first virtual simulator with more than 60 training exercises and tridimensional case videos to help surgeons improve clinical decision-making and procedural knowledge [57-59]. The Da Vinci Skills Simulator (dVSS, Intuitive Surgical) is similar to the dV-Trainer but uses the robotic surgery console which allows surgeons to familiarize themselves with the actual surgical machines while obtaining performance tracking [60]. The Robotic Surgery Simulator (RoSS, Simulated Surgical Systems, San Jose, CA, USA) is a portable platform composed of a tridimensional display, master controllers, and foot pedals that are programmed with 16 training modules [61]. These tasks are compiled in modules for Fundamental Skills Robotic Surgery (FSRS), an on-site robotic-assisted training surgery program [62]. After completing FSRS modules, trainees may test performance using the RSA (Robotics Skills Assessment) score which assesses safety in the operative field, critical error, economy, bimanual dexterity, and time [60]. The RobotiX Mentor (3D Systems, Simbionix Products, Cleveland OH, USA) platform consists of a workplace, master controllers, and foot pedals and is programmed with some modules including the Robotic Basic Skills, Fundamentals of Robotic Surgery (FRS), Robotic Essential Skills [63], and other surgical procedures [64-66]. Automated Performance Metrics (APM) and Machine Learning Algorithms have recently been developed as another approach to assess skills in robotic surgery.

Generally, these simulators allow surgeons to improve competencies while preserving patient safety [64]. However, hospitals with limited resources lack enough simulators for residents or attendees, limiting familiarity with the actual platform and proper development of psychomotor skills [60, 65]. Many simulation devices have achieved face, content, and construct validity reducing the learning curve of laparoscopic and robotic surgery. They allow the capture of time, motion, number of errors, instrument collisions, excessive instrument force, and mastery of workspace range to assess surgical performance [60]. Under these circumstances, it is clear that the development of these, as well as other low-cost simulators, are essential for medical education as they offer the possibility to improve dexterity in surgical procedures remotely from the actual surgical scenario while maintaining the challenges inherent to stressful real-life situations. Currently, there is no surgical training system that has a symbiotic utilization with two applications for simulation of laparoscopic and robotic procedures that can be performed on the Earth and Space, for that reason we introduce a novel platform called SETY©, which has been described in this manuscript.

5- Future Work

This proposal is applied to the field of Minimally Invasive Surgery (MIS), where "Hybrid Cyber-Physical Surgery (HYS©)" terminology defines a new procedure that combines human-machine interaction inside an operating room. So, related to Figure 14, it is planned that the SETY© platform includes 2 main parts, the "Master", where controls command the "Slave", then the Slave part has 2 sides: a) "Endo-Robotic, which includes 1 endoscopic tool and 2 robotic arms, both equipped with a camera, one for inside navigation and the other for outside navigation and b) "Laparoscopic", where the tools are manned by human-hand. Also, the remote-controlled actions can be optimized by Virtual Reality and Artificial Intelligence, therefore here is described the use of the coupled technologies that will improve the learning curve:

a) Virtual Reality (VR) Integration: VR is a valuable tool for enhancing the learning experience and improving surgical skills: I) Identify Learning Objectives: Determine the specific surgical skills and procedures you want to focus on in the VR training. Understanding the learning objectives will help you design targeted and effective VR modules. II) Develop VR Simulations: Create realistic and accurate surgical simulations using 3D modeling and VR development tools. These simulations should mirror real surgical procedures and scenarios to provide a lifelike experience for trainees. III) Expert Guidance: Involve experienced surgeons and medical professionals in the development of the VR simulations. Their expertise will ensure that the virtual training accurately reflects real surgical techniques and best practices. In addition, IV) Continuous Updates and Improvements: VR technology is evolving, so keep updating and improving the VR training modules to stay current with advancements in surgical practices and VR capabilities [66].

b) Artificial Intelligence (AI) Integration: These technologies continue to mature; their application holds the potential to revolutionize the way surgical training is designed and conducted, with the aim to explore the following advantages: I) Personalization: Tailors simulators and tutorials based on the learner's specific progress and needs. II) Immediate Feedback: provides real-time feedback, allowing timely corrections. III) Detailed Analysis: evaluates the accuracy and efficiency of surgical techniques, potentially optimizing ergonomics. IV) Realistic Simulation: potential for the creation of realistic scenarios and pathologies. V) Error Reduction: optimizes simulation, helping to minimize mistakes by training in a controlled environment before real procedures. VI) Constant Updates: quickly adapts to new techniques and procedures [67].

c) Magneto Integration: It holds an immense potential to revolutionize surgical education and enhance the skills of aspiring surgeons, which utilizes magnetic fields to control and guide instruments to develop a realistic and immersive training environment, simulating the intricacies of laparoscopic and robotic surgical procedures. By incorporating magnets into surgical instruments and training models, trainees can experience the realistic tissue resistance and feedback encountered during actual surgeries. This integration enables refined hand-eye coordination and dexterity facilitating a seamless transition to performing complex surgeries with minimal risks and better patient outcomes. In the context of laparoscopic surgery, magnets can be implemented in training platforms to improve the ergonomics and stability of laparoscopic instruments. For robotic surgery, magnets can be utilized to enhance manipulation of the robotic arms, precise tissue dissection, and suturing. Thus, the implementation of magnets in training platforms facilitates a more efficient learning process, enhancing the skills and confidence of surgeons-in-training [68].

d) Endoscopic integration: The aim is to use this technology in a Natural Orifice Transluminal Endoscopic Surgery (NOTES) [69] or Transoral robotic surgery (TORS) simulation [70], replacing one of the robotic mini-arms with a mini-endoscope that is also controlled by a remote device. More recently, the Fundamental of Endoscopic Surgery (FES) program certificate [71] also became a requirement to be eligible for board certification in general surgery. Currently, there is no standardized curriculum for training and assessment of robotic surgery. However, this is increasingly being investigated [72].

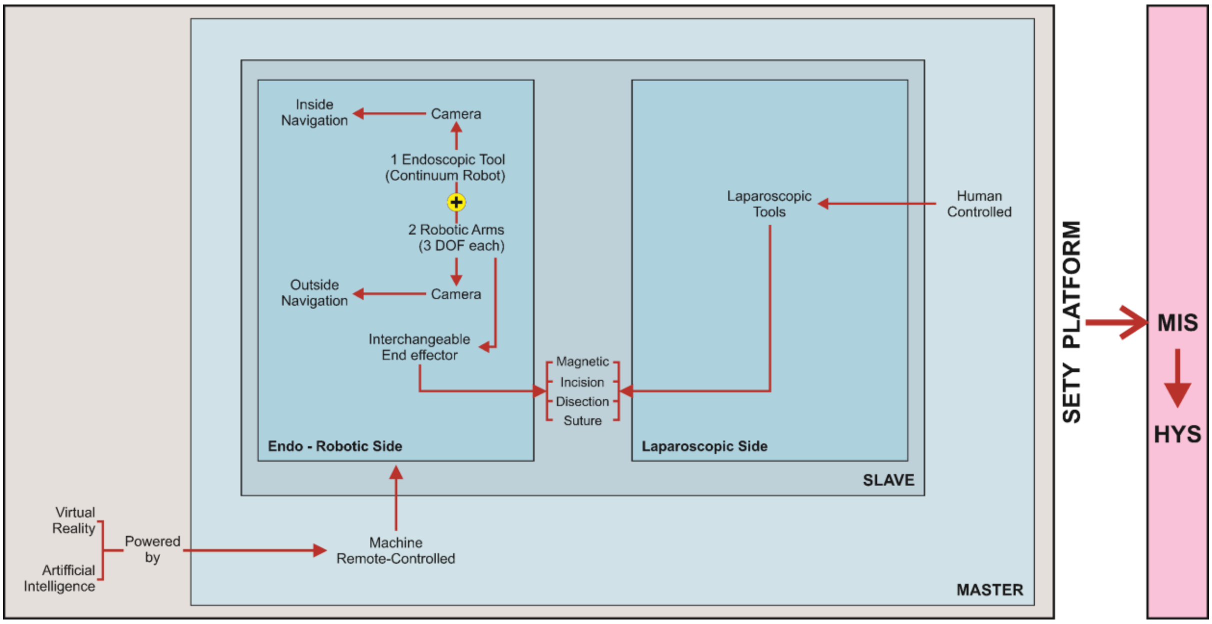


Figure 14. **SETY© platform - a biomedical design concept for Hybrid Cyber-Physical Surgery**

6- Conclusion

SETY© is currently a novel proposed system designed to train future healthcare students/professionals and flight surgeons in order to offer an excellent experience performing Hybrid Cyber-Physical Surgery (HYS©) in a simulated environment. Despite the location (Earth or Space), surgical simulation is a vital part of improving technical skills and ensuring patients' safety during the real procedure. Following the 3 standards: i) Biomedical design: ISO 9001-13485 / FDA 21 CFR 820.30 / ASTM F1744-96(2016); ii) Aerospace human factors: HF-STD-001; iii) Mechatronics design: VDI 2206. This system integrates the use of 2 laparoscopic tools and 2 anthropomorphic mini-robotic arms (6 DOF). In addition, it has been validated by the Evaluation of Technical Criteria, getting a total score of 90% related to clinical assessment, machine adaptability, and robustness. Therefore, the next step of the project is the mechatronics system design, which consists of the selection of sensors, actuators, and materials to drive the multi-degrees of freedom of SETY©, including the surgical robotic arms and the mechanical support for laparoscopic instruments. Then, the integration and testing validation procedures are expected to be developed. Finally, the rapid advancements in aerospace medicine create the need for more comprehensive medical care and training, which is the reason for including SETY© in minimally invasive surgery procedures, not only for space but also for hospital-university applications. To sum up, the development of the SY-MIS© project promotes the use of advanced technologies to improve surgical procedures and human-machine medical cooperation for the next frontier of habitability on other planets.

7- Abbreviations

AESOP	Automated Endoscopic System for Optimal Positioning	AI	Artificial Intelligence
APMs	Automated Surgical Performance Metrics	AR	Augmented Reality
AsMA	Aerospace Medical Association	BM	Biomedical
CABG	Coronary Artery Bypass Graft	D-H	Denavit- Hartenberg
DOF	Degrees of Freedom	ED-C	Education Centers
E-RS	Endo-Robotic Surgery	FDA	Food and Drug Administration

FES	Fundamental of Endoscopic Surgery	FLS	Fundamentals of Laparoscopic Surgery
FS	Flight Surgeons	E-E	Electrical and Electronics
ESA	European Space Agency	HM	Homemade
HTAM	Hierarchical Task Analysis Model	HTA	Health Technology Assessment
HYS	Hybrid Cyber-Physical Surgery	IEEE	Institute of Electrical and Electronics Engineers
LS	Laparoscopic Surgery	MDRS	Mars Desert Research Station
MT	Mechatronics	MEC	Mechanics
MD	Medical Doctors	MD-STD	Medical Students
M-C	Medical Centers	MIS	Minimally Invasive Surgery
Multi-DOF	Multi-Degree of Freedom	NOTES	Natural Orifice Transluminal Endoscopic Surgery
NATO	North Atlantic Treaty Organization	OSAT	Objective Structured Assessment of Technical Skill
PLA	Polylactic Acid	ROB	Robotics
RSA	Robotics Skills Assessment	SAGES	Society of American Gastrointestinal and Endoscopic Surgeons
S-C	Software and Computer	SDG	Sustainable Development Goals
SETY	Surgical Engineering and Mechatronic System	SPS	Single-Port Surgery
SY-MIS	Space System for Minimally Invasive Surgery	TORS	Transoral Robotic Surgery
UN	United Nations	VR	Virtual Reality

8- Declarations

8-1- Author Contributions

Conceptualization, J.C., J.C., and M.V.; data curation, J.C., J.C., M.V., M.C., G.R., C.M., S.C., P.S., R.P., and S.A.; formal analysis, J.C., J.C., and M.V.; investigation, J.C., J.C., M.V., M.C., G.R., C.M., S.C., P.S., R.F.C., M.C.J., E.P.L., L.S., R.P., S.A., and M.R.; methodology, J.C., J.C., M.V., M.C., G.R., C.M., S.C., P.S., R.P., and S.A.; project administration, J.C., J.C., and M.V.; resources, J.C., J.C., and M.V.; supervision, J.C., J.C., M.V., P.P., J.A.DLC-V., and E.F.E.; validation, J.C., J.C., M.V., P.P., R.C-L., and L.A.E.; visualization, J.C., J.C., and M.V.; writing—original draft, J.C., J.C., M.V., M.C., G.R., C.M., S.C., P.S., R.F.C., M.C.J., E.P.L., L.S., R.P., S.A., and M.R.; writing—review & editing, J.C., J.C., M.V., and E.F.E. All authors have read and agreed to the published version of the manuscript.

8-2- Data Availability Statement

The data presented in this study are available on request from the corresponding author. The design and development of the SY-MIS © project are protected by copyright and trademark laws.

8-3- Funding

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8-4- Acknowledgements

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8-5- Institutional Review Board Statement

Not applicable.

8-6- Informed Consent Statement

Not applicable.

8-7- Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this manuscript. In addition, the ethical issues, including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, and redundancies have been completely observed by the authors.

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Appendix I

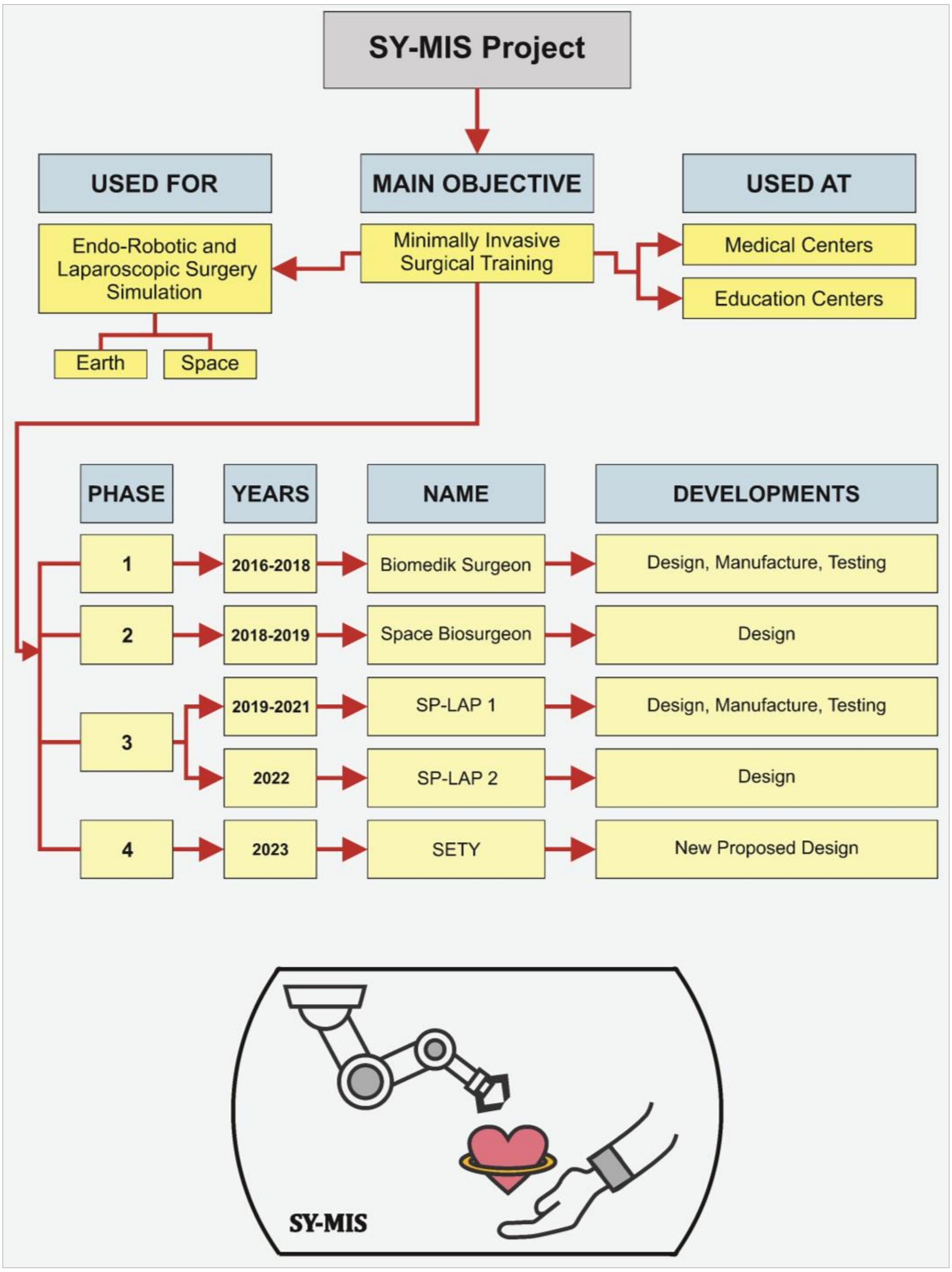

Figure A-1. SY-MIS© Project – Timeline Development

Appendix II

Table A-1. Review of Laparoscopic and Robotic Simulators in the literature

Author (Year)	Title	Purpose or content	Document type	Language	Place
		Laparoscopic/Robotic Simulators			
Alfa-Wali & Antoniou (2011) [73]	Eco-friendly laparoscopic home trainer	Novel home laparoscopic trainer is designed using a mobile phone, torch, and shoe box. Then, surgical trainees with variable laparoscopic experience used the device and provided feedback by filling in a Likert scale questionnaire	Journal article	English	UK
Xiao et al. (2013) [55]	A newly designed portable ergonomic laparoscopic skills Ergo-Lap simulator	Scientifically-based development of an inexpensive and portable Ergo-Lap simulator with multiple tasks. Then, surgical trainees with variable laparoscopic experience used the device and provided feedback by filling in a Likert scale questionnaire	Journal article	English	Netherlands
Hennessey & Hewett (2013) [20]	Construct, concurrent, and content validity of the EoSim laparoscopic simulator	Validate the EoSim box laparoscopic simulator. Novice and expert participants were tested on both the FLS trainer and EoSim laparoscopic simulators, using established scoring mechanisms. A questionnaire was completed.	Journal article	English	Australia
Wong et al. (2013) [74]	Construction and validation of a low-cost laparoscopic simulator for surgical education	Construct a trainer that would achieve the equivalent goals of the Fundamentals of Laparoscopic Surgery (FLS) trainer at an economical cost. A validation study comparing the homemade (HM) trainer vs FLS trainer was performed.	Journal article	English	USA
Prince et al. (2020) [54]	A robotic system for telementoring and training in laparoscopic surgery	The LapaRobot trainer, is introduced. The system is designed to create a high-fidelity approximation of the intracorporeal workspace, incorporate commercially available surgical instruments, and provide a wealth of high-resolution data for quantitative analysis and feedback.	Journal article	English	USA
Kenney et al. (2009) [57]	Face, content, and construct validity of dV-trainer, a novel virtual reality simulator for robotic surgery	Assess the face, content, and construct validity of the dV-Trainer, a virtual reality simulator for the da Vinci Surgical System that was in beta development. The subjects were prospectively categorized as novice or experienced. The performance was recorded using a built-in scoring algorithm.	Journal article	English	USA
Hung et al. (2011) [75]	Face, content, and construct validity of a novel robotic surgery simulator	Evaluate a novel robotic surgical simulator for robotic surgery using the da Vinci Si Surgeon Console and Mimic virtual reality. Subjects were categorized according to their robotic experience. Each participant completed different tasks to evaluate the validity of the system. The performance among participants was evaluated.	Journal article	English	USA
Kesavadas et al. (2011) [61]	Validation of robotic surgery simulator (RoSS)	A new virtual reality simulator, called RoSS is presented. Face and content validity were assessed. It is described that RoSS has the potential to become an important training tool for the DaVinci surgical robot.	Journal article	English	USA
Alshuaibi et al. (2020) [63]	Concurrent, face, content, and construct validity of the RobotiX Mentor simulator for robotic basic skills	Assess several criteria, such as concurrent, face, content, and construct validity of the RobotiX Mentor (RXM) simulator for basic robotic skills. Participants were divided into three groups according to their initial surgical training and evaluated in terms of six basic robotic exercises as recommended by the fundamentals of robotic surgery.	Journal article	English	France