TREND OF SURGICAL ROBOT TECHNOLOGY AND ITS INDUSTRIAL OUTLOOK

BYUNG-JU YI

Electronic Systems Engineering Department, Hanyang University, Korea
E-mail: bj@hanyang.ac.kr

Abstract - Since the launch of the da Vince robot by Intuitive Surgical Co., Ltd., the surgical robot market has started to be launched in earnest. Mako Surgical's knee replacement robot has been released as the second successful model. Recently, many existing medical device companies or other global companies stepped into surgical robot market due to the large demand and the possibility of market expansion. The market is divided into two major divisions: fast follower following da Vince type robot and first mover sector for surgery except laparoscopic surgery. Surgical robot system is a fusion technology of various core technologies such as robot technology, sensor technology, navigation technology, surgical tool technology, and integration of these technologies, so it is difficult for companies, research institutes and researchers, which do not have experience, to form global competitiveness in a short time. It is recognized that global companies are moving into new surgical robot market through M&A or cooperation as needed. There is an urgent need for each national policy to encourage cooperation models.

Keywords - Surgical Robot, Minimally Invasive Surgery, Fusion Technology, Navigation Technology.

I. INTRODUCTION

Surgery has been evolved from open-surgery to robot surgery. Most of the surgeries were performed by laparotomy, but they have disadvantages such as excessive bleeding from large incisions, wounds, side effects, and long recovery time. Minimally Invasive Surgery (MIS) has become possible in line with the development of diverse types of diagnostic techniques and diagnostic devices. The development of medical imaging devices such as MRI, CT, PET, and 3D graphics technology enables visualization. During the operation, X-ray, angiography, and endoscopy were used to make a MIS without a lot of incision. Although MIS has contributed a lot to improving the quality of surgery, the precise positioning of the lesion and the operations requiring fine manipulation are still the limitations. Therefore, combining the precise robot manipulation technology with the 3D medical image navigation technology is necessary to allow more stable and successful operation.

In 1985, medical robots started to use PUMA560, an industrial robot, for brain surgery. After confirming the possibility of medical robots, various researches and products using robots in medical field were developed. da Vinci (Intuitive Surgical Inc.), which opened the era of full-scale robot surgery, promoted the popularization of robot surgery and the development of related technologies.

Currently, robots are used not only for surgery but also for all medical applications, including diagnosis, treatment, rehabilitation, and nursing assistance. This paper will describe the state of technology development and future prospects of surgical robots in particular.

Surgical robots are divided into two main categories as shown in Fig. 1: Intelligent eyes and intelligent hands. Intelligent eyes include hardware and navigation software technology that allows for invisible lesions to be seen in the interior, or to enlarge or reveal invisible lesions or small appearances. Intelligent hands include surgery tools for surgery, surgical robots and remote control devices that perform surgery on behalf of doctors.

There are two types of surgical robots as shown in Fig. 2. The first one is a surgical robot system for the soft tissues of the abdominal cavity, thoracic cavity, and vagina of the human body. The camera and a number of surgical instruments are inserted into the human body through small incisions. The da Vince robotic system is a representative example.

The second one is a surgical robot system that targets lesions in the brain, bone, or muscle. The 3D model of the patient's lesion is created based on the medical images taken before surgery. Based on this visual information, a surgical plan is established. During surgery, the 3D patient coordinate system created before surgery and the coordinate system of the patient lying on the operating table can be matched using various sensors, so that the relative position between the surgical tool and the lesion can be known. Thus, the surgeon can predict the location of the invisible lesion. ROBODOC, developed in early 1990, is the first model of the image guided surgical robot system. Since then, this market has not been largely established and currently there is no special major player.

According to the 4th industrial revolution, the market for medical robots will grow by 15% annually, reaching to $ 11.4 billion by 2020, and the market for surgical robots will reach 60% of the entire robot

market. (New Concept Medical Devices Report, Korean FDA, February 2017)

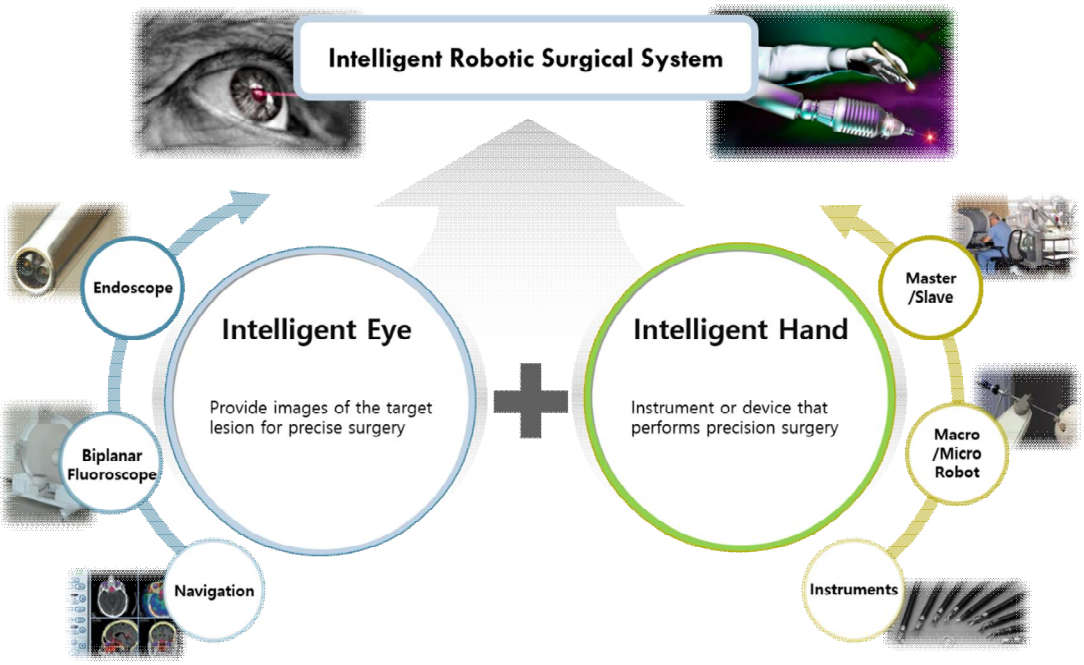

Figure 1. Category of Surgical Robot Technology

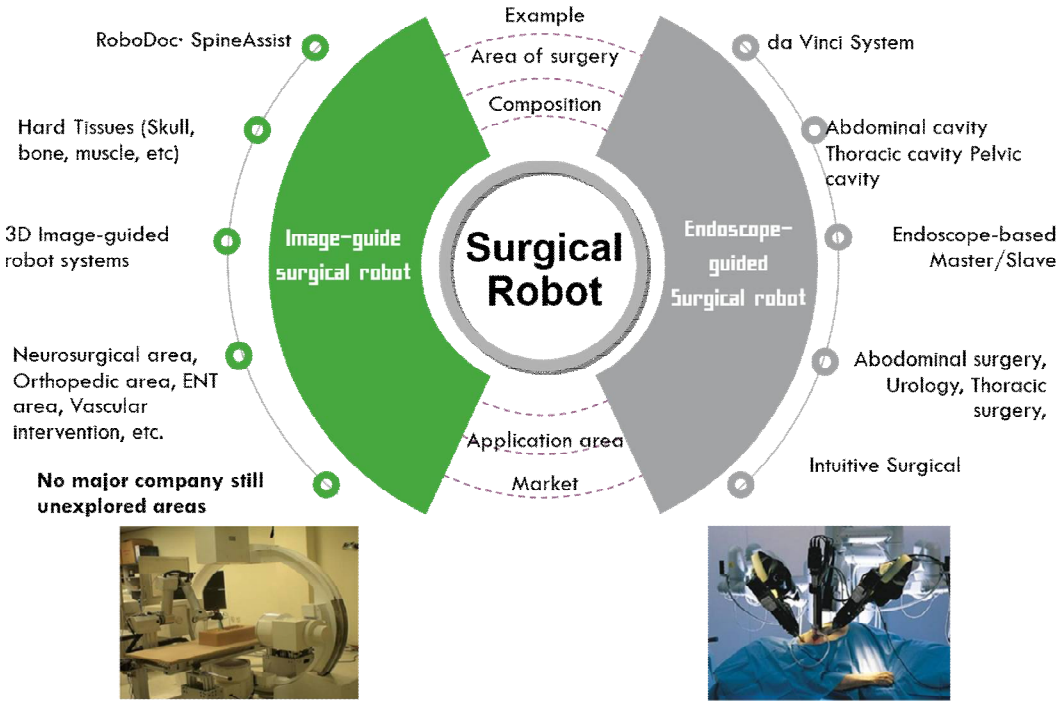

Figure 2. Classification of Surgical Robot

The sales of laparoscopic surgery robots increased from 400 million won in 2013 to 15.4 billion won in 2014, followed by 3 billion won for medical diagnosis and inspection robots, and 2 billion won for rehabilitation robots. Joint surgery robots, navigation-based surgical robots, surgical robots, surgical tools, and patient-moving lift bed robots showed poor results. According to data released by Frost & Sullivan, the Korean surgical robot market is expected to grow to US $ 49.1 million by 2018 and grow to an annual average of 45.1%.

According to the analysis of patent trends of medical service robots analyzed by WIPS, 411 cases in the United States, 215 cases in Korea, 203 cases in Japan, and 139 cases in Europe. An innovative research firm in the United States (Intuitive Surgical Co) has filed

the most patents on medical service robots in the world. [Source: Patent Story / Patent and Prospect of Medical Robot, 2014]

The market for robotic medical devices is steadily increasing and is expected to explode. However, there is no appropriate international standard for licensing and standards being. The robotic medical devices developed so far are used in combination with common standards for medical devices such as quality management system (ISO 13485), risk management (ISO 14971), medical electrical equipment (IEC 60601-1). In addition, IEC 60601-2-X and IEC 80601-2-X are applied to products that develop individual specifications as needed. As the development of robotic medical devices has been activated, international standardization of robotic medical devices has been actively developed and representative regulations are being developed in ISO TC 299.

As international standards for robotic medical devices are under development, international standards and specifications applicable to medical robots at present can be applied to the common standards of IEC 60601-1, 3.1 edition.

II. R&D TREND OF SURGICAL ROBOT

2.1. da Vinci type surgical robot

Mirae Company: Revo-i, the second da Vinci-type surgical robot system developed in the world, has recently completed clinical trials on gallbladder and prostate resection, and is in the process of manufacturing GMP and item approval for product launch. Revo-i is expected to be commercialized starting from domestic market after securing additional user convenience.

TransEnterix (USA): ALF-X system, a robotic surgical instrument that complements da Vinci's shortcomings was developed. A camera moving to the doctor's point of view was attached to the robotic arm, and a physician sitting at the console with a haptic reaction sensor made it possible to distinguish between touch and bone tissue. Surgical equipment costs $ 1.8 million more than da Vinci, but the cost of surgical instruments is cheaper. TransEnterix is preparing to license the US Food and Drug Administration (FDA) with its market entry target in 2017.

Verb Surgical (USA): Google and Johnson & Johnson (J & J) created a joint venture. Verb Surgical aims to commercialize a digital surgery platform five years later. Technologies will be based on robot learning, surgical tools, and video technology through machine learning and application of cloud computing technology.

2.2. Other surgical robots

Stryker, MAKO-surgical (USA): It is a robotic system that is used for knee or hip surgery. This robotic system is a commercially successful model by complementing the shortcomings of ROBODOC, which was developed in the 1990s but fails to secure markets.

MAZOR (Israel): As the first spinal surgery robot, about 80 units have been sold globally over the past decade and have not been able to form a market yet. In 2016, Medtronics, a medical device company, took over and launched a new model called MAZOR-X.

ROSA (US): The purpose of this robot is to perform percutaneous surgery by removing Leksell frame and using navigation software and It is a commercialized brain stem surgery robot, but has not yet formed a large market.

MED-Robotics (US): It is the first commercially available larynx surgical robot. It is composed of a motor-controlled flexible tube equipped with a camera at the end and multiple flexible surgical tools. The flexible tools are inserted through a hollow tube mounted next to a flexible tube and is directly operated by a doctor.

Hansen Medical (USA): Engineers of Intuitive Surgical started up a company to develop the first general-purpose vascular interventional robot and have completed the FDA registration. However, its market is not yet formed.

Koh Young Technology (Korea): A DBS surgical robot for neurosurgery has been licensed and is now undertaking clinical test.

The Table 1 shows the surgical robotic systems developed and being developed globally.

Area	Company	Product	Market
Abdominal	Intuitive surgical	da Vinci	O
	Mirae company (KOR)	da Vinci type robot	
	Google/J&J	Verb Surgical	
	TransEnterix	ALP-X system, TiTan Medical	
Orthopedic	Stryker(MAKO)	Knee/Hip	O
	Think Surgical	Knee/Hip	
	OMNI(OMNIBotics)	Knee	
Neurosurgical	Hyundai heavy industry (KOR)	Knee	
	Medtronic/Mazor	Spine/Neuro	O
	ZimmerBiomet/Medtech (ROSA)	Spine/Neuro	O
	Globus Medical	Spine	
	7-D Surgical	Spine	

	KBMedical(AQrate)	Spine	
	ORION	Endoscopic disk surgery	
	Kohyoung (KOR)	Neuro	
ENT	Medrobotics	Throat surgery, NOTES	
	Kohyoung (KOR)	ENT	
	Hansen Medical	Vascular intervention robot	

Table 1. Surgical Robots

III. IMPLICATIONS FROM INTERNATIONAL RECHEARCH TRENDS

As strategies to enter the market in the earliest times, existing global medical device companies are entering into the surgical robot field or business collaboration is taking place.

Example: Stryker + MAKO-surgical
Medtronix + Mazor
Johnson & Johnson + Google

The core technology of surgical robot can be classified into robot mechanism design technology, control and operation technology, medical image and navigation technology, and simulation technology.

Many groups are making efforts to acquire sensor development and navigation solution with self-improved function without relying on NDI, a strong player in the navigation market.

Fierce competition has been accelerated in the field of spine surgery and orthopedic surgery, which is based on navigation software in particular. Currently, no major company does not yet exist in these fields world widely.

Further research and development in the core technology field is urgently needed for leading technology development and commercialization.

Classification	Contents
Robot mechanism design technology	Slave Robot, Haptic Device, Surgical Tool New technologies required: Flexible mechanism technology
Control and operation technology	Robot control technology Robot-user interface technology, Design technology of sensor and mounting mechanism suitable for medical environment New technologies required: sensor technology to ensure high accuracy and reliability
Medical imaging and navigation technology	3D stereo imaging technology Technique to track patient's three-dimensional position and posture Image registration technology between diagnostic images at the stage of surgery planning In order to reach the affected part of the patient, the spatial registration technique which defines the position and posture of the affected part as reference coordinates of the surgical tool New technologies required: less than 0.5mm precision registration technology
Simulation technology	Modeling and simulation technology of operating room environment

Table 2. Classification of Core Technology

CONCLUSION

We must pursue a strategy to accelerate the market entry cycle by inducing collaboration between domestic companies or domestic companies and global companies.

For commercialization, it is very important to certify medical devices that meet international certification. To do this, all technical development projects that the government will support in the future should be designed according to the standardized international certification (IEC 60601-1 3.1ed), which will be licensed from the U.S.A. since August 2016 and from the EU in January 2018.

As a developer, it is necessary to establish a commercialization plan considering the right understanding of medical device certification level shown in Table 3, whether the number of insurance is set, whether it is versatile, and so on.

ACKNOWLEDGMENTS

This work was supported by the Technology Innovation Program (10052980, Development of microrobotic system for surgical treatment of chronic

total occlusion) funded by the Ministry of Trade, Industry & Energy (MOTIE, Korea). This work performed by ICT based Medical Robotic Systems Team of Hanyang University, Department of Electronic Systems Engineering was supported by the BK21 Plus Program funded by National Research Foundation of Korea (NRF).

REFERENCES

[1] Research on Technology Competitiveness in Medical Robotics, Chungbuk National University, Korea, 2016.
[2] New Concept Medical Device Report by the Food Stations, February 2017.
[3] Frost & Sullivan, Image-guided Surgery and Robot-Assisted Surgery Market in Asia-Pacific.
[4] 4. Domestic skill level of medical robots, KISTEP, 2015.

Risk Level			Definition
Korea	EU	Risk	
Class 1	Class I	Lowest	Not in contact with the body, or contact with the body, but almost no potential risks
Class 2	Class IIa	Low	The probability of failure exists, but potential risks are low
Class 3	Class IIb	Moderate	Inserted into the body for a certain period of time or potential risks are high
Class 4	Class III	High	Inserted into the human boy permanently or used for CVS, CNS, and the heart system

Table 3. Risk Level of Medical Devices

★★★