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UNIVERSITÀ DEGLI STUDI DI TORINO

Doctoral Dissertation
Doctoral Program in Bioengineering and Medical-Surgical Sciences (36th Cycle)

Towards AUtonomous RObotic MicroSurgery

Training in the use of basic functions of the daVinci Xi® robot:
comparison study of resident's skill

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* * * * * *

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I would like to acknowledge Professor Mario Morino and Professor Paolo Gontero for their consistent support.

Summary

Background
The rapid spread of the robotic surgical system has not been accompanied by an equally rapid creation of standardized training courses for the use of this technology.
The purpose of our study was to evaluate skill acquisition in the handling and use of the Davinci Xi by comparing two groups of surgical residents.

Methods
Surgical residents from the University of Turin were enrolled. The participants were divided into two groups: Group A: residents who had participated in at least 8 robotic surgical procedures, and Group B: residents who had never attended robotic surgery. All were administered two instructional videos on the patient cart and console exercises to be performed. Subsequently, the residents were tested and recorded to be evaluated by a senior surgeon experienced in robotic surgery, according to a previously assessed evaluation score. The time of the procedure was also recorded for each test.

Results
Patient cart exercises were completed by all participants. We found statistically significant differences as regards the execution times between two groups for the first (use of the arms and endoscope aiming; p=0.0000) and third (tool replacement and gearbox eye endoscope; p=0.0002) patient cart tests and for every test on the surgeon's console except the endoscope handling exercise. Group A scored higher on the patient cart exercises, and the difference reached statistical significance (p=0.0001). We didn’t found statistically significant differences as regard the total score between two groups for the console exercises. The placement of a single hand-sewn knot on the silicone suture pad was the only exercise that was not fully completed by all participants and showed no statistical difference. The correlation analysis between surgical experience and final score was significant in group A.

Conclusions

DaVinci Xi® robotic platform could be adequately managed in its basic functions by young surgeons after a short education program, albeit with significant differences in execution times of some excercises. Patient-side cart training seems conditioned by technical characteristics of daVinci Xi® platform. Nevertheless, surgeon console appears to be more manageable, and thus independently from previous surgical and robot specific experience, highlighting the great advancement of biomedical engineering.

Overcoming the limitations related to the absence of tactile feedback and reducing usage times are closely related to training pathways regardless of theoretical training. Further studies are needed to validate and standardize a training model that reduces learning curve times in clinical practice.

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I INTRODUCTION

1.1 History of Robotic Surgery

The last decades have been characterized by an exponential development of medical technology in all areas. One of the results of research in this regard has been the application of robotic technology to surgery. Although over the years there have been numerous proposals, the most widespread robotic surgical system, approved by the FDA (Food and Drug Administration), is represented by the da Vinci® platform (Intuitive Surgical, Sunnyvale, CA, USA).

The term "robot" derives from the Czech word "robota," which means heavy work, and it was the Czech writer Karel Capek who first used the term in 1920 in his theatrical drama "Rossum's Universal Robots." Although the term is relatively recent, the first true robot to imitate human movements of the jaw, arms, and neck was in 1495, the so-called "Knight Automaton," created by Leonardo Da Vinci. Various inventions of androids and automatons followed until 1961 when the first industrial robot, Unimate, was developed. It had a magnetic drum to store commands and six degrees of freedom to effectively handle die casting and perform welding, replacing high-intensity tasks previously performed by humans [1]. This was a decisive invention as the influence of Unimate led to the development of new technologies that were then applied in the automotive industry. The concept of a "robotic arm" programmed to replace human movements entered the field of medicine with the invention of the Programmable Universal Manipulation Arm (PUMA, figure 1). Developed in 1978 by Victor Scheinmann, the PUMA 560 had 6 degrees of freedom and effectively became the first truly flexible robotic arm. Its first application in surgery, as demonstrated by Kwoh et al., occurred when the PUMA 560 was used to guide a needle during a CT-guided brain biopsy [2]. Providing more precise and stable guidance than a human hand, the PUMA 560 helped pave the way for future robots in surgery.



Figure 1. PUMA - Programmable Universal Manipulation Arm

At the end of the 1980s, Imperial College London developed a robotic system called PROBOT to assist surgeons in transurethral prostatectomies [3]. With its four axes of movement, a rotating blade at 40,000 rpm for resection, and compact dimensions, PROBOT was ideal for performing this procedure. Using a computer-generated 3D model of the prostate, the surgeon outlined a specific resection area. Based on this data, PROBOT calculated the excision trajectories, and the procedure was performed by the robot without further assistance from the surgeon [4,5].

The application of robotics in surgery stems from the modern human's desire to achieve two objectives: telepresence and the execution of precise and repetitive tasks. Thus, in 1992, ROBODOC (Integrated Surgical Systems, Sacramento, CA, USA) revolutionized orthopedic surgery by enabling total hip arthroplasty [6]:

Using a high-speed drill and data provided by CT (computed tomography) images, ROBODOC performed precise drilling into the femoral head, allowing the surgeon to optimize the size of the prosthesis based on the patient's physical characteristics [7]. Currently, ROBODOC is marketed by Curexo Technology Corporation after the acquisition of Integrated Surgical Systems in 2007 and has

been used in 24,000 procedures to date [8]. In August 2008, ROBODOC received FDA approval for total hip arthroplasty and is currently the only robot used in orthopedic surgery.

Also in the 1990s, the first "master-slave" system was developed, consisting of a robot with remote manipulators controlled by a surgeon at a location away from the patient [9].

The next breakthrough for robotic surgery came in 1994 with the Automated Endoscopic System for Optimal Positioning 1000 (AESOP 1000; Computer Motion, Santa Barbara, CA, USA). In the following years, the FDA approved AESOP (Figure 2) as a remote manipulator for an endoscope controlled by the surgeon's voice commands, effectively eliminating the need for an assistant to perform this task [10-12]. Literature describes cases of AESOP application in general surgery procedures such as laparoscopic cholecystectomy, hernioplasty, fundoplication, and colectomies.



Figure 2. AESOP - Automated endoscopic system for optimal positioning

Dissatisfied with the concept of endoscope telemanipulation, Wang obtained funding from DARPA (Defense Advanced Research Projects Agency) to develop

a robot capable of reproducing the surgeon's arm movements. Thus, the ZEUS system (Computer Motion, Santa Barbara, CA, USA) was born, created with arms and surgical instruments controlled by the surgeon remotely (Figure 3).

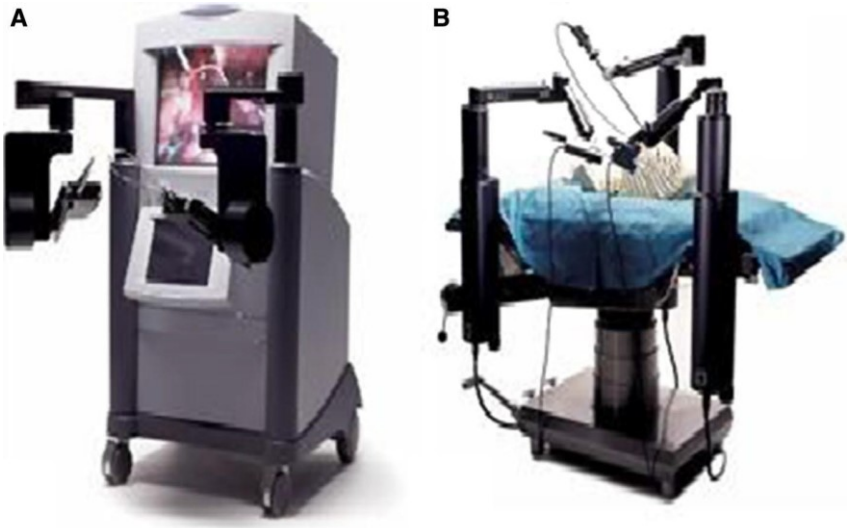


Figura 3. ZEUS (A. Surgical Console; B.Robotic arms

The robotic surgical system ZEUS was first used in a Fallopian tube anastomosis at the Cleveland Clinic, Ohio, USA, in July 1998 [13]. There are articles in the literature describing the use of ZEUS in various general surgery procedures (cholecystectomy, appendectomy, bariatric surgery, hernioplasty, gastrectomy, fundoplication, splenectomy, and colectomy), urological, gynecological, and cardiothoracic surgeries [14]. On September 3, 2001, ZEUS was first used to perform a transatlantic telesurgery: a laparoscopic cholecystectomy was performed on a patient in Strasbourg while the surgeon, Dr. Jacques Marescaux, was in New York [15].

This technological push led in the following years to the development of the da Vinci® robotic platform.

1.2 The da Vinci® Robot

The da Vinci® robot is a master-slave device developed by Intuitive Surgical Inc.

Currently, it is the most widely used robotic surgical system with more than 4100 units sold worldwide (Figure 4) and numerous publications [16].

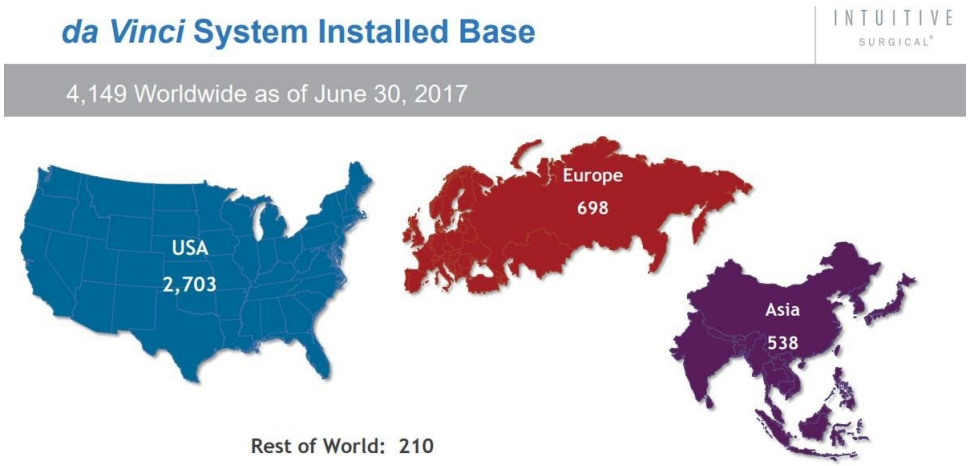


Figure 4. Installations of da Vinci® Worldwide

The first robotic-assisted cholecystectomy was performed by Jacques Himpens and Guy Cadiere in Brussels, Belgium, in 1997 [17]. Following the success of this procedure, myocardial revascularization surgeries were performed at the University of Leipzig, Germany, in 1998 [18]. Although cardiothoracic surgery initially appeared to be the primary field of application for da Vinci®, the results achieved in this direction were not as satisfactory as those achieved in general surgery [19]. In the following years, numerous robotic surgical procedures were performed in Europe, mainly cholecystectomies and fundoplications, to demonstrate the feasibility and safety of this new technology. In the United States, the use of the da Vinci® device for abdominal surgeries in humans was approved by the FDA on July 17, 2000, and since then, various authors, not only Americans but also Europeans and Asians, have described the various techniques of different robot-assisted surgical procedures, demonstrating their technical validity (Table 1).

Table 1. Timeline of da Vinci® Robot use in General Surgery:

Year	Surgeon	Surgery
1997	Cadiére [17]	Cholecystectomy
1998	Cadiére [20]	Adjustable gastric banding
1999	Cadiére [21]	Fundoplicatio sec. Nissen
2000	Horgan [22]	Roux-en-Y Bypass
	Giulianotti [23]	Total Gastrectomy
	Hashizume [24]	Colectomy
	Hashizume [24]	Splenectomy
	Hashizume [24]	Unilateral and bilateral inguinal hernia repair
2001	Weber [25]	Colectomy
	Horgan [22]	Adrenalectomy
	Giulianotti [23]	Hepatic resection
	Giulianotti [23]	Pancreaticoduodenectomy and distal resection of pancreas
	Melvin [26]	Miotomy sec. Heller
	Melvin [26]	Transthoracic Esophagectomy
2002	Ballantyne [27]	Ventral hernia repair
2003	Horgan [28]	Tranhiatal Esophagectomy
	Giulianotti [23]	Anterior resection of rectum
2007	Kang [29]	Thyroidectomy

1.2.1 Technical Features of the da Vinci® Platform

The da Vinci® robotic system, according to various authors, surpasses some of the technical limitations of laparoscopic surgery, particularly the 2D visualization of the operative field, the fulcrum effect, and non-articulating instruments [30]. Technical improvements, such as magnified 3D vision, precise control of instruments with seven degrees of freedom, and maintaining the natural alignment of binoculars with instruments, have made the robotic platform more appealing to surgeons who have performed a wide range of procedures during the first decade of the millennium. Other features, including stable image of the operative field, magnification up to 10x, cancellation of physiological tremor, motion scaling up to 5:1, and improved ergonomics, are mentioned in various scientific articles [18, 31].

The da Vinci® robot is the most advanced platform for minimally invasive surgery available on the market today. It is available in two systems:

da Vinci Si®: Considered the gold standard for medium-complexity procedures in defined surgical fields such as urology, gynecology, and general surgery in a single quadrant since its introduction to the market in 1999.

da Vinci Xi®: An innovation of the Si system, introduced in Italy in 2014, it aims to be the ideal tool for high-complexity surgery in large and multi-quadrant surgical fields, allowing extreme freedom of movement. These features make it suitable for complex urological, gynecological, and general surgery procedures, maximizing anatomical access and ensuring 3D-HD vision.

Da Vinci Xi® HD

It allows the surgeon to perform complex surgical interventions with minimally invasive techniques, thanks to the integration of high-definition 3D vision with EndoWrist® instrumentation and the intuitive tool control system.

It consists of three main components: the surgical console, the patient cart, and the vision cart.

Surgical Console

It is the control center of the da Vinci Xi® system (Figure 5). Through the console, positioned externally to the sterile field, the surgeon controls the 3D endoscope and EndoWrist® instruments using two manipulators (masters) and pedals.

In the stereo viewer, the tips of the instruments align with the surgeon's hands gripping the manipulators. This is aimed at simulating the natural alignment of eyes, hands, and instruments typical of open surgery, while using a minimally invasive procedure. Scaling of movements and tremor reduction provide additional control that minimizes the impact of physiological hand tremor or involuntary movements. The operator at the surgical console also has the ability to switch from full-screen view to a multi-screen mode (TilePro™ display), which shows the 3D operative field along with two other images (ultrasound, ECG, etc.) provided by auxiliary inputs.



Figure 5. da Vinci Xi® Surgical Console

Patient Cart

It is the operative component of the da Vinci® system (Figure 6) and consists of four arms dedicated to supporting instruments and endoscope.

The da Vinci® system uses remote center technology, a fixed point in space around which the arms of the patient cart move. This technology allows the system to manipulate instruments and endoscopes within the surgical site while minimizing force exerted on the patient's abdominal wall.

At the back of the cart, corresponding to the handles for movement, the da Vinci Xi® system has a touchpad and controls for pre-operative selection of the type of intervention, based on which the arms are automatically positioned. It is also possible to perform manual adjustments in terms of height and advancement relative to the base and rotation of the arm group, up to a maximum of 270°.



Figure 6. da Vinci Xi® Patient Cart

Vision Cart

It contains the central unit for image processing and processing (Figure 7). It includes a 24-inch touchscreen monitor, an ERBE VIO dV® electrosurgical unit for the delivery of monopolar and bipolar energy, and adjustable shelves for optional auxiliary surgical equipment, such as insufflators. The da Vinci Xi® system also includes a high-definition video system (full HD).



Figure 7. da Vinci Xi® Vision Cart

EndoWrist Instruments

The EndoWrist® instruments of the da Vinci Xi® (Figure 8) have a diameter of 8mm and a length of approximately 60cm. They are equipped with a wrist that allows freedom of movement on seven axes and rotation of almost 360°. In the range of robotic instruments, we can find graspers, cautery scissors, cold scissors, graspers, and bipolar dissectors of various types.



Figure 8. EndoWrist® Instruments for da Vinci Xi®

1.3 Robotic Surgery Training

In recent decades, there has been a development and widespread adoption of robotic technology. Alongside its implementation and the increasing use of robots in surgical practice, there has been a recognized need for an effective training program in robotic surgery. This is to ensure that surgeons possess the necessary surgical skills and to guarantee patient safety [32,33].

The development of a robotic training program is limited by several factors: the high costs of purchasing and maintaining the robot, the costs of training, the effects of the learning curve on surgical outcomes, and the scarcity of experienced robotic surgeons [34].

A basic robotic surgery training program should include training to be carried out both at the patient cart and at the console. Training for the role of patient cart assistance involves acquiring knowledge and skills related to proper patient positioning, trocar placement, robot docking and undocking, and laparoscopic skills for handling and using instruments. Control of the console is also fundamental, and adequate preparation is necessary to manage optics, pedals, and manipulators to ensure correct execution of major surgical gestures [35].

In addition to technical skills, indispensable non-technical skills have also been described, such as the ability to work and communicate in teams, risk awareness and management, response to errors and unforeseen events, decision-making ability, and the ability to modify decisions during surgery [35].

Over the years, the growing interest in acquiring skills in robotic surgery before operating directly on the patient has led to the development of numerous alternative learning methodologies and tools. In the various proposed models, the role of the experienced surgeon has been conceived as a "proctor," evaluating the trainee's performance, or as a "preceptor," guiding and accompanying the learner in the learning process, even remotely as in "telementoring" [34]. Intensive courses are considered one of the best training modalities, as they make learning more easily reproducible through a more structured and systematic teaching methodology, ensuring a smoother acquisition of the required skills [34].

In 2008, the SAGES-MIRA consensus conference [36] emphasized that robotic training programs should be a combination of didactics, careful observation of procedures to be reproduced, and practical experience under the guidance and supervision of experienced surgeons.

In 2013, Smith et al. [37], with the contribution of a consensus group, proposed a curriculum describing 25 fundamental competencies that a surgeon must possess to practice robotic surgery, regardless of their specialty. It is an online self-learning training program that provides information on robotic surgery and commands to know, methods to develop the skills to be acquired, and evaluation tools through four distinct modules. The daVinci Technology Training Pathway [33] also offers a similar online training program.

In the following years, other curricula have been presented, such as the Fundamental Skills of Robot-assisted surgery training program and the Robotics Training Network, which offer structured training programs at multiple levels of difficulty [33]. Additionally, various types of simulators have been developed to enhance the surgeon's experience at the console and enable the repeated performance of a surgical gesture or procedure in a safe yet realistic context [33].

A 2017 review [34] described the different settings in which practical exercises can be carried out. The "dry lab" allows simulating the main surgical gestures by performing them on artificial anatomical models. The "wet lab" allows testing tissue reaction to the action of surgical instruments, understanding the management of vessel control, and using diathermic devices, performing excisions and dissections on frozen animal or human specimens. Finally, training can be carried out in the operating room where, based on the acquired skills, simpler procedures or entire surgical steps can be completed.

To assess the level of skills achieved in robotic surgery, some scores have been proposed. The Global Evaluative Assessment of Robotic Skills (GEARS) described by Goh et al. in 2015 [38], for example, is an evaluation system that considers 6 skills to which a score (1-5) is assigned: depth perception, use of both hands, efficiency of gestures, quality of movements, autonomy, overall control of the robot, and use of the third arm in the performances carried out. Another useful tool is the Robotic-Objective Structured Assessment of Technical Skills (R-OSATS) which evaluates depth perception, tissue manipulation, hand coordination, and the efficiency of gestures performed [39].

The numerous training methods have thus sought to respond to the shared need to have a program capable of ensuring surgeons have adequate preparation in robotic surgery. However, the lack of a standardized methodology leads to disparities in the quality of surgery offered by different minimally invasive surgery centers [32]. Further studies are needed that, starting from the comparison of the curricula already proposed, lead to the development of a standardized and shared training project [33,40].

II TRAINING IN THE USE OF BASIC FUNCTIONS OF THE DAVINCI XI® ROBOT: COMPARISON STUDY OF RESIDENT'S SKILL.

2.1 Introduction

Since the early 2000s, the field of minimally invasive surgery has witnessed the advent of robotic technology: the daVinci® robot currently represents the most widely used system available on the market for performing complex surgical procedures [41,42]. While numerous studies have been published on the feasibility and safety of robotic surgery in terms of both technical and oncological outcomes [16], there is still a lack of evidence and consensus in the literature regarding the training of surgeons in this field. The diffusion of this new technology has indeed led to the need for specific training for both experienced and trainee surgeons. Proponents of robotic surgery and manufacturing companies highlight the effectiveness and safety of the technology, facilitated by the intuitiveness and ease of use of the platform in reproducing surgical gestures. However, these claims have not yet been scientifically proven by dedicated and validated studies.

Study purpose.

The purpose of our study was to verify the intuitiveness in learning the management and technical use of the daVinci Xi® robot platform by comparing two groups of young surgeons in training.

2.2 Materials and Methods

A questionnaire was sent to trainee surgeons affiliated with the Department of Surgical Sciences at the University of Turin (General Surgery, Otorhinolaryngology, and Maxillofacial Surgery) serving at the Molinette Hospital of the City of Health and Science (Turin, Italy), to test previous experience in robotic surgery. Based on previous experience and interest shown in the study, 30 residents were recruited.

The participants were divided into 2 groups: Group A consisted of trainee surgeons who had actively participated in at least 8 robotic surgery procedures with varying degrees of proficiency in using both the patient cart and the console of the daVinci Xi® platform; Group B comprised trainee surgeons who had never participated in robotic surgery procedures.

All participants were asked to perform basic exercises related to the use of the daVinci Xi® robot to test the different specific phases of learning and the acquisition of specific technical skills. The tests were divided into two categories: those concerning the patient cart and those considering the use of the console.

The test included a training session and a practical session, both identical for the two analyzed groups. The training course involved watching two video tutorials (Figure 9) in which an experienced technician from the leading company in the production of medical robots (Intuitive Surgical, Sunnyvale, CA, USA – Ab Medica SPA, Milan, Italy) explained the components of the robotic platform and their functioning. The video tutorials were recorded in the robotic surgery operating room at Molinette Hospital in Turin, so that the platform and the work environment shown in the videos were the same as those in the practical session.

Participants were allowed to watch the instructional videos only once, without pauses and individually, before the practical session. During the practical test, only the participant of that session was admitted to the operating room.

In the first video tutorial, lasting 8 minutes and 10 seconds, the characteristics and functioning of the patient cart elements were illustrated, including:

1. Components and functionalities of the arms:

- Use of the instrument clutch to perform fine movements around the remote center and for inserting instruments;

- Use of the port clutch to perform broader arm movements, to attach the trocar to the arm and/or move it away, or to "make a curtain" to give more maneuverability to the instruments in function;

- "Grab and move" functionality;

- Use of the "patient clearance" and "instrument reach" buttons, which control the outermost elbow of the arm to move it closer to or away from the patient;

2. Components and functionalities of the endoscope (0° or 30°): eye change button and pointing; snapshot button; light button.
3. Approaching the cart after correct patient positioning on the operating table and arm anchoring mode to the trocars.
4. Insertion of the endoscope and pointing to the reference anatomy, with subsequent arrangement of the arms to facilitate their anchoring to the trocars.
5. Insertion and removal of instruments in sight, also explaining the meaning of memory upon reinsertion.

In the second video tutorial, lasting 3 minutes and 39 seconds, the characteristics and functioning of the console components were illustrated, including:

1. Buttons located on the left armrest, useful for positioning the console itself to be as ergonomic as possible by being able to raise or lower the stereoscopic viewer, modify its inclination and armrest height, and bring the pedal closer/farther away.
2. The pedalboard:

- Optical pedal and its functioning through the use of the master;

- Clutch pedal that allows moving and repositioning the masters by dissociating them from the movement of the instruments when they are too close together or in uncomfortable positions;

- Switch pedal to switch the controlled instrument;

- Pedals for controlling electrified instrumentation (mono/bipolar).

3. Finally, the masters and the stereoscopic viewer and how to take control of the instruments through them.

In the third part of the training session, participants were shown videos (Figure 10) regarding the exercises they would perform on a prepared pelvic trainer.

For the practical tests, the videos were divided into two categories: tests on the patient cart (3 exercises) and tests on the console (5 exercises).

The patient cart tests consisted of robotic docking:

Exercise 1: Attachment of the trocar to the endoscope arm, its insertion, and pointing to the target.

Exercise 2: Attachment of the other arms to the trocars and insertion of the remaining three instruments in sight.

Exercise 3: Participants had to replace all the instruments and alternate the endoscope eye.

The console tests were divided as follows:

Exercise 1: Repositioning of the optics while keeping the instruments in sight: the participant was given eight voice commands on endoscope movement (right and left, up and down, approach and withdrawal, right rotation, and left rotation).

Exercise 2: The participant was asked, using two operative instruments to be kept constantly in sight, to pick up a gauze within the surgical field, reachable only using the clutch, and subsequently to place it inside a basket, without moving the optics.

Exercise 3: Movement of instruments within the surgical field (picking up four gauzes and placing them in a basket while keeping the 2 instruments constantly in sight).

Exercise 4: Use of the switch pedal and therefore of the third arm, which was used to hold a gauze suspended, thus allowing, through the use of the other 2 instruments, to collect a smaller one and place it in a basket.

Exercise 5: Application of a simple 2/0 silk suture, making 3 knots, on a horizontal defect in a silicone intestine model, properly fixed to the bottom of the pelvic box. The participant was required to perform the exercise in no more than 7 minutes.



Figure 9. Video tutorial 1

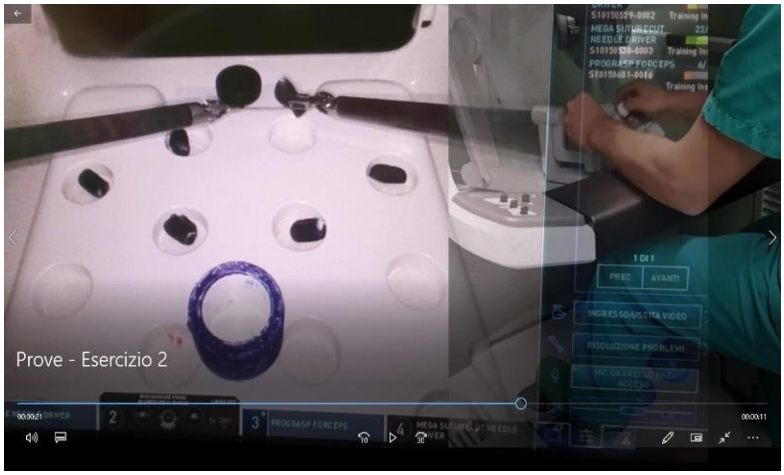


Figure 10. Tests – Exercise n°2

The practical tests carried out by the participants were video-recorded, after obtaining privacy consent, and subsequently evaluated by an expert surgeon in robotic surgery who did not know to which of the two groups the participant belonged. The evaluation for each exercise took into consideration both a quantitative aspect, referring to the execution time, and a qualitative aspect to verify the learning process and therefore the acquisition of the various proposed skills; for this purpose, a score was assigned according to tables 2 and 3. Following the evaluation, a database was compiled, reporting for each exercise the execution time and the scores given by the expert.

Table 2: Scores assigned for patient-side cart exercises:

Excercise/Skill	Scores
1. Use of the arms and endoscope aiming	
Use of instrument clutch	0 to 2: 0 not used; 1 if used only in one phase of the exercise (eg introduction of the endoscope); 2 own use during all phases of arm positioning
Use of port clutch	0 to 2: 0 not used; 1 if used only in one phase of the exercise (eg trocar attachment); 2 proper use during all positioning phases arm
Attachment of the trocar	0 to 1: 0 trocar engagement not performed (at least 3 unsuccessful attempts to engage the trocar); 1 done correctly
Endoscope aiming	0 to 1: 0 aiming not performed (or failed after 3 attempts); 1 pointing correctly performed
2. Insertion of tools	
Attachment of the trocar	0 to 1: 0 trocar engagement not performed (at least 2 unsuccessful attempts to engage the trocar); 1 done correctly

Correct insertion and positioning of instruments	0 to 2: 0 if instruments introduced out of the visual field; 1 if introduction performed correctly, but instruments not triangulated or not fully visible; 2 if introduction was done correctly with triangulated instruments and in vision
3. Tool replacement and gearbox eye endoscope	
Correct re-insertion of instruments after replacement	0 to 2: 0 repositioning of the instruments out of the visual field; 1 reintroduction of instruments not using the memory function; 2 correct reintroductions using the memory function
Use of eye change control	0 to 1: 0 key changes eye not identified; 1 key change eye identified

Table 3: Scores assigned for console exercises:

Exercise/Skill	Scores
1. Endoscope use	0 to 8: one point for each command performed correctly
2. Clutch pedal use	0 to 2: 0 clutch function not used / operation not completed; 1 correct use of the clutch with errors in the coordination of the instruments (eg loss of grip, collision with the basketball); 2 correct use and good clutch coordination of tools

3. Handling of instruments within the operating field	0 to 2: 0 exercise not completed in 3' or loss of both instruments from the visual field; 1 exercise performed not always keeping two instruments in view; 2 if performed while keeping always in vision the instruments. Only one penalty point was awarded for loss of grip or collision against the basketball
4. Use of switch pedal and third arm	0 to 2: 0 if loss of 2 instruments from the visual field; 1 if loss of a single instrument from the visual field; 2 exercise performed correctly with all instruments always in view. Only one penalty point has been assigned if errors are made in the coordination of instruments (e.g. loss catch, bump against basketball)
5. Simple stitch affixing and knotting	
- **Stitch affixing**	0 to 2: 0 exercise performed beyond the limit of 7' (however it was considered as the exercise execution time) or failure in passing needle; 1 passing needle without coordination of second instrument or not correctly addressing the margins of the silicone model; 2 needle passage performed with fluid movement using both tools and correctly addressing the margins of the silicone model. Only 1 penalty point was awarded if the following occurred during the test: breakage of the needle or thread, loss of
- **Knotting**	silicone model 0 to 3: one point for each knot performed within the established time limit

For each participant, the total time and score obtained in the two categories of exercises were calculated.

Outcomes

The primary outcome of the study was to evaluate the intuitiveness of the daVinci Xi® robot, defined as the ability to perform basic procedures on a robotic platform never tested before and complete them within a predetermined time. The secondary outcomes were the execution times, blind qualitative evaluation of acquired skills based on predetermined scores, and finally the impact of years of training and previous experience in using robotic technology on both times and overall evaluation.

Statistical Analysis

STATA 14.1 software was used for statistical analysis.

The Shapiro-Wilk test was performed to test for normal distribution.

Independent samples t-tests were conducted on all execution times of the exercises. The test compares all means of the two groups and is significant if the p-value is less than 0.05. The Kruskal-Wallis test was performed for a non-parametric analysis of variance based on ranks. The test is significant if the p-value is less than 0.05. Values are reported as median and respective standard deviation (SD) for discrete quantitative variables, while categorical variables are reported as numbers and percentages.

A Spearman test was calculated to verify the correlation between the quantitative variable "years of training" and the variables "total score of exercises on the patient cart," "total score of exercises at the console," and "time" of all tests. The Spearman test ranges from -1 to 1: when it is negative, the correlation is negative, and when it is positive, the correlation is positive; when it is zero, there is no correlation.

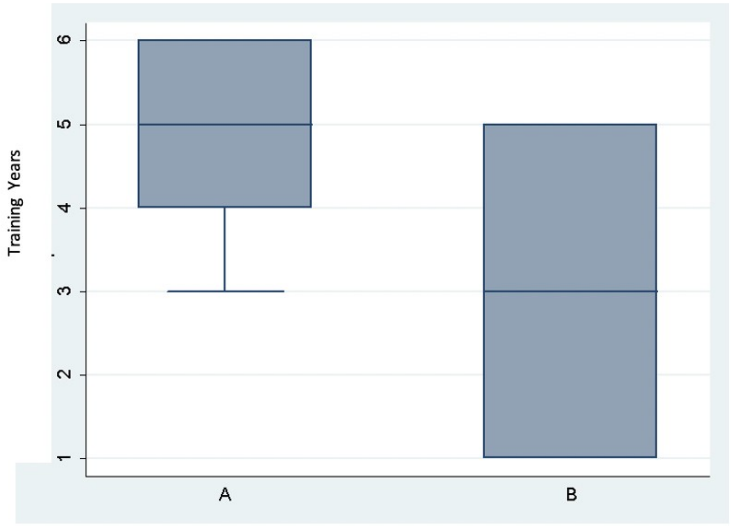
Subsequently, linear regression was performed with the dependent variable "years of training" and the independent variable "time" for each exercise in which the significance of the Spearman test was found. We also conducted a regression between the total score on console exercises and years of training and between the total score of exercises on the patient cart and years of training.

2.3 Results

Thirty young surgeons in training participated in the study: 15 belonging to group A and 15 to group B. Twenty-eight of them were surgical trainees in general surgery, one in otolaryngology, and one in maxillofacial surgery. In group A (graphs 1 and 2), 4 (26.7%) residents were in their sixth and final year of training, 7 (46.7%) in the fifth year, 3 (20%) in the fourth year, and 1 (6.7%) in the third year. Group B included 4 (26.7%) surgeons in their first year of training, 3 (20%) in the second year, one (6.7%) in the third year, 2 (13.3%) in the fourth year, and 5 (33.3%) in the fifth year. The difference between the two groups in terms of years of training was statistically significant (p=0.0008): median for group A was 5 (SD 1), median for group B was 3 (SD 1.7) (graphs 1 and 2).



Graph 1. Distribution of group A and B participants by years of training

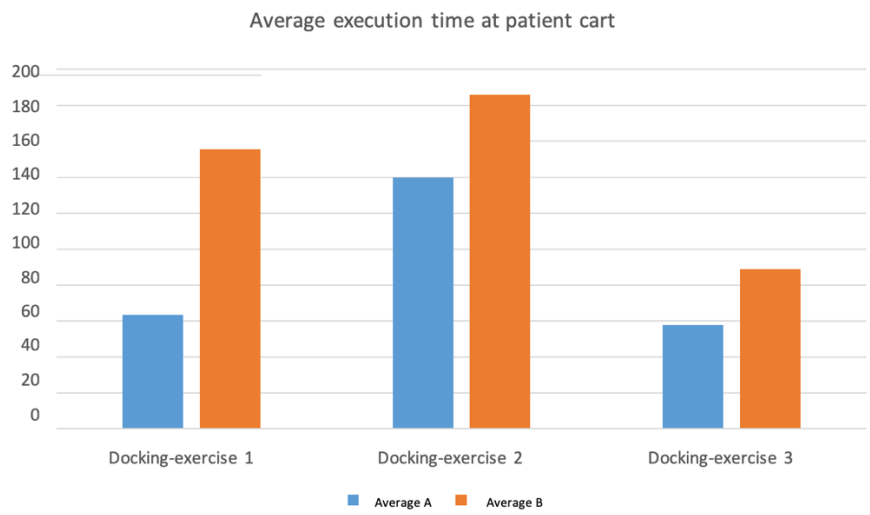


Graph 2. Boxplot years of training group A and B.

Patient Cart Exercises

All participants in the study performed exercises on the patient cart.

A statistically significant difference was observed between the two groups regarding the execution times of the first (p=0.0000) and third (p=0.0002) exercises. Specifically, the mean execution times (graph 3) for the first exercise (use of arms and aiming of the optics) were 63.5 seconds for group A and 155.5 seconds for group B; the third exercise (replacement of instruments and change of endoscope eye) was completed on average in 57.9 seconds by participants in group A, while in 88.8 seconds by those in group B. There were no statistically significant differences (p=0.0934) in the execution times of the second exercise (instrument insertion).



Graph 3: Averages of patient cart exercise times

In the first exercise, the median score for the use of the port clutch was 2 for group A (SD 0) and 2 for group B (SD 0.6) (p=0.0730). In the use of the instrument clutch, the median score for groups A and B was 2 (SD A 0.3; SD B 0.7) (p=0.0136). Participants in group A all correctly performed (100%) the trocar engagement; 3 (20%) participants in group B engaged the trocar after three attempts (median score 1, SD 0.5). However, they correctly performed the endoscope pointing after 3 attempts, 1 (6.7%) participant in group A and 8 (53.3%) in group B (A: 1, SD 0.3; B: 0, SD 0.5; p=0.0061).

Regarding the second exercise, the trocar engagement phase was performed by all participants in group A and by 14 (93%) in group B (A: 1, SD 0; B: 1, SD 0.3; p=0.3173); in the instrument insertion phase, the median scores assigned by the expert to participants in groups A and B were 2 (A: SD 0.4; B: SD 0.5; p=0.0502). As for the third exercise, the median score for participants in group A was 2 (SD 0.5), while for those in group B it was 1 (SD 0.5) (p=0.0309). All study participants correctly identified the endoscope's eye change button.

In the exercises involving the patient cart, the median total score obtained by participants in group A was 11 (SD 0.63), while for group B it was 9 (SD 1.46) (p=0.0001).

Console Exercises

In the first four console exercises, all participants from both groups completed them. However, in the fifth exercise (passing points and knotting on a silicone model of the intestine), it was not completed within the established time limit of 7 minutes by 2 (13.3%) participants from group A and by 6 (40%) from group B.

In the console exercises, the average execution time for the first one (optical use) was 51.9 seconds for group A participants and 45.7 seconds for group B (p=0.1281). The second exercise (clutch use) was completed on average in 34.3 seconds by group A trainees, while in 80.4 seconds by those in group B (p=0.0095). In handling instruments (exercise 3), group A took an average of 79.2 seconds, while group B took 113.7 seconds (p=0.0072). During exercise 4 (third arm use), the mean execution time was 85.6 seconds for group A and 142.3 seconds for group B (p=0.0065). Finally, in the last test, the mean time obtained by group A was 208.7 seconds, and by group B was 299 seconds (p=0.0323).

In the first test, the median for the correct execution of optical repositioning movements was 7 for both groups (SD A 1.6, SD B 1.5; p=0.5309): 5 trainees from group A (33%) achieved the maximum score of eight, while in group B, there were 7 (47%). The median score for clutch usage in the second console exercise was 2 for both groups (SD A 0.4; SD B 0.5; p=0.3694). Similarly, in the third exercise (instrument handling in the operating field), the median score assigned by the expert was 2 for both groups (SD A 0.5; SD B 0.7; p=0.7735). Managing the third arm and switch pedal in exercise 4 resulted in a median score of 2 for group A (SD 0.5) and 1 for group B (SD 0.6) (p=0.1217). Finally, in the last test, concerning the passing of the point, a median score of 2 (SD 0.7) was recorded for participants from group A and 1 (SD 0.8) for those from group B (p=0.0771). 10 trainees from group A (66.7%) and 7 from group B (46.7%) executed 3 knots within the established time limit (median 3, SD 1.1 for group A; median 2, SD 1.1 for group B) (p=0.3330).

In the console exercises, the median total score obtained by participants from group A and B is 15 (SD A 3.09, SD B 2.58; p=0.3801).

The data analysis is described in tables 4 and 5.

Table 4: data analysis, times and scores on the patient's cart

		GROUP A			GROUP B			
		Median	Mean	SD	Median	Mean	SD	P-value
1. Use of the arms and endoscope aiming:								
Time(s)		62.0	63.5	35.4	144.0	155.5	61.0	0,0000
	Use *port clutch*	2	2	0	2	1,7	0,6	0,0730
	Use *instrument clutch*	2	1,9	0,3	2	1,4	0,7	0,0136
	Attachment of the trocar	_	_	_	_	_	_	0,0347
	Aiming	_	_	_	_	_	_	0,0061
2. Insertion of tools:								
Time(s)		153.0	139.8	45.5	162.0	186.0	92.4	0,0934
	Attachment of the trocar	_	_	_	_	_	_	0,3173
	Correct insertion and positioning of instruments	2	1,9	0,4	2	1,5	0,5	0,0502
3. Tool replacement and gearbox eye endoscope								
Time(s)		51.0	57.9	20.7	89.0	88.8	18.88	0,0002
	Correct re-insertion of instruments after replacement	2	1,7	0,5	1	1,3	0,5	0,0309
	Use of eye change control	_	_	_	_	_	_	_
Total score		11	11,40	0,63	9	9,13	1,46	0,0001

Table 5: data analysis, times and scores on the console

	GROUP A			GROUP B			
	Median	Mean	SD	Median	Mean	SD	P-value
1. Endoscope use							
Time(s)	56	51.9	9.4	45	45.7	12.3	0,1281
	7	6,4	1,6	7	6,7	1,5	0,5309
2. Clutch pedal use:							
Time(s)	28.0	34.3	18.7	60	80.4	61.2	0,0095
Management joystick via clutch	2	1,9	0,4	2	1,7	0,5	0,3694
3. Handling of instruments within the operating field:							
Time(s)	79	79,20	21,00	100	113,70	41,71	0,0072
movement skills	2	1,6	0,5	2	1,5	0,7	0,7735
4. Use of switch pedal and third arm:							
Time(s)	80	85,60	40,40	117,00	142,30	63,00	0,0065
Arms manage-ment & switch	2,00	1,70	0,50	1,00	1,40	0,60	0,1217
5. Simple stitch affixing and knotting:							
Time(s)	182,00	208,70	110,10	281,00	299,00	109,40	0,0323
Stitch affixing	2,00	1,40	0,70	1,00	0,90	0,80	0,0771
Knotting	3,00	2,30	1,10	2,00	2,00	1,10	0,3330
Total score	15,00	15,33	3,09	15,00	14,40	2,58	0,3801

Analyzing the correlation (Table 6) between the quantitative variable "years of training" and "patient cart exercise score" (Figures 7a and 8a), it appears significant for group A (p=0.0083), while it is not significant for group B (p=0.2448). There is no correlation between the quantitative variable "years of training" and "console exercise score" (Figures 7b and 8b) in both groups (p A and B > 0.05).

Regarding the correlation between "years of training" and the times of individual tests, this appears significant for group A for exercises one (p=0.0051) and three (p=0.0053) on the patient cart. There is also a correlation between years of training and the time of exercise 4 on the console (p=0.0382).

Linear regression with the dependent variable "years of training" and the time of the first exercise on the patient cart is significant for group A (p=0.0017), as well as for the third exercise (p=0.0029). Regression is also significant for group A for the fourth exercise on the console (p=0.0014). Regression between total score on patient cart exercises and years of training is significant for group A (p=0.028). It is not significant for both group A (p=0.5640) and group B (p=0.0985) the regression between total score on console exercises and years of training. Table 7 reports the regression analysis for the variables that resulted significant.

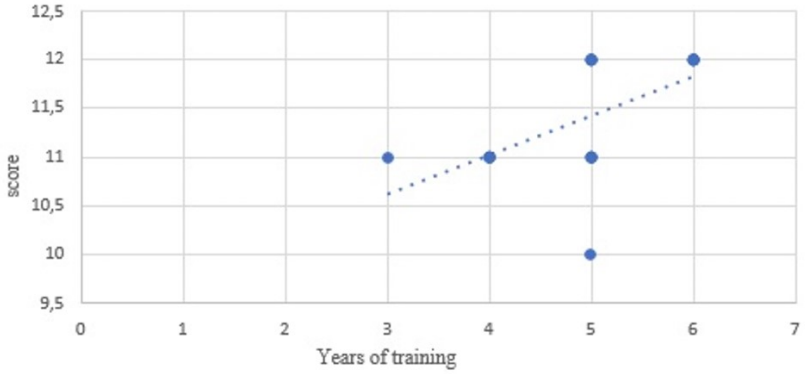
Table 6. Analysis of the correlation between total scores-single times of the exercises and years of training

	GROUP A		GROUP B	
	RHO	**p value**	**RHO**	**p value**
Years of training and console scoring	1,520139	0,4332	0,3162	0,2508
Years of training and patient-cart scoring	0,6534	0,0083	0,3201	0,2448
Years of training and exercise 1 patient-cart time	-0,6824	0,0051	0,3677	0,1776
Years of training and exercise 2 patient-cart time	-0,0987	0,7265	0,0645	0,8192
Years of training and exercise 3 patient-cart time	-0,6793	0,0053	0,0434	0,878

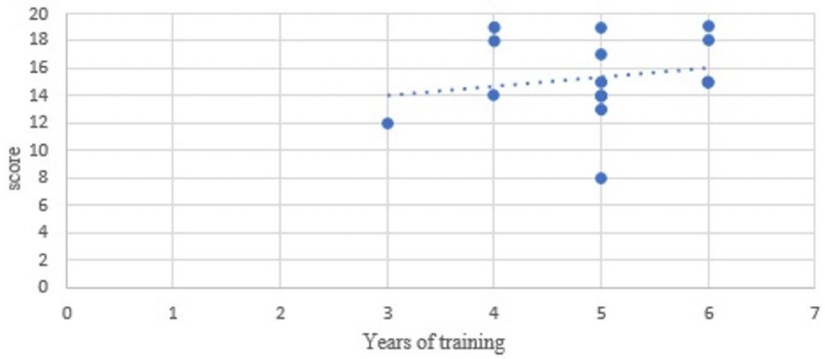
Years of training and exercise 1 console time	-0,2889	0,2963	0,1672	0,5514
Years of training and exercise 2 console time	0,2283	0,4131	0,1863	0,5062
Years of training and exercise console time	-0,3719	0,1723	0,1199	0,6704
Years of training and exercise 4 console time	-0,5389	0,0382	0,2732	0,5382
Years of training and exercise 5 console time	-0,3361	0,2206	0,3476	0,2042

Table 7. Regression analysis of statistically significant parameters to Spearman's test.

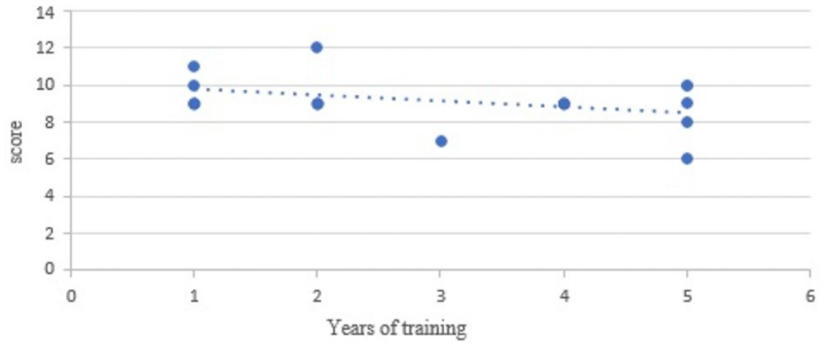
	A		**B**	
	p value	**years of training coefficient**	**p value**	**years of training coefficient**
Years of training and patient-cart scoring	**0,0283**	0,36	0,1667	_
Years of training and exercise 1 patient-cart time	**0,0017**	-0,26	0,3227	_
Years of training and exercise 3 patient-cart time	**0,0029**	-0,15	0,9361	_
Years of training and exercise 4 patient-console time	**0,0145**	-0,25	0,5298	_



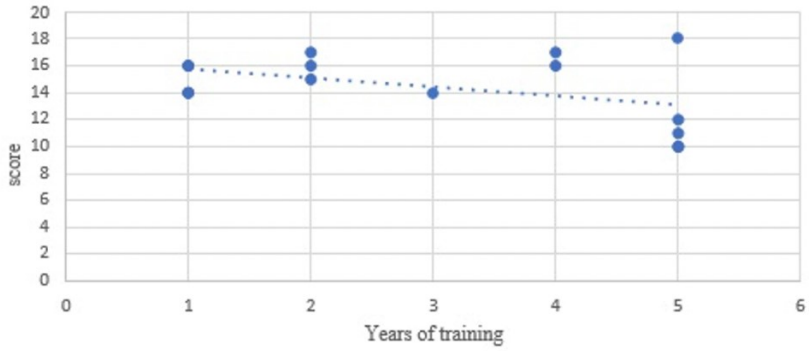
Graph 7a: Correlation of total patient cart scores/years of training Group A



Graph 7b: Correlation of total console scores/years of training Group A

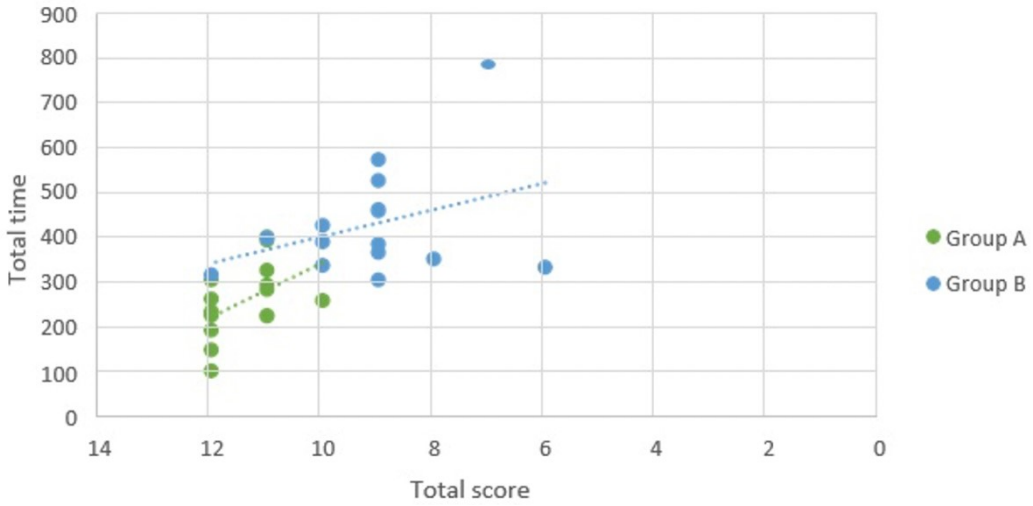


Graph 8a: Correlation of total patient cart scores/years of training Group B

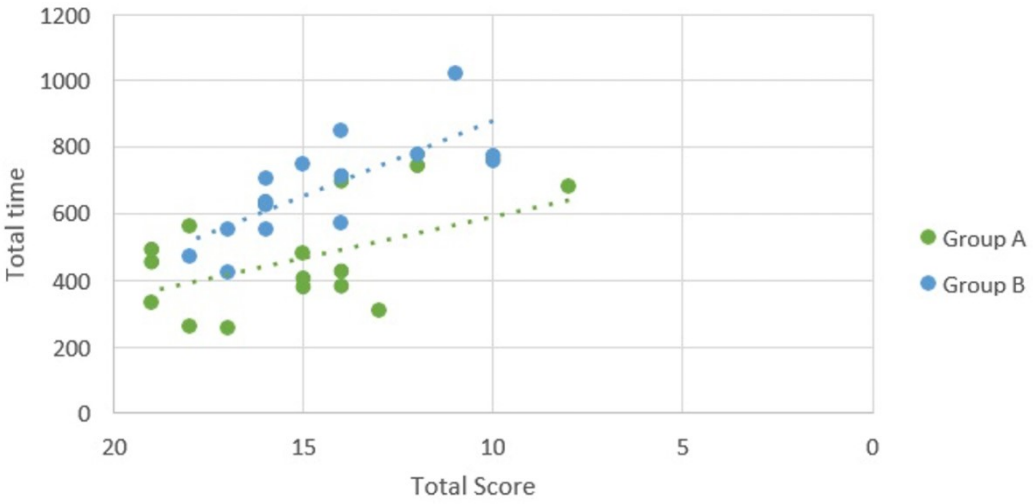


Graph 8b: Correlation of total console scores/years of training Group B

In graphs 9 and 10, the distribution of participants is shown based on the relationship between the total time spent in all patient cart exercises and the total score obtained.



Graph 9: Distribution of two groups according to total time/total score at the patient cart.



Graph 10: Distribution of two groups according to total time/total score at the console

2.4 Discussion

The advent of robotic technology in the field of minimally invasive surgery has been extolled in the literature in recent years, with over 4000 publications, as it is potentially capable of overcoming some of the limitations attributed to laparoscopy in terms of stereoscopic vision, compromised natural hand-eye coordination, and reduced dexterity due to the fulcrum effect created by the abdominal wall [43]. However, the superiority of robot-assisted surgery over laparoscopic surgery in terms of intra- and perioperative outcomes and oncological outcomes has never been demonstrated [44].

The increased intuitiveness and ease of use of new robotic platforms have contributed to the widespread adoption of this new technology, which, in specific fields such as urological surgery, has allowed some institutions to transition from traditional open surgery to robot-assisted minimally invasive surgery.

There has been a significant effort in this regard by medical engineering to make the machinery more versatile and adaptable to individual surgical procedures, leading to the current platform that allows management of various abdominal quadrants with a single docking of the patient cart, improved ergonomics of the robotic arms, and their management at the surgical console. Future scenarios predict further technological evolution with miniaturization of the system and integration with pre- and intra-operative instrumental imaging systems.

However, in clinical practice, especially in the field of abdominal surgery, a series of limitations have emerged in recent years, including high costs, longer operative times, increased consumption of operating room resources, complete elimination of tactile feedback, and more limited options for trocar placement [45]. Another problem that has emerged in recent years is the need for an effective dedicated training program for this new technology, both to ensure that operators possess adequate surgical skills and to guarantee patient safety [32,33].

Various tools have been developed to assess technical skills in both open and laparoscopic surgery, subsequently validated by scientific evidence [46,47]; for example, the GOALS score (Global Assessment tool for evaluation of intraoperative Laparoscopic Skills) has been developed and validated for intraoperative assessment of laparoscopic skills in various surgical procedures [46,48]. The need to develop similar assessment tools for robotic surgery is

mandatory in order to create standardized training pathways [49,50]. Such tools would allow trainee surgeons to identify deficiencies in their skills and objectively monitor their professional growth. The GEARS score (Global Evaluative Assessment of Robotic Skills) aims to provide a valid, reliable, and reproducible assessment of intraoperative robotic surgical skills [38]. It is an evaluation system that considers six skills, each assigned a score (from 1 to 5): depth perception, use of both hands, efficiency of movements, quality of movements, autonomy, overall robot control, and use of the third arm in performances. The limitations of the study include the fact that the trainer was known to the evaluator and that the evaluation was based only on a specific time of the intervention, which was the dissection of the seminal vesicles. However, it remains a valid evaluation system, simple to perform, and cost-free.

Despite the development of such evaluation systems, currently, the lack of standardized training pathways is reflected in the lack of evidence on learning curve times. Some studies indeed show significantly different casuistries in the number of procedures required to achieve competence in performing a robotic prostatectomy [51-53].

In order to verify the intuitiveness and reproducibility of basic functions of the robotic platform currently used in clinical practice (daVinci Xi® - Intuitive Surgical, Sunnyvale, CA, USA – Ab Medica SPA, Milan, Italy) and to try to propose a standardized training model, we compared two groups of young surgeons with different experiences both in their training path and in robotic technology.

The primary outcome of the study, to verify intuitiveness, understood as the ability to perform basic procedures on a robotic platform never tested before and complete them within a predetermined time, was achieved by all participants.

Regarding the patient cart exercises of the daVinci Xi® robot, the results of our study demonstrate that, after a brief educational video tutorial, regardless of the group, all participants were able to perform the proposed exercises. The two groups were heterogeneous in terms of years of training, with group A having a higher number of participants with more than 3 years of previous training. The evaluation scale devised and used by us seems to well differentiate the group more experienced in robotic surgery from the one without experience in terms of the tasks analyzed on the patient cart, both in the evaluation of individual exercises and in terms of total score. Group A, indeed, achieved a significantly better total score in the use of the patient cart and a better evaluation in the use of

some components of the cart arms (table 4). Additionally, participants in group A made good use of the instrument memory function upon reinsertion. Multivariate analysis showed a correlation between years of surgical training and total score obtained in patient cart exercises; for group A, regression analysis is significant, as each additional year of training increases the score by 0.35 points (coefficient of years of experience = 0.35). Similar results have been reported by Goh et al. regarding the validation of the GEARS score in intraoperative practice, in terms of distinguishing young surgeons based on years of training [38].

For group B, the analysis of the results of the patient cart exercises highlighted that in the pointing phase, 7 (46.7%) of the trainee surgeons completed the pointing after the 3rd attempt: during the first three, although the pointing button was well identified, participants did not keep it pressed until completion. Probably, the technological evolution associated with this function presents limitations in terms of feedback from the machine to the operator, as the button was well identified, and the function was clear, but the operation was interrupted before completion. Regression analysis also showed an inverse correlation between years of training and times at the first and third exercises (each additional year of experience decreased execution time).

Regarding the secondary outcome "time" in the patient cart exercises, there were statistically significant differences between group A and group B, especially in the docking phase and in the replacement of surgical instruments.

Contrary to the tasks tested on the patient cart, those at the console showed greater uniformity between the two groups in terms of expert qualitative evaluation, both for individual exercises and overall; statistically different were the execution times, except for the first exercise. Console management in its basic functions was therefore intuitive in all exercises, although not all participants were able to complete the last exercise within the predetermined time; there were no significant differences between the two groups in the expert evaluation even in this exercise (table 5).

Thus, the console skills were well acquired, considering the evaluations obtained.

In the use of the switch pedal and the third arm within the visual field, the median score of group A was higher than that of group B, within which the most common error was keeping the third instrument out of the operating field, although there was no significant difference in the evaluation given by the expert. Correlation analysis between exercise execution time and years of training also showed a

significant regression only for group A: each additional year of experience reduced execution time by 25 seconds.

Both among participants in group A and those in group B, not everyone completed the task testing more surgical skills performed at the console within the predetermined time, namely that of applying a suture and executing three knots. Probably the fact that within group A there were participants with different levels of experience with the robotic platform and at different years of training can explain why two young surgeons, one in the third year and the other in the fifth, did not complete the knotting. Similarly, in group B, the different surgical experience acquired over the years resulted in the non-acquisition of the skill in the first execution in 9 (60%) young surgeons. The most frequently shown difficulty by participants in both groups in this type of exercise was the breaking of the thread or the needle due to excessive traction. The lack of tactile feedback is indeed one of the limitations that scientific literature has always attributed to robotic surgery, which is confirmed in our experience.

From our study, it emerges that although participants completed the required tests, most of the difficulties are related to the use of the patient cart, where machine-specific functions are used, and therefore specific to the robot. For the acquisition of these technical skills, focused and more intense training is necessary, as a brief educational video tutorial has not been sufficient. The main differences between the two groups that reached statistical significance mainly concern execution times. The multivariate analysis performed showed, for certain exercises, a decrease in execution time based on years of experience; one of the limitations reported in the literature concerns longer operative times compared to traditional open or laparoscopic surgery, especially during the learning curve.

Regarding the exercises at the console, although there was still a difference in terms of execution times, participants did not show systematic difficulties in execution. The console was more intuitive compared to the patient cart. One of the reasons for this result may be related to the fact that console exercises are more closely related to the surgical field itself compared to those on the patient cart, regardless of robotic-specific experience. Furthermore, another explanation for this could be the concept of "gamification" of the surgical act, a characteristic discussed in the literature regarding robotic surgery and to which newer generations of surgeons are more predisposed. Recently, robotic simulators have been introduced for young surgeons aimed at improving operative skills. These simulators have undergone various validation studies, but none have shown

predictive validity in transferring skills acquired through simulation to the operating room [51-53].

The evaluation scale proposed by us could be useful for trainee surgeons to monitor their improvements in specific skills. Further studies are needed to understand how improvements achieved during training translate into better performance during surgery.

The low sample size and the heterogeneity of the control group in terms of robotic procedures performed may represent limitations of our study, which we intend to continue by recruiting all participants again and subjecting them, after a predefined time, to the same practical tests to verify any improvements or deteriorations in the acquisition of specific skills while maintaining the same training scheme.

In conclusion, the use of the daVinci Xi® robotic platform is manageable in its basic functions by young surgeons in training after a brief training course; this data is particularly evident considering that one group of participants had no prior experience with this technology, albeit with significant differences in execution times. Training regarding the patient cart appears to be more conditioned by the technical characteristics of the current platform, which will probably require further technological advancements to improve intuitiveness and/or specific training. The surgical console appears to be more easily manageable, even with little educational knowledge, regardless of previous surgical and robot-specific experience, confirming the progress of biomedical engineering in this field. Overcoming the limitations related to the absence of tactile feedback and reducing usage times are closely related to training pathways regardless of theoretical training. Further studies are needed to validate and standardize a training model that reduces learning curve times in clinical practice.

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