Robotic Systems in Current Clinical Practice

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***Abstract*—Medical robotic systems are successfully employed in various surgical specialties today. Yet, a substantial number of remarkable systems that have been developed and piloted, have failed to reach commercialization and thus adoption in clinical practice. This is partly due to the strict regulatory requirements, which typically occupy a significant amount of the development time while incurring additional costs. Pertinent to regulatory approvals is the field of Human Factors, which plays a central role in the design of safe and efficient medical devices. This study briefly introduces the FDA regulatory approval process, discusses the role of human factors in the design process and highlights specific robotic systems that have obtained approval for clinical use. The purpose is to show the status of robotic technologies in relation to the current clinical practice.**

Keywords*—*Robotic Surgery, Medical Robotics, Regulatory Approvals, Human Factors.

I. INTRODUCTION

Robotic systems have been utilized in various surgical specialties including general surgery, orthopaedic and neurosurgery, as well as other therapeutic procedures such as radiation treatments. In general surgery there exists a tendency towards less invasive procedures. With the use of laparoscopy, patients' scarring and hospitalization periods have been considerably reduced. Furthermore, computer and robotics technologies have introduced novelties that enhance the surgeons' skills to accomplish high precision during complex surgical processes [1].

Robotic surgery became a reality before the end of the last century. Key developments include the *Aesop* voice-controlled camera-holding device and the *Zeus* robotic system, both by *Computer Motion*. The company *Intuitive Surgical*, developer of the *da Vinci Surgical System*, played a leading role in the medical robotic systems landscape. The two abovementioned companies merged in 2003 and the da Vinci system became one of the dominant systems in the market. A master-slave system architecture was implemented in relation to the Zeus and da Vinci robotic systems, where the surgeon is located at a console at the side of the operating table and controls the surgical instruments. Notable surgical robots have also been developed for a range of applications including orthopedic surgery, stereotactic brain surgery and urological interventions.

Depending on the used imaging method, image-guided interventional systems can be specific to laparoscopy, ultrasound, computed tomography (CT), magnetic resonance imaging (MRI), and X-ray fluoroscopy. Each method presents different advantages but also unique challenges, as for example the MR-compatible robotic systems [2], [3]. New possibilities are nowadays provided by telerobotics, which allow procedures such as surgeries, treatments, and diagnoses to be conducted over long distances [1], [4], [5].

Even though numerous systems have been developed, only a few of them have been commercialized and established in clinical practice. This is partly due to the high cost of the equipment, which is also associated to the strict regulatory requirements. In the United States, the development, testing and evaluation of any medical robotic device is controlled by the *Food and Drug Administration* (FDA). Similar, but not identical, regulatory requirements apply in Europe. As a result, robotic products are often required to comply with both, while national policies may impose additional requirements. A brief description of the FDA regulatory process is presented in Section II.

The development of medical robotic systems combines clinical as well as engineering challenges necessitating an interdisciplinary approach. Moreover, human factors greatly affect the effectiveness and safety of medical robots and as such, constitute an integral part of the design process. Human factors considerations are discussed in Section III.

The emerging and rapidly growing medical robotic systems market is introduced in Section IV. Finally, Section V discusses the status and potential of medical robotic systems in standard clinical practice, while describing selected medical robotic systems that have been approved for clinical use.

II. FDA REGULATORY PROCESS

In the United States a prerequisite for commercialization of medical devices is to obtain regulatory approval from FDA. This process usually takes a significant amount of the development time and cost. For a medical device there are two paths to market depending on its classification:

- via the Premarket Approval (PMA) process [6]. This is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of all medical devices that involve a high level of risk.
- via the 510(K) [7] pre-market notification process. Clearance is obtained if the new device is ''substantially equivalent'' (i.e., at least as safe and effective) to a legally marketed device that is not subject to PMA (referred to as a "predicate" device).

Among the requirements is the implementation of a Quality Management System (QMS) that meets the FDA Quality System Regulation (QSR) [8]. It requires manufacturers to establish and follow quality assurance procedures to ensure that their products consistently meet

applicable requirements and specifications. This extends to all major suppliers involved in the design and production of the device. Once authorization is granted, it remains valid as long as the design of the device or its intended use are not altered. The equivalent regulatory requirements for medical devices in Europe include the CE marking and compliance with ISO 9001 and 9002 standards for the manufacturing processes (often these are grouped together under the term ISO 9000).

III. The Role of Human Factors in the Design of Medical Robotic Systems

Human factors are an integral part of the regulatory examination procedure. In general, they provide a framework for designing more usable, appealing, efficient and safer devices. Nowadays, with the improved reliability of engineering systems, when human-machine interaction is involved, accidents are more likely to occur because of human error. Therefore, considering human factors as part of product design yields error resilient systems. The profound approach is to embed human factors aspects in the system's design specifications, thus becoming an integral part of the design procedure, rather than implementing adjustments and/ or fixes to the final product, which can be both costly and inefficient. The importance of human factors in the design of medical devices has attracted considerable scientific attention in recent years [9], [10].

Well-established sets of guidelines for the design of man-machine interfaces also apply to the case of medical robotics. Indicative examples include: (i) Controls and displays should be appropriately grouped together, spaced, colored, labeled, and be intuitive and readily identifiable; (ii) Appropriate force resistance and travel should be assigned to controls and the direction of activation should be intuitive. When appropriate, tactile coding should be used, i.e., making the controls identifiable by touch (through shape, size and texture); (iii) Auditory displays and alarms should have appropriate frequency, amplitude, and coding; and (iv) Monitors should not be overcrowded and must provide the user with sufficient and readily useable information rather than overwhelmed with excessive, unprocessed or redundant information.

The ergonomic aspects also require systematic analysis. Relevant considerations extent beyond the ergonomics of human-robot interaction to the ergonomics of the overall operating room (OR) setup. This needs to be reconsidered in order to appropriately accommodate the robotic hardware and the rest of the OR equipment (e.g., monitoring and anesthesia). It is also worth mentioning that human factors not only play a role in preventing accidents but also in the investigation process in case of an accident.

IV. Medical Robotic Systems Market

The medical robotic systems market is driven by the acceptance of the technology by hospitals, the rise of research and development in new applications, and the increasing demand for safe and effective minimally invasive surgical procedures. The broader scope of medical robotic systems includes various types, such as surgical robots, non-invasive radiosurgery robotic systems, prosthetics and exoskeletons, and rehabilitation robots. It also includes non-medical robots operating in hospitals [11] and assistive robotics for elderly care [12].

In terms of revenue, the U.S. is likely to continue to dominate the global medical robotic systems market due to the early adoption of relevant technologies. Among the abovementioned categories, surgical robots are expected to enjoy the largest revenue share. The global market for medical robotic systems is driven by factors such as:

- Technological advancements in healthcare industry
- Investments in relevant research and development
- Increase of elderly population worldwide
- Increasing demand for efficient, precise and minimally-invasive surgical techniques

Restraining factors of the market include:

- Cost of equipment
- Safety concerns
- Complexity of procedures
- Lack of trained surgeons

TABLE I. Reviewed Medical Robotic Systems with Regulatory Approvals

Robotic System	***Company***	***Web-site***	***Application Area***
Da Vinci Surgical System	Intuitive Surgical, Inc	https://www.intuitive.com	General Surgery
Senhance Surgical System	TransEnterix	https://www.senhance.com	General Surgery
Monarch Platform	Auris Health	https://www.aurishealth.com	General Surgery
REVO-I	Meere Company	http://www.meerecompany.com	General Surgery
Mako system	Stryker	https://www.stryker.com	Ortopaedic Surgery
TSolution-One Surgical System (ROBODOC)	THINK Surgical	https://thinksurgical.com	Ortopaedic Surgery
ROSA Surgical Robot	Medtech	https://www.medtech.fr	Brain & Spinal Surgery
Mazor X	Medronic	https://www.medtronic.com	Brain & Spinal Surgery
Neuromate	Renishaw	https://www.renishaw.com	Neurosurgery
CorPath GRX	Corindus	https://www.corindus.com	Percutaneous Coronary Interventios
CyberKnife	Accuray	https://www.cyber-knife.net	Stereotactic Radiosurgery

V. FDA-APPROVED PLATFORMS

Some renowned robotic systems that have obtained permissions for clinical use are briefly presented to show the current status of medical robotics in relation to their clinical applications. These systems are listed in Table I. A short description of their individual characteristics, capabilities and special features is provided below.

A. Da Vinci surgical system

At present, a widely used surgical robot is the *da Vinci Surgical System* (*Intuitive Surgical, Inc.,* Sunnyvale, CA), which is suitable for laparoscopic procedures. It is currently used in various surgical areas including general surgery, urology, gynecology, lung surgery, and oncology.

Figure 1. Components of the da Vinci Surgical System: Patient cart, Vision cart, Surgeon console (Figure courtesy of Intuitive Surgical, Inc. - The copyrights are protected by Intuitive)

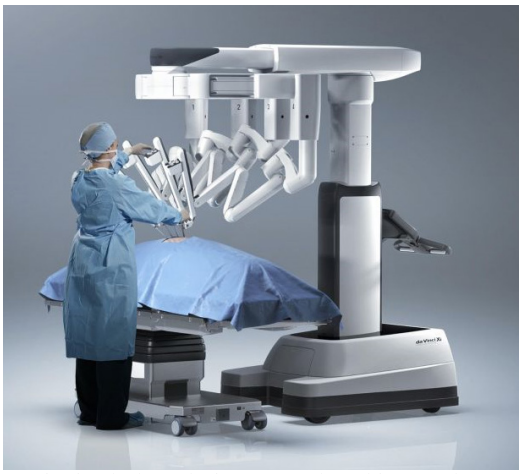

Figure 2. The da Vinci Surgical System patient-side cart (Figure courtesy of Intuitive Surgical, Inc. - The copyrights are protected by Intuitive)

The da Vinci Surgical System's latest model, the *Xi* (Fig.. 1), comprises a master console and a mobile platform with four robotic arms manipulating the surgical instruments. The surgeon is provided with a magnified HD–3D view of the surgical field through the endoscope optics. The vision cart is installed with a large HD display that shows a live feed of the procedure. The robotic arms are controlled in a master–slave control mode through the surgeon's console that provides a comfortable ergonomic position. The console allows various adjustments to match the operator's height and reach. Tremor filtration is among the features of the control system. Various surgical instruments can be attached to the arms to fit the requirements of a large range of procedures. These instruments are highly dexterous and include graspers, needle drivers, clip appliers, and energy instruments.

B. Senhance Surgical System

Senhance is produced by *TransEnterix* and is a system that involves four robotic arms (Fig. 2). It is a reconfigurable system that facilitates remotely-operated 3D endoscopy procedures by utilizing haptic sensation and a unique eye-tracking system, allowing less reliance on other operating room staff or delays while stopping to reposition the camera. The haptic feedback provides the surgeon with sensing of the pressure/tension through alerts when some thresholds are exceeded. This information is considered vital in the case of delicate surgical tasks. As with other surgical robotic systems with multiple arms, one of the arms is dedicated to holding and manipulating the laparoscopic camera. The surgeon's ergonomically-designed console provides for a comfortable position that minimizes strain and fatigue. The system's "digital laparoscopy" philosophy aims at enhancing the familiarity with laparoscopic surgery through the abovementioned features. Applications include laparoscopic colorectal, gynecologic, and cholecystectomy interventions [13].

C. The Monarch Platform

A robotic endoscopy system is the *Monarch Platform* (*Auris Health, Inc.*), shown in Fig. 4. It is a teleoperated endolumenal bronchoscope. It was designed to support surgeons to perform diagnostic (e.g., early diagnosis of lung cancer) and interventional tasks (e.g., endoscopically remove lung tumors) [14]. It is composed of flexible arms equipped with cameras and instruments, which are controlled via a joystick. It exploits the capabilities of flexible robots to endoscopy, which uses small cameras that enter the body through natural orifices. The physician can effectively control the bronchoscope to make precise movements while moving through the bronchial tree.

D. REVO-I Robotic Surgical System

The *REVO-I* system was developed by the *Meere Company* in South Korea. This model obtained national regulatory approval and is available for patient clinical work. The REVO-I system is a master-slave system designed for laparoscopic surgery. It comprises of an ergonomically-designed surgeon control console, a four-armed robotic operation cart, an HD vision cart and reusable endoscopic instruments. The vision system provides enhanced depth perception, which is important for visual accuracy and precise spatial orientation during surgical procedures. The available surgical instruments are endowed with the required dexterity and their design is analogous to the conventional ones that are familiar to surgeons. Successful clinical studies on actual patients include radical prostatectomy [15]. The latest version integrates haptic feedback, which is, in general, considered as one of the major enhancements to robotic surgery.

E. Mako System

The *Mako system* by *Stryker* was designed for hip and knee replacement (arthroplasty). It takes preoperative images for patient-specific 3D modeling of the joint to help in precise implant positioning following a preoperative plan [16]. Successful clinical outcomes depend on correct component placement. While surgeons use the robotic arm to resurface the knee for placement of implants, the system provides real-time intra-operative visual, tactile and auditory feedback, enabling a high level of precision and optimal positioning of the implants.

F. TSolution-One Surgical System

The *Tsolution-One* (previously *Robodoc*) was originally developed by *Curexo Techonology*, Fremont, CA, which later became *THINK Surgical, Inc*. The system includes two components: a 3D preoperative planning workstation and a computer assisted tool utilized for precise cavity and surface preparation for hip and knee replacement surgeries. Preoperative planning is patient-specific and the milling procedure is implemented with high precision while preparing the bone cavity and joint surface. Specialized drill bits are used for this purpose. Advantages of this technology include dimensional accuracy, precision milling (submillimeter accuracy), optimal alignment and high rate of bone to implant contact rate [17]. The preoperative planning involves 3D modeling based on CT scans. Using the models, the surgeon can select an implant from an open library of commercially available ones and manipulate it until an optimal placement is found for the particular patient's anatomy.

G. ROSA surgical robot.

The *ROSA Brain system* by *Medtech*, France is used in brain surgery. It is suitable for various types of cranial interventions requiring surgical planning based on preoperative data, precise location of the patient's anatomy, and accurate positioning and handling of instruments [18]. The purpose of the system is to make surgical interventions safer and more effective without modifying the neurosurgeon's standard operating protocol. The system is endowed with six degrees-of-freedom providing dexterity and ability to reproduce the movements of the human arm. In general, for this application robotic systems capitalize on key features of manipulation: steady-hand, precision and repeatability. It provides haptic feedback to surgeons and uses laser measurements for touch-free registration or navigation in the skull (without requiring fiducials or stereotactic frames). The device assists the surgeon with interventions such as biopsies, electrode implantation for functional procedures (stimulation of the cerebral cortex, deep brain stimulation), and open skull surgical procedures requiring a navigation device. More recently the scope of the platform's applications was extended to spine surgery.

H. Mazor X

The *Mazor X,* by *Medronic* is intended for precise positioning of surgical instruments or spinal implants during general spinal and brain surgery. It can be used in either open or minimally invasive procedures [19]. The Mazor X navigation system tracks the position of instruments, during spinal surgery, in relation to the surgical anatomy and identifies this position on diagnostic or intraoperative images of a patient. Its imaging cross-modality registration process allows the robotic system to analyze and pair images from different modalities (e.g., preoperative CT with intraoperative fluoroscopy or 3D surgical imaging). Among the system's imaging capabilities is to use 2D fluoroscopic projections from standard C-Arms and convert them into volumetric 3D images. The system allows for pre-operative or intra-operative planning. Once a plan is created the software guides the surgical arm through the desired trajectory to the required positions.

I. Neuromate

The *Neuromate* (*Renishaw*) (Fig. 3) robot provides a platform for a broad range of neurosurgical stereotactic procedures facilitating precise and safe targeting while saving time. It has been used in numerous electrode implantation procedures for deep brain stimulation and stereoelectroencephalography, as well as stereotactic applications in neuroendoscopy, and biopsy [20]. The system is compatible with procedures using both general and local anaesthesia.

Figure 3. Neuromate for stereotactic neurosurgery (Figure courtesy of Renishaw - The copyrights are protected by Renishaw)

The Neuromate robot can be either used with a stereotactic frame, or in frameless mode for reduced patient trauma. The planning software can fuse CT and MRI data sets, and automatically register patient images to the stereotactic space. The software also allows to improve safety and save time through clear visualization of anatomical features and definition of safety corridors around trajectories.

J. CorPath GRX Vascular Robotic System

The *CorPath GRX Vascular Robotic System* by *Corindus* (Fig. 4 & 5) is a robotic-assisted platform developed for percutaneous coronary interventions [21]. It belongs to the "precision vascular robotics" category. It capitalizes on the accuracy of robotic precision and radiation protection advantage for the primary operator. The physician can work from a comfortable radiation-shielded workstation, without wearing a radiation protection apron. Using joysticks and touchscreen controls the physician operate the robotic device to control coronary stent balloon catheters and guidewires with high accuracy. Compared to manual methods, the robotic-assisted intervention provides better visualization to assess anatomy and facilitate navigation, enables high-accuracy measurements, more precise stent positioning, and more effective stent deployment.

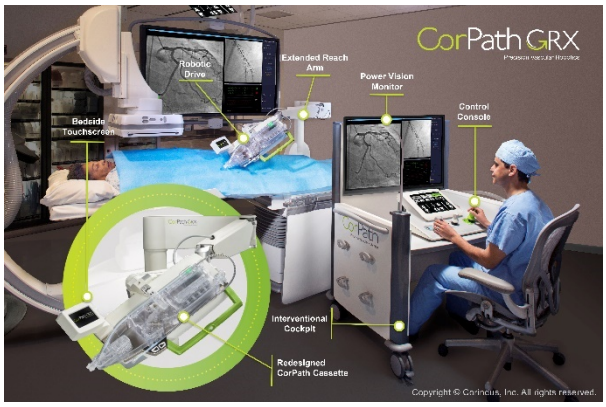

Figure 4. CorPath GRX Vascular Robotic System (Figure courtesy of TransEnterix, Inc., © 2019 TransEnterix, Inc.)

Figure 5. CorPath GRX Cassette (Figure courtesy of TransEnterix, Inc., © 2019 TransEnterix, Inc.)

K. *CyberKnife*

The *CyberKnife* by *Accuray* is a robotic stereotactic radiosurgery system for precise, and non-surgical treatment of tumors and lesions (including prostate, lung, brain, spine, liver, pancreas, and kidney) [22]. It consists of a lightweight and compact radiation device mounted on a robotic arm and a computer assisted image guidance targeting system. Treatment planning is based on preoperative CT/MRI images. The system is capable of compensating any patient movements during the treatment and also adjusting its position for targets that move with breathing (respiratory compensation). For this purpose, a camera system monitors external breathing motion and then correlates this information with the motion of the internal tumor. This is particularly important for tumors on organs that move considerably with breathing, such as the lung and the liver. The accuracy of the system allows delivering the maximum dose to the tumor, while minimizing healthy tissue exposure.

VI. Conclusions

In the past 25 years, the field of surgical robotics experienced a tremendous growth. Robotic surgery solutions are now increasingly used in standard clinical practice. In that context, significant growth is expected once tangible clinical benefits are linked with cost-effectiveness. Early systems were expensive, complex and occupied a large space in the operating theatre. Nowadays, developments focus on cheaper, sensor-rich devices that integrate human factors by design and provide for specific and high precision operations. Regulatory standards compliance and Intellectual Property (IP) protection are critical issues towards facilitating wider adoption. In addition to the regulatory issues for the acceptance of medical robotics, wider ethical, legal and insurance aspects need to be systematically addressed.

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