SCHOOL OF SOCIAL SCIENCES

Master in Business Administration (MBA)

Postgraduate Dissertation

Feasibility study of a new robotic system in medical science: an application in the Urology discipline

Evangelos N. Liatsikos

Supervisor:Dr. Anastasios Magoutas

Patras, Greece, May 2021

Feasibility study of a new robotic system in medical science: an application in the Urology discipline

Evangelos N. Liatsikos

Supervising Committee

Supervisor:

Dr. Anastasios Magoutas

Associate Professor
National and Kapodistrian
University of Athens

Co-Supervisor:

Dr. Barbara Myloni

Assistant Professor

University of Patras

Patras, Greece, May 2021

To my wife for her patience!

Abstract

The use of a robotic system in surgical practice is not novice. The da Vinci robotic system was first introduced in 1999. The end of the patent license of the existing company opens the field for new robotic systems to enter the market ie. the Avatera Medical system that was founded in 2011 with the aim to bring patients the highest surgical standards in reduced and affordable costs.

Robotic system integration into the laparoscopic surgeries is an increasing trend in current years. During the last 2 decades da Vinci robotic system was the only product available in the market. In 2015 almost 3600 da Vinci surgical systems were installed in the world. While the overwhelming majority are installed in several developed countries (USA, Germany, Italy, Britain, France), there is still a limited number of robotic systems accessible in other part of the world. The aforementioned creates a huge demand for new systems to fill the gap.

The business model will be constructed using SWOT analyses or comparative analyses. The advantages and possible improvement areas of the new robotic system in comparison to da Vinci robotic system will be identified. The aforementioned will allow to understand market niche, buyers profile and market position. As a result, pricing and distribution policies of a new robotic system will be created. Risk identification will be performed based on SWOT analyses and according risk mitigation mechanisms will be designed.

As a final step, an economic model of the new robotic system with a 5-year forecast will be created.

Keywords

Robot-assisted surgery; da Vinci robotic system; Avatera robotic system; business modeling; cost effectiveness

Περίληψη

Η χρήση ενός ρομποτικού συστήματος στη χειρουργική πρακτική δεν αποτελεί κάτι νέο στην Ιατρική Επιστήμη. Το ρομποτικό σύστημα daVinci κυκλοφόρησε για πρώτη φορά το 1999. Το τέλος της άδειας ευρεσιτεχνίας της υπάρχουσας εταιρείας ανοίγει το πεδίο για την είσοδο νέων ρομποτικών συστημάτων στην αγορά, όπως για παράδειγμα για το ιατρικό σύστημα Avatera που ιδρύθηκε το 2011 με σκοπό να φέρει στους ασθενείς τα υψηλότερα χειρουργικά πρότυπα με μειωμένο και προσιτό κόστος.

Η ενσωμάτωση του ρομποτικού συστήματος στις λαπαροσκοπικές χειρουργικές επεμβάσεις παρουσιάζει μια αυξανόμενη τάση στην εποχή μας. Τις τελευταίες 2 δεκαετίες, το ρομποτικό σύστημα daVinci ήταν το μόνο προϊόν που ήταν διαθέσιμο στην αγορά. Το 2015, σχεδόν 3600 χειρουργικά συστήματα daVinci εγκαταστάθηκαν παγκοσμίως. Ενώ η συντριπτική πλειοψηφία είναι εγκατεστημένη σε αρκετές ανεπτυγμένες χώρες (ΗΠΑ, Γερμανία, Ιταλία, Βρετανία, Γαλλία), εξακολουθεί να υπάρχει περιορισμένος αριθμός ρομποτικών συστημάτων προσβάσιμων σε άλλα μέρη του κόσμου. Όλα τα ανωτέρω δημιουργούν μια τεράστια ζήτηση για νέα συστήματα για την κάλυψη του κενού.

Κατά τη διατριβή αυτή, αρχικά το επιχειρηματικό μοντέλο θα κατασκευαστεί με την χρήση συγκριτικής ανάλυσης SWOT. Θα προσδιοριστούν τα πλεονεκτήματα και οι πιθανές περιοχές βελτίωσης του νέου ρομποτικού συστήματος σε σύγκριση με το ρομποτικό σύστημα daVinci. Τα προαναφερθέντα θα επιτρέψουν την κατανόηση της θέσης της αγοράς, του προφίλ των αγοραστών και της θέσης της αγοράς. Ως αποτέλεσμα, θα δημιουργηθούν πολιτικές τιμολόγησης και διανομής ενός νέου ρομποτικού συστήματος. Η αναγνώριση του κινδύνου θα πραγματοποιηθεί με βάση τις αναλύσεις SWOT και θα σχεδιαστούν μηχανισμοί περιορισμού του κινδύνου.

Ως τελικό βήμα, θα δημιουργηθεί ένα οικονομικό μοντέλο του νέου ρομποτικού συστήματος με 5ετή πρόβλεψη.

Λέξεις – Κλειδιά

Ρομποτικά υποβοηθουμενα χειρουργεία, Ρομποτικό σύστημα daVinci; Ρομποτικό σύστημα, Επιχειρηματικό μοντέλο Avatera, αποτελεσματικότητα κόστους

Table of Contents

List of Diagrams

List of Tables

List of Abbreviations & Acronyms

Df – Degree of Freedom

DTC – Direct-To-Consumer

HD – High-Definition

MIS – Minimally Invasive Surgery

NASA – National Aeronautics and Space Administration

TECABG – Totally Endoscopic Coronary Artery Bypass Grafting

CRSRTP – Colon and Rectal Surgery Robotic Training Program

RACS – Robot-Assisted Colorectal Surgery

RS – Robotic System

RAS – Robot-Assisted Surgery

RP – Radical Prostatectomy

RN – Radical Nephrectomy

ORP – Open Radical Prostatectomy

RARP – Robot-Assisted Prostatectomy

PN – Partial Nephrectomy

OPN – Open Partial Nephrectomy

LPN – Laparoscopic Partial Nephrectomy

RAPN – Robot-Assisted Partial Nephrectomy

RARC – Robot-Assisted Radical cystectomy

RATS – Robot-Assisted Thoracic Surgery

RAKT – Robot-Assisted Kidney Transplantation

RAVV – Robot-Assisted Vasovasostomy

SWOT – Strengths, Weaknesses, Opportunities, Threats

TORS – Transoral Robotic Surgery

VATS – Video-Assisted Thoracic Surgery

1. Introduction

During the last 2 decades, several robotic systems have emerged to improve the quality of care of different medical disciplines. While many of the introduced systems disappeared due to the absence of any clinical experiments, still some remained in the market leaving a huge footprint in the development of surgical techniques (1). First introduced in 1999, the da Vinci robotic system (Intuitive Medical, Sunnyvale, CA, USA) was then successfully implemented in many of the surgical fields. Four generations of the Da Vinci systems have been released. With the dramatic increase in installations of Da Vinci robots > 5800 units worldwide and with the annual number of robotic surgeries > 8.5 million cases, urology, gynecology and visceral surgery represent the main fields utilizing those systems (2).

Robotic surgery possessing the advantages of conventional laparoscopy is associated with additional benefits. The latter includes avoidance of hand tremor and instrument tip movement with 7 degrees of freedom (df) allowing to achieve fine dissection and meticulous suturing. Three-dimensional vision with full control over the working instruments and camera is achieved by operating surgeons limiting the importance of the assistant's expertise. Moreover, it gives more comfortable ergonomics to the surgeon, particularly notable during long surgeries (3). Another important advantage favoring the robotic approach is a potential reduction of a learning curve (4).

The main limitation of the current da Vinci system is the higher acquisition and maintenance costs resulting in higher procedural costs compared to the open and laparoscopic counterparts. Yu et al. evaluated the use, costs and outcomes of robotic-assisted laparoscopic prostatectomy, nephrectomy, partial nephrectomy and pyeloplasty using a population-based approach. They reported decreased rates of perioperative morbidity and mortality of robotic-assisted procedures compared to open analogues. In contrast to open approach, most robotic-assisted procedures were more costly (5). It can become cost-effective when utilized in high-volume centers with high-volume surgeons (6). Despite its higher costs, and the absence or marginal benefits in comparison to laparoscopic alternatives, there is a continuous increase in the number of Da Vinci systems worldwide.

Partly the rising number of implemented da Vinci systems can be explained by an increase in interest of specialists and patients towards robot-assisted surgery (RAS). Obviously, patient's preferences come from their knowledge of existing options and it is believed that media coverage together with marketing have played an essential role in the widespread of robotic surgery (7). Currently, the main source of distribution of information is performed with many various websites. It was reported that direct-to-consumer (DTC) marketing was more pronounced for robotic procedures. Alkhateeb et al. evaluated the DTC advertising of robotic-assisted radical prostatectomy (RARP) in Google and Yahoo searching engines. From retrieved sites, DTC advertising for RARP was found in 64% and 80% in Google and Yahoo, respectively (7). The authors reported also significantly more News over the years regarding RARP in comparison to laparoscopic and open prostatectomy.

It is important to highlight that a vast majority of studies reporting RAS were performed using the da Vinci robotic system. Over the last 20 years, Intuitive Surgical has confirmed many patents on intellectual property, formed training centers and reached a large installation base with thousands of cases performed worldwide. In 2019, with the expiry of key patents period of Intuitive Surgical new RSs had the possibility to enter the market. Some of these devices have been already tested clinically in Europe and Asia. The robotic alternatives to da Vinci systems are the Senhance system (Transenterix, Morrisville, NC, USA), Revo-I (Meere Company, Hwasong, Korea), Hugo RAS (Medtronic, Dublin, Ireland), Versius (CMR Surgical, Cambridge, GB), Flex Surgical System (Medrobotics, Raynham, USA) and Avatera (Avateramedical, Jena, Germany) (8, 9).

The Avatera (Avateramedical, Jena, Germany) was founded in 2011 with the aim to bring patients the highest surgical standards at reduced and affordable costs. The robotic system is space-saving and consists of a robotic cart with 4 arms and a closed-console control unit for an operating surgeon. The particular design of the eyepiece leaves the surgeon's ear and mouth uncovered facilitating unobscured cooperation of the surgeon with his operating team during procedures. The system incorporates a full HD resolution with high color fidelity. Higher, clear picture resolution displaying the same size of the natural field of eye vision makes the robotic system more appealing. It utilizes single-use instruments minimizing the risk of instrument contamination, eliminating the need for re-sterilization and thereof associated costs. The slender instruments with a diameter of 5 mm have a higher range of mobility due to 7df. Furthermore, as a unique characteristic of the Avatera system, all instruments can accommodate bipolar energy excluding the potential risk of injury due to use of the monopolar energy.

Currently, the overwhelming majority of Da Vinci systems are installed in several developed countries (USA, Germany, Italy, Britain, France), there is still a limited number of robotic systems accessible in other parts of the world. On the other hand, even in high-volume centers having robotic systems in their armamentarium most of the benign and some of the malignant conditions are managed with laparoscopic or open alternative approaches. The introduction of new devices will potentially decrease the cost of robotic surgery and open the field for new competition. The developing competition will lead to an additional decrease in the prices of robotic equipment while the quality of the product will be improved. Based on the aforementioned the following two potential market gaps can be distinguished: 1. Installation of robotic systems in centers without existing da Vinci system for treatment of benign and malignant conditions, 2. Installation of new robotic systems in centers with already existing robotic platforms to treat the cases which are considered as not cost-effective to be treated with the current da Vinci systems.

1.1 Aims and research questions

The aim of the current study was to investigate the role and the trends of robotic surgery among different medical specialties, identify the potential issues slowing down the pace of its spread, perform market analysis and evaluate the potential opportunities and possible competitiveness of new alternative high precision robotic devices.

1.2 Business strategy

In our study business strategy analysis was performed using strengths, weaknesses, opportunities and threats (SWOT) statistical analysis method. The latter statistical analysis technique was preferred, as it allows to understand the current strengths and limitations of any new strategy. Furthermore, the SWOT analysis could demonstrate future threats and facilitate the development of specific strategies to overcome those issues. The accurate evaluation of four components of SWOT analyzes can facilitate faster development and/or reduce the chances of failure. The interpretation of the role of the Avatera system was performed on a hypothetical level since no available clinical data exist so far. For calculation of purchase costs of the Avatera system, the current available prices of the da Vinci Xi and the Senhance robots were considered.

1.3 Study novelty

For the first time SWOT analysis of a new robotic platform was performed. Proper market targeting and pricing strategies were proposed to reach fast and continuous invasion of the Avatera robotic system.

1.4 Structure of the dissertation

The dissertation work is presented on 73 pages. The work consists of 6 chapters: introduction, theoretical framework, commercial launch of alternative robotic system, research design and data collection, feasibility study and conclusion. The study includes 122 English-language references. The work is depicted with 2 tables and 7 diagrams.

2. Theoretical framework

2.1 The impact of technology in medical science

2.1.1 The evolution and development of laparoscopic surgeries

Every year an estimated 234.2 million major surgical procedures are performed worldwide. In 2004 the number of major surgeries ranged between 187.2 and 281.2 million cases. The rates of surgeries differ between countries and were reported as low as 148 per 100,000 in Ethiopia and as high as 23,369 per 100,000 population in Hungary (10). According to the National Center for Health Statistics, in 2009 48 million inpatient surgical procedures were performed only in the United States. Most of the procedures were performed for the cardiovascular and digestive systems, 7.3 million and 6.1 million, respectively. In the same year, the number of urinary system surgeries constituted 1.1 million procedures (11).

Nowadays minimally invasive procedure is the preferred surgical approach for the management of various conditions. The invention of laparoscopic procedure was done in the early 20th century. German surgeon George Kelling was the first to use a cystoscope to evaluate the effect of pneumoperitoneum in dogs in 1901. Thereafter, the technique was applied to humans and the results were published in 1910. The modern term "laparoscopy" was first used by Swedish surgeon Hans Christian Jacobaeus. Similar to his German colleague, he started his animal studies in 1901 by performing laparoscopy using a cystoscope without pneumoperitoneum creation (4). His clinical outcomes of 17 laparoscopic procedures with pneumoperitoneum were published in 1910. Both of the surgeons were highly criticized for their work at that time.

The therapeutic features of the laparoscopic technique were first appreciated by gynecologists. In 1933, the first laparoscopic adhesiolysis using cautery was performed by Karl Fevers. The first laparoscopic sterilization with the electrocoagulation of fallopian tubes was performed already in 1936. Although operative laparoscopy was already practiced, the pace of development was very slow. Enough to mention that till 1971 laparoscopy was limited mainly to diagnostic purposes and only 1% of female sterilizations in the United States were performed laparoscopically. This slow development was partly related to the limitations of technology. Skepticism and the inability to accept novelties by the established surgeons further impacted its development. In general surgery, the first use of laparoscopy for surgical purposes (laparoscopic cholecystectomy) was described only in 1986 and was performed by a German surgeon Erich Muhe, who was again received major criticism.

A new era of laparoscopic surgery was started with the advancement of video technologies in the late 1970s and early 1980s by CamranNezhat(12). Although video technology was available already in the 1960s, the low resolution of videoscopic images did not allow to perform surgical procedures, thus, the use of video technology was limited only to teaching and documentation (13, 14). The application of video technology in the performance of endoscopic and laparoscopic procedures occurred in the mid-1980s. Thanks to a urologist Dr. John Wicker a new term "minimally-invasive surgery (MIS)" was introduced in the literature in 1983. He then founded a department of minimally invasive surgery at the Institute of Urology in London (15). The start of video-laparoscopic procedures was initiated in 1987 by French surgeon Phillip Mouret. Thereafter, video-laparoscopic procedures were introduced in gynecology and urology and soon gained wide popularity (12).

In urology, diagnostic laparoscopy for identification of undescended testes was already described in 1985 (16). The first video-laparoscopic urologic procedures were documented in the early 1990s. Schuessler et al. reported outcomes of a feasibility study of performing laparoscopic pelvic lymphadenectomies in patients with prostate cancer in 1991 (17). At that time active treatment for prostate cancer was reserved for patients with negative lymph nodes invasion. In the aforementioned study, 12 pelvic lymphadenectomies were performed for staging purposes prior to the prostatectomy or radiotherapy (17). In the same year, a successful case of a laparoscopic nephrectomy was presented for the first time by Clayman et al. (18). In 1992 the first laparoscopic adrenalectomy for Cushing's syndrome and pheochromocytoma was successfully completed by Canadian urologists Gagner et al. (19). Already in 1997, the outcomes of the first 9 patients undergoing laparoscopic radical prostatectomy were reported by Schuessler et al. (20). Although the average duration of the procedures was 9.4 hours and the results did not show any advantage over the open radical prostatectomy (ORP) technique, the authors were able to show the feasibility of the laparoscopic technique for performing such complicated surgical procedures as radical prostatectomy (RP) (20). Subsequent technological advancements in laparoscopy increased the interest of specialists and led to an exponential increase of the laparoscopic interventions for all kinds of surgeries. Currently, laparoscopy is the recommended gold standard surgical approach for patients requiring radical nephrectomy and preferred modality for other intra-abdominal urological surgeries due to the decreased blood loss, decreased postoperative pain and hospital stay, and better patients' tolerability to the procedure (21).

2.1.2 The evolution of robotic-assisted surgical procedures

The increasing interest in laparoscopic surgery and the popularization of techniques for different procedures led to new technological advancements and the introduction of robotic systems (RS). The first voice-controlled AESOP camera arm was proposed in 1994 by Computer Motion (Computer Motion, Santa Barbara, CA) (2, 12). The latter together with the ZEUS robotic system consisting of a control unit and 2 arms allowed long-distance manipulation. The system incorporated two-dimensional (2D) and three-dimensional (3D) visualization and provided 4 degrees of freedom (df) for instrument movements. Few laparoscopic procedures including pelvic lymph node dissection and pyeloplasty were performed using this system. In 2004 its further production and development was stopped and the system was acquired by Intuitive Surgical (2).

The ARTEMIS system introduced in 1996 was another attempt for the development of a telesurgical laparoscopic system. It included an open console and three single arms. A 3D visualization was achieved using polarizing glasses. The system was tested on porcine models performing laparoscopic cholecystectomies. Although patents were received, it has been never investigated in clinical studies (2).

The first da Vinci 2000 system (Intuitive Surgical, Sunnyvale, CA, USA) was designed based on a National Aeronautics and Space Administration (NASA) project to ensure telepresence battlefield surgery. The particularities of the system included a closed surgical console with a 3D visualization and 3 robotic arms mounted on a transportable cart. Its second generation, the da Vinci S, featured characteristics such as longer robotic arms, implementation of bipolar energy, with possible incorporation of a fourth arm or high-definition (HD) video system on demand. The unique characteristic of the latter RS was the improved range of motion of robotic arms through Endowrist technology providing 7df movements (22). In addition, a special loop-like design of handles with an integrated clutch feature facilitated superior ergonomics and better handling of the tissues. The system initially designed for coronary artery surgery received approval in Europe and the USA in 1999 and 2001, respectively. Wider use of the system was achieved in robot-assisted radical prostatectomy (RARP), the first case already performed in 2001 in Europe (22, 23).

The further advancement of the system, da Vinci Si, was introduced and received FDA approval in 2009. In addition to the HD video technology and finger-based clutch mechanism, it included Fire-Fly™ technology allowing intraoperative isocyanine-green fluorescence guidance (24). It provided also a possibility of having a second console joined to the main working console, representing an ideal teaching tool for gaining hands-on clinical experience (25).

The latest da Vinci robotic system, Xi was launched in 2014. The improved features of the system were the "camera hopping" mechanism allowing to reposition an 8mm 3D camera to any of the robotic arms. With the latter mechanism, different areas could be reached from various angles using the same number of initially placed ports, thus facilitating the easy performance of multi-quadrant surgery. The new robotic system incorporated newer instruments with a finer design minimizing their clashing. Another benefit is the "Table motion" technology allowing operative table movement while the robot is docked adds to its strengths. These technological improvements have opened space for a new level of robot-assisted single-site procedures, the feasibility of which has been recently shown even for complex urologic procedures (26, 27).

2.2 A mapping of the current situation

Market analysis is a must for every product before its mass production. To clearly evaluate the importance and need of a new robotic device, different aspects of the existing robotic system should be viewed in adjunct. It is essential to know the current situation and implementation of robot-assisted surgeries (RAS) in the practice of different medical specialties, evaluate the cost-effectiveness of different robotic procedures, understand the teaching opportunities for novice specialists and finally, view patients' preferences and needs from the current era of surgery.

Since its first introduction in the market, the number of installed da Vinci robotic systems has been increased exponentially. According to Intuitive Surgical, the manufacturer of the da Vinci® Surgical System (Intuitive Surgical Inc.), at the end of 2020 already 5989 robotic platforms were installed globally in 67 countries, and in total > 8.5 million RAS were performed worldwide accounting all disciplines Globally, estimated annual case volumes increased from form 877 000 in 2017 to >1.2 million in 2020 (28). Technology is invading new medical fields and the number of cases treated with robotic systems is continuously increasing. Currently, the system is actively involved in the clinical practice of almost all surgical specialties including urology, general surgery, gynecology, thoracic and cardiac surgery and otolaryngology.

In general surgery, the da Vinci robotic system was used both for upper and lower gastrointestinal tract surgery. General surgery represented the fastest-growing specialty performing RAS in the US in 2018 (29). Its superiority in terms of postoperative local complications and have been demonstrated after robot-assisted gastrectomy and esophagectomy compared to the laparoscopic approach (30). Different robotic surgical techniques for the treatment of hepatobiliary diseases were also developed starting from 2001. A recently published systematic review and network meta-analysis included 62,529 patients undergoing pancreaticoduodenectomy till 2019. While the proportion of robotic cases was 3% (2131 patients), most of the studies were performed during recent years (31). Minimally-invasive surgery (MIS) was found to possess similar oncological outcomes compared to the open technique. However, it was associated with lower rates of surgical-site infection and pulmonary complications, and shorter hospital stay (31). A similar number of robotic cases (2.728 patients) were reported for liver surgery in a recent meta-analysis (32). Compared to laparoscopic liver surgery, the robotic alternative was associated with an improved hospital stay, rate of complications and operative time. Unlike the laparoscopic approach, the ratio of benign/malignant resections was lower for the robotic approach. The limitation of the robotic approach was the increased cost of the procedure, calculated to be $ 5,000 (7).

For robotic-assisted colorectal surgery (RACS) the comparative studies did not demonstrate any benefit over the laparoscopic technique. In contrast, the RACS was associated with increased costs of the procedure and longer operative time (33). Despite a clear advantage of RACS over the conventional approach, a recently published prevalence study found an increase in the following parameters of RACS in the US: the number of procedures, the percentage of robotic procedures, the number of centers performing RACS and the volume of procedures per center (34).

Gynecologists were one of the first specialists along with urologists and general surgeons to use the robotic-assistance in their practice. Hysterectomy, the most often performed gynecological surgery, was one of the first procedures tested with the da Vinci system. Already in 2010, the nationwide trends of robot-assisted laparoscopic hysterectomy showed a dramatic increase from 0.8% to 8.2% in the US over a period of 2 years (35). The use of RS has been described for the management and reconstruction of benign conditions including endometriosis, tubal reanastomosis, uterine fibroids and sacrocolpoplexy for apical prolapse (36, 37). In the case of malignant conditions such as endometrial cancer, the percentage of patients receiving conventional laparoscopy was < 9% before 2006 in the US. After initiation of the RS the percentage of minimally invasive approaches, mainly (robot-assisted), increased to 72% over the following 5 years and exceeded 90% in 2015 (38). In contrast to endometrial cancer, management of early-stage cervical cancer represents one of few conditions where the performance of MIS is restricted. The decrease occurred after 2018, when the Laparoscopic Approach for Cervical Cancer (LACC) trial reported inferior disease-free and overall survival for women undergoing MIS. Within the following 2 years, the percentage of MIS dropped down to 15% from the initial 50% (39).

The implementation of RSs in thoracic surgery (robot-assisted thoracic surgery (RATS)) has also gained more popularity in recent years. In the United States a total of 7600 lobectomies were performed up to 2017. Although the procedure of RATS in Europe was less, there was also an incremental rise over years. For example, in Germany since its first introduction in 2013, the number of annually performed RATS has grown and reached >300 cases in 2018 (40). Advantages of RATS included excellent lymph node dissection with minimal morbidity and mortality, and less postoperative pain (41). In addition, it was associated with a shorter learning curve compared to video-assisted thoracic surgery (VATS). The higher cost of the RATS procedure was the main limitation reported in the literature (41).

Transoral robotic surgery (TORS) using the da Vinci system received approval in 2009. Since then there is a continuous rise in the number of performed surgeries and publications already reaching > 100 with searched keywords of "robotic surgery + transoral". The main indications for TORS includes oropharyngeal and supraglottic cancers. It can be also utilized on hypopharynx, nasopharynx, skull base and parapharynx(42) anatomical regions. Although some of the procedures are off-labeled, TORS is more and more expanding.

An interesting, novel robotic approach has been described for mastectomy and further reconstruction. The robotic system appeared to be particularly important for harvesting the latissimus dorsi muscle to perform immediate breast reconstruction after nipple-saving mastectomy. Although the cosmetic effect is superior compared to laparoscopic technique and open technique, the robotic approach has not gained an FDA approval yet and there is still little data regarding its outcomes (43).

Initially, RSs were designed to assist the procedures of cardiac surgery. The performance of the totally endoscopic coronary artery bypass grafting (TECABG) procedure was only possible with the application of the da Vinci Si system. The key parameters enabling the successful performance of the procedure were Endowrist technology and the availability of an endoscopic suction stabilizer installed in da Vinci S and Si systems (44). As a result of the slow adoption of the robotic technique due to the difficulty of the procedure and longer learning curve, the endoscopic suction stabilizer device was not integrated into the latest da Vinci Xi system anymore, limiting further use of RSs for this type of surgery (44). In cardiology, the use of a robotic platform has been additionally described for mitral valve surgery. The meta-analysis performed by Cao et al. demonstrated the feasibility of the robotic technique for selected patients. However, due to the low number of included studies in the meta-analysis the interpretation of the findings should be done with caution (45).

2.3 The current guidelines of robotic surgery in the urology discipline

In urology, robot-assisted technology has been most utilized for the treatment of oncological diseases. The RARP is probably one of the most widely established procedure among RAS worldwide. Since its first description, the technique gained wide popularity and became the standard of surgical care in many centers worldwide. The benefits related to this technique include a reduced rate of intraoperative blood loss and transfusion, shorter catheterization and length of hospital stay, a lower rate of overall complications, better control of potency and continence, as well as lower readmission rates (46). Already in 2009 RARP comprised more than 60% of all radical prostatectomy (RP) cases in the US (47). Further decrease in open cases was reported analyzing nationwide inpatient sample data. During 2009-2014 total number of 77,054 RP cases were reported. Interestingly, proportion of RARP increased from 63.8% 2009 to 81.5% 2014 (46). Similar trends were observed in other western countries. In Germany, the rate of RARP improved from 0.6% in 2006 to 25.2% in 2013 (48). This increase in the practice of RARP can be explained with more installations of RSs worldwide and with standardization and spread of knowledge of the operative technique allowing its safe and effective replication.

The use of robotic assistance is also important for other urological malignancies, such as Bladder and renal cancer. Currently, the standard of care for the management of muscle-invasive bladder cancer is radical cystectomy with subsequent urinary diversion. The open approach is still the preferred procedure by most of the centers worldwide. Robot-assisted radical cystectomy (RARC) either with extracorporeal and intracorporeal urinary diversion has gained more popularity over time. The first case of RARC was already described in 2003 by Menon et al. (49). Already in 2012 18.5% of radical cystectomies were performed robotically which in comparison to 2003 demonstrated a 25-fold increase (50). Fujimura T. reported the distribution of RARC cases worldwide in 2019 (51). Among 399 published studies 50% (198) were originated from the USA followed by the United Kingdom (9% or 37 papers), Sweden (5.8% or 23 papers) and Germany (5% or 20 papers). Overall 202, 130, 62 articles were published in Northern America, Europe and Asia (including Turkey and Iran), respectively. Apart from Egypt (4 papers) and Brazil (1 paper), no paper was originated from the African or South American continent (51).

The clinical outcomes of RARC compared to open radical cystectomy (ORC) are well-documented. A recent randomized non-inferiority trial comparing open and robot-assisted radical cystectomy procedures with 302 included patients reported similar outcomes for robotic approach (52). While the reported rates of progression-free survival, overall and major complications were similar, the RARC was associated with the statistically significant decreased rate of blood loss and blood transfusion and improved rate of hospital stay (52). A complete intracorporeal urinary diversion is now preferred if a patient undergoes RARC. According to the international robotic cystectomy consortium (IRCC) evaluating the data of 935 patients, a dramatic increase of intracorporeal diversion in member centers from 5% in 2005 to 97% in 2016 was found (53). It was also demonstrated that the increasing practice of the latter technique was associated with the improved learning curve and decreased rate of major complications, encountered in 25% of patients in 2005 compared to 6% in 2015 (53).

The surgical management of renal tumors, particularly T1 and T2 tumors has been greatly impacted by the advent of robotic technology. According to the National Cancer Data Base of the US, robot-assisted partial nephrectomy (RAPN) surpassed the utilization of its open counterpart already in 2012. The trends of practicing RAPN among US urologists increased from 41% in 2010 to 63% in 2013 (54). As such, in many centers, the RAPN is, currently, considered as a "gold standard" surgical approach in a case when partial nephrectomy (PN) should be performed. A similar shift in trends towards RAPN has been described in other countries including France (55), Australia (56) and Great Britain (57). Important to note, that the robotic assistance allows excision of more complex renal tumors expanding the indication for partial nephrectomies (PN) (56). The data shows that there has been a continuous increase in the numbers of PNs, whereas a decline in the number of radical nephrectomies (RN) has been observed (55, 56). The role of robotic technology in RAPN is further expanding with recent advancements. The intraoperative real-time guidance with indocyanine green (ICG) and augmented reality take the surgery to another level (58). The latest series of da Vinci system allows the intraoperative overlay of a preoperatively constructed 3D image directly into the console. Given this, the operating surgeon receives a real-time reconstruction of the renal anatomy with detailed depiction and relationship of intrarenal structures (58). Apart from partial nephrectomy, RS is increasingly used for adrenalectomies and complex procedures such as RNs with caval thrombectomies (59).

The role of RAS in the management of non-malignant conditions in urology has been recently demonstrated in a systematic review conducted by Pal et al. (60). The evaluated surgical procedures were robot-assisted simple prostatectomy, salvage radical prostatectomy, distal ureteric reconstruction, retroperitoneal lymph node dissection, augmentation ilecystoplasty, artificial urinary sphincter insertion, and procedures directed to the management of urolithiasis. Overall, the RAS was associated with decreased blood loss and length of stay while having the same clinical outcomes compared to open alternatives. When compared to laparoscopic equivalent procedures, RAS improved the learning curve and operative time (60). The feasibility of performing robot-assisted kidney transplantation (RAKT) has been also reported in the literature (61). The major benefits favoring RAKT were the low rate of complications. However, careful patient selection and a high level of expertise are required before commencing RAKT, which, in fact, limits the pace of integration of RS in kidney transplantation surgery. Not considered a reference surgical approach, the robotic alternative is currently performed in several centers worldwide. Nevertheless, it attracts much interest among urologists and remains an evolving surgical field for improvement (61).

In urology, the RS can be effectively utilized for extracorporeal reconstructive procedures where delicate work with tissues is expected. Robot-assisted vasovasostomy (RAVV) is one of the examples of successful implementation of robotic technology (62). The number of published articles is still low. Nonetheless, the outcomes prove the feasibility of the approach with similar patency outcomes compared to an established microsurgical approach. Upon revision of the existing literature, several advantages of robotic alternative were demonstrated including shorter learning curve, improved and easy controlled vision and, most important, instrument movement precision with the elimination of physiological tremor of surgeon's hands (62). The main limitation of the technique was its higher procedural cost.

The pediatric population is another clinical area where the da Vinci robotic system was implemented for the treatment of different conditions. First cases of robot-assisted pyleoplasty have been described by Atug et al. in 2005 (63). Possessing the advantages of laparoscopic procedures, better control of postoperative pain and decreased length of hospital stay, robot-assisted pyeloplasty was associated with lower complications and higher success rate and decreased average operative time (64). Later, the system was implemented for surgical procedures such as ureteral reimplantation, uretero-ureterostomy, appendicovesicostomy, bladder neck reconstruction, and augmentation ileocystoplasty(65). Despite its advantages, the widespread of the robotic technique among the pediatric population has been limited mainly due to its higher costs.

In conclusion, currently, RAS is most practiced to treat malignancies. It has already become a standard technique of care for surgeries such as radical prostatectomy and partial nephrectomy with more cases performed robotically than in open fashion in many centers. The literature review shows an expanding use of robotic technology in recent years even for the management of many benign conditions with improved outcomes. The main discussed limitation for all procedures is the higher cost of the procedure compared to the open or laparoscopic approach.

2.4 Training in robotic surgery

Robotic procedures are associated with a steep learning curve, and most of the surgical errors are observed during the initial training period. Basic procedural skills can be improved with the use of different robotic simulators. Although most of the validated training courses include short-term programs, improvement of robotic skills could be achieved after a 3-day simulation course (66). A simulation duration of as low as 10h was reported sufficient for acquiring proficiency in basic skills among junior specialists (67). Simulation-based training was not found to be inferior even compared to human proctorship. In a study by Beulens et al., 70 Dutch medical students, PhD-students and surgical residents were randomly assigned to proctored guidance, simulator-generated guidance and no guidance (while training on virtual reality model) groups. No statistical differences were observed between the groups in terms of improvement of surgical skills. Nevertheless, the satisfaction was higher among participants receiving human proctorship (68).

Many residency programs currently integrate some level of robotic training. While a well-structured curriculum is still an issue, in recent years more and more studies have emerged proposing standardized robotic training curriculum for residents. A survey of 26 Integrated Thoracic Surgery Residency Program Directors in the US demonstrated that introduction of robotic training already in residency was believed to be an essential factor for subsequent success. Subsequently, a 2-phase training curriculum including preclinical and clinical stages was proposed for postgraduate years 2-6 (69). Moit et al. designed an educational program for residents of general surgery (70). Similar to the thoracic surgery training program, the curriculum included 2 phases which should be completed during the 5-year residency program. The last task was to perform a minimum of 10 procedures with 2 separate attending surgeons. The authors concluded that the standardized training curriculum had the ability to produce surgeons operating robotically without completing a specialized robotic fellowship (70).

Recently the importance of a training curriculum of different separate procedures has been reported (71, 72). Addressing the issue of developing competence in a complex surgery such as a RARC, a 4-step program was suggested based on the survey outcomes of 28 experts. Its structure included theoretical training, preclinical simulation-based and nontechnical skills training, clinical training of at least 6 months duration and final evaluation of video-recorded RARC cases (71).

Robotic training among graduating urologic residents has been assessed by Merril et al. (73). Overall, 89,199 RASs performed by 209 graduates were documented within a period of 6 years in the field of reconstructive, oncologic and pediatric urology. In all subspecialties, a significant increase in the number of robotic cases performed by residents was observed. While the open approach was more practiced for reconstructive and pediatric procedures, more robotic onco-urologic procedures were performed by residents in 2017 (73). The impact of specific robotic training in colorectal surgery was also evaluated. A national Colon and Rectal Surgery Robotic Training Program (CRSRTP) was already designed and implemented during the 2010-2011 academic years. Martin et al. evaluated the outcomes of the implemented training program among residents from the academic year 2016-2017 with a novel case-log system. Out of 93 included residents 65% reported ≥ 20 complex cases performed robotically as console surgeons during their training (74).

Apparently, residents are the future surgeons who with adequate training will be using the evolving technologies. The RAS is trendy and, not surprisingly, very attractive for junior specialists. In a recent survey among urology residents in the Netherlands, more than 80% of participants were interested in performing RAS after completing their residency training (75). Another study conducted in the US revealed that 95% of general surgery residents preferred a residency program including a da Vinci robotic system (29). On one hand, increasing utilization and popularization of robotic systems worldwide necessitate the implementation of standardized robotic training programs for residents. On the other hand, implementation of a robotic training curriculum in the surgical residency programs of different specialties improves the confidence and expertise of residents and surgeons resulting in a further growth of the popularity of RAS (76).

2.5 Acquisition of robotic system, patients' preference and media marketing

Apparently, several factors may influence the decision of a hospital to invest in this technology. It was demonstrated that patients were more likely to receive robotic procedures in highly competitive regional markets (77). Hospitals' profit margins were also found to influence the decision of system acquisition. More favorable profit margins were reported for hospitals with robotic surgical systems (78).

Spaulding et al. assessed hospital robotic use for colorectal cancers. They failed to find any association between robotic surgery use and hospital competition or disease burden. In contrast, they reported increased odds of robotic use in hospitals with a higher total average margin and caseload (79). Another study found that hospital volume itself was responsible for the acquisition of the system. The authors showed that the hospital which decided to purchase the system had the mean quarterly prostatectomy volume of > 16 cases. Interestingly, the fact of possessing the robotic system further increased the mean numbers of the procedures, indicating that the device itself can act as a tool for gaining new patients.

Patient preference and demand is another factor shaping the supply. Obviously, patient's preferences come from their knowledge of existing options and it is believed that media coverage together with marketing have played an essential role in the widespread of robotic surgery (7). Currently, the main source of distribution of information is performed with many various websites. It was reported that direct-to-consumer (DTC) marketing was more pronounced for robotic procedures. Alkhateeb et al. evaluated the DTC advertising of robotic-assisted radical prostatectomy (RARP) in Google and Yahoo searching engines. From retrieved sites, DTC advertising for RARP was found in 64% and 80% in Google and Yahoo, respectively (7). The authors reported also significantly more News over the years regarding RARP in comparison to laparoscopic and open prostatectomy.

The advertisement is performed either directly from manufactures or hospitals/surgeons. In general, hospital's/surgeon's publications are regarded to be more objective by the public with better quality (80). Several studies have evaluated the content, quality and accuracy of the information for different robotic surgeries (7, 80, 81). The same aforementioned study of Alkhateeb et al. revealed that only 14% and 10% of Google and Yahoo searched websites met the quality criteria defined by World Health Organization as the Honesty on the Internet (7).

Biased information favoring only the benefits of robotic surgery was also described as an issue by Mirkin et al. (80). When reviewing the webpages with DTC advertisement of RARP, 42% of the sites failed to report the potential risks of the procedure. Moreover, most of the sites were unsupported by any evidence (80). A general analysis of 432 hospital webpages with more than 200 beds contained marketing for robotic gynecologic surgery in 44.4% (81). Perioperative benefits of robotic surgery were reported in most of the cases, whereas limitations such as higher cost, complications and operative time were only presented in 3.7%, 1.6% and 3.7%, respectively (81).

To understand the beliefs and attitudes of practicing gynecologists Wright et al. conducted a survey and evaluated the responses stratified based on robotic use (82). From 310 responders, the robotic system was actively practiced in 27.8%. There was a statistically significant difference in responses regarding the benefits of robotic surgery. The majority of robot users (82%) and only 21% of non-robot users believed that robotic surgeries were associated with improved outcomes. Furthermore, non-robot users were more prone to think that marketing was the factor driving the demand for robotic surgery (64% versus 22%) (82).

2.6 Financial analysis

As already shown a large piece of literature from many disciplines has reported technical advantages of the RAS. The safety and efficacy of the procedures have been comparable to their open and laparoscopic counterpart. In this context, cost-effectiveness remains a major concern directing the utilization of the treatment approach. Cost-analysis studies are required for hospital administrators, health ministries and governing bodies to design future strategies and justify the investments. As such, cost analysis of the da Vinci robotic system has been performed for a variety of surgical interventions. The analysis can be very challenging and the reporting can have great variability due to inclusion or exclusion of purchase and maintenance costs, differences of applied costing methods, as well as consideration of re-hospitalizations and complications (83, 84).

A systematic review assessing cost-effectiveness of robotic procedures in urology reported significantly higher costs for RARP compared both to laparoscopic RP and open RP (85). There were much discrepancies between the included studies, with costs ranging from 2000$ to 39,251$ for RARP. Nevertheless, RARP was more expensive. Similar, higher costs for robotic procedures were reported for RARC described in 6 out the 9 studies included in the recent systematic review (86). The partial nephrectomy is probably one of few surgeries, for which better cost-effectiveness of the robotic approach has been demonstrated (87, 88). Lower procedural costs and complication rates were reported after RAPN compared to the open technique (88). However, this implication can be true for high-volume centers. The cost for RAPN can be increased, when the cases are performed by less-experienced centers due to a higher risk of developing postoperative complications (88, 89). In contrast, for small renal masses, the best profitability was achieved using the pure laparoscopic approach offered (90).

Armijo et al. evaluated the trends and costs of 5 surgical procedures including colectomy, cholecystectomy, inguinal and ventral hernia repairs, and bariatric surgeries. Over a 7-year period, he proportion of robotic cases for all surgeries increased significantly. Nevertheless, the cost-analysis showed that all the robotic procedures carried higher costs while possessing the same outcomes as that of laparoscopic alternative (91). The higher costs of RAS were also reported for complex surgeries such as colectomy, hepatectomy and gastrectomy (92-94). In a recently published randomized controlled trial assessing the safety and efficiency of robotic rectal surgery compared to laparoscopic 26 sites for 10 countries were included (95). In total 471 patients were included and randomized into 2 surgical arms. Although the robotic approach carried a lower rate for conversion to laparotomy, it appeared more expensive even after the exclusion of maintenance and acquisition costs (95).

Cost-effectiveness of the da Vinci system was also evaluated in gynecology (96), thoracic surgery (97) and TORS (98). The findings were not that much different from other disciplines. For almost all conditions involvement of the da Vinci robotic platform increased the expense. Only for the lobectomy procedure the total costs were similar for the robotic and open approaches. However, when compared to video-assisted thoracic surgery the costs were significantly higher while the outcomes were documented to be similar (97).

Much can be discussed here regarding the similarities and discrepancies of existing literature. Several separate studies might show similar or even improved costs for robotic procedures, mainly in high volume centers and with a high number of robotic cases. However, systematic reviews and meta-analysis do not support these data and a conclusion which can be made on cost-analysis today is that RAS using da Vinci robotic platform still remains significantly more expensive compared to open or laparoscopic approaches for most of the disciplines and most surgical procedures. Adoption and practice in hospitals with a low number of robotic cases can be difficult and result in the closure of robotic programs due to higher costs (99). The future spread of the robotic approach is expected either with the emerging evidence showing its clear superiority over the open and laparoscopic technique or with the decrease of the cost per procedure. The introduction of new robotic systems will potentially reshape the market and convince policymakers and healthcare specialists to defend the robotic platform.

2.7 Market gaps

Health is a fundamental right of each human and providing a similar quality of care should be the primary goal of all healthcare providers. The treatment strategy for every patient should carry minimal harm without jeopardizing the treatment outcomes. With this concept, MIS surgery and, in particular, laparoscopic surgery was introduced, which revolutionized the surgical procedures of many malignant and benign conditions. The RAS was another step forward in this process. Possessing the same advantages of laparoscopic surgery, several benefits were added including full 3D magnified visualization, improved range of motion of working instruments with 7df, elimination of hands' tremor, improved ergonomics of the operating surgeon and increased autonomy for controlling the 3 instruments and the camera are encountered (100, 101). All of those features make the system very attractive for surgeons as well as for patients. The growth of interest in RAS can be easily concluded for the annual number of published articles. While up to 2014 there was a gradual increase of published articles in the field of RAS a drastic growth was documented thereafter, probably due introduction of the da Vinci Xi system (102). In 2020 the total number of articles referencing RS exceeded 3000 (28).

As previously shown, the row number of robotic cases and installed robotic systems is continuously increasing. However, the da Vinci system is mainly reserved for oncological procedures where cost-effectiveness might be justified. Even in high-volume centers having robotic systems in their armamentarium most of the benign and some of the malignant conditions are managed with laparoscopic or open alternative approaches. In addition, most of the installed systems appear in few developed countries. The higher purchase and maintenance costs limited their spread in less developed countries with moderate healthcare resources. This creates a huge gap for less expensive high precision systems.

Currently, each year more than 50 million surgeries can be potentially performed robotically. Nevertheless the actual annual number of RAS is about 1.2 million procedure, which comprises only 2% of all surgical procedures worldwide being worth $5 billion (8). Most of the remaining surgeries, more than 60%, are still performed open and 30-35% of cases are treated with conventional MIS. With the decreased procedural costs and increased cost-effectivity the RSs can invade the MIS and open surgical marked more rapidly and exponentially increase the annual number of performed RAS. Although not all surgeries will require robotic assistance within the next 5 years, this can be expected to happen within the following 20-30 years. The aforementioned offers new players a huge marked, which is 98% or about 50 million surgeries per year.

To reach fast acceptance, two marketing direction for new RSs can be distinguished: 1. Installation of robotic systems in centers without existing da Vinci system for treatment of benign and malignant conditions, 2. Installation of new robotic systems in centers with already existing robotic platforms to treat the cases which are considered as not cost-effective to be treated with the current da Vinci systems. Therefore, the new players are required to possess similar operational features as that of the da Vinci system but carry lower purchase and maintenance costs, and making them an affordable instrument for most of the procedures in most of the countries. In addition, the developing competition will lead to an additional decrease in the prices of robotic equipment while the quality of the product will be improved. In theory, patients, surgeons, hospitals and robotic companies including Intuitive Surgical (manufacturer of da Vinci robotic system) will win from this competition, since the invasion of robotic procedures in all medical disciplines can be expected to a pace several times faster than now.

3. Commercial launch of an alternative high-tech precision instrument

In 2019, with the expiry of key patents period of Intuitive Surgical new RSs had the possibility to enter the market. Some of these devices have been already tested clinically in Europe and Asia. The robotic alternatives to Da Vinci systems are Senhance system (Transenterix, Morrisville, NC, USA), Revo-I (Meere Company, Hwasong, Korea), Hugo RAS (Medtronic, Dublin, Ireland), Versius (CMR Surgical, Cambridge, GB), Flex Surgical System (Medrobotics, Raynham, USA) and Avatera (Avateramedical, Jena, Germany) (8, 9). Some of the systems have already gained CE and FDA approval and have been tested in clinical studies, and others have been investigated in preclinical, cadaveric and/or animal, trials (8, 9). Although the initial results are promising, more clinical data are still required to evaluate the safety and efficacy profiles of these devices. Further improvement of available features is expected from RS producers. The possible feature can be multiple columns with one single-arm rather than one patient cart with multiple arms, automatic collision detection of robotic arms, 3D vision for all team members. Finally, a specialty-specific robotic system can be produced to maximize the benefits for each medical discipline (44).

The Senhance system (Transenterix, Morrisville, NC, USA), formerly known as Alf-X is currently available in several countries of Europe, North America, Asia and Africa and is used for gynecologiocal, urological and general surgery procedures (8). The RS is more similar to conventional laparoscopy than the da Vinci platform. Its main characteristics are a 3D vision open console with an infrared eye-tracking feature to control camera movement, up to 4 separately installed robotic arms, possibility of haptic feedback, and use of 5 and 3mm mini-laparoscopic instruments (8, 103). After receiving FDA and CE approval the number of performed cases has continuously increased over the last 3 years. With only 35 published studies, this RS appears to be the second widely used system so far. The most recent study conducted in 5 European countries between February 2017 and July 2020 included 871 patients of visceral surgical disciplines (104). The early outcomes prove the feasibility and safety of the system for performance of various surgical procedures including unilateral hernia repair, a bilateral hernia repair, a cholecystectomy, a prostatectomy and other visceral surgeries (104). It seems that this system can decrease the procedural costs significantly. In a series of 40 prostatectomies, additional costs comprised a total of 2x1700€ + 373€ per patient (3x48€ for disposable draping of the robotic arms + 229€ for additional materials) (105). Although it has been claimed to reduce procedure costs in comparison to da Vinci, a robust data of well-conducted studies is currently missing.

The Revo-I (Meere Company, Hwasong, Korea) is another robotic system that received FDA approval in Korea in 2017 and has been practiced already in urology and in general surgery (106, 107). The Revo-I system is similar to the da Vinci Si robotic platform consisting of a separate closed console with 3D vision, a robotic operation cart with 4 mounted arms. It incorporates 5mm multi-use instruments with the 7df movements and a 10mm optic. Although feasibility of the system has been demonstrated, the total number of clinical studies in Pubmed is still limited to 4, making it impossible to evaluate the effectiveness of the system on humans so far.

The Versius (CMR Surgical, Cambridge, GB) is another recently introduced RS from GB designed for abdominal, thoracic and ENT surgeries (9). It received CE approval in 2019 and FDA approval is still pending. This robotic system is more similar to the Senhance system and includes an open console control unit with 3D HD vision. Each robotic arm is mounted on a separate cart providing independent arm positioning in the operating theatre. Similar to other RSs, the instruments allow a 7df range of movements for the surgeon similar to other RS. The first cases with a Versius platform has been recently reported in colorectal and gynecological surgeries (108, 109).

The Hugo RAS (Medtronic, Dublin, Ireland), is another RS similar to Versius and Senhance robotic systems. It again includes an open-console control unit. The 3D vision is achieved with the use of polarizing glasses. The robotic arms come on independent carts. The system includes 5mm working instruments providing a 7df range of movements (8). The platform has been tested on cadavers so far and the CE and FDA approvals have not been granted yet. The CE approval is projected in 2021 (9).

The MiroSurge (DLR, Institute of robotics and mechatronics, Wessling, Germany), is a modular system for MIS robotic surgery. The system consists of an open-console surgeon's unit and 3 robotic arms with a potential of 7df range of movements. Similar to other open-console RSs the 3D vision is accomplished with the aid of polarized glasses. The MiroSurge is equipped with haptic input and collision detection functions. It also offers a table with 7df movements. The given characteristics allow uninterrupted performance of the surgical task even when the table is moving. Currently there is no data regarding its use or expected approval (110).

The Flex Surgical System (Medrobotics, Raynham, USA) is a robotic platform mainly reserved for minimally invasive gastroenterological and ENT procedures. It enables better access and visualization of difficult anatomical regions thanks to flexible design of camera. The surgeon controls the camera movements from a separate open console that integrates a joystick. The RS can be accompanied be fully flexible instruments for performing under direct vision (9).

The Avatera (Avateramedical, Jena, Germany) was founded in 2011 with the aim to bring patients the highest surgical standards at reduced and affordable costs (111). The robotic system is space-saving and consists of a robotic cart with 4 arms and a closed-console control unit for an operating surgeon. The particular design of the eyepiece leaves the surgeon's ear and mouth uncovered facilitating unobscured cooperation of the surgeon with his operating team during procedures. The system incorporates a full HD resolution with high color fidelity. Higher, clear picture resolution displaying the same size of the natural field of eye vision makes the robotic system more appealing. It utilizes single-use instruments minimizing the risk of instrument contamination, eliminating the need for re-sterilization and thereof associated costs. The slender instruments with a diameter of 5 mm have a higher range of mobility due to 7df. Furthermore, as a unique characteristic of the Avatera system, all instruments can accommodate bipolar energy excluding the potential risk of injury due to use of the monopolar energy (111).

Table 1: Comparative analysis of alternative high-tech precision robotic systems.

Name	Features	Use	Approval	Advantages	Disadvantages
Openconsoleroboticsystems					
Senhance system (Transenterix, Morrisville, NC, USA)	- A 3D visionwithglasses - An infrared eye-tracking feature to control camera movement - Up to 4 robotic arms on independent carts - Feature of hapticfeedback - 5 and 3mm mini-laparoscopic instruments	Abd. surgery, Gynecology, Urology	FDA and CE approval in 2017	- Hapticfeedback - 3mm mini-laparoscopicinstruments - Independentcarts - Easierintraoperativecommunication - No need for system specific trocars	- Camera control w (limits the surgeo - 3D visionwithgla - Handlessimilarto - 4df range of mov laparoscopy
Versius (CMR Surgical,	- A 3D visionwithglasses	Abd. surgery, gynecology,	Only CE approval in 2019	- Independentcarts - Upto 5 arms	- Camera control w (limits the surgeo

Cambridge, GB)	- Up to 5 robotic arms on independent carts - 7df range of movements - 5 mini-laparoscopicinstruments	urology, thoracicsurgery, ENT		- Easierintraoperativecommunication - No need for system specific trocars	- 3D visionwithgla - Instruments hand compared to "clu
Hugo RAS (Medtronic, Dublin, Ireland)	- A 3D visionwithglasses - Up to 4 robotic arms on independent carts - 7df range of movements - 5 mini-laparoscopicinstruments	Notapplicable	CE approvalprojected in 2021	- Independentcarts - Easierintraoperativecommunication	- Camera control w (limits the surgeo - 3D visionwithgla - Instruments hand compared to "clu
MiroSurge (German AeroSpace	- Feature of hapticfeedback - A 3D	Notapplicable	Notapplicable	- Independentcarts - Easierintraoperativecommunication - Hapticfeedback	- Camera control w (limits the surgeo - 3D visionwithgla

Center (DLR), Institute of robotics and mechatronics, Wessling, Germany)	visionwithglasses - 3 roboticarms on independentcarts - 7df range of movements - 5 mini-laparoscopicinstruments			- Instrumentcollisiondetectionfeature	- Instruments hand compared to “clu
Flex Surgical System (Medrobotics, Raynham, USA)	- Flexible design of camera system operated with a simplified joystick. - Accompanied by 3mm flexible instruments with articulating wrists	Colorectal, ENT	FDA and CE approval in 2019	- Flexible camera - Flexible 3mm instruments	- Designed for EN surgeries
Closeconsoleroboticsystems					
Revo-I (Meere Company, Hwasong,	- Closed-consolecontrolunit - 3D HD vision - Roboticcartwith 4	Abd. surgery, gynecology, urology	Korean FDA approval	- Closed-consolecontrolunit - “Clutch” function - Trainingmodule	- Obscuredintraope - Instrumentclashi

Korea)	roboticarms - 7df range of movements - 5mm instruments - Clutchfunction - Trainingmodule				
Avatera (Avateramedical, Jena, Germany)	- Closed-consolecontrolunit - 3D HD vision - Slender eyepiece design (surgeon's mouth and ears remain uncovered) - Roboticcartwith 4 roboticarms - 7df range of movements - 5mm single-useinstruments - Use of onlybipolarenergy	Abd. surgery, gynecology, urology	CE approvalprojected in 2021	- Closed-consolecontrolunit - Slender eyepiece design (surgeon's mouth and ears remain uncovered) - Single-useinstruments - Use of onlybipolarenergy - Clutchfunction	- Instrumentclashi

	- Clutchfunction				

4. Research design

The aim of the current study was to investigate the role and the trends of robotic surgery among different medical specialties, identify the potential issues slowing down the pace of its spread, perform market analysis and evaluate the potential opportunities and possible competitiveness of new alternative high precision robotic devices. For those purposes, the usage of both quantitative and qualitative research design methods was initially considered. Using a qualitative design, the surgeons', patients' and policy makers' perceptions as well as potential pitfalls and gaps of the existing RSs could be evaluated. Analyzing non-numerical data could provide additional information on the concepts, opinions, and general experiences and would serve as a basis to generate new ideas for further research. The given research method would have been suitable if no or limited number of studies were available in the literature.

Based on our personal practical experience and available literature it became clear, that there is already a well-established and accepted robotic system in the market. The last two decades were detrimental to the development of robotic systems in medicine and their successful implementation in the surgical practice. Apparently, the question whether robotic systems can have any impact on shaping medical care currently falls out. With a large piece of qualitative and quantitative data, the da Vinci platform and, in general, robot-assisted surgeries are shown to be very attractive for surgeons and patients. In the current scenario, the qualitative research method would not be sufficient to accurately depict the existing gap and future perspectives for new RSs.

Given the aforementioned, a descriptive and projective quantitative research design was applied to establish the statistical relevance of the results to the described objective. This research method allows deploying mathematical frameworks and objectively evaluate findings. In comparison, to qualitative research analysis, quantitative method is based on numeric and unchanged data using structured and replicable instruments. As a result, the data interpretation and conclusions are less biased.

An essential step of any research to derive statistical inferences and make a reasonable and objective conclusion is data analysis. In this study after the collection of secondary data, its interpretation was performed using the strengths, weaknesses, opportunities and threats (SWOT) statistical analysis method.

In our study, the strengths are the actual advantages of the Avatera company making it distinguishable in the market at this current point of time. Understanding the difference between necessity and advantage, and appreciation of the existing advantages is crucial. Evaluation of weaknesses is an integral and important step of SWOT analyses. In our current scenario, appropriate evaluation of alternative robotic systems is essential to correctly direct the resources.

Apparently, developing a business strategy cannot be limited to a short time period. Future predictions can ensure continuous and steady development. Although making a prediction can be challenging, a clear understanding of previous trends might help to identify potential insights for development. Recognizing the robot's potential operational difficulties and developing strategies to avoid those issues is also required.

The latter statistical analysis technique was preferred, as it allows to understand the current strengths and limitations of any new strategy. Furthermore, the SWOT analysis could demonstrate future threats and facilitate the development of specific strategies to overcome those issues. The accurate evaluation of four components of SWOT analyzes can facilitate faster development and/or reduce the chances of failure.

Due to the fact, that our institution does not possess any robotic system, data from secondary sources were used. To complete our analysis, data on the da Vinci system from other institutions were collected and considered. Based on these data the need for a new robotic system, the existing and expected market gaps were identified. In addition, the issues of the da Vinci robot were examined and analyzed to understand its potential capacity to feel the gap. The interpretation of the role of the Avatera system was performed on a hypothetical level, since no available clinical data exist so far. For calculation of purchase costs of the Avatera system, the current prices of the da Vinci Xi robot and Senhance robot were considered.

5. Feasibility study

5.1 Business modeling

The term 'business model' has expanded its popularity over the economics and is increasingly invading many different fields including medicine. With a proper application, business modeling can be a strong functioning tool to accurately shape the competitiveness of the firm, to develop strategic priorities for decision-making, and thus, increased the performance of a company (112). Nevertheless, there is still a lack of consensus regarding the interpretation of its core concepts, proper application and precise interpretation (113-115).

In recent years, the business model concept has gained popularity both among practitioners and academics. Currently, the term is increasingly used in academic publications with a dramatic increase of its usage since the mid-1990s (113, 115, 116). The research in the medical field constitutes a significant portion of academic literature. With the increasing role of technology in the medical field, the importance of business models becomes more pronounced. Robotic surgery is a recently evolved medical field with very few players in the market, but with great opportunities. The Avatera system is one of the few companies entering the market of robotic surgery after the expiration of patents of the previous RS in 2019. A projective business model development and its critical analysis are therefore needed to properly evaluate the opportunities strategic directions of the company.

The Avatera (Avateramedical, Jena, Germany) robotic system is a novel teleoperated robotic surgical system designed to assist surgeons in performing MAS, overcome the limitations associated with laparoscopic surgery, as well as provide solutions to the challenges of currently available surgical robots (111). Inspired by an initiative of a leading German surgeon and designed by one of the highly experienced German industry companies, the device is developed to improve surgeons' performance and provide the highest quality of care of MAS procedures to people all over the world. To guarantee the recognized benefits of RASs the robotic platform was crafted in close cooperation with renowned robotic surgeons and clinical staff. Maintaining a consistent focus on all essential functions of current robotic techniques, the system was developed with the optimization of cost, quality, comfort and reliability (111).

The Avatera robotic platform meets all the required standards of robotic surgery. Similar to the da Vinci robot, it is a 2 component robotic system consisting of a closed-console control unit for an operating surgeon and a robotic cart with 4 robotic arms mounted on it. Thanks to its fine design the whole RS is space-saving and can be easily incorporated in most of the surgical theatres. Its 4 arms are intended to hold the camera and 3 working instruments simultaneously, all controlled by the operating surgeon. A possibility to have an additional 4^{th} arm is of great importance for the surgeon. In cases with complicated anatomy and/or restricted working area, it can facilitate precise, controlled and desired traction of the tissues, thus opening and presenting the operating field to the surgeon. Full control over the working camera makes the flow of the surgery uncomplicated and eliminates the need for a trained assistant. Furthermore, a 3D HD magnified high color fidelity visualization of the operating field allows a realistic and clear depiction of the anatomic structures similar to the same size of the natural field of eye vision. The surgical team follows the procedure with a 2D HD visualization (111).

The Avatera robot is accompanied by 5mm working instruments. Due to their fine design, a precise and meticulous dissection can be achieved. The robot allows a full range of movements mimicking the human arm. As such, fully articulated instruments possess 7df, a characteristic particularly important for working in narrow operative regions such as the pelvis. The movement of the instrument branches is accomplished with an index and a big finger. The incorporated clutch mechanism allows delicate and precise handling of different anatomic structures. The company offers a wide variety of instruments suitable for most visceral surgical procedures (111).

In addition to the main requirements, the Avatera robot possesses several unique characteristics differentiating it from its competitors. The main such feature is the utilization of fully disposable instruments. The single-use concept for all instruments is associated with several advantages for surgeons and patients. Every single surgery is performed with completely new instruments and there is no potential risk of including damaged instruments in the surgery. Since the instruments are disposable, no risk for cross-contamination exists. The sterilization and cleaning of the instruments is time and cost demanding. Moreover, sterilization and increasing manipulation with the instruments (which for da Vinci robot are quite expensive) can cause their inadvertent damage. All the aforementioned are eliminated with the single-use concept (111).

Another important feature is that all instruments without an exception use bipolar energy. It is well known that transmission of monopolar energy through patient's body can cause undesirable complications including serious cardiovascular events. To avoid these rare but life-threatening complications all instruments of the Avatera robotic platform accommodate only bipolar energy. Last but not least is the communication between the surgical team members. Although the da Vinci robot includes microphone, the transmission of the voice can be sometimes distorted. The Avatera platform seems to overcome this issue. A specifically designed eyepiece covering only eyes and leaving the surgeon's mouth and ears open facilitates easier and unobscured communication. Moreover, the absence of microphones eliminates the transmission of external fans making the performance of the surgery more comfortable (111).

In comparison to other alternative robotic systems, the Avatera system is one of the few to have a closed-console control unit. Most of the emerging RSs have open-consoles and 3D vision is achieved with the help of the glasses. In those systems, the camera control is based on the surgeon's head movements. The camera control of the Avatera system is more intuitive adding comfort to the surgeon. The Revo-I is the only emerging RS having a closed-console control unit. However, it resembles more to the da Vinci Si system and does not possess the aformentioned advantages of the Avatera robot (8, 9).

At a first glance, these technological refinements might seem to be minimal. However, they are all directed to providing better quality to the receiver of the medical services, in this case, patients. These core characteristics will reduce the price of procedures by eliminating additional unnecessary logistic steps and improve their safety. As a result, we could expect to observe fewer surgical site infectious complications following various procedures with the Avaterarobot.

In the meantime, patient's and surgeon's satisfaction will not be impacted. Patients seeking robotic surgery will be satisfied as they will receive high-quality service at reduced prices. The latter will encourage the surgeons to expand the use of the Avatera robot for the treatment of a wider population.

5.2 SWOT analysis

To better understand the current situation, future marketing opportunities, marketing direction SWOT analysis was applied for the current study. In this subchapter, we will present characteristic particularities of the Avatera system, its strengths and weaknesses and their implications for entering the market of robotic medicine. In addition, future opportunities and possible threats will be discussed.

5.2.1 Strengths

The first component of SWOT analysis is the appropriate identification of strengths which is believed to be essential for facilitating the acceptance and spread of the Avatera robot. The differentiating device characteristics such as single-use instruments, use of bipolar energy and slender eyepiece design might affect the quality of the procedures, reducing perioperative complications and improving the clinical outcomes. With all the proposed advantages the Avetera system has similar features to that of the da Vinci platform, considered the standard robotic system for visceral surgeries (9). Not being significantly different the Avatera robot proposes easy-to-learn handling and a modern simplified training concept (111).

An important point is its timely introduction to the market along with the other recently developed alternative robotic platforms. Although some of these RS have already received approvals the number of studies is and the pace of their spread is very slow (9). With a clearly defined marketing strategy, the Avatera has all the possibilities to become the main competitor of the da Vinci system. The specific marketing strategies can be directed to target the existing gaps. As such the primary targets should be the academic and private hospitals of middle and low-income countries where da Vinci robotic system is not implemented yet due to its higher purchase and maintenance costs.

The aforementioned strengths are important but not sufficient for decision-making. The most important factor making the Avatera system appealing for hospital policymakers will be its significantly reduced purchase and maintenance costs. To achieve lower procedural costs, the company has implemented several key concepts. Incorporation of basic features together with the most used set of instruments limits undesirable increases in costs. The elimination of instrument sterilization and damage costs due to their single-use design will further decrease the pricing of procedures (111).

5.2.2 Weaknesses

It is not possible to focus on strengths without a proper evaluation of the weaknesses. Probably the most important weakness of the Avatera system is that there are no performed clinical studies and published articles in the literature. Although this is a natural limitation of each new company entering the market, the importance of the latter factor is probably more pronounced in the medical field. Having well-conducted studies supporting the strengths of the system is particularly important during the initial steps of marketing. It can be expected that over time with the increasing number of articles documenting operational characteristics of the system and clinical outcomes of patients, the issue will become less relevant. Worth to emphasizing that having the first Avatera robots in active academic centers and building supportive evidence in different specialties and procedures should be the priority of the company.

The main competitor of the Avatera remains the da Vinci, despite the fact that there are already alternative RSs in the market. In contrast to the Avatera, there is a piece of huge evidence from the last 20 years from almost all surgical disciplines. Da Vinci is accepted as the standard robotic platform associated with high-quality clinical outcomes (28). In addition, there has been substantial media marketing popularizing it among surgeons and patients. There is already a developed positive attitude towards the da Vinci system (82). Changing these beliefs and attitudes can be somehow challenging and may require some time and effort.

5.2.3 Opportunities

Obviously, planning the future and trying to predict opportunities and threats, as well as designing strategic solutions for different scenarios is detrimental for the continuous growth and expansion of the company. In the case of Avatera robot, some set of technical improvements can be expected. Although current RSs including the Avatera are technologically very sophisticated there is still a place for further improvement. An example of such advancement can be an articulated sealing instrument with an incorporated blade for cutting the sealed tissues. The latter instrument will most probably decrease the surgical time since currently this step is performed by bedside assistants who have a 2D vision, so worse dexterity associated with it. The introduction of 3D vision for the bedside surgical team can be another technical improvement of the Avatera, which might itself shorten the duration of the surgery and improve the overall clinical outcomes (44).

One of the few criticisms of the technical parameters of RSs is that some operating theatres are small and cannot accommodate both the console and robotic cart (44). Thus, the purchase of medical robots can become costlier associated with a need to redesign operating theatre. Although this issue was one of the main criteria of the Avatera and the robotic cart is very slender, having each robotic arm on separate carts can even improve the space usage in the operating theatre with limited space.

The role of RSs has been more emphasized during last year due to the Covid-19 pandemic. Since the beginning of 2020, the situation in many of the countries continues to be very challenging. Many of the planned surgical procedures are postponed due to the overload of hospitals and the caution of nosocomial transmission (117). Even with optimistic predictions, the Covid-19 situation will continue for at least several years. The given necessitates use of such systems which involve minimal number of surgical personnel (118). Further development of artificial intelligence and its integration in the medical systems can eliminate the need for bedside assistance. In addition, the teleoperating RS, which in fact is the Avetera will allow performing surgeries from a separate room without the continuous need to stay with the patient at the same operating theatre.

5.2.4 Threats

Based on the literature review and observation of potential issues of initial models of the da Vinci system, as well as investigation of the current pandemic situation all over the world several potential threats can be mentioned. Although the operational characteristics of the Avatera system have been tested in cadaveric studies, no clinical studies have been performed so far. With future implementation of the RS and increasing clinical use, some technical issues might occur requiring revisions.

In the previous section of future opportunities, the Covid-19 pandemic was considered as a potential stimulus for technological advancement. However, it can impose additional logistic problems on companies. In particular, due to closed borders and impaired inter-country communications, some difficulties in supply and service for the system might arise. Moreover, on-site training might be complicated in some countries. Apparently, these are global issues not dependent on a single company.

Table 2: Strengths, weaknesses, opportunities and costs of the Avatera robotic system.

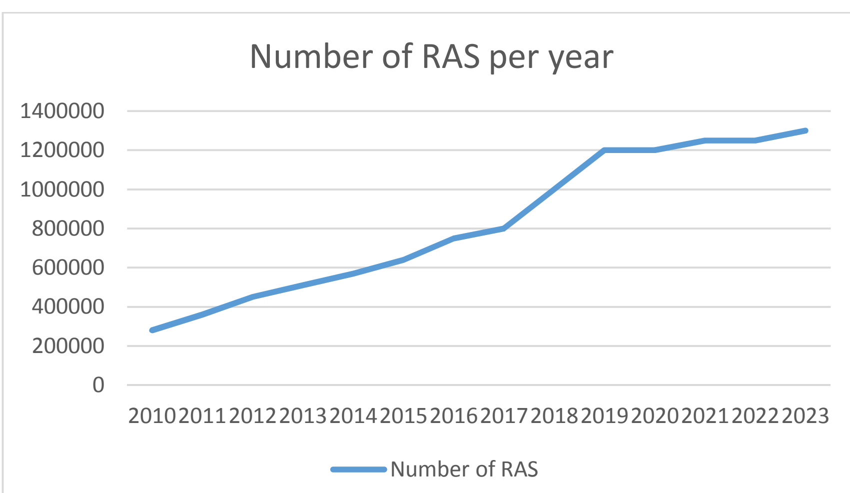
Strengths	Weaknesses
1. Unique device characteristics - Single-use instruments - Use of only bipolar energy - Slender eye-piece design 2. Similar high quality as the standard robot 3. Focusing on essential system functions 4. Easy-to-learn handling and modern training concept 5. Timely introduction of the RS 6. Reduced costs for robotic service	1. No clinical studies on the Avatera platform 2. Well established operational and functional features of da Vinci robot 3. Difficulties in changing surgeons' attitudes and beliefs.
Opportunities	**Threats**
1. Further technological improvements - Robotic sealing instruments (simultaneous cutting and hemostasis) - 3D vision for all bedside surgical team - Separate carts for each arm 2. Covid-19 - Surgeries requiring minimal surgical personal involvement - The increasing need for one-day MAS surgeries	1. Technical defects of the robot 2. Covid-19 associated issues - Supply difficulties - Training difficulties

5.3 Future opportunities of the Avatera system

In previous chapters, the role of and the expanding use of the da Vinci system has been emphasized. The benefits of RAS are improved vision and a better range of instruments movements. In addition, the robotic platform has significantly improved the comfort for surgeons and raised the attractiveness for patients towards different surgical procedures. Despite the monopoly and high purchase and maintenance costs, marginal improvements of clinical outcomes or even the absence of any improvement that probably have slowed down the pace of its spread, the company continued to prosper and increase the annual number of performed procedures and installed systems worldwide.

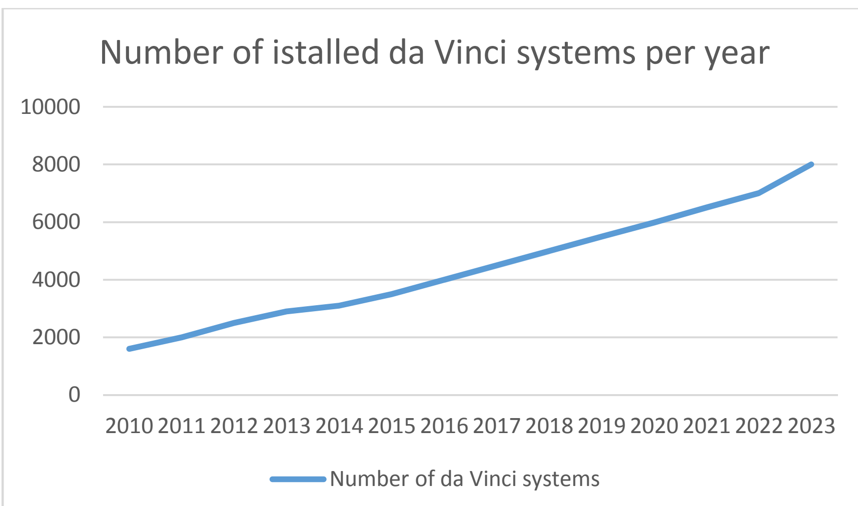
To demonstrate the trends of the da Vinci robotic platform, a projective statistical estimation based on secondary data, including the trends toward 2023, was performed. As shown in Diagram 1 the annual number of RAS has significantly increased during the last decade. In 2010 was approximately 360.000 RAS performed worldwide. Within 10 years a continuous increase was observed reaching annual number of 1.2 million surgeries (119, 120). Although during the last 2 years the numbers tend to increase, this tendency was not as pronounced as that of in 2017-2019. Based on the existing data a projective ≈10% increase in the annual number of da Vinci surgeries was assumed till 2023.

Diagram 1: The projective annual number of RAS performed by da Vinci systems worldwide



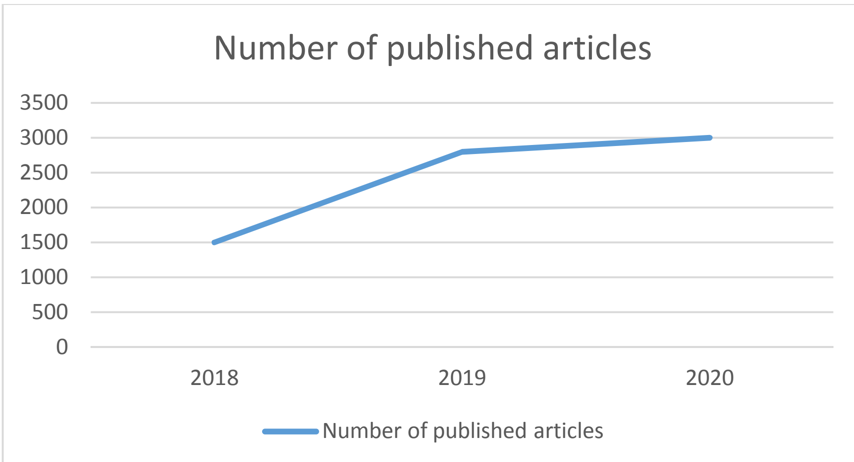
To correctly interpret the real situation in the robotic market it is essential to analyze the trends of the annual number of installed da Vinci systems in conjunction with the volume of the surgeries worldwide. Diagram 2 shows a highly linear increase with a mean number of 500 additionally installed da Vinci RSs every year (119, 120). Overlaying the 2 latter diagrams allows us to come to a logical conclusion. Despite a linear increase in the number of da Vinci robots, the annual number of surgeries seemed to reach its plateau in 2019, probably due to the saturation with the expensive da Vinci systems. Currently, it seems the da Vinci platform does not possess the ability to further increase the productivity of the robots. The aforementioned in addition to the current Covid-19 pandemic, which definitely has affected the economy of many countries and the income of people, requires new devices for delivering medical care at better prices. It can be assumed that both the medical care providers and patients, in general, will search for cheaper alternatives possessing the same quality. Therefore, the introduction of a cheaper robot is very timely and has the potential to significantly affect the existing market.

Diagram 2: The number of installed da Vinci RSs worldwide



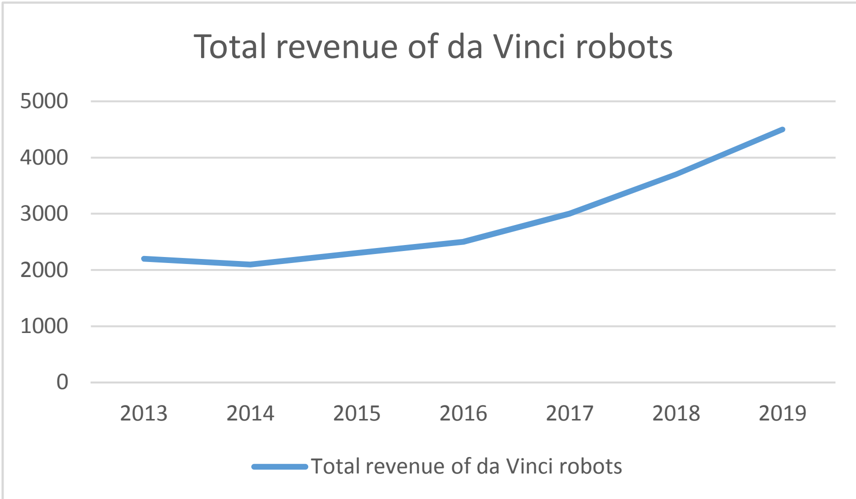
Currently, there are more than 24.000 papers published in Pubmed referencing da Vinci robots. A pronounced increase was observed during the last 2 years (24.2%) (Diagram 3). In 2019 the number comprised approximately 2.800 whereas in 2020 it already surpassed 3.000 paper (28, 120). The given indicates, an increasing interest in the da Vinci system in the academic community. It can be assumed that this high interest was due to performing RAS and not due to the use of the specific RS. The emerging alternative RSs and the possible competition will further result in an incremental increase in the number of published articles.

<u>Diagram 3:</u> The number of published articles during the last 3 years



As expected, the described trends in numbers of procedures and RSs installment increased the overall revenue of the company. While the annual revenue from da Vinci robots was approximately 2 – 2.5 billion US dollars (120), a dramatic increase was observed within the last 2 years reaching a maximum of 4.5 billion US dollars (Diagram 4) (121). Even in 2020 with the crisis caused by the Covid-19 pandemic, a 4% increase and a total of 1.33 billion US dollars were reported for the last quarter compared to the same period in 2019 (total revenue of the last quarter in 2019 comprised 1.28 billion US dollars) (122). Considering the profits of the da Vinci system, we can assume that in the worst case scenario small revenues can still be expected from the launching of the Avatera system. It can be also assumed that fewer years will be required from the latter system to reach the annual numbers RAS of the da Vinci system depicted in Diagram 1.

Diagram 4: Overall revenue from da Vinci RSs



All of the aforementioned parameters are important to understand the existing trends and predict the future of RAS. Intuitive has revolutionized the medical field and currently, robotic surgery is not anymore a novelty. In 2018 the surgical robot market was worth 6.8 billion US dollars. It is expected that the market will reach the 17 billion US dollars threshold, a market of almost 3 times bigger than that of in 2018, already in 2025 (121). In addition, the presence of RSs has changed the competition between different hospitals. Recently it has been reported that the absence of RS resulted in the closure of 25% of centers performing RARP in the English National Health Service (121). It can be now definitely claimed that the da Vinci robot has a huge role in the current development of surgical specialties, however, higher costs associated with its use still remain a major limitation. What do new systems, and the Avatera in particular offer, is the same quality comfort for surgeons, same reputation for the medical centers and possibility of performing similar high-quality procedures at lower costs. To be able to adequately evaluate the future development of the company and effectively organize the fast pace of spread of the current alternative RS, it is crucial to develop appropriate pricing strategy and outline primary, secondary and tertiary targets.

Apparently, calculation of procedural costs is difficult. Several technical components including purchase and maintenance costs of the robotic device itself, instrument sterilization and potential damage can contribute to cost formation. In addition, to evaluate cost-effectiveness of the RAS procedures, perioperative clinical outcomes such as surgery duration and length of postoperative hospital stay, development of perioperative complications and readmission rates should be additionally encountered. To make our calculations simple we would assume that the Avatera robot will possess a similar clinical safety profile for patients as that of the da Vinci robot. For our gross calculation, we will consider a hypothetical average cost of around €5.000 (≈ $6.000) for a RARP at a standard private hospital in Greece (considered a high-income country). Extracting administrative costs, medication, hospitalization, and surgery including charges for robotic instruments and maintenance (cost per use = $1.500), a 20% (€1.000 ≈ $1.200) grossly estimated profit can be expected. With a purchase price for the da Vinci Xi robot of approximately $2 million, adding the annual maintenance costs, a mean annual number of 500 RAS, almost 5 years will be required from the hospital to compensate for its purchase costs. Calculating for a single procedure the utilization of the da Vinci Xi robot will increase the price of the surgery by almost $2.500. Worth mentioning that the recent modification of the da Vinci Xi robot, the da Vinci X has the potential to be assembled according to the customer's needs eliminating the incorporation of expensive services. The given allows decreasing the purchase cost from 2 million to approximately 1.5 million.

From the alternative systems, the recently introduced Senhance surgical robot device is available with a purchase price of $1-1.2 million. In comparison to da Vinci, approximate costs per use constitute $1.500, the Senhance robotic system is associated with $200-500 additional costs. As such the latter robot has demonstrated significant purchase and per-use cost reduction (103). According to the provided costs, an almost $1.500 cost reduction ($1.000 (difference of per-use costs) + $500 (difference of purchase costs calculated for 5years)) can be achieved for each procedure. Nevertheless, the Senhance system should be viewed more as an alternative/competitor to the conventional laparoscopy. The system consists of separate a surgeon-console and 3 robotic arms, can be claimed to improve the ergonomics for the surgeons and has some features of other RSs, it still lacks one of the main and distinctive functions (Endowrist function with 7df) responsible for the reported better clinical outcomes.

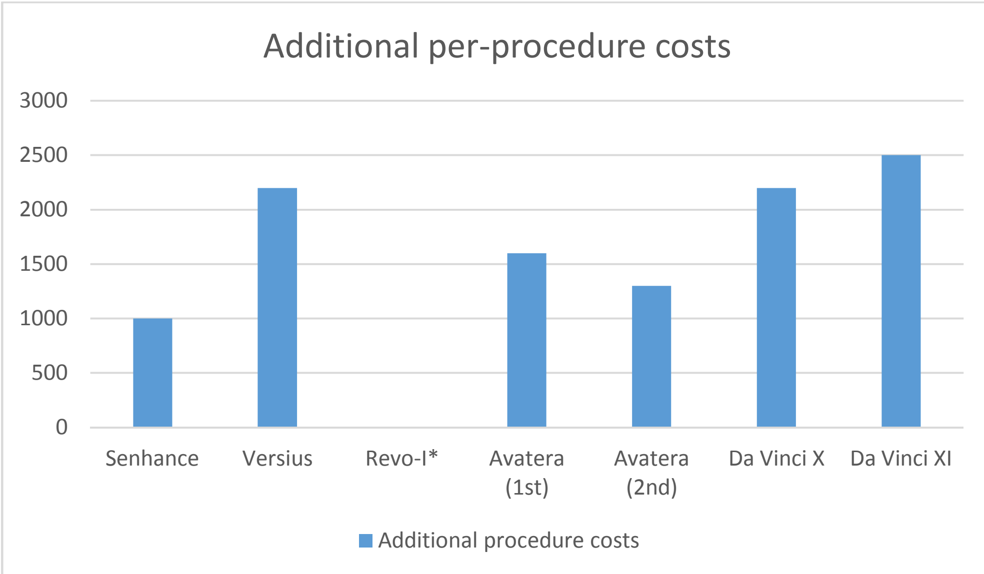
The official pricing of another CE-approved Versius robotic system is not available yet. However, the approximate possible purchase price can be around $1.5 million and with the costs of per-procedure instruments of $1.500. Apparently, a question may arise. Why should hospitals invest in a new, less tested and investigated robotic platform with minimal cost benefits?

To have a better understanding of the effect of the purchase cost on the final procedural cost, two different scenarios will be discussed. In the first scenario setting the purchase cost of the Avatera at around $1.3-1.5 million, in the same range as the Senhance and the Versius, a total $400 (i.e. $600 required) reduction of the procedural can be calculated assuming a similar hypothetical annual number of performed RAS. Further, cost reduction can be expected with the utilization of cheaper single-use instruments (< $1.000) and elimination of their sterilization. As such, the price of the RARP at a standard private hospital in Greece can be expected to decrease by as much as €800-900 reaching a hypothetical 4.100€ from the estimated 5.000€.

For the second scenario, the initial purchase cost of the Avatera robot will be set at $700.000. Considering a 5-year period with an annual RAS volume of 500 procedures, only an additional $300 will be attributed to the robot. Adding the instrument costs (≈ $1.000), procedural costs of $1.300 can be expected, which will be significantly lower compared to the da Vinci ($2.500) and a little higher compared to Senhance ($1.000). Assuming that the Avatera has similar characteristics to that of the da Vinci system, the aforementioned cost reduction can change the vector of decision making toward acquiring the Avatera robot. The comparisons of the per procedure costs are demonstrated in Diagram 5.

The latter can make the procedure more affordable for a wider population and thus increase the profitability of the Avatera RS. However, in our estimation, we assumed that the clinical outcomes for both RS are similar. Since the da Vinci system is extensively studied while no publications exist so far to support the Avatera platform, a further decrease of the purchase cost for Avatera might be needed to make the system more appealing for hospitals. Thus, a purchase cost between 700.000 – 800.000$ seems reasonable during the initial phases of market entrance.

Diagram 5: Additional per-procedure costs attributed to the utilization of the robotic system



**Not available*

An essential component for a successful business strategy is to identify the potential targets. According to our observation, the potential buyers can be included into 2 target groups.

1. Hospitals that do not have any RS but want to purchase one
2. Hospitals that have already da Vinci robot, but not all procedures are treated robotically due to cost constraints

The first and the biggest target group for the Avatera are the hospitals that are not equipped with any robot. This category can include public and private hospitals in countries with already existing RS and most important countries, where RS is not affordable due to higher purchase costs of da Vinci and the absence of technical assistance. Up to now, most of the da Vinci systems are installed in Northern America and Europe, with limited numbers in Asia, Africa and Southern America. This opens a huge field for a new system to easily enter the market and become the only player.

The second target group is hospitals that already possess da Vinci. For the second target immediate and delayed possibilities for the Avatera can be visualized. Since the da Vinci system is expensive, it is reserved for more complex surgeries mostly. Bringing the costs down can allow the hospitals to acquire the Avatera and utilize it for procedures deemed to be not cost-effective for da Vinci assistance. Over time with the increased experience and rising popularity it may replace the da Vinci robot for already standardized procedures. Having the trends of the da Vinci system as a reference, a projective development of the Avatera system can be estimated. Entering the market in 2022, we expect an incremental rise in the annual number of surgeries from 2025-2026 (Diagram 6). Similarly, it can be assumed that the number of installed Avatera systems will demonstrate a significant increase starting from 2026 (Diagram 7). Thus, the first 3 years will be allocated to deliver the systems to several hospitals, increase the number of publications, build supportive evidence showing its clinical outcomes and improved cost-effectiveness, and perform large-scale media marketing. Hypothetically, the following goals can be achieved by Avatera in 10-years period:

- Major RS player in countries without any RS till now (Avatera comprising about 70 – 80% of the market in those countries)
- Approximately 50% installation rate in hospitals without any RS in countries already possessing the da Vinci system
- 10-20% installation rate by the hospitals already possessing the da Vinci system

Diagram 6: Projective annual number of RAS using Avatera robotic system

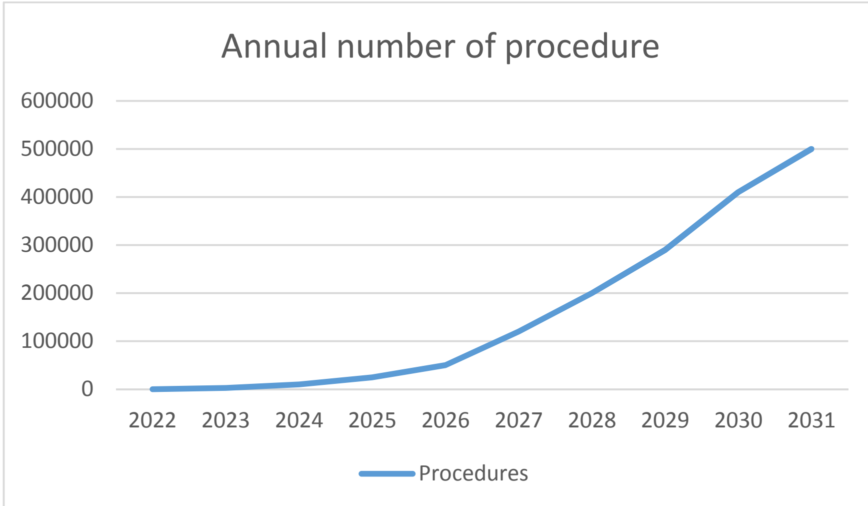
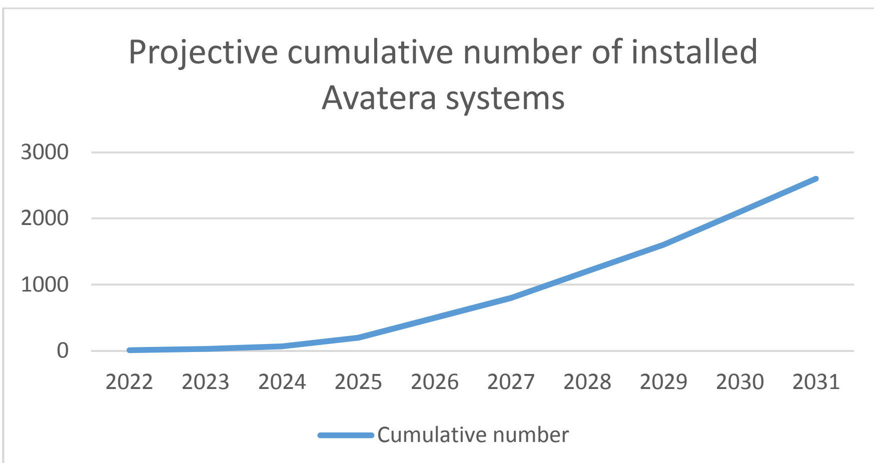


Diagram 7: Projective cumulative number of installed Avatera robotic systems worldwide



6. Conclusions

The first robot-assisted surgery was performed in 2001 to treat prostate cancer. Since its first introduction, there is a continuous and constant increase in the number of RAS in all disciplines. Most of the RAS are performed in general surgery, urology and gynecology. Currently, the da Vinci robotic system is the main player in the market with more than 8.5 million performed cases and almost 6000 installed systems worldwide. Due to the various patents, the latter system had a monopoly in the market till 2019. With the expiry of the existing patents, new alternative RS had the possibility to enter the market. The new alternative systems include the Senhance system (Transenterix, Morrisville, NC, USA), Revo-I (Meere Company, Hwasong, Korea), Hugo RAS (Medtronic, Dublin, Ireland), Versius (CMR Surgical, Cambridge, GB), Flex Surgical System (Medrobotics, Raynham, USA) and Avatera (Avateramedical, Jena, Germany). Several systems have already received FDA and CE approval, while other systems are in the preclinical stage and approval is expected in 2021. The Avatera represents one of the most promising platforms emerged so far. Founded in 2011 it aims to bring patients the highest surgical standards at reduced and affordable costs. The robotic system is space-saving and consists of a robotic cart with 4 arms and a closed-console control unit for an operating surgeon. The particular design of the eyepiece leaves the surgeon's ear and mouth uncovered facilitating unobscured cooperation of the surgeon with his operating team during procedures. The system incorporates a full HD resolution with high color fidelity. Higher, clear picture resolution displaying the same size of the natural field of eye vision makes the robotic system more appealing. It utilizes single-use instruments minimizing the risk of instrument contamination, eliminating the need for re-sterilization and thereof associated costs. The slender instruments with a diameter of 5 mm have a higher range of mobility due to 7df. Furthermore, as a unique characteristic of the Avatera system, all instruments can accommodate bipolar energy excluding the potential risk of injury due to use of the monopolar energy.

With so many alternative systems emerging, there is currently a need for market analysis to understand the real gaps of robotic medicine. Thus, the aim of the current study was to investigate the role and the trends of robotic surgery among different medicalspecialties, identify the potential issues slowing down the pace of its spread, perform market analysis and evaluate the potential opportunities and possible competitiveness of new alternative high precision robotic devices. Given the aforementioned, a descriptive quantitative research design was applied to establish the statistical relevance of the results to the described objective. After the collection of secondary data, its interpretation was performed using the strengths, weaknesses, opportunities and threats (SWOT) statistical analysis method. Its main strengths are unique device characteristics, timely introduction to the market and significantly reduced purchase and service costs. The absence of clinical studies and positive surgeons' attitudes and beliefs towards the da Vinci robots can the initial obstacles of the Avatera robots. The Covid-19 pandemic can impose additional supply and training difficulties. On the other hand, a future increase of demand for the RAS can be expected since these surgeries are minimally invasive, provide telesurgery opportunities and shorten the hospital length of stay. The given opens a great opportunity for Avatera to reach fast expansion worldwide.

To potentiate the chances of success the marketing should be directed according to primary and secondary target groups. In our opinion, the biggest target group for the Avatera are the hospitals that are not equipped with any robot. The second target group includes hospitals that already possess da Vinci. For the second target immediate and delayed possibilities for the Avatera can be visualized. Hypothetically, the following goals can be achieved by Avatera in 5-years period:

- Major RS player in countries without any RS till now (Avatera comprising about 70 – 80% of the market in those countries)
- Approximately 50% installation rate in hospitals without any RS in countries already possessing the da Vinci system
- 10-20% installation rate by the hospitals already possessing the da Vinci system

To reach the aforementioned goals a flexible pricing policy should be applied. In order to have significant procedure cost reduction and make the Avatera system appealing for the hospital decision-makers the purchase cost should be set to less than 800,000$.

6.1 Implications for public and private hospitals

It is expected that the production and utilization of the Avatera system will greatly affect and reshape the market of robotic surgery. Those changes will additionally affect both the private and public sectors. As such following implications can be expected in the public sector:

1. Making the robotic system more affordable, a higher number of patients will receive the highest standard minimally invasive treatment modality in the public sector. As such, patients will not be rejected to receive any RAS due to higher procedural costs. The given is particularly important for medical conditions for which RAS has already been proven to be superior. Providing the highest standards of care to patients will definitely have a public health implication.
2. Another public health implication will be an installment of robotic systems in many regions of different countries. The patients will not be forced to travel to other regions to receive the best treatment. It will also decrease the waiting time, the time period between the diagnosis and definitive treatment, and potentially improve postoperative morbidity and mortality.
3. Due to reduced procedural costs, robots can be utilized for conditions initially considered non-cost-effective. As a result, using the advantages of robotic systems, improvement of clinical outcomes following different conditions can be expected.

Similar positive implications can be expected for private sector.

1. In the private sector, reduction of procedure costs will increase the attractiveness of the RAS for patients, resulting in an increased number of RAS procedures. This will increase the profits of

the hospitals and increase the profits of the robotic companies. Thus, cost reduction of the Avatera systems may possess a win-win situation for all parties.

6.2 Research limitations

Our research was associated with several limitations. A major criticism can be the absence of any clinical data for the Avatera system. Although its effectiveness has been proven in the cadaver studies, no data on human studies are available so far. With the implementation of Avatera in the clinical practice the real effectiveness, as well as potential disadvantages of the RS, can be accurately identified and evaluated. The absence of clinical data is one of the major threats and is discussed in SWOT analysis. Another drawback of the research is that the Avatera robotic system has not been launched and the costs of the system are not known yet. Having the exact purchase and maintenance costs, better market predictions could be possible. In order to minimize the inaccuracies for calculations of procedural costs, two different scenarios with different purchase costs were presented and thoroughly discussed. As such this research demonstrates what can be expected if the purchase price of the Avatera system is in the range of $1.2-1.5 million and $700,000-800,000.

None withstanding to the discussed limitations, the current study is the first to evaluate market opportunities for the new Avatera robotic system using the SWOT analysis method.

Bibliography

1. Nakadate R, Arata J, Hashizume M. Next-generation robotic surgery--from the aspect of surgical robots developed by industry. Minimally invasive therapy & allied technologies : MITAT : official journal of the Society for Minimally Invasive Therapy. 2015;24(1):2-7.
2. Rassweiler JJ, Autorino R, Klein J, Mottrie A, Goezen AS, Stolzenburg JU, et al. Future of robotic surgery in urology. BJU international. 2017;120(6):822-41.
3. Matanes E, Boulus S, Lowenstein L. The Implementation of Robotic Surgery in Israel. The Israel Medical Association journal : IMAJ. 2015;17(9):563-6.
4. Kaye DR, Mullins JK, Carter HB, Bivalacqua TJ. Robotic surgery in urological oncology: patient care or market share? Nature reviews Urology. 2015;12(1):55-60.
5. Yu HY, Hevelone ND, Lipsitz SR, Kowalczyk KJ, Hu JC. Use, costs and comparative effectiveness of robotic assisted, laparoscopic and open urological surgery. The Journal of urology. 2012;187(4):1392-8.
6. Liberman D, Trinh QD, Jeldres C, Zorn KC. Is robotic surgery cost-effective: yes. Current opinion in urology. 2012;22(1):61-5.
7. Alkhateeb S, Lawrentschuk N. Consumerism and its impact on robotic-assisted radical prostatectomy. BJU international. 2011;108(11):1874-8.
8. Gozen A, Rassweiler J. [Robotic surgery in Urology : New kids on the block]. Der Urologe Ausg A. 2020;59(9):1044-50.
9. Kinross JM, Mason SE, Mylonas G, Darzi A. Next-generation robotics in gastrointestinal surgery. Nature reviews Gastroenterology & hepatology. 2020;17(7):430-40.
10. Weiser TG, Regenbogen SE, Thompson KD, Haynes AB, Lipsitz SR, Berry WR, et al. An estimation of the global volume of surgery: a modelling strategy based on available data. Lancet. 2008;372(9633):139-44.
11. Statistics NCfH. Surgery Statistics 2009. Available from: https://stanfordhealthcare.org/medical-clinics/surgery-clinic/patient-resources/surgery-statistics.html.
12. Kelley WE, Jr. The evolution of laparoscopy and the revolution in surgery in the decade of the 1990s. JSLS : Journal of the Society of Laparoendoscopic Surgeons. 2008;12(4):351-7.
13. Berci G. Present and future developments in endoscopy. Proceedings of the Royal Society of London Series B, Biological sciences. 1977;195(1119):235-42.
14. Berci G, Davids J. Endoscopy and television. British medical journal. 1962;1(5292):1610-3.
15. Litynski GS. Endoscopic surgery: the history, the pioneers. World journal of surgery. 1999;23(8):745-53.
16. Manson AL, Terhune D, Jordan G, Auman JR, Peterson N, MacDonald G. Preoperative laparoscopic localization of the nonpalpable testis. J Urol. 1985;134(5):919-20.
17. Schuessler WW, Vancaillie TG, Reich H, Griffith DP. Transperitoneal endosurgical lymphadenectomy in patients with localized prostate cancer. J Urol. 1991;145(5):988-91.
18. Clayman RV, Kavoussi LR, Soper NJ, Dierks SM, Meretyk S, Darcy MD, et al. Laparoscopic nephrectomy: initial case report. J Urol. 1991;146(2):278-82.
19. Gagner M, Lacroix A, Bolte E. Laparoscopic adrenalectomy in Cushing's syndrome and pheochromocytoma. The New England journal of medicine. 1992;327(14):1033.
20. Schuessler WW, Schulam PG, Clayman RV, Kavoussi LR. Laparoscopic radical prostatectomy: initial short-term experience. Urology. 1997;50(6):854-7.
21. Ljungberg B, Albiges L, Bensalah K, Bex A, Giles RH, Hora M, et al. EAU Guidelines on Renal Cell Carcinoma. European Association of Urology 2020.

22. Rassweiler J, Frede T, Seemann O, Stock C, Sentker L. Telesurgical laparoscopic radical prostatectomy. Initial experience. European urology. 2001;40(1):75-83.
23. Pasticier G, Rietbergen JB, Guillonneau B, Fromont G, Menon M, Vallancien G. Robotically assisted laparoscopic radical prostatectomy: feasibility study in men. European urology. 2001;40(1):70-4.
24. Autorino R, Zargar H, White WM, Novara G, Annino F, Perdona S, et al. Current applications of near-infrared fluorescence imaging in robotic urologic surgery: a systematic review and critical analysis of the literature. Urology. 2014;84(4):751-9.
25. Autschbach R, Falk V, Stein H, Mohr FW. Experience with a new OR dedicated to robotic surgery. Minimally invasive therapy & allied technologies : MITAT : official journal of the Society for Minimally Invasive Therapy. 2000;9(3-4):213-7.
26. Kaouk J, Garisto J, Bertolo R. Robotic Urologic Surgical Interventions Performed with the Single Port Dedicated Platform: First Clinical Investigation. European urology. 2019;75(4):684-91.
27. Kaouk J, Garisto J, Eltemamy M, Bertolo R. Single-port Robotic Intracorporeal Ileal Conduit Urinary Diversion During Radical Cystectomy Using the SP Surgical System: Step-by-step Technique. Urology. 2019;130:196-200.
28. Surgical I. Sustainability report 2020 2020. Available from: https://www.intuitive.com/en-us/-/media/Project/Intuitive-surgical/files/pdf/2020-intuitive-sustainability-report.pdf.
29. Khalafallah YM, Bernaiche T, Ranson S, Liu C, Collins DT, Dort J, et al. Residents' Views on the Impact of Robotic Surgery on General Surgery Education. Journal of surgical education. 2020.
30. Nakauchi M, Uyama I, Suda K, Mahran M, Nakamura T, Shibasaki S, et al. Robotic surgery for the upper gastrointestinal tract: Current status and future perspectives. Asian journal of endoscopic surgery. 2017;10(4):354-63.
31. Kamarajah SK, Bundred JR, Marc OS, Jiao LR, Hilal MA, Manas DM, et al. A systematic review and network meta-analysis of different surgical approaches for pancreaticoduodenectomy. HPB : the official journal of the International Hepato Pancreato Biliary Association. 2020;22(3):329-39.
32. Ciria R, Berardi G, Alconchel F, Briceno J, Choi GH, Wu YM, et al. The impact of robotics in liver surgery: A worldwide systematic review and short-term outcomes meta-analysis on 2,728 cases. Journal of hepato-biliary-pancreatic sciences. 2020.
33. Fung AK, Aly EH. Robotic colonic surgery: is it advisable to commence a new learning curve? Diseases of the colon and rectum. 2013;56(6):786-96.
34. Damle A, Damle RN, Flahive JM, Schlussel AT, Davids JS, Sturrock PR, et al. Diffusion of technology: Trends in robotic-assisted colorectal surgery. American journal of surgery. 2017;214(5):820-4.
35. Wright JD, Herzog TJ, Tsui J, Ananth CV, Lewin SN, Lu YS, et al. Nationwide trends in the performance of inpatient hysterectomy in the United States. Obstetrics and gynecology. 2013;122(2 Pt 1):233-41.
36. Li C, Hua K. The current status of sacrocolpopexy in the management of apical prolapse. Minerva ginecologica. 2020;72(3):165-70.
37. Arian SE, Munoz JL, Kim S, Falcone T. Robot-assisted laparoscopic myomectomy: current status. Robotic surgery. 2017;4:7-18.
38. O'Malley DM, Smith B, Fowler JM. The role of robotic surgery in endometrial cancer. Journal of surgical oncology. 2015;112(7):761-8.
39. Smith AJB, Jones TN, Miao D, Fader AN. Minimally Invasive Radical Hysterectomy for Cervical Cancer: A Systematic Review and Meta-analysis. Journal of minimally invasive gynecology. 2020.

40. Moller T, Egberts JH, Eichhorn M, Hofmann HS, Kruger I, Ruckert JC, et al. Current status and evolution of robotic-assisted thoracic surgery in Germany-results from a nationwide survey. Journal of thoracic disease. 2019;11(11):4807-15.
41. Kanzaki M. Current status of robot-assisted thoracoscopic surgery for lung cancer. Surgery today. 2019;49(10):795-802.
42. Nakayama M, Holsinger FC, Chevalier D, Orosco RK. The dawn of robotic surgery in otolaryngology-head and neck surgery. Japanese journal of clinical oncology. 2019;49(5):404-11.
43. Donnely E, Griffin MF, Butler PE. Robotic Surgery: A Novel Approach for Breast Surgery and Reconstruction. Plastic and reconstructive surgery Global open. 2020;8(1):e2578.
44. Bonatti J, Wallner S, Winkler B, Grabenwoger M. Robotic totally endoscopic coronary artery bypass grafting: current status and future prospects. Expert review of medical devices. 2020;17(1):33-40.
45. Cao C, Wolfenden H, Liou K, Pathan F, Gupta S, Nienaber TA, et al. A meta-analysis of robotic vs. conventional mitral valve surgery. Annals of cardiothoracic surgery. 2015;4(4):305-14.
46. Qin Y, Han H, Xue Y, Wu C, Wei X, Liu Y, et al. Comparison and trend of perioperative outcomes between robot-assisted radical prostatectomy and open radical prostatectomy: nationwide inpatient sample 2009-2014. International braz j urol : official journal of the Brazilian Society of Urology. 2020;46(5):754-71.
47. Trinh QD, Sammon J, Sun M, Ravi P, Ghani KR, Bianchi M, et al. Perioperative outcomes of robot-assisted radical prostatectomy compared with open radical prostatectomy: results from the nationwide inpatient sample. European urology. 2012;61(4):679-85.
48. Groeben C, Koch R, Baunacke M, Wirth MP, Huber J. Robots drive the German radical prostatectomy market: a total population analysis from 2006 to 2013. Prostate cancer and prostatic diseases. 2016;19(4):412-6.
49. Menon M, Hemal AK, Tewari A, Shrivastava A, Shoma AM, El-Tabey NA, et al. Nerve-sparing robot-assisted radical cystoprostatectomy and urinary diversion. BJU international. 2003;92(3):232-6.
50. Tyritzis SI, Collins JW, Wiklund NP. The current status of robot-assisted cystectomy. Indian journal of urology : IJU : journal of the Urological Society of India. 2018;34(2):101-9.
51. Fujimura T. Current status and future perspective of robot-assisted radical cystectomy for invasive bladder cancer. International journal of urology : official journal of the Japanese Urological Association. 2019;26(11):1033-42.
52. Parekh DJ, Reis IM, Castle EP, Gonzalgo ML, Woods ME, Svatek RS, et al. Robot-assisted radical cystectomy versus open radical cystectomy in patients with bladder cancer (RAZOR): an open-label, randomised, phase 3, non-inferiority trial. Lancet. 2018;391(10139):2525-36.
53. Khetrapal P, Conroy S, Kelly JD, Catto JWF. Comparing open-radical cystectomy and robot-assisted radical cystectomy: current status and analysis of the evidence. Current opinion in urology. 2020;30(3):400-6.
54. Alameddine M, Koru-Sengul T, Moore KJ, Miao F, Savio LF, Nahar B, et al. Trends in Utilization of Robotic and Open Partial Nephrectomy for Management of cT1 Renal Masses. European urology focus. 2019;5(3):482-7.
55. Ouzaid I, Bernhard JC, Bigot P, Nouhaud FX, Long JA, Boissier R, et al. Trends in the practice of renal surgery for cancer in France after the introduction of robotic-assisted surgery: data from the National Health Care System Registry. Journal of robotic surgery. 2020;14(5):799-801.
56. Ali S, Ahn T, Papa N, Perera M, Teloken P, Coughlin G, et al. Changing trends in surgical management of renal tumours from 2000 to 2016: a nationwide study of Medicare claims data. ANZ journal of surgery. 2020;90(1-2):48-52.

57. Cheung H, Wang Y, Chang SL, Khandwala Y, Del Giudice F, Chung BI. Adoption of Robot-Assisted Partial Nephrectomies: A Population-Based Analysis of U.S. Surgeons from 2004 to 2013. Journal of endourology. 2017;31(9):886-92.
58. Porpiglia F, Checcucci E, Amparore D, Piramide F, Volpi G, Granato S, et al. Three-dimensional Augmented Reality Robot-assisted Partial Nephrectomy in Case of Complex Tumours (PADUA >/=10): A New Intraoperative Tool Overcoming the Ultrasound Guidance. European urology. 2020;78(2):229-38.
59. Seetharam Bhat KR, Moschovas MC, Onol FF, Rogers T, Roof S, Patel VR, et al. Robotic renal and adrenal oncologic surgery: A contemporary review. Asian journal of urology. 2021;8(1):89-99.
60. Pal RP, Koupparis AJ. Expanding the indications of robotic surgery in urology: A systematic review of the literature. Arab journal of urology. 2018;16(3):270-84.
61. Breda A, Territo A. Can the robotic approach replace open surgery in kidney transplantation? World journal of urology. 2020.
62. Gozen AS, Tokas T, Tawfick A, Mousa W, Kotb M, Tzanaki E, et al. Robot-assisted vasovasostomy and vasoepididymostomy: Current status and review of the literature. Turkish journal of urology. 2020;46(5):329-34.
63. Atug F, Woods M, Burgess SV, Castle EP, Thomas R. Robotic assisted laparoscopic pyeloplasty in children. The Journal of urology. 2005;174(4 Pt 1):1440-2.
64. Light A, Karthikeyan S, Maruthan S, Elhage O, Danuser H, Dasgupta P. Peri-operative outcomes and complications after laparoscopic vs robot-assisted dismembered pyeloplasty: a systematic review and meta-analysis. BJU international. 2018;122(2):181-94.
65. Chen CJ, Peters CA. Robotic Assisted Surgery in Pediatric Urology: Current Status and Future Directions. Frontiers in pediatrics. 2019;7:90.
66. Puliatti S, Mazzone E, Dell'Oglio P. Training in robot-assisted surgery. Current opinion in urology. 2020;30(1):65-72.
67. Wiener S, Haddock P, Shichman S, Dorin R. Construction of a Urologic Robotic Surgery Training Curriculum: How Many Simulator Sessions Are Required for Residents to Achieve Proficiency? Journal of endourology. 2015;29(11):1289-93.
68. Beulens AJW, Hashish YAF, Brinkman WM, Umari P, Puliatti S, Koldewijn EL, et al. Training novice robot surgeons: Proctoring provides same results as simulator-generated guidance. Journal of robotic surgery. 2020.
69. Raad WN, Ayub A, Huang CY, Guntman L, Rehmani SS, Bhora FY. Robotic Thoracic Surgery Training for Residency Programs: A Position Paper for an Educational Curriculum. Innovations. 2018;13(6):417-22.
70. Moit H, Dwyer A, De Sutter M, Heinzel S, Crawford D. A Standardized Robotic Training Curriculum in a General Surgery Program. JSLS : Journal of the Society of Laparoendoscopic Surgeons. 2019;23(4).
71. Dell'Oglio P, Turri F, Larcher A, D'Hondt F, Sanchez-Salas R, Bochner B, et al. Definition of a Structured Training Curriculum for Robot-assisted Radical Cystectomy with Intracorporeal Ileal Conduit in Male Patients: A Delphi Consensus Study Led by the ERUS Educational Board. European urology focus. 2021.
72. Klapczynski C, Sallee C, Tardieu A, Peschot C, Boutot M, Mohand N, et al. Training for next generation surgeons: a pilot study of robot-assisted hysterectomy managed by resident using dual console. Archives of gynecology and obstetrics. 2020.
73. Merrill SB, Sohl BS, Thompson RH, Reese AC, Parekh DJ, Lynch JH, et al. The Balance between Open and Robotic Training among Graduating Urology Residents-Does Surgical Technique Need Monitoring? The Journal of urology. 2020;203(5):996-1002.

74. Martin R, Hsu J, Soliman MK, Bastawrous AL, Cleary RK. Incorporating a Detailed Case Log System to Standardize Robotic Colon and Rectal Surgery Resident Training and Performance Evaluation. Journal of surgical education. 2019;76(4):1022-9.
75. Beulens AJW, Vaartjes L, Tilli S, Brinkman WM, Umari P, Puliatti S, et al. Structured robot-assisted surgery training curriculum for residents in Urology and impact on future surgical activity. Journal of robotic surgery. 2020.
76. Balbona J, Patel T. The Hidden Curriculum: Strategies for Preparing Residents for Practice. Current urology reports. 2020;21(10):39.
77. Wright JD, Tergas AI, Hou JY, Burke WM, Chen L, Hu JC, et al. Effect of Regional Hospital Competition and Hospital Financial Status on the Use of Robotic-Assisted Surgery. JAMA surgery. 2016;151(7):612-20.
78. Shih YT, Shen C, Hu JC. Do Robotic Surgical Systems Improve Profit Margins? A Cross-Sectional Analysis of California Hospitals. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research. 2017;20(8):1221-5.
79. Spaulding AC, Hamadi H, Osagiede O, Lemini R, Cochuyt JJ, Watson J, et al. Hospital robotic use for colorectal cancer care. Journal of robotic surgery. 2020.
80. Mirkin JN, Lowrance WT, Feifer AH, Mulhall JP, Eastham JE, Elkin EB. Direct-to-consumer Internet promotion of robotic prostatectomy exhibits varying quality of information. Health affairs. 2012;31(4):760-9.
81. Schiavone MB, Kuo EC, Naumann RW, Burke WM, Lewin SN, Neugut AI, et al. The commercialization of robotic surgery: unsubstantiated marketing of gynecologic surgery by hospitals. American journal of obstetrics and gynecology. 2012;207(3):174 e1-7.
82. Wright JD, Raglan GB, Schulkin J, Fialkow MF. Attitudes and Beliefs Regarding the Utility of Robotically Assisted Gynecologic Surgery Among Practicing Gynecologists. Journal for healthcare quality : official publication of the National Association for Healthcare Quality. 2017;39(4):211-8.
83. de Oliveira RAR, Guimaraes GC, Mourao TC, de Lima Favaretto R, Santana TBM, Lopes A, et al. Cost-effectiveness analysis of robotic-assisted versus retropubic radical prostatectomy: a single cancer center experience. Journal of robotic surgery. 2021.
84. McBride K, Steffens D, Stanislaus C, Solomon M, Anderson T, Thanigasalam R, et al. Detailed cost of robotic-assisted surgery in the Australian public health sector: from implementation to a multi-specialty caseload. BMC health services research. 2021;21(1):108.
85. Ahmed K, Ibrahim A, Wang TT, Khan N, Challacombe B, Khan MS, et al. Assessing the cost effectiveness of robotics in urological surgery - a systematic review. BJU international. 2012;110(10):1544-56.
86. Morii Y, Osawa T, Suzuki T, Shinohara N, Harabayashi T, Ishikawa T, et al. Cost comparison between open radical cystectomy, laparoscopic radical cystectomy, and robot-assisted radical cystectomy for patients with bladder cancer: a systematic review of segmental costs. BMC urology. 2019;19(1):110.
87. Bahler CD, Monn MF, Flack CK, Gramm AR, Gardner TA, Sundaram CP. Assessing Cost of Robotic Utilization in Partial Nephrectomy with Increasing Utilization. Journal of endourology. 2018;32(8):710-6.
88. Buse S, Hach CE, Klumpen P, Schmitz K, Mager R, Mottrie A, et al. Cost-effectiveness analysis of robot-assisted vs. open partial nephrectomy. The international journal of medical robotics + computer assisted surgery : MRCAS. 2018;14(4):e1920.
89. Buse S, Hach CE, Klumpen P, Alexandrov A, Mager R, Mottrie A, et al. Cost-effectiveness of robot-assisted partial nephrectomy for the prevention of perioperative complications. World journal of urology. 2016;34(8):1131-7.

90. Piechaud-Kressmann J, Bellec L, Delchier-Bellec MC, Beauval JB, Roumiguie M, Game X, et al. [Treatment of small renal masses: Effectiveness and cost-comparison analysis]. Progres en urologie : journal de l'Association francaise d'urologie et de la Societe francaise d'urologie. 2016;26(2):89-95.
91. Armijo PR, Pagkratis S, Boilesen E, Tanner T, Oleynikov D. Growth in robotic-assisted procedures is from conversion of laparoscopic procedures and not from open surgeons' conversion: a study of trends and costs. Surgical endoscopy. 2018;32(4):2106-13.
92. Hu L, Yao L, Li X, Jin P, Yang K, Guo T. Effectiveness and safety of robotic-assisted versus laparoscopic hepatectomy for liver neoplasms: A meta-analysis of retrospective studies. Asian journal of surgery. 2018;41(5):401-16.
93. Merola G, Sciuto A, Pirozzi F, Andreuccetti J, Pignata G, Corcione F, et al. Is robotic right colectomy economically sustainable? a multicentre retrospective comparative study and cost analysis. Surgical endoscopy. 2020;34(9):4041-7.
94. Qiu H, Ai JH, Shi J, Shan RF, Yu DJ. Effectiveness and safety of robotic versus traditional laparoscopic gastrectomy for gastric cancer: An updated systematic review and meta-analysis. Journal of cancer research and therapeutics. 2019;15(7):1450-63.
95. Jayne D, Pigazzi A, Marshall H, Croft J, Corrigan N, Copeland J, et al. Robotic-assisted surgery compared with laparoscopic resection surgery for rectal cancer: the ROLARR RCT. Efficacy and Mechanism Evaluation. Southampton (UK)2019.
96. Iavazzo C, Gkegkes ID. Cost-benefit analysis of robotic surgery in gynaecological oncology. Best practice & research Clinical obstetrics & gynaecology. 2017;45:7-18.
97. Singer E, Kneuertz PJ, D'Souza DM, Moffatt-Bruce SD, Merritt RE. Understanding the financial cost of robotic lobectomy: calculating the value of innovation? Annals of cardiothoracic surgery. 2019;8(2):194-201.
98. Byrd JK, Paquin R. Cost Considerations for Robotic Surgery. Otolaryngologic clinics of North America. 2020;53(6):1131-8.
99. Secin FP, Coelho R, Monzo Gardiner JI, Salcedo JGC, Puente R, Martinez L, et al. Robotic surgery in public hospitals of Latin-America: a castle of sand? World journal of urology. 2018;36(4):595-601.
100. Azhar RA, Elkoushy MA, Aldousari S. Robot-assisted urological surgery in the Middle East: Where are we and how far can we go? Arab journal of urology. 2019;17(2):106-13.
101. Esposito C, Masieri L, Castagnetti M, Pelizzo G, De Gennaro M, Lisi G, et al. Current Status of Pediatric Robot-Assisted Surgery in Italy: Epidemiologic National Survey and Future Directions. Journal of laparoendoscopic & advanced surgical techniques Part A. 2020.
102. Mottrie A, Larcher A, Patel V. The Past, the Present, and the Future of Robotic Urology: Robot-assisted Surgery and Human-assisted Robots. European urology focus. 2018;4(5):629-31.
103. Rao PP. Robotic surgery: new robots and finally some real competition! World journal of urology. 2018;36(4):537-41.
104. Stephan D, Darwich I, Willeke F. The TransEnterix European Patient Registry for Robotic-Assisted Laparoscopic Procedures in Urology, Abdominal, Thoracic, and Gynecologic Surgery ("TRUST"). Surgical technology international. 2021;38.
105. Kastelan Z, Hudolin T, Kulis T, Penezic L, Gidaro S, Bakula M, et al. Extraperitoneal Radical Prostatectomy with the Senhance Robotic Platform: First 40 Cases. European urology. 2020;78(6):932-4.
106. Chang KD, Abdel Raheem A, Choi YD, Chung BH, Rha KH. Retzius-sparing robot-assisted radical prostatectomy using the Revo-i robotic surgical system: surgical technique and results of the first human trial. BJU international. 2018;122(3):441-8.
107. Ku G, Kang I, Lee WJ, Kang CM. Revo-i assisted robotic central pancreatectomy. Annals of hepato-biliary-pancreatic surgery. 2020;24(4):547-50.

108. Dixon F, O'Hara R, Ghuman N, Strachan J, Khanna A, Keeler BD. Major colorectal resection is feasible using a new robotic surgical platform: the first report of a case series. Techniques in coloproctology. 2021;25(3):285-9.

109. Puntambekar SP, Goel A, Chandak S, Chitale M, Hivre M, Chahal H, et al. Feasibility of robotic radical hysterectomy (RRH) with a new robotic system. Experience at Galaxy Care Laparoscopy Institute. Journal of robotic surgery. 2020.

110. Hagn U, Konietschke R, Tobergte A, Nickl M, Jorg S, Kubler B, et al. DLR MiroSurge: a versatile system for research in endoscopic telesurgery. International journal of computer assisted radiology and surgery. 2010;5(2):183-93.

111. Avatera. Avatera System 2020. Available from: https://www.avatera.eu/en/avatera-system.

112. Massa L, Tucci CL, Afuah A. A Critical Assessment of Business Model Research. Academy of Management Annals. 2017;11(1):73-104.

113. DaSilva CM, Trkman P. Business Model: What It Is and What It Is Not. Long Range Planning. 2014;47(6):379-89.

114. Wirtz BW, Pistoia A, Ullrich S, Göttel V. Business models: Origin, development and future research perspectives. . Long range planning. 2016;49(1):36-54.

115. Zott C, Amit R. The business model: A theoretically anchored robust construct for strategic analysis. Strategic organization. 2013;11 (4):403-11.

116. Foss N, Saebi T. Fifteen years of research on business model innovation: How far have we come, and where should we go? Journal of Management. 2017; 43(1): 200-27.

117. Bhat KRS, Moschovas MC, Rogers T, Onol FF, Corder C, Roof S, et al. COVID-19 model-based practice changes in managing a large prostate cancer practice: following the trends during a month-long ordeal. Journal of robotic surgery. 2020.

118. Steward JE, Kitley WR, Schmidt CM, Sundaram CP. Urologic Surgery and COVID-19: How the Pandemic Is Changing the Way We Operate. Journal of endourology. 2020;34(5):541-9.

119. Intuitive. Intuitive Surgical Investor Presentation 110515 2015. Available from: https://ru.scribd.com/document/290566330/Intuitive-Surgical-Investor-Presentation-110515.

120. Intuitive. Investor Presentation Q3 2019. Available from: https://isrg.intuitive.com/static-files/880bf027-e866-4c32-b910-5332467cd8dc.

121. Crew B. Worth the cost? A closer look at the da Vinci robot's impact on prostate cancer surgery. Nature Index [Internet]. 2020; 580:[S5-S7 pp.].

122. Intuitive. Intuitive Announces Fourth Quarter Earnings 2021. Available from: https://isrg.gcs-web.com/node/17986/pdf.