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# THE FUTURE OF ROBOTIC-ASSISTED LAPAROSCOPIC SURGERY

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## **List of abbreviation**

AI *artificial intelligence*  
CCU *camera control unit*  
DOF *degrees of freedom*  
FDA *food and drug administration*  
HD *high definition*  
IoT *internet of things*  
ISS *integrated surgical system*  
LOS *length of stay*  
LS *laparoscopy surgery*  
MIS *minimally invasive surgery*  
OR *operation room*  
RALS *robotic assisted laparoscopic surgery*  
RAS *robotic assisted surgery*  
SD *standard definition*  
THA *total hip arthroplasty*

**Keywords: Da Vinci, Kymerax, Robotic-assisted surgery, Laparoscopic surgery**

## **Abstract**

**Introduction:** Since the first revolution of robotic-assisted surgery officially happened in 2000, the healthcare service worldwide has transformed into a new era due to its superior technological advancements, particularly in laparoscopic surgery. Da Vinci which is seen as a master-slave system and Kymerax which is categorized as a hand-held device are commonly used in robotic-assisted laparoscopic surgery. Whilst a conventional or open method requires a large incision to perform a surgery, laparoscopy - a minimally invasive surgery (MIS) is an advantageous surgical method which reduces an abdominal incision to a minimum, and effectively exploited with robots.

**Methods:** Based on available articles with the object of robotic surgical surgery, two SWOT analysis for Da Vinci and Kymerax were formulated to understand strengths, weaknesses, opportunities and threats of each system in comparison with the traditional laparoscopic surgery. From that, the future outlook is anticipated based on the scientific background.

**Results:** Alongside technological advantages of Da Vinci mainly known as 6-degree of freedom, dexterity enhancement, stereovision, tremor filtering and especially minimal invasive surgery, it still has disadvantages that are not neglectable such as huge investment and lack of haptic feedback. Although the malfunction rate of Da Vinci is not significantly high, surgeons should be aware of it to fix or alter instruments in time. Kymerax is not as advanced as Da Vinci but it can fill in the gap of the Da Vinci which includes the large investment and bulky instruments. The Kymerax is the low-cost hand-held device allowing multiple degrees of freedom. It is an optimal combination between traditional performance and robotic performance allowing surgeons to manipulate in their hands and ensure haptic feedback.

**Conclusions:** Both Da Vinci and Kymerax systems offer superior benefits for medical service due to the ongoing technological growth. The cost-effectiveness of Da Vinci system is currently a problematic issue when medical institutions consider to install them. The surgical instruments market, however, has become highly competitive which is likely leading to the decline of the costly investments. In the digital world nowadays, it will be a promising future for more integrated medical inventions.

## **Chapter 1: Introduction**

### **1.1. Research background**

Thanks to the significant development of technology in industrial revolution 4.0, thousands of scientific inventions have been developed to gain higher living standards for humans in decades. Since the 1950s (“Unimate - the First Industrial Robot” 2020), the appearance of robotics has contributed huge benefits for industrialization and modernization widely in factory automation and even in the medical industry. Nowadays, robotic surgery has already become an advanced option in neurological, urological, gynecological, cardiothoracic as well as numerous general surgeries (“History of Robotic Surgery and FDA Approval - Robotic Oncology” 2020). Instead of operating conventional surgery by doctors only, patients now can choose a robotic-assisted surgery (RAS) as the minimally invasive surgery (MIS) which means small trauma, short operation time, rapid postoperative recovery, and light mental burden on medical staff (Lin et al. 2016). If at first surgical robots were used to support, move and orient the camera in the operating field, subsequently it came to complex surgical robots in which the surgeon operates from a remote console far from the patient (Husty and Hofbaur 2018). Over the years, the continuous evolution of the robotic surgical system has invented a number of more sophisticated robotics that are used by surgeons worldwide. According to the study of Sheetz et al., the use of robotic surgery increased from 1.8% in 2012 to 15.1% in 2018 (Sheetz, Claflin, and Dimick 2020). There is a significant trend toward the growth of robotic-assisted surgery which has extended throughout the world and to all surgical specialties (Pietrabissa et al. 2013).

Launching in 1985s, PUMA 560 - the robotic surgical arm was used in the neurosurgical biopsy, a non-laparoscopic procedure that was seen as the first application of the robot-assisted surgery. In 2000, the Da Vinci surgery system was approved by the FDA (Food and Drug Administration) and became the first robotic surgery for general laparoscopic surgery (“History of Robotic Surgery and FDA Approval - Robotic Oncology” 2020). Currently, robotic surgery is implemented with the use of Da Vinci as a master-slave system that comprises unique components of specialized arms for holding instruments and a camera, a magnified screen, and a console (Appendix 1). This evolution markedly reduces the risk of infection and less contact between interior tissue and the

surgical devices, so the future of robotic surgery will be promising with more sophisticated medical procedures (“About Robotic Surgery: What Is Robotic Surgery? | UCLA Health” 2020).

Unlike those master-slave systems, hand-held instruments were designed to fill in the gap of the bulky and expensive machines. They offer simpler surgical procedures by using a hand-held manipulator and an endoscopic monitor (Sieber et al. 2017). Particularly, Kymerax (Terumo, Japan) is one of the cost-effective hand-held instruments which combine both robotic and classic laparoscopic operation. The Kymerax system consists of three components including a console, handles, and interchangeable instruments (Hacketh et al. 2012). It allows higher degrees of freedom and is manipulated by a surgeon's hands in a traditional procedure (Sieber et al 2017).

## **1.2. Problem statement**

At any institution, the adoption of RAS needs a well-structured facility to ensure the successful implementation of a complicated robotics program. Furthermore, once the installation phase is done, maintenance and growth must be focused to maximize the benefits of the program (Palmer et al. 2008). Development of a RAS system requires a huge initial cost of buying it and of the associated materials, staff recruitment and staff training. Also, possible operating room modifications would be important to support consoles and other equipment (Palmer et al. 2008). However, the actual benefit of robotic surgery has only been proven for certain indications by clinical studies and has even been disproven in certain cases (evidence-based medicine). Therefore, the use of robotic surgical systems is currently being controversially discussed with regard to surgical skills and patient safety as well as economic profitability. Simultaneously, the medical industry is continuously working on the optimization of existing and the development of new technologies, such as the specification of the surgical steps by the system using artificial intelligence (Hamann, C. et al. 2020).

However, the robotic-assisted surgery has not been used widely in hospitals in 2020, it is more likely common in academic hospitals. Many researchers supposed that the main problem is the cost. The surgery performed by robots is roughly 2,500 euro per patient, while normal operation without robotics costs approximately 250 euro on average. The cost of the Da Vinci system ranges from \$1.2-1.7 million depending on the type of system and overhead charges from local agents (Palmer et al. 2008). In fact, doctors still can handle the procedures by themselves. Furthermore,



according to some reports, device malfunction also happened and aggravated the patient's situation. Thus, this is questioning whether the cost of using such a system is worth the improved outcomes.

As a result, two research questions are formulated:

1. Why does Robotic-assisted laparoscopic surgery have less widespread application nowadays?
2. How does Robotic-assisted laparoscopic surgery look like in the future?

To answer those research questions, the SWOT analysis is undertaken to understand the strengths, weaknesses, opportunities and threats of applying robots in laparoscopic surgery. From two robotic categories mentioned in the introduction of this paper, Da Vinci as a master-slave system and Kymerax as a hand-held device are chosen for the SWOT analysis. In the robotic research field, there are some preceding research conducted base on SWOT analysis. For instance, the research by Bora et al. (2020) has applied SWOT analysis to scrutinize the rise and the future of robotic surgery. However, the authors only focus on the Indian market with the object of the Da Vinci system. Consequently, they concluded that robotic surgery is potential in India following judicious reporting of results. Another research by Nwosu et al. (2019) used SWOT to examine the possible future impact of medical robotics on palliative, supportive care and end-of-life care. Unlike the aforementioned study, they did not concentrate on a specific robotic system, instead, the robotic technology was aimed to generally. It also shown a positive relationship of numbers of robotic applications in palliative, supportive and end-of-life care, however, under a mindful consideration of technical, societal, economic and ethical dimensions.

In fact, there are not many previous research papers applied SWOT analysis for robot-assisted surgery in both master-slave and hand-held systems in comparison with the traditional surgery, especially in the laparoscopy. Hence, this paper will fill in the gap by conducting two SWOT analyses for one master-slave system which is Da Vinci and one hand-held device which is Kymerax. Since Da Vinci was approved by the FDA in 2000, this system has become prevalent in the robotic surgery field. Compared to Da Vinci, there is less academic research on Kymerax although this device has a wide range of applications in laparoscopy. Recently, there is no research considering both Da Vinci and Kymerax with the approach of SWOT analysis in the

laparoscopic field. Based on the aforementioned reasons, it is therefore reasonable to examine this research in order to understand deeply and thoroughly the application of RAS in laparoscopic surgery and its future outlook.

### **1.3. Scope of the study**

This research will be analyzed by taking a detailed look at robotic laparoscopic surgery. Besides, we are going to analyze the current status of surgical robotics mainly in the framework of SWOT by analyzing strengths, weaknesses, threats and opportunities. The paper will examine two SWOT analyses which are (1) the comparison between Da Vinci-assisted and traditional surgery (2) the comparison between Kymerax-assisted and traditional surgery. Additionally, secondary data will be collected through scientific researches regarding economic, medical as well as technological views to provide comprehensive perspectives of robotic laparoscopic surgery. As a result, this paper aims to figure out potential reasons or obstacles that prevent popularizing this application in general. From that point, the future outlook of medical robotics will be anticipated.

## **Chapter 2: Theoretical background**

### **2.1. Robotics-assisted surgery**

In 1985, the adjusted industrial robotic arm Unimation PUMA 200 was the first use of robotic surgery for biopsy of the brain. In 1992, Japan adjusted another industrial robot SCARA applying in surgery for total hip arthroplasty. At the same year, a similar robotic system Robodoc was introduced in the USA by Integrated Surgical System (ISS). It was also the first autonomous system used on humans for total hip arthroplasty (THA), and for total knee arthroplasty which was approved by FDA in 1998 and 2009 respectively (Husty and Hofbaur 2018) (see Figure 1).

The advanced robots were greatly innovated in 1999 when the first surgical system Da Vinci was launched by Intuitive Surgical Inc. which is USA-based. The Da Vinci consists of three main components that are one or two working consoles for surgeons alongside the 3D visualization system (vision cart), and a patient cart placed near the operating table that has three or four robotic arms for the endoscopic visualization system (Husty and Hofbaur 2018; “Intuitive | Robotic Assisted Systems | Da Vinci Robot” 2020), (see Appendix 1 and 2).

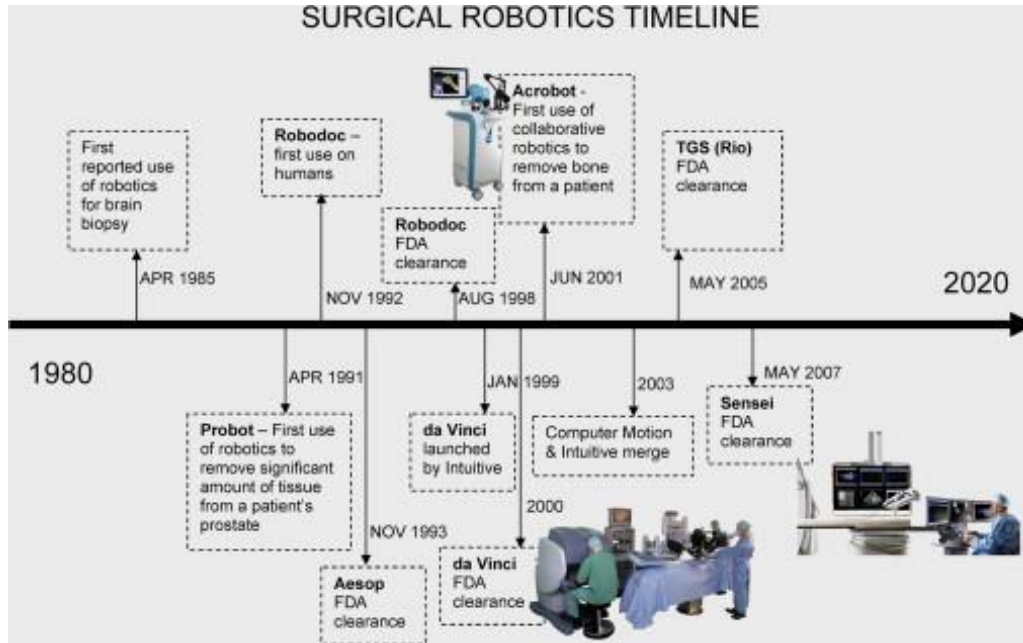


Figure 1 Surgical robotics timeline (Gomes 2011, 262)

## 2.2. SWOT theories

The research will be conducted based on two SWOT analyses regarding the application of the Da Vinci system and the Kymerax device in laparoscopic surgery. The following parts will introduce the history and details of SWOT, and explain reasons why it will be chosen for this research paper.

### Origin of SWOT

The origin of the term “SWOT” is undefined. According to Benaven, SWOT analysis originated from the publication *Business Policy: Text and Cases* (1965), created by four professors at Harvard University – Edmund Philip Learne, Roland Chris Christensen, Kenneth Richmond Andrews (and William D. Guth. (Benaven, 2015). SWOT analysis was described by Christensen et al. (1978) and has developed as an important tool for solving complex strategic situations by reducing the quantity of information to improve decision-making. Online wikis credit SWOT’s origination with Stanford University Professor Albert Humphrey who conducted a research project in the 1960s and 1970s based upon the United States’ Fortune 500 companies but academic references to support this claim have not been found (Helms and Nixon 2010, 216).

However, regardless of the exact historical credit concerning the term “SWOT”, it has a half-century of use and documentation in the literature (Helms and Nixon 2010, 216).

### **Details of SWOT**

SWOT analysis is one of the most important tools in strategic management. The main purpose of SWOT analysis is to identify the strategies that will create a company-specific business model that will best align, fit, or match a company’s resources and capabilities to the demands of the environment in which it operates. SWOT analysis is the comparison of strengths, weaknesses, opportunities, and threats (Charles W. L. Hill, Gareth R. Jones 2012, 10).

Strengths are components of an organization that positively affect its development and competitive position. Generally, strengths are considered to be particularly significant as they do not characterize the competition. The SWOT analysis identifies the competitive advantages held by a company over its competitors.

Weaknesses are also connected to the organization's internal functions, but in general, they have a negative impact on its development and competitive position. The ability to clearly identify the internal weaknesses of an organization is vital. It allows for the improvement of relevant issues and the re-orientation of work in order to make them less vulnerable.

Opportunities for an organization depend on those available in the external environment. They can be exploited to improve progression and competitive position. Once this is done, they can become forces that positively influence the development of an organization.

Threats also originate from the external environment of an organization. Their identification is often the result of traditional strategic work. As long as they are detected in time, threats can be better anticipated and their impact on performance reduced (and vice versa) (Benaven 2015).

However, SWOT also has some limitations. The biggest weakness of SWOT analysis is that it remains atheoretical without the necessary theoretical support to validate the popular construct. This may be partly because SWOT analysis is conducted at a point in time. Because the environment is constantly changing and strategies also change accordingly internal strengths and weaknesses, environmental scanning is needed regularly to update the SWOT analysis (Helms and

Nixon 2010, 239–40). Besides, the categorization of variables into one of the four SWOT quadrants is also challenging. Strengths that are not maintained may become weaknesses. Opportunities not taken, but adopted by competitors, may become threats. The classification of a variable also depends on the purpose of the exercise. Criteria to assign a variable to one of the four quadrants may be difficult (Helms and Nixon 2010).

### **2.3. Robotics assisted surgery: Impact on laparoscopic surgery**

#### **2.3.1. Introduction on laparoscopy**

Laparoscopy (LS) or “minimally invasive surgery (MIS)” is a common surgical procedure to diagnose and treat abdominal diseases. The main characteristic of the laparoscopic approach is to minimize the abdominal incision to a minimum entering through one or more ports of five to ten mm, whereas in conventional or open surgery a large incision (laparotomy) is required to reach the surgical field (Nakadate and Hashizume 2019).

To be able to perform laparoscopic procedures, the surgeon has to create an environment in which he can clearly view all intraabdominal structures and successfully manipulate all instruments. This happens through the creation of pneumoperitoneum in which air or gas is used for inflating the abdomen under controlled pressure (Nagelhout and Elisha 2018). After that, a 5 to 10-mm-diameter trocar is inserted through a small periumbilical skin incision and allows the surgeon to pass instruments into the abdominal cavity (Jones and Soper 1994). In order to operate through those small incisions, an endoscope (optical system) is inserted into the abdominal cavity along with surgical devices, such as graspers, scissors or suturing instruments (see Figure 2). The operating field is displayed through the endoscopic camera and presented indirectly via video monitors (Xin, et al., 2006).

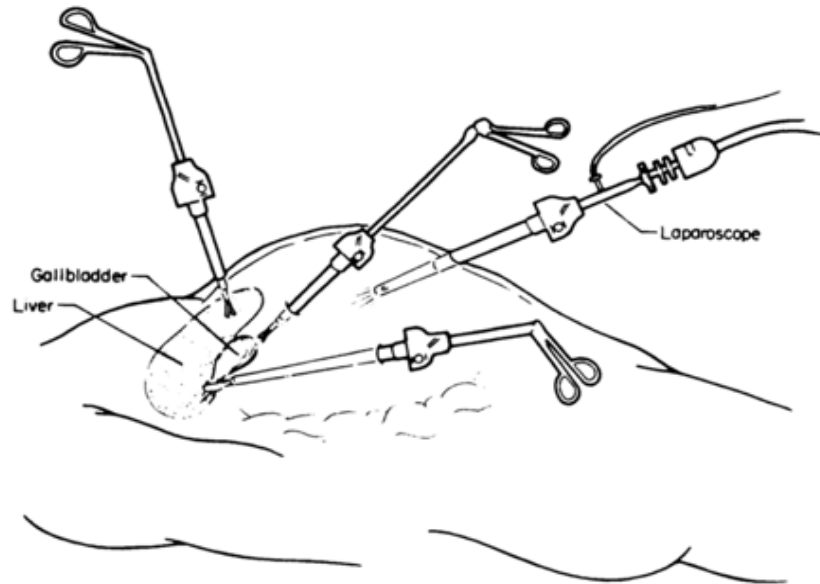


Figure 2 Laparoscopic instruments are inserted through ports after pneumoperitoneum (Jones and Soper 1994, 1296)

Laparoscopic surgery has gained a leading role in the treatment of many indications as it provides a variety of advantages compared to conventional surgery. In patient terms, the major advantage of LS is the reduction of complications that are associated with laparotomy, such as postoperative pain, blood loss and discomfort. Additionally, this results in a shorter hospital stay and faster recovery time for the patient (Riaz & Gordon, 2003, p. 544).

Despite the benefits of LS, it also presents new challenges to surgeons which require advanced surgical skills. One major challenge consists in not seeing the operative field directly. The field of view can be limited, and the surgeon relies on the monitor's indirect visual input, usually displayed in two dimensions. These factors can lead to a reduction of sense of orientation and impede depth perception. However, the visualization of the operating field can be improved by endoscopes with a broader viewing angle (e.g. 30° instead of 0°).

Three-dimensional imaging systems are nowadays widely available but only partly used, e.g. due to discomfort associated with wearing 3D glasses, revealing that there is still room for improvement.

Additionally, laparoscopic instruments are supposed to be as slim as possible to reduce the size of the incision to a minimum. Furthermore, in order to reach the operating field, a certain length of the instrument sheath is required. This impairs the haptic feedback which plays an important role not only when it comes to motor control but also to identify tissue structures in order to localize organs and to differentiate between healthy and defective tissue (Xin, et al., 2006). When there is a lack of haptic feedback, the surgeon can only estimate the force that is used and the tissue's texture based on visual cues (Longmore, Naik, and Gargiulo 2020).

For the free motion of the wrist, six degrees of freedom are required. However, since most classic laparoscopic instruments do not have a bendable distal tip, the motion is reduced to four degrees of freedom which negatively affects the surgeon's dexterity (Xin, et al., 2006).

Another limitation of instrument movement in LS consists in the mirror effect. The fact that the instrument inside the abdominal cavity goes in the opposite direction to the handle which complicates the manipulation even more.

In order to overcome the highlighted limitations of LS, surgeons have to go through long training time, collect experience and practice intensively. The restrictions are mostly due to technical issues, wherefore technology, such as robotic-assisted surgery, can be of great importance to overcome those challenges in LS (Nakadate and Hashizume 2019).

### **2.3.2. Robots in laparoscopic surgery**

Over the past decade, surgical robots have experienced a strong development and nowadays they are used in many types of surgeries as shown in Figure 3.

In the following, we will focus on robots used in laparoscopic surgery which has become one of the most active areas for research and development of surgical robots (Tokyo Medical and Dental University 2019, 1).

Intuitive Surgical Inc. has become a market leader with its master-slave Da Vinci system since its FDA approval in 2000. More than 4.500 systems were installed as of August 2018 (Nakadate and Hashizume 2019). The patents which began to expire in 2016 enabled Intuitive to expand their

lead, wherefore this paper focuses on Da Vinci. However, nowadays there are various systems available resulting in increasing competition in this former monopoly market. Therefore, it is essential to also take emerging systems into account. In general, those systems can be divided into master-slave and hand-held systems, which will be further evaluated in the following (Tokyo Medical and Dental University 2019, 2).

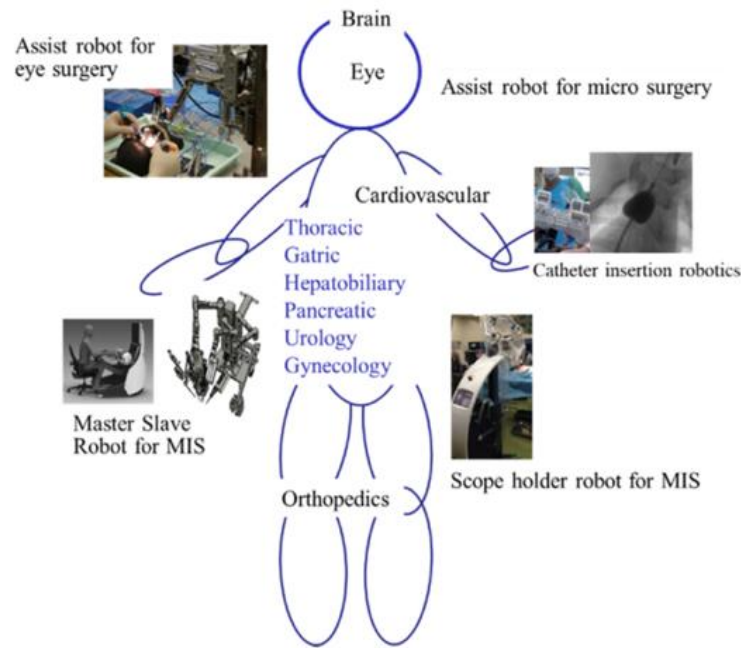


Figure 3 Applications of surgical robots (Tokyo Medical and Dental University 2019, 2)

## 2.4. Master-slave systems

### 2.4.1. Da Vinci System by Intuitive

The Da Vinci system is a master-slave telemanipulation system consisting of three major components: the ergonomically designed surgeon console from where movements are controlled, a patient-side cart with four interactive robotic arms to which the operating instruments are attached, and a high definition 3D visualization system (see Figure 4) (Schreuder and Verheijen 2009).



The surgeon sits behind the console (master unit) and controls the surgical carts (slave unit) by manipulating two master controllers. The shared core technology enables physical separation of the surgeon from the patient through telepresence by providing 3D images with superior resolution and high contrast of the operative field (Ishikawa et al. 2012) and (Ramos, Souza Bastos, and Kim 2015). The system was originally designed to make complex surgeries easier using a minimally invasive approach (Fakhoury et al. 2015). In the following, the three main components of the Da Vinci System are explained in detail.



Figure 4 Da Vinci robotic systems have three major components: the surgeon console, the surgical cart, and the vision cart (Schreuder and Verheijen 2009, 200).

### **The Surgeon Console**

The surgeon console serves as a control element and allows the operator to move the camera and instrument arms using hand manipulators and foot pedals. Additionally, the console provides some extra features like personalization and settings control which “remembers” the surgeon’s last position if they need to rest, so the robotic arms return to the same spot to continue surgery (Fakhoury et al. 2015).

The surgeon console system includes the following components:

- Master controllers
- Stereo viewer

- Left and right-side pods
- Footswitch panel (Shamseldin 2017)

The master controllers support the surgeon to move the instruments and endoscope inside the patient. The design offers a natural range of motion, dexterity and ergonomic comfort which is crucial especially during long procedures helping to prevent fatigue. The stereo viewer offers a 3-dimensional stereoscopic image with up to ten times magnification. To guarantee optimal comfort during long procedures, the stereo viewers are also ergonomically designed to support the head and neck of the surgeon. Additionally, the view port displays messages and icons informing the operator about the current settings (Ramos, Souza Bastos, and Kim 2015). The left and right-side pods are located on both sides of the surgeon console offering user interface functions for system configuration. The footswitch panel allows the operator to adjust settings during the surgery, if necessary, this includes instrument arm repositioning, camera and focus control as well as energy use (Shamseldin 2017).

### **The Patient Side Cart**

The second component is the patient side cart to which the robotic arms are attached. This is the operative component of the Da Vinci System. One robotic arm is equipped with a stereoscopic camera with an endoscope of either 0° or 30° viewing angle and an outer diameter of 12 mm, consisting of two optical channels of 5 mm each. The other robotic arms are equipped with “Endowrist” instruments which are one of the system’s key components. The instruments can easily be changed intraoperatively by the surgical staff if the procedure and surgeon require it. The movement of the robotic instruments are designed to mimic the dexterity of the human hand and wrist allowing seven degrees of freedom and 90 degrees of articulation. This increases the flexibility compared to the five degrees of freedom of standard laparoscopic instruments (Fakhoury et al. 2015; Schreuder and Verheijen 2009).

The movements of the instruments automatically align with the surgeon’s hand movement (fingertip) at the console. Motion scaling (up to 1:10) enables performing with greater precision.

While operating the system filters out normal physiological hand tremor which is of great importance when operating on delicate structures such as the bowel or the bladder etc.

### **The “Insite” Vision System**

The third main component is the “Insite” Vision System. Currently, there are two types of vision systems available with the Da Vinci System:

- The standard definition (SD) vision system
- High definition (HD) vision system

The vision cart is equipped with the following components: illuminator, endoscopes, stereo camera head, camera control units (CCUs), vision cart touch screen, intercom system, isolation transformer and power strip and tank holders (Shamseldin 2017).

Two camera control units and two light sources generate a three-dimensional (3D) image.

The 3D view allows the surgeon to work very precisely due to the excellent visual feedback, even without haptic feedback. The HD camera allows a 60-degree field of view and when combined with the stereo endoscope, the vision system enables an average of 6-10 x magnification of the surgical field. The robotic visualization system provides a high-resolution image providing more clarity and detail to simplify surgical procedures (Schreuder and Verheijen 2009).

#### **2.4.2. Senhance™ by Transenterix Inc. and the Versius Robotic System by CMR Surgical Ltd.**

Currently, there are various master-slave systems available that serve as an alternative to the Da Vinci robot. However, FDA registration is still pending for many of them. Senhance™ (TransEnterix, Inc. 2020) and the Versius Robotic System (CMR Surgical Ltd., UK) serve as examples to compare those emerging surgical robots to the Da Vinci system (Peters et al. 2018) and (Gueli Alletti et al. 2018).

The Telelap ALF-X Robotic system (now called Senhance™ - Transenterix USA) was originally developed in Europe and was then sold to a US medical company, called Transenterix, Inc. The surgical system was introduced in 2013 and is the first abdominal robotic surgery platform to receive FDA approval since 2000. Furthermore, the system received its CE mark for major laparoscopy surgery (Gueli Alletti et al. 2018; TransEnterix, Inc. 2020). The Senhance platform consists of three independent robotic arms for the coordination of the 3D camera and instruments. The surgeon manipulates the arms from the so-called “cockpit” via robotic controls (Gueli Alletti et al. 2018). The Versius system was introduced into the CE market in 2019. However, FDA approval is still pending (Longmore, Naik, and Gargiulo 2020). The surgeon uses 3D glasses and controls the system via the console’s joysticks, similar to the Senhance system.



Figure 5 Senhance™ (Nakadate and Hashizume 2019, 3)



Figure 6 Versius Robotic System (Kent 2019)

The key differences of both systems in comparison to the Da Vinci consist of single robotic arms attached to individual patient carts as well as haptic feedback. The modularity is supposed to increase flexibility with regard to positioning and in case of a technical malfunction. However, this is linked to a higher effort regarding alignment and wiring connection (Longmore, Naik, and Gargiulo 2020). Both systems offer realistic tactile feedback. Additionally, the Senhance system provides information about the applied force and can even enhance the force, for instance during suturing (Longmore, Naik, and Gargiulo 2020; Peters et al. 2018). Another advancement of the Senhance system is its eye-tracking function. Camera motion is automatically controlled by the surgeon's eye motion via an infrared sensor. The surgeon can adjust the camera zoom by moving their head forward or backward (Gueli Alletti et al. 2018).

Because of monetary issues, TransEnterix now offers hospitals leasing agreements serving as a trial period before deciding whether to acquire a system. This recent shift of strategy is used to get a certain market penetration to overcome high investment hurdles (Newmarker 2020).

The technical features of master-slave systems are constantly enhanced in order to compete with the well-established Da Vinci system. Two key advancements consist of modularity and haptic feedback. Although emerging systems are less expensive than the da Vinci, it becomes clear that the manufacturers still face high investment hurdles. TransEnterix provides a good example of how approaching new strategies can help to overcome those barriers.

## **2.5. Hand-held Devices**

Despite its advanced technological features, master-slave robots are linked to high investment and maintenance costs as well as the necessity for additional space within the OR for the master console. In order to fill the gap between conventional laparoscopic instrumentation and master-slave robots, various hand-held robotic devices have emerged to enhance precision, triangulation and dexterity. These systems can be divided into two groups: hand-held mechanical and robotic instruments (Tokyo Medical and Dental University 2019, 4; Sánchez-Margallo, J. A. and Sánchez-Margallo, F. M. 2017).

### 2.5.1. Mechanical Hand-held Devices

For instance, the FlexDex (FlexDex Inc., USA) needle holders are purely mechanically driven. Motion is transmitted to the instrument's distal tip by a tool frame mounted to the surgeon's forearm. This enables controlling the instrument's seven degrees of freedom by the motion of the hand, wrist and forearm (Sánchez-Margallo, J. A. and Sánchez-Margallo, F. M. 2017). Another example for a mechanical hand-held device is the Radius r2 DRIVE (Tübingen Scientific Medical GmbH, Germany). The handle contains a lever for deflection and a knob for rotation, wherefore the instruments can be manipulated by fingertip movement (Sánchez-Margallo, J. A. and Sánchez-Margallo, F. M. 2017).



Figure 7 The FlexDex surgical instrument (Plew 2018)



Figure 8 r2 DRIVE instrument  
(Alkatout and Mettler 2020, 40)

### 2.5.2. Robotic Hand-held devices

In contrast, hand-held robotic devices are driven by actuators. Examples of these are the Kymerax (Terumo, Japan) and the DEX system (Dextérité Surgical, France). Both systems are low-cost surgical instruments, providing multiple degrees of freedom and represent a good alternative which is why we focus on. Whereas DEX offers only needle holders, the broader Kymerax portfolio additionally contains scissors, graspers and hooks. Both systems are maneuvered by joystick interfaces that are integrated into the instrument handle and offer rotation and deflection (Sieber, Fellmann-Fischer, and Mueller 2017) and (Sánchez-Margallo, J. A. and Sánchez-Margallo, F. M. 2017).



Figure 9 Kymerax (Sieber, Fellmann-Fischer, and Mueller 2017, 4299).



Figure 10 DEX system (ELSAN 2020)

Among the hand-held instruments, needle holders are the most common due to the complexity of laparoscopic suturing. Additionally, different models, such as scissors, graspers and

electrosurgical instruments have been developed. Their major advantage over conventional laparoscopy consists of enhanced maneuverability. Usually, they offer seven degrees of freedom due to the additional features of rotation and deflection. Different manufacturers offer reusable and disposable solutions. However, the extent of financial benefits in comparison with robotic surgery is highest when reusable instruments are chosen. Depending on the construction, placement and change of instruments can be more complex compared to conventional instrumentation and bulky systems may conflict with other surgical devices (Sánchez-Margallo, J. A. and Sánchez-Margallo, F. M. 2017).

Table 1 Summary of the handheld surgical instruments for laparoscopic field

| <i>Device</i>   | <i>Type</i>  | <i>Instrument</i>                               | <i>Handle</i>                 | <i>DoF</i> | <i>Diameter (mm)</i> | <i>Clinical setting</i>              | <i>Tasks/ Procedures</i>  |
|---|--------------|---|-------------------------------|------------|----------------------|--------------------------------------|---|
| <b><i>FlexDex</i></b><br>( <i>FlexDex Inc., USA</i> )                                 | Mechanical   | Needle holder                                   | Forearm mounted               | 7          | -                    | OR                                   | Laparoscopy<br>Nissen fundoplication  |
| <b><i>Radius r2 DRIVE</i></b><br>( <i>Tübingen Scientific Medical GmbH, Germany</i> ) | Mechanical   | Scissors<br>Dissector<br>Needleholder           | Pistol with a lever mechanism | 7          | 5                    | Box trainer<br>Ex vivo porcine model | Cutting and suturing tasks<br>Gastro-jejunal anastomoses  |
| <b><i>Kymerax</i></b><br>( <i>Terumo, Japan</i> )                                     | Robot driven | Scissors<br>Dissector<br>Needleholder<br>L-hook | Pistol                        | 7          | 8.8                  | Box trainer<br>Ex vivo porcine model | basic laparoscopic urological<br>Anastomosis tasks<br>Laparoscopic hysterectomy<br>LESS partial nephrectomy<br>LESS sigmoidectomy<br>LESS radical prostatectomy |
| <b><i>DEX system</i></b><br>( <i>Dextérité Surgical, France</i> )                     | Robot driven | Needleholder                                    | Grip-type                     | 7          | 10                   | Box trainer                          | Precision task<br>Suture on porcine stomach<br>Urethrovesical anastomosis   |



## **Chapter 3: SWOT analysis of robotic-assisted laparoscopic surgery**

### **3.1. SWOT analysis for Da Vinci-assisted surgery in comparison with the classic surgery**

#### **3.1.1. Strengths**

##### *Technological advancement*

According to the aforementioned framework, the Da Vinci system has different modifications for different purposes. In fact, the system is standardized to ensure error-free operation without the effects of the human characteristics and applied for different kinds of laparoscopic surgeries, for instance general surgery, gynecology or urology (Nwosu et al. 2019). Generally, the Da Vinci system brings outstanding technical advantages over conventional laparoscopic surgery, singling out six degrees of freedom, dexterity enhancement, stereovision and tremor filtering (John and Wikl 2008, 39; Sieber, Fellmann-Fischer, and Mueller 2017). Furthermore, additional benefits are offerings of minimally invasive surgery and better cosmetic effects (Shin et al. 2020). Because the Da Vinci system improves the incidence of surgical complications, postoperative infection, blood transfusions, postoperative pain management and simplifies postoperative nursing care, it boosts the operating efficiency in general (John and Wiklund 2008).

##### *Precision*

Due to the high quality of vision and precision of gestures for difficult steps of radical prostatectomy, robotic assistance allows a very precise cut or dissection which also can be applied in other anatomical specifics of patients (John and Wiklund 2008). In addition, the video laparoscope is not held by human hands which may shake, rather is stabilized in the robotic arm. This feature affirms precise dissections in surgical movements. In another word, robotics has an advantage of tremor filtration (Nezhat 2008). Moreover, the 10-fold magnification allows the surgeons to exactly control smaller bleeding vessels that function blood flows in the body (John and Wiklund 2008).

### *Less physical burden*

In some researches, scholars stated that robotic-assisted laparoscopic surgery (RALS) reduces physical burdens for both surgeons and patients. On one hand, it lowers physical strain for operating surgeons due to forearm rests at the robotic console supporting the weight of the arm, the lightweight design and the working plane of the master controls. That reduces activation of the muscle during RALS (Hislop et al. 2020; Sieber, Fellmann-Fischer, and Mueller 2017). As the aforementioned console of the system, the surgeons can settle in a comfortable seat and perform the surgery away from the patients (Nezhat 2008). Therefore, RALS is optimally superior to traditional laparoscopic surgery not only in terms of technology but also in terms of coincident benefits. On another hand, the single-port laparoscopy improves patients' satisfaction as well as alleviates their pain (Shin et al. 2020).

### *Open surgical skills consolidation*

In specific, Da Vinci surgical system permits surgeons without laparoscopic training to directly transfer their general surgical skills to the laparoscopic arena. A senior open surgeon is able to achieve operative times as similar as those of an accomplished laparoscopist within 18 surgical cases (Menon et al. 2004)

### *Shorter learning curve*

Additionally, the system enables the surgeon to perform a RALS in less than five hours within ten cases, and only in the average operative time of 3.45 hours thereafter (see Figure 11). Typically, the classic laparoscopic surgery performance has a steep learning curve although performed by high experience laparoscopists (John and Wiklund 2008). As a result, it offers a shorter learning curve even in the hands of non-experience laparoscopic surgeons (Sieber, Fellmann-Fischer, and Mueller 2017).

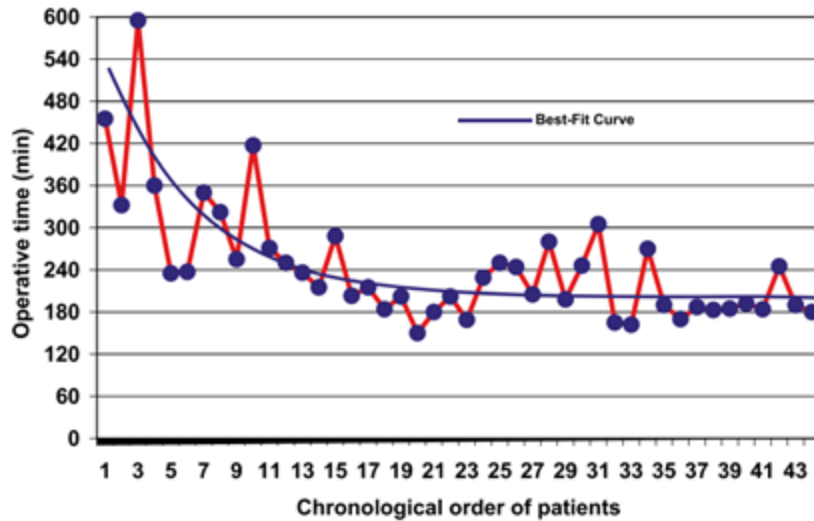


Figure 11 Robotic-assisted radical prostatectomy experience at UCI (first 45 patients) (John and Wiklund 2008, 135)

*Low complication rate*

Unlike traditional surgery, it may cause some unexpected complications for patients afterward, One research proved that there was a low complication rate of the robotic radical prostatectomy in his research by reporting a series of 200 continuous RALSs (Patel et al. 2005). Besides, there were no blood transfusions or conversions to open surgery during RALS (John and Wiklund 2008). Furthermore, in another research, scholars pointed out that the complication rate was only approximately 8.1 percent (Abhishek C 2015).

*Shorter length of stay (LOS) and faster recovery*

Regarding the length of stay in the hospital, patients who have RALS discharge from the hospital shortly afterward compared to traditional surgery. Specifically, a mean LOS was reported within 1.08 – 1.2 days following RALS compared to 3.5 days following traditional open surgeries (John and Wiklund 2008, 143; Nifong et al. 2003). As a result, patients are recovered faster and stay in the hospital shorter.

### *Less blood loss*

High magnification, tremor reduction, articulating instrument allow the surgeon to better identify and preserve precisely dissection that leads to decreasing blood loss during surgical operation (John and Wiklund 2008). In a cohort of 49 patients, the blood loss was 200 ml in average (Abhishek C 2015).

### *Less risk of infection*

As a result of a shorter hospital stay and faster recovery, another advantage is lowering risks of nosocomial infections for patients as well as health care costs for hospitals (John and Wiklund 2008). More time spending in hospitals, more risky exposure to various infectious sources.

### *Independent 90-degree articulation*

Robotic surgery is taken to a new level of rotational capacities with the independent 90-degree articulation of the tip (see Figure 12) which facilitates the operation more intuitively. It also explained the fewer need for surgical assistants during the RALS (Nezhat 2008).

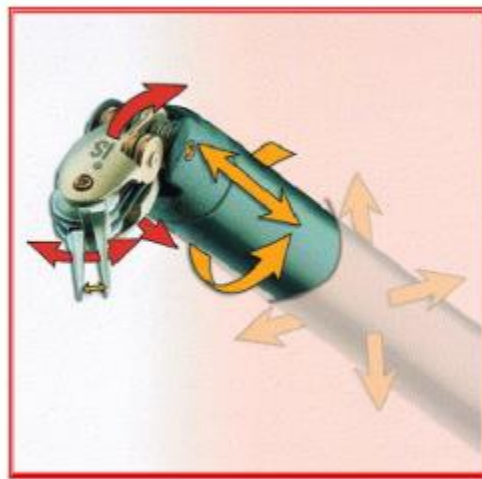


Figure 12 Yellow arrows indicate range of motion for traditional laparoscopy, whereas the red arrows show the added movements provided by robotic instruments (Nezhat 2008, S30)

### *No training*

Obviously, robots do not need training and education for years in the same way as humans. Artificial Intelligence is integrated into the robotic brain with all crucial information in a specific field. Indeed, modern technological background such as sensor-based technology, fifth-generation (5G) Internet, Internet of things (IoT), Artificial Intelligence (AI), Big Data has facilitated rapid adaptation and improvements in software (Nwosu et al. 2019).

### *Extending market share*

In addition to the superior functions of the Da Vinci system, hospitals also capture existing market share and create a competitive advantage. Figure 13 shows the increase in the market share of prostatectomy which is one of laparoscopic surgery in relation to the decrease of traditional open surgery. Moreover, they are able to become the leading health care system due to the application of advanced technology in surgery (John and Wiklund 2008). Accordingly, it proves a broader hospital-wide benefit in response to the growth of market share. Moreover, the Da Vinci system offers clinics and hospitals a broader base of demanding surgical patients (John and Wiklund 2008).

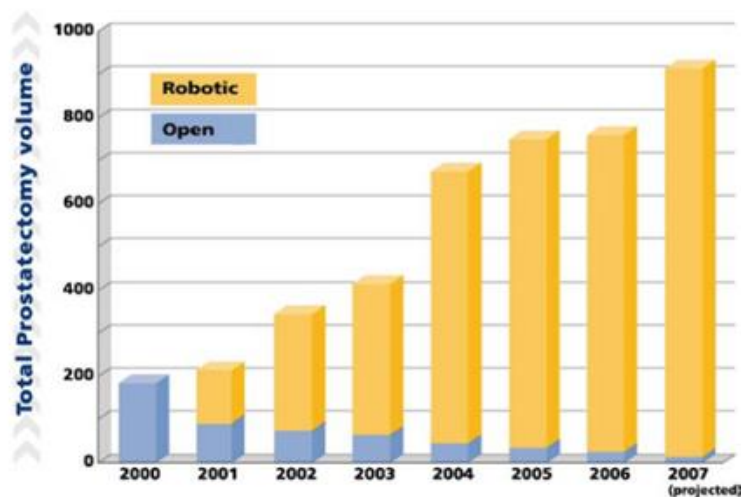


Figure 13 Market share growth case studies: total procedure volume (John and Wiklund 2008,

266)

### 3.1.2. Weaknesses

#### *Huge investment*

First of all, the initial investment is significantly high. The robot currently costs around the US \$1,500,000 as an initial investment with a yearly maintenance cost of US \$100,000 (Bora et al. 2020). Meanwhile, the real benefits are still controversial as a result of lacking authentic evidence. Furthermore, the Da Vinci system also requires huge investment in hospital facilities and infrastructure to adapt to the technologically sophisticated system. Besides, Da Vinci needs an operating room large enough to install because it is very bulky and complicated.

#### *Inflexible response*

Unlike humans, robotics is unlikely to sense and express real emotions leading to the lack of empathic and flexible reactions. Obviously, robots have outstanding capacities to store, access and recall large amounts of integrated data, however they cannot be flexible or adaptive in extraordinary situations as humans (Nwosu et al. 2019). Consequently, it is difficult for surgeons to trust and rely on it completely.

#### *Technical limitations*

The dexterity of the robotic arms is still restrictive because the manipulation of objects is usually challenging. Although the system can perform perfectly repetitive tasks for longer periods of time without weariness, it cannot gain experience to do better unless the operating system is updated (Nwosu et al. 2019). During the robotic surgery using Da Vinci, surgeons claimed difficulties in handling the semi-rigid, single-site instruments due to limitations of the range of movements (Shin et al. 2020). Furthermore, other difficulties are added alongside particularly triangulation, the instruments clashing and unfavorable ergonomics (Shin et al. 2020).

#### *Doctor and staff training*

Beside the traditional study, surgeons need to participate in one more comprehensive professional education and program service to be able to manipulate the Da Vinci instruments (“Intuitive | Robotic Assisted Systems | Da Vinci Robot” 2020). Furthermore, surgery assistants are also required to take part in the further training of draping and docking equipment to enhance efficient

operative times (Nezhat 2008). In the nutshell, it takes a longer time for doctors and staff to readily perform the Da Vinci surgery.

#### *Lack of haptic feedback*

Because surgeons no longer perform directly on the patients, visual cues become pivotal to ensure tissue manipulation under moderate force. Especially, while performing intracorporeal knots, the manipulation must be done carefully without undue force from the robotic arms (Nezhat 2008). Such feedback totally depends on the surgeon's visual cues because of the restriction of the robot's abilities.

#### *Limited instrumentations*

The robot or even Da Vinci still does not have full of necessary instruments for a certain surgery, for instance endoscopic or vessel sealing devices, it needs extra efforts to change or exchange those instruments which are quite troublesome during the whole performance (Nezhat 2008).

### **3.1.3. Opportunities**

#### *Expired patents*

Since the FDA first approved the dominant design Da Vinci in 2000, Intuitive Surgical Inc. has become a monopolist in the marketplace with a 16-year patent. Nowadays, more patents start to expire from 2016 has opened great opportunities for more players likely entering this robotic surgical market (Warren 2013).

#### *Customers' willingness*

Customers' willingness is quite open to RAS thanks to the superior advantages. Particularly, in robotic prostatectomy which is a category of laparoscopy, the survey of 800 patients was implemented and it showed a positive perception amongst correspondents. The main reasons for the interest of RAS were the possibility of decreased morbidity (54%), potentially improved outcomes (37%), and other reasons (9%) (John and Wiklund 2008).

#### *Increasing demand and new enters*

The high cost is usually a challenge for every clinic and hospital, however nowadays it is no longer a problematic issue when the demand generally has been increased and more competition in the market (Husty and Hofbaur 2018). Furthermore, the market has been more competitive as a result of more institutions entering this market, which makes the prices more reasonable (John and Wiklund 2008).

### *Technological developments*

Digital technology nowadays plays a crucial role in further development and inventions. Indeed, it provokes the integration of possible all-inclusive applications into RAS. For example, improvements in battery storage capacity, graphene, quantum computing, fifth-generation (5G) Internet artificial intelligence (AI) and Internet of things (IoT) technology (Nwosu et al. 2019).

### **3.1.4. Threats**

#### *Infancy*

Besides the outstanding advantages of robotic surgery, the RALS is still in its infancy phase compared with open radical prostatectomy. In order to define the true value of robotics, John et al. stated that validated questionnaires and analog assessment scales should be held to determine the real functional outcomes, especially considering the long-term follow-up results (John and Wiklund 2008).

#### *Device malfunction*

In robotic surgery, FDA data announced that there were 1535 (14.4%) adverse events with huge negative patient impacts, singling out 1391 injury cases, 144 mortality cases and over 8061 (75.9%) cases relevant to device malfunction during the surgical operations (Bora et al. 2020). There were 7 out of 37 procedures with the Da Vinci surgical system which were delayed because some device parts were necessarily changed which were camera control unit, battery supply, lamp module, master tool manipulator and camera manipulator. Meanwhile, the most common errors happen in the optical system and robot arm (Lavery et al. 2008; Kozlowski, Porter, and Corman 2006) (see Figure 2).



Table 2 Errors and their impact on procedures (Shrivastava, N. et al. 2015, 914)

|                    | Errors, n (%) <sup>a</sup> | Open conversion (n = 8) | Laparoscopy (n = 7) | Prolonged surgery (n = 7) | Rescheduled (n = 6) |
|--------------------|----------------------------|-------------------------|---------------------|---------------------------|---------------------|
| Camera             | 5 (33)                     |                         | 2 PL                | 3 PL<br>1 RARP            | 3 PL<br>1 RARP      |
| Power supply       | 4 (27)                     | 5 PL<br>1 RARC          |                     | 1 PL<br>1 UL              | 1 PL                |
| Master manipulator | 3 (20)                     | 1 RARC                  | 1 RARC<br>1 UR      | 1 RARP                    |                     |
| Arm                | 1 (7)                      | 1 RARP                  |                     |                           |                     |
| Set-up joint       | 1 (7)                      |                         | 1 UR                |                           | 1 RARP              |
| Unknown            | 1 (7)                      |                         | 1 AD<br>1 RAPN      |                           |                     |

PL = pyeloplasty; RA = robot-assisted; RARP = RA radical prostatectomy; RARC = RA radical cystectomy; RAPN = RA partial nephrectomy; RARC = RA partial cystectomy; AD = adrenalectomy; UL = ureterolithotomy; UR = ureteric reimplant.

### *Risk of infection*

In fact, the system assembles with very sophisticated components, especially robotic instruments that directly interact with the body incisions, these are difficult to disinfect thoroughly. Hence, patients may bear a higher risk of infection. There are higher levels of contamination of proteins and residues in robotic instruments in comparison with other instruments (Saito et al. 2017). Thus, novel standards of disinfection and classification are important to remove completely the protein from surgical instruments after every surgery (Bora et al. 2020).

### *Ethical issues*

There has raised a controversial topic concerning the responsibility of robots and their software when the malfunction happens and aggravate symptoms of patients, especially in the case of fatality. Besides, data privacy and protection are also another aspect of ethical issues as the robots can record, access and analyze a large amount of personal data without their permissions (Nwosu

et al. 2019). Actually, each surgical instrument has its potential dysfunctional risk due to its characteristics. It is difficult to attribute the responsibility of operators or manufacturers to failure unless a flaw is proven.

The following table is the summary table for the whole SWOT analysis of the comparison between Da Vinci and classic surgery.

| Table 3 Summary of SWOT analysis between Da Vinci and classic laparoscopic surgery  |   |
|---|---|
| Strengths   | Weaknesses  |
| <ul style="list-style-type: none"> <li>• Technological advancement</li> <li>• Precision</li> <li>• Less physical burden</li> <li>• Open surgical skills consolidation</li> <li>• Shorter learning curve</li> <li>• Low complication rate</li> <li>• Shorter length of stay (LOS) and faster recovery</li> <li>• Less blood loss</li> <li>• Less risk of infection</li> <li>• Independent 90-degree articulation</li> <li>• No training</li> <li>• Extending market share</li> </ul> | <ul style="list-style-type: none"> <li>• Huge investment</li> <li>• Inflexible response</li> <li>• Technical limitations</li> <li>• Doctor and staff training</li> <li>• Lack of haptic feedback</li> <li>• Limited instrumentations</li> </ul> |
| Opportunities   | Threats   |
| <ul style="list-style-type: none"> <li>• Expired patents</li> <li>• Customers' willingness</li> <li>• Increasing demand and new enters</li> <li>• Technological developments</li> </ul>   | <ul style="list-style-type: none"> <li>• Infancy</li> <li>• Device malfunction</li> <li>• Risk of infection</li> <li>• Ethical issues</li> </ul>  |

### 3.2. SWOT analysis of Kymerax-assisted surgery in comparison with the classic surgery

#### 3.2.1. Strengths

##### *Improved triangulation*

One major advantage of Kymerax compared to conventional surgery consists of providing two additional degrees of freedom (Takazawa et al. 2016). These additional features of instrument rotation and deflection help to reach hidden structures and to perform especially advanced movements, such as intracorporeal suturing, more easily (Hackethal et al. 2012).

### *Dexterity & precision*

Compared to conventional laparoscopic surgery, Kymerax has shown enhanced dexterity and precision. A performance test revealed improved needle control in suturing, more precise cutting along lines and sharper cutting edges than with conventional instruments (Sieber, Fellmann-Fischer, and Mueller 2017).

### *Ergonomics*

When accessing the abdominal cavity, the aim is to use a minimal amount of incisions which are located to optimally reach the operating field with conventional instruments. This often results in nonergonomic posture of the surgeon leading to shoulder and elbow strain. Increased triangulation can allow more flexible trocar placement which may reduce these common side effects of performing laparoscopic surgery (Hackethal et al. 2012).

### **3.2.2. Weaknesses**

#### *Less intuitive movements*

While overall ergonomics are reported to be enhanced, the movements required to manipulate the instrument are described as less intuitive. This makes surgery more tiring and may lead to earlier loss of concentration (Sieber, Fellmann-Fischer, and Mueller 2017).

#### *Longer learning curve and surgery time*

The mentioned performance above test revealed that operating with Kymerax is linked to a longer learning curve in order to control the instrument's movements and fully make use of its additional features. Additionally, it was reported that the operation steps are carried out more slowly with Kymerax, leading to increased surgery time (Sieber, Fellmann-Fischer, and Mueller 2017).

#### *Impaired view*

Due to the enhanced positioning of the instruments, one could assume that the visualization of the surgical field is enhanced. Surprisingly, a study revealed the opposite. The view is described as

worse which is explained by the sheath's outer diameter of 7 mm in comparison to 5 mm of conventional laparoscopic instruments (Sieber, Fellmann-Fischer, and Mueller 2017).

### **3.2.3. Opportunities**

#### *Great opportunity in the European market*

The Kymerax is a commercially hand-held robotic device offered by Terumo Medical Corporation, Japan (Payne, C. J. and Yang 2014). Kymerax is a handheld articulating laparoscopic device, that provides improved triangulation while preserving precise motions, has been introduced to the European market recently (Hackethal et al. 2012, 203). The Department of Gynecology and Obstetrics at the University Clinic of Giessen, Germany was the first facility worldwide to perform a gynecologic case. First clinical experiences and a guide for familiarization with the new motor-driven, articulating instrument system are discussed (Hackethal et al. 2012, 203–4). Meanwhile, Terumo closed down its Kymerax Business by October 2013. Nevertheless, the technique was bought by KARL STORZ GmbH & Co. KG© and might be released with some modifications in the future (Sieber, Fellmann-Fischer, and Mueller 2017, 4299).

#### *Greater benefits in other surgery fields*

Kymerax was successfully used during a total laparoscopic hysterectomy. The first clinical use in gynecologic laparoscopy proved to be feasible with the new robotic-driven, articulating, handheld surgical system. Kymerax may offer benefits in advanced laparoscopy, NOTES, and single-port surgery (Hackethal et al. 2012, 203).

Furthermore, this device is useful for oncological procedures because it allows for more accurate movements and better results in complex surgery (Iacoponi et al. 2015, 85).

#### *The opportunity in advancing tasks in laparoscopy*

A study conducted with 30 medical students without laparoscopic experience were prospectively randomized into 3 groups of 10 probands: group A - a standard instrument in both hands; group B - Kymerax instrument in the dominant hand; group C - Kymerax instrument in both hands.

The knot-tying exercise showed a substantial advantage in group A, but both Kymerax groups showed a steep learning curve, which could reach the level of group A in the end (Hruby et al. 2013, e22)

#### *Great potential in reducing cost and training time*

Compared to other full robotic consoles, Kymerax seems to be reasonably priced, therefore allowing for a wider spread distribution (Hackethal et al. 2012, 205). This innovative device offers a path-breaking alternative between conventional laparoscopic surgery and the unrivaled Da Vinci Robotic system (Hackethal et al. 2012, 206).

Robotic-driven handheld instruments could help inexperienced physicians acquire basic skills in laparoscopic techniques (Zapardiel, Hernandez, and Santiago 2015, 106).

#### **3.2.4. Threats**

##### *Require further clinical studies and validation*

Although Kymerax performed successfully in the first clinical use in gynecologic laparoscopy (Hackethal et al. 2012) and the efficacy of this robotic instrument has been tested with the European training in basic laparoscopic urologic skill and anastomosis tasks on a box trainer (Sánchez-Margallo, F. M., Sánchez-Margallo, J. A., and Szold 2018, 83), the studies about Kymerax are still limited. Therefore, further clinical validation and adequate clinical studies must be conducted to highlight the benefits of this instrument (Payne, C. J. and Yang 2014).

##### *Potential issues in concentration*

The performance between Kymerax and conventional laparoscopic instruments were compared in the study of Sieber, Fellmann-Fischer, and Mueller (2017). This study shows that although Kymerax brings an advantage to fulfill the tasks, there was an earlier loss of concentration. While 80% of the participants maintain concentration until the end of the study with traditional laparoscopic instruments, only 60% of users of Kymerax could stay focused until the end. Currently, this has not brought any risks for the patients yet. However, this should be further investigated and issues should be solved if there are any potential risks.

Table 4 Summary of SWOT analysis between Kymerax and classic laparoscopic surgery

| Strengths   | Weaknesses  |
|---|---|
| <ul style="list-style-type: none"> <li>• Improved triangulation</li> <li>• Dexterity &amp; precision</li> <li>• Ergonomics</li> </ul>   | <ul style="list-style-type: none"> <li>• Less intuitive movements</li> <li>• Longer learning curve and surgery time</li> <li>• Impaired view</li> </ul> |
| Opportunities   | Threats   |
| <ul style="list-style-type: none"> <li>• Great opportunity in the European market</li> <li>• Greater benefits in other surgery fields</li> <li>• The opportunity in advancing tasks in laparoscopy</li> <li>• Great potential in reducing cost and training time</li> </ul> | <ul style="list-style-type: none"> <li>• Require further clinical studies and validation</li> <li>• Potential issues in concentration</li> </ul>        |

**3.3. Comparison between Kymerax and Da Vinci robot in term of Strengths and Weaknesses**

Emerging hand-held devices might offer an alternative to master-slave robots, depending on the surgeon’s needs. In the following analysis, the Kymerax system is evaluated in comparison to the da Vinci robot.

Table 5 Summary of comparison between Kymerax and Da Vinci

| Kymerax  |   |
|--|---|
| Strengths  | Weaknesses  |
| <ul style="list-style-type: none"> <li>- Decreased investment &amp; maintenance costs</li> <li>- Compact design &amp; less setup time</li> <li>- Haptic feedback</li> <li>- Directly manipulated at the operating table</li> </ul> | <ul style="list-style-type: none"> <li>- Less ergonomics &amp; intuitive handling</li> <li>- Limited triangulation</li> <li>- Impaired view depending on imaging system</li> <li>- Earlier loss of concentration</li> </ul> |

One major advantage of Kymerax consists in lower costs for primary investment as well as maintenance and service which makes the system more affordable which might result in a broader distribution (Hackethal et al. 2012) and (Takazawa et al. 2016). Its compact design allows portability and less space required in the OR. Additionally, this is linked to a shorter setup time resulting in a decrease in operation costs (Payne and Yang 2014).

Kymerax offers haptic feedback which not only enables the surgeon to identify anatomical structures but even more importantly for better motor control. This can reduce the risk of damaging tissue by applying too much force, hence increase safety (Takazawa et al. 2016) and (Sieber, Fellmann-Fischer, and Mueller 2017). Furthermore, surgery is performed directly at the operating table, allowing the use in combination with any other desired conventional laparoscopic instrument. Additionally, in case of surgical complications, faster management, such as a change to emergency laparotomy, is possible (Ibrahim and Liselotte 2020).

With regard to instrument handling, the Kymerax system is criticized in terms of intuitive handling and ergonomics and its triangulation is limited to 270° of rotation and 85° of deflection (Alain, 2017, p. 7). Since Kymerax does not have an integrated imaging unit, it can be used with all available systems. Since the majority are still 2D systems, as elaborated earlier, this can impair the intraoperative view compared to the da Vinci. Additionally, working with Kymerax is described as more tiring and early loss of concentration is reported (Sieber, Fellmann-Fischer, and Mueller 2017).

It is essential to state that some weaknesses of the Kymerax become strengths and vice-versa when comparing the system to Da Vinci, such as costs, ergonomics and triangulation.

## **Chapter 4: Conclusions and Future outlook**

### **4.1. Conclusion**

In decades, the emergence of the robotic-assisted surgery has become a novelty in the medical field. The robotic surgery has developed rapidly and positioned itself as a predominant approach for many surgical procedures. Commonly, surgical robots can be divided into two main categories which are master-slave robotic systems and hand-held devices. One of the most active areas for research and development of surgical robots is laparoscopy surgery.

Despite many advantages of robotic-assisted surgery compared with classical surgery, the application of robotic surgical systems remains limited and controversial. Currently, many research conduct to review the validity of robotic surgery for either master-slave systems or hand-

held devices. Another concern is why RAS have less widespread application and the future of robotic for those two systems remain unknown. Therefore, this paper is conducted to examine the possible future impact of medical robotics. SWOT analysis is applied for the representative of master-slave systems and hand-held devices are Da Vinci and Kymerax.

The findings of this paper suggest that both Da Vinci and Kymerax offer great benefits for laparoscopic surgery in response to technological advantages. On one hand, Da Vinci is still all known as the most advanced surgical technology in 2020. Not only bringing significant improvement for the patient, mainly known as short operative time, shorter length of hospital stay due to faster recovery in most of the cases as well as lower blood loss but also gaining remarkable benefits for surgeon himself or herself by less physical burdens during the operation and shorter learning curve, which are results of six-degree of freedom, dexterity enhancement, stereovision and tremor filtering. Obviously, every instrument has the potential of risk of the device malfunction, as it was recorded from some existing research that the dysfunction of the machine is a considerable problem. Although this rate remains very low, surgeons need to be aware of it and make proper decisions in time.

On the other hand, Kymerax is the optimal choice regarding cost comparison. Kymerax improves dexterity and triangulation which shows enhanced precision. Additionally, Kymerax offers a compact design and enables less setup time. Furthermore, the surgeon manipulates directly at the operating table. In case of surgical complications, faster management, such as a change to emergency laparotomy, is possible. Nevertheless, it should be mentioned that the Kymerax also has disadvantages such as limited triangulation, impaired view and earlier loss of concentration which can negatively influence the performance of the surgeon. Due to the fact that many clinical applications conducted successfully with Kymerax, there is great potential for this device in the European market. This opportunity together with the cost-effectiveness could be a good foundation for Kymerax to be further developed and applied in the worldwide market. Furthermore, Kymerax has the potential opportunity to perform tasks not only in laparoscopy but also in other surgical fields. On the other hand, it is necessary to conduct further clinical study to further confirm the benefits and reduce potential issues in concentration.



The presented RAS-systems, such as the Da Vinci robot and the Kymerax hand-held device, offer good solutions to the limitations of open surgery. Nevertheless, both systems have their disadvantages and need to be further developed in the future. In the following chapter, some examples are given.

In the nutshells, the adoption of these robots largely depends on the cost of investment and the training time for surgeons. Despite the arising challenges to improve the practicality, opportunities for robotic surgery can be clearly seen. In the digital world nowadays, robotics has a promising prospect to shape the future of surgery.

#### **4.2. Future outlook**

In the past, Intuitive could set and maintain high investment and maintenance prices because of their monopoly position in the market. However, due to increasing competition recently, market prices of master-slave systems are likely to decrease in the future. Since healthcare systems are increasingly price-driven, those robotic systems could become more affordable and create a certain market penetration that has not been achieved so far. Furthermore, the attractiveness of robotic surgery will be increased by technical advancements, such as reduced weight, simplified transport or possibly a fixed installation on the deck of the OR wherefore master-slave systems are likely to spread more widely in the future.

In order to cover the gap between conventional laparoscopy and master-slave systems, various hand-held devices were introduced into the market. The term 'hand-held device' is actually misleading because it is a conventional instrument with two additional movements controlled by servo motors. Some disadvantages of these systems were described in this paper. However, creating more intuitive and ergonomical hand-held devices which allow all DOFs in space will likely lead to real competition for master-slave systems.

In fact, both Da Vinci and Kymerax are standardized and consistent which enables installment for every hospital or institution as long as the infrastructure is secure. Hence, it will open many opportunities of robotic-assisted laparoscopic surgery in the near future due to their superior advantages.

## **Chapter 5: Limitations**

There are four major limitations in this study that could be addressed in future research. Firstly, the study only includes secondary data analysis which was collected through scientific research papers. For a more comprehensive study, primary data could be included. Secondly, there are various master-slave systems and hand-held devices currently available. In this study five robotic systems were introduced, from that two were chosen to do the SWOT analysis. However, various systems are in the development or release processes that could be examined for future studies. Thirdly, not many studies on the Kymerax-system are currently available. In order to make scientifically valid statements, further studies with a high degree of evidence are necessary. Finally, due to the time limitation, the depth of this paper might be limited, the research could be further conducted when there are more clinical studies and academic papers.

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## Appendix

### Appendix 1. Three components of the da Vinci system<sup>1</sup>



**SURGEON CONSOLE**

Your surgeon sits at the console, controlling the instruments while viewing your anatomy in high-definition 3D.



**PATIENT CART**

Positioned alongside the bed, the patient cart holds the camera and instruments that the surgeon controls from the console.



**VISION CART**

The vision cart makes communication between components possible and supports the 3D high-definition vision system.

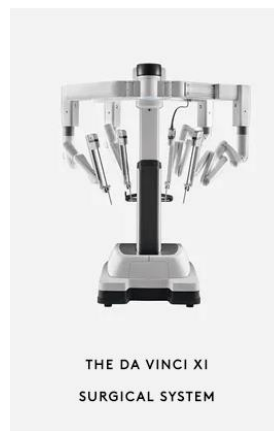
### Appendix 2. A family of technologies<sup>2</sup>



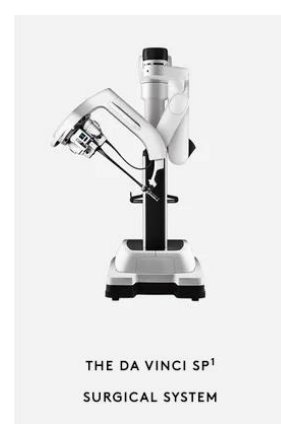
**THE DA VINCI SI  
SURGICAL SYSTEM**



**THE DA VINCI X  
SURGICAL SYSTEM**



**THE DA VINCI XI  
SURGICAL SYSTEM**



**THE DA VINCI SP<sup>1</sup>  
SURGICAL SYSTEM**

<sup>1</sup> <https://www.davincisurgery.com/da-vinci-systems/about-da-vinci-systems##>

<sup>2</sup> <https://www.davincisurgery.com/da-vinci-systems/about-da-vinci-systems##>