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Trend in the Introduction and Development of Robotic Surgical Systems

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1 Introduction

Various problems involved in medical treatments are one of the subjects, for which solutions need to be sought eternally, in particular, they are under closer scrutiny as these challenges have become more serious in Japan, facing the problem of an aging population. Although most of the people born and raised in Japan don't know that Japan is not always a medically developed country, European and American residents in Japan point out that not only the level of provided medical services but also the technologies for medical treatments are not commensurated with the national economic power[1]. Generally, Japanese tend to believe that "medical treatments are naturally given to them" like water[2] and the quality of the services is high, and, furthermore, they have no choice in medical treatment even if less satisfied with the existing service.

Over the past decade, Japan has imported an excessive number of medical equipments, in particular the volume of imported curative treatment equipments is twice more than that of exported equipments[3, 34, 42]. Besides in the sector of diagnostic equipments where Japan has so far enjoyed an advantage over other countries, a concerned voice has begun to be heard saying, "How long can this advantage be retained ?"

On the other hand, this year is when "Tetsuwan-Atom (Astro Boy)" was born in that story, so many robotics-related events are being held in various locations[4]. Japan is a world leader in industrial robot holding, is a robotics developed country universally recognized as a country devoted to the development of the technology for bipedal robots walking on two legs and for humanoid robots[5]. For this reason, many engineering researchers have never suspected the existence of a drawback in the development of robotics in Japan.

The present situation of medical robotics in Japan is as described above. In this report, the robotic surgical system is presented. It is just one of the curative equipments, but it has attracted great attention, in that it can bring a change into the existing medical technology. This report focuses directly on the actual situation in the medical world, which is undergoing a drastic change by the introduction of robotics. It will be discussed the reason why Japan, though considered as a robotics developed country, has fallen behind in its introduction and development. It may provide useful suggestion for the future research and development of medical engineering technology in Japan.

2 Development of Robotic Surgical Systems

2.1 Overview of technological development

In Japan, various endoscopic techniques have already been used widely in curatives and diagnoses in the actual medical scenes. Giving a familiar example, a photogastroscope is a kind of optical fiber with a camera attached to its tip, which is a typical tool for endoscopic diagnosis. "Diagnosis" had been a main objective of the endoscopic technique. The camera tube was introduced directly into the body to capture images. Then, a next approach has been developed, where manipulators (forceps) were also brought into the body for "curative". Since about 1990, endoscopic treatments (also referred to as laparoscopic surgery) had rapidly spread, which is said to be the largest change in the

Figure 1:Two stages of development in surgical operation

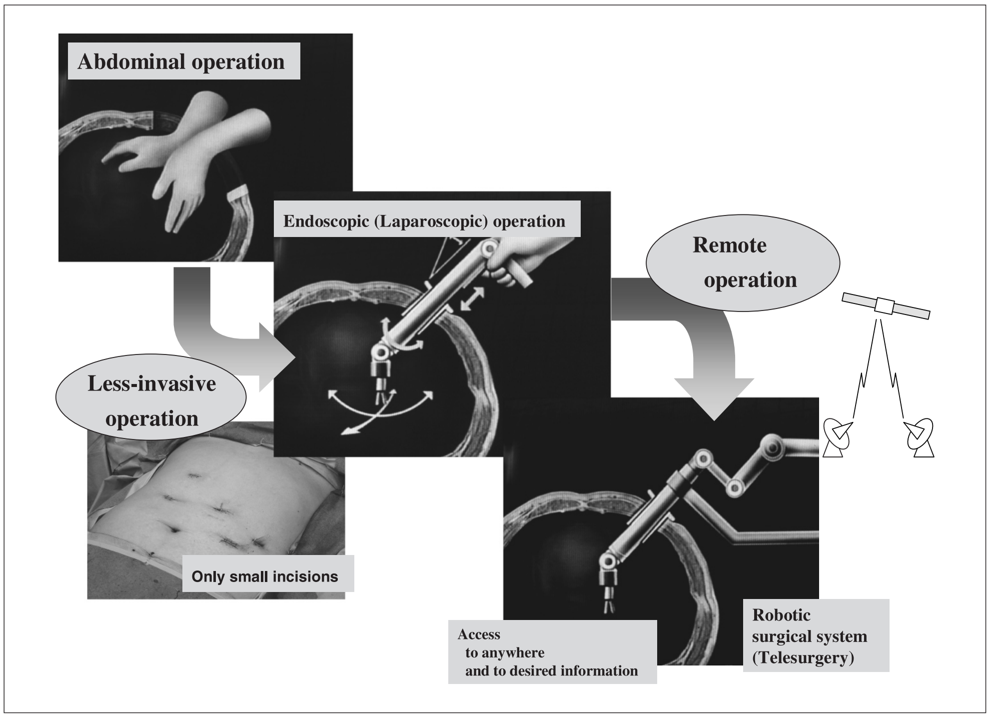

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Table 1:Functions expected for surgical robotics

Eye functions	Manual functions
To see the entire scene before eyes (wide view) • Subconscious and unconscious scenes To see invisible information • All information visualized • Real-time update • On-demand acquisition • Fluoroscopy (structures & functions of organ) • Augmented reality (Extended reality)	Flexibly like human hands Extended functions of human hands Reconsidering of basic handling • Ablation some new approach • Cutting non-invasive • Knotting auto-suturing • Coagulation ultrasonic coagulation & cutting • Suture simple single handling • Resection only disease focus

Source: Supplied by Prof. M. Hashizume

medical world over the past decade. Today, some type of endoscopic technique is used in about 30% of all surgical operations.

Paying attention mainly to the manipulator technology, the development history of the robotic surgery by present is briefly shown in Figure 1.

At the first stage, the surgical operation technique was changed from a direct manual mode to the endoscopic mode, where a major breakthrough was made in the techniques for imaging using an endoscope and for introducing a manipulator into the body. It is these techniques at the first stage that have changed significantly the conventional method of surgical operations in Japan. Meanwhile, turning our eyes to the world scene, the second stage has already been opened since about 1997, where great attention was paid to an advance in integrated technology for developing robots capable of being remote computer-controlled[6]. The typical examples of these robots are robotic systems called "Da Vinci"[7] and "Zeus"[8], both of which were developed by venture businesses in the U.S. These robotic systems are considered to be on the extension of the conventional endoscopic surgical method in Japan. On the other hand, this method is called "telesurgery" based on robotics in Europe and the U.S., where it seems to be viewed from an aspect different from the existing endoscopic technique. At the second stage, it was a great progress that the function of eyes and hands were completely separated from surgical operators. Table 1 lists such functions of these robots, which surgical operators will be eager to use in the future.

2.2 Significance of the development at the first stage – from manual surgery to endoscopic surgery –

The progress at the first stage was in that both the camera tube and manipulator could be brought into the patient's body. The world-first, endoscopic cholecystectomy was successfully performed in France in 1987. At this first stage, where the surgical operation method was changed from the manual mode to the endoscopic mode, the noteworthy feature of minimal invasiveness was given to surgical operations. The incision on the patient's body could be minimized to less than several centimeters, eliminating the need for abdominal operations in many cases. This brought great benefits to the patients including elimination of the need for blood transfusion, relief of post-surgery pains, reduction in the duration of hospital stays, and a dramatic decrease in days until the return to a normal life. Giving an example of splenectomy, 30 cm or more incision was made on the patient's abdomen in the conventional technique, though at present, incisions as small as 0.5-1 cm are made at three points only. For this reason, about 95% of the applicable cases undergo endoscopic cholecystectomy in Japan. The duration of postoperative hospital stays has been reduced to about four days on the average, achieving the same NHI (National Health Insurance System) point levels for endoscopic operations as those for general treatments. These minimally invasive treatments are expected to reduce the occurrence of complications, enable older people to undergo surgical operations, and decrease the number of patients confined to the bed. So it is said that such a phenomenon has partially occurred where patients would not go to the hospitals in which no minimally invasive treatments can be done.

The combination of the endoscopic definite diagnosis and the advanced curatives minimizes the need for hospitalization, enabling patients to return to their homes on the day or next day of the surgical operation. This short-term treatment method is called "day surgery"[9]. The day surgery-specific operation rooms are being constructed in some university[10] and private[11] hospitals in Japan. It has been reported that the hospitals can also enjoy the management benefits of the short-term treatments like day surgery in that the turnover rate of patients is high[12].

Simply assuming that the development of medical robotics aims at achieving advanced endoscopic cameras and high-precision manipulators, it could be fair to say that the intended goal had been almost attained at this first stage. Endoscopic surgery seems to be favorably accepted by both many physicians and patients in Japan. Some cases of academic-industrial collaboration for the development of these enabling technologies have been reported. Some Japanese companies stand at cooperative positions in developing the technologies in this field. However, turning our attention to the timing when a total endoscopic surgery-supporting system was accepted as a medical device in Japan, it was a first approval in 2002 that the MTLP-1 system (Hitachi, Ltd.). On the other hand, in the U.S., it was in 1994 that the Aesop 1000 system (Computer Motion Inc.) was first approved by Food and Drug Administration (FDA)[13].

2.3 Significance of the development at the second stage – from endoscopic surgery to remote surgery –

The most important point of the development at the second stage lies in that individual endoscopic technologies have been integrated into one robotic surgical system beyond the role of medical tools. This integrated system, not only reduces considerably the time and physical exertion falling on surgeons, but also enables remote surgery. In 2000's, migration to robotic systems is attracting great attention in Europe and the U.S.

In the later half of the 1990s, a computer-controlled and integrated robot-supported treatment system with three or more robotic arms composed of surgical tools and endoscope was introduced into the surgical field[14]. In this type of system, a mainframe as equipment and some optional variation of functional parts are prepared. Figure 2 shows the difference in surgical operation between the procedure using typical robotic surgical systems; Da Vinci (Intuitive Surgical Inc.: approved by the FDA in 2000)[7] , Zeus (Computer

Motion Inc.: approved by the FDA in 2001)[8], and the conventional endoscopic approach. With the robotic surgical system, the operator can perform surgical operations at the remote site, while only an anesthetist and an assistant operator stand by the patient on the surgical bed.

Table 2 describes the cases, in which surgical operations have been performed using Da Vinci or Zeus. It has been demonstrated that these robotic surgical systems can be fundamentally used in the area almost all endoscopic surgical operations could be preferred. In foreign countries, 7,000 or more cases of robotic surgical operations have been reported up to 2002, and the use of these systems is increasingly spreading in 2003, so it is hard to know the exact number of the cases . Da Vinci systems have already come up to 160 or more installed all over the world.

These robotic surgical systems have a significant meaning in that they can facilitate surgical operations being performed on a daily basis throughout the world, mitigate patients' strain, and enable the operators to perform surgical operations remotely. It provides the potential for a great advance in the improvement of the whole medical system. In the field of cardiac surgery, in particular, great attention is paid to these systems in that a large benefit

Figure 2:Comparison between operations using conventional endoscope and the robotic surgical system

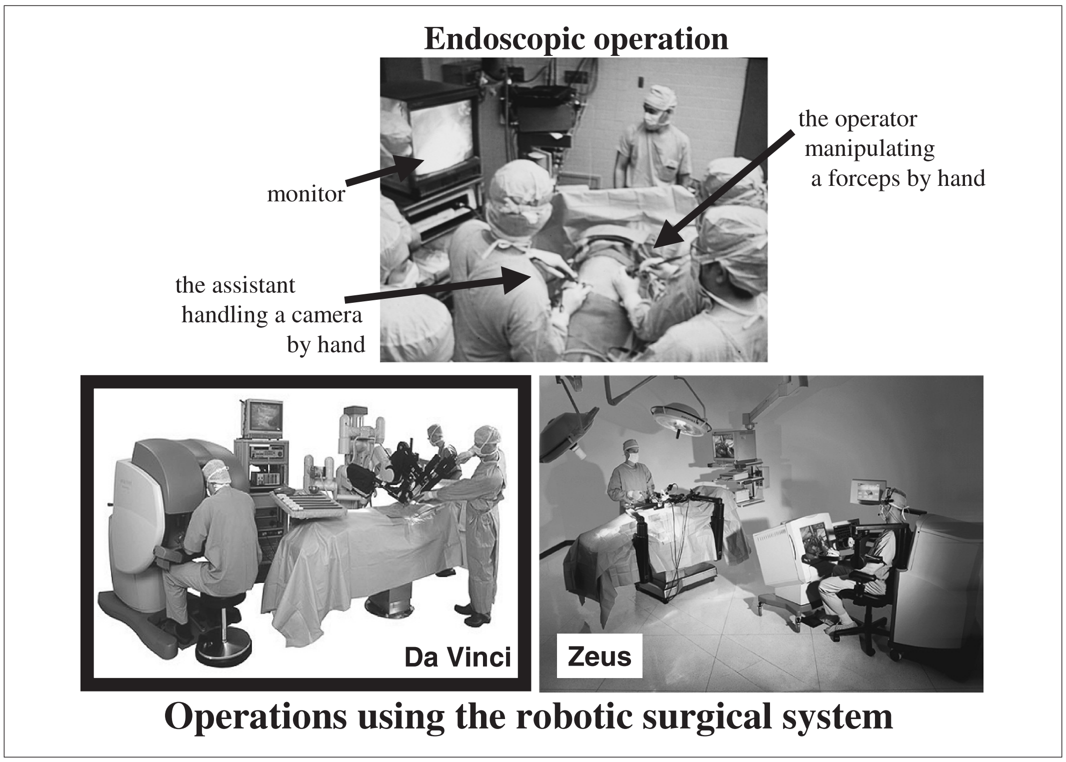

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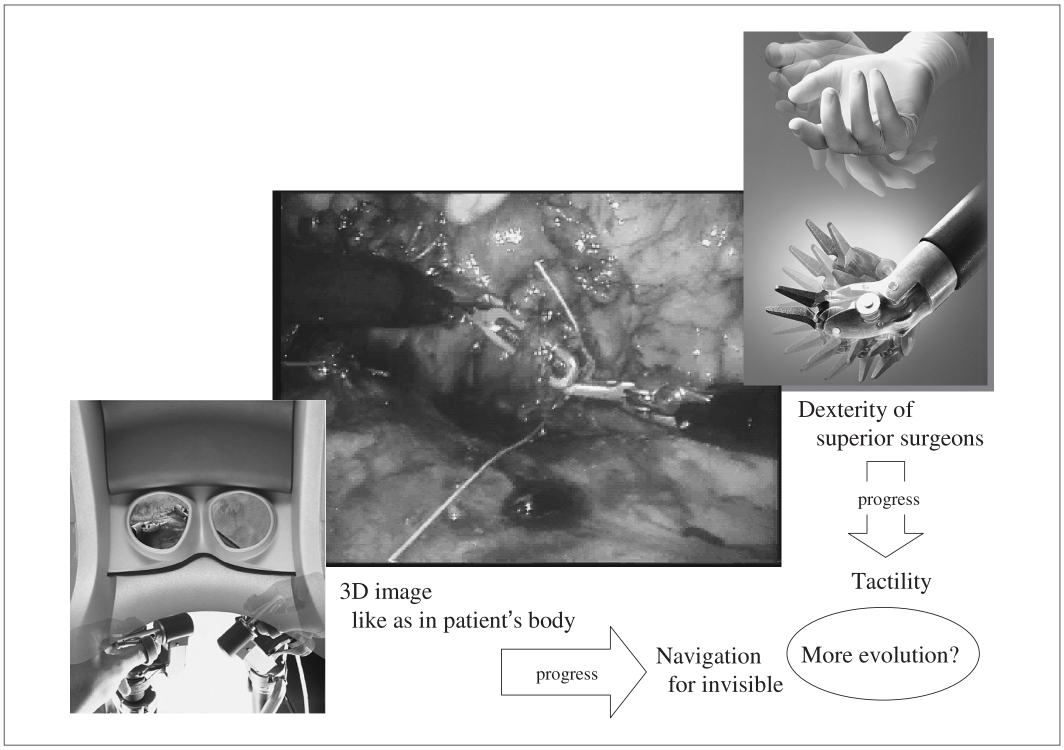
Table 2:Cases of robot-supported surgical operations

Cardiac surgery	ablation of internal mammary artery, coronary-artery bypass surgery (closed), mitral valveloplasty
Chest surgery	pneumectomy, pneumothorax, mediastinal tumorectomy, mammary gland tumorectomy, thoracic gangliosympathectomy (hyperhidrosis)
Digestive apparatus surgery	radical operation for reflux esophagitis, esophagectomy (esophageal cancer), gastrectomy (gastric cancer), gastric mucosectomy, pyloromyotomy, colectomy (colorectal cancer)
Abdominal surgery	pancreatectomy, splenectomy, proximal gastric transection, hepatectomy, cholecystectomy (cholelithiasis), choledochotomy, lumbar gangliosympathectomy, radical operation for inguinal hernia, tubal ligation, hysterectomy, ovariectomy, oophorocystectomy, nephrectomy (renal cancer), total prostatectomy
Vascular surgery	resection and reconstruction of aorta (arteriosclerosis obliterans)
Transplantation (donor operation)	Renal transplantation

Source: Supplied by Prof. M. Hashizume

Figure 3:Present and perspective levels of the robotic surgical system



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can be enjoyed from them because the needs for thoracotomy and stoppage of blood flow as well as heartbeat are eliminated and facilitating postperative recovery is imported. It has been reported that the case of a patient in Keio University, who underwent the surgical operation using the robotic system, got back to his carpenter's work about 2-3 weeks after the operation. In Leipzig, Germany, about 4,000 robotic operations in cardisosurgy itself were performed for the year 2002. These robotic systems satisfy the ever-increasing demands of surgeons working at actual sites, because the technologies for them are continuously making progress.

2.4 Enabling technologies developed in the second stage and their spreading effects

Comparing with conventional endoscopic technologies (Figure 3), enabling technologies used in these robots have an advantage in that the imaging technology, which serves as human eyes, has been developed to the extent that real 3D images can be acquired. The surgical operator, sitting in front of the console of a robotic surgical system and matching the monitor, can perform a surgical operation while having a feeling of shrinking in size and operating in the body of a patient. Clearly different from the conventional operations, which are performed through a monitor screen installed by the side of a patient's bed, the new surgical method using the robotic surgical system provides the operator with more real and detailed live views of the operative field throughout the entire operation. The manipulator of the robotic surgical system is far smaller than human hands which rotates by 360 degrees dexterously, and enables the surgical operator to perform the operations, which are several times more precise than those human hands can do, just as he/she intends, including easy suture of the finest blood vessels. Most Japanese surgeons have already accepted that robotic surgical systems can perform surgical operations at the same dexterity level as that of leading surgeons' skills. This means that even inexperienced surgical operators could perform the highest level of operations in the view point of the manipulating skills. It eliminates any operator hand tremor and reduces the time for operations to less than half of laparotomy. Even elder operators, who have reached their physical potential, could keep the highest level of operations. For these reasons, the existing unevenness in skills among surgeons would be able to decrease.

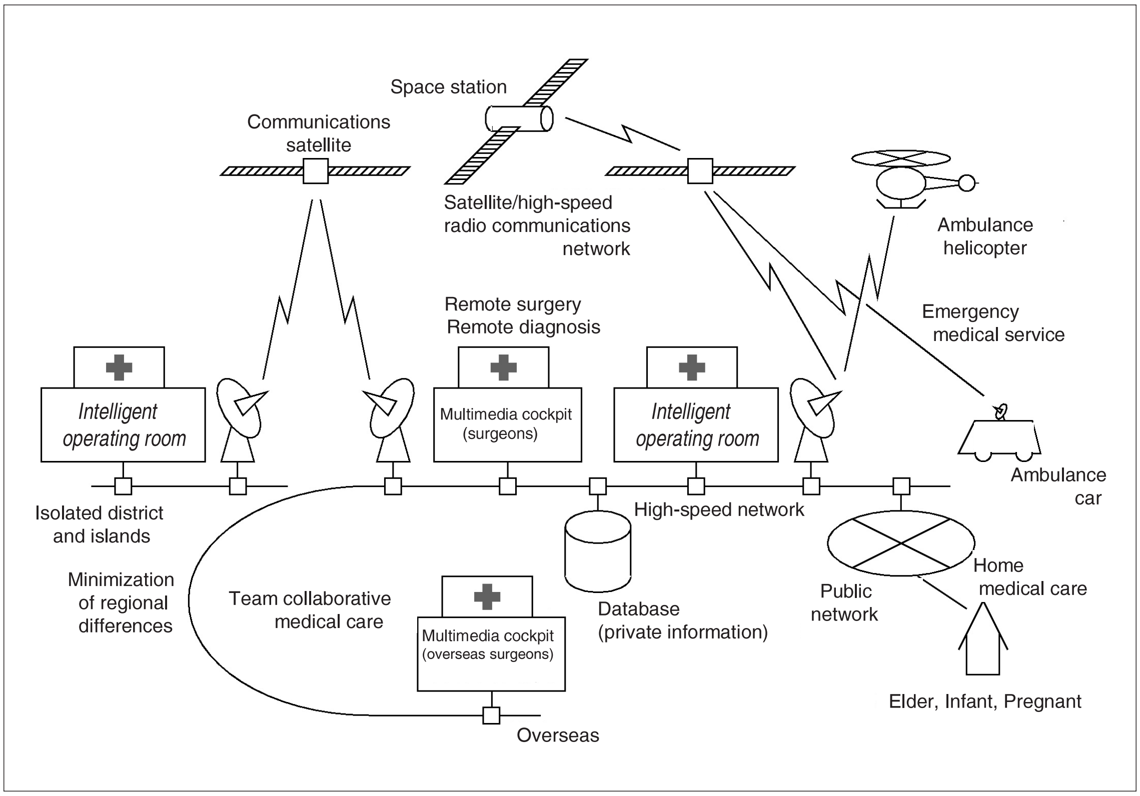
It goes without saying that these robotic surgical systems have some shortages. Meanwhile, the study on enabling technologies is being proactively developed to provide surgical operators with support at a higher level than human performance. The cases of studies conducted in Japan include: technology enabling tactile impression to be transmitted to the operators using a high-sensitivity sensor to bring close to the feeling of direct operations; imaging technology, virtual freeze-frame technology, enabling the operators to perform operations while showing the still images of organs by detecting organ movements and transmitting them to the manipulator in sync; another imaging technology, augmented reality, enabling the update information on intraorgan structures including blood vessels, which varies with the progress of operation, to be overlapped on the target organ by combining with an internal diagnostic equipment; and functionality to feed back to the system the information on organs, which may deform when the operator makes contact with them. To minimize the apprehension of complications and residual tumors, pre-operative angiography and tumor site confirmation will allow the operators to determine with confidence whether these events have occurred, though the observations of them have relied largely on the operators' intuitive judgments. In future, robotic surgical systems will provide the navigation function to view images invisible to operators. To promote these enabling technologies, the activities of international academic associations are made. The Japan Society of Computer Aided Surgery was founded to conduct these studies in a new domain of computer-aided surgery[15].

It is expected that these robotic surgical systems will be used in such operations as organ transplantation and reconstructive surgery in the future. Moreover, it is considered in the U.S. that they may be applicable to special surgical domains, such as antenatal care of fetus which has been undertook since 1980[16].

Among the wide variety of advantages, the most promising one lies in the remote-controlled operability. Surgical operators even in plain clothes can perform the operations on the target patient from a neighboring room of the operating room and even also on patients overseas by means of Internet or satellite communications. Concerning the problem of medical care in isolated districts where no physician resides, remote-controlled diagnoses and curatives by telecommunications have been expected long before[17], which are one of the proactive IT-exploiting promotion items among the e-Japan Strategy Second planned out by the IT Strategic Head Office in July 2003[18]. Note that in Japan, medical examination had been conventionally confined to the face-to-face system in principle (Article 20 of the Medical Practioners Law), but the deregulation has already started; the application of the remote-controlled medical care system using information communications equipment was approved by the authorities in 1997[19]. Great expectations are put on remote-controlled medical care from many aspects; health care in isolated districts, as well as; surgical operations in case of a disaster, team collaborative operations by surgical operators in different places, and the need for protecting against infection during surgical operation[20]. In the first case of intercontinental surgical operations, an American surgical operator performed an operation using Zeus via an optical fiber on a 68-year-old French woman (Sep. 2001). It is called "Lindberg Operation". With only one exception of the problem of securing quality communications, he could perform the operation as if he was in a neighboring room of the operating room.

In the case of brain surgery, since it requires a finer special manipulator, any robotic surgical system has not been able to support such surgical operators. However, such a system was developed that a medical specialist gives advice to the surgical operator actually performing the operation on a patient via the remote-controlled system, like a TV conference. It was reported that cases of brain surgical operations were performed by combining this system with the endoscopic operation method[21]. The study has been started for achieving a complete remote-controlled brain surgical system[22].

Figure 4:perspective of whole medical care system including remote-controlled treatments in the future



Source : Supplied by Prof. M. Mitsuishi

In addition, the computer control system has brought out high-speed simulators, allowing surgical operators to be well clinically trained in practical operating fields. Also in Japan, where some residents have no experience in laparotomy as the endoscopic operation method has advanced, the introduction of the robotic surgical system enables them to be trained using simulation like intern pilots. In Kyushu University, the Center for Integration of Advanced Medicine, Life Science and Innovative Technology (CAMIT) was established for education and training[23]. Someday, the need for resident training using animals may be eliminated. At present, a remote-controlled educational system with realistic sensations is also being developed. In October 2002, an Australia-Canada virtual surgical operation across the Pacific Ocean was demonstrated[24] . It suggests that an international medical e-learning system has begun. Many Japanese surgical operators have won international approval for their operating skills, so remote-controlled surgical operations and education using these systems would be one of great contributions to the international society in the future.

Figure 4 is the schematic view of an ideal medical care system within the 21st century envisioned by Japanese robotic researchers[20].

2.5 How are robotic surgical systems accepted in Japan ?

It seems that the medical robotics have advanced in the second stage much more higher than most Japanese surgeons expected. At present, these systems have not been well recognized among Japanese clinicians, some of whom seem to reject them.

In Japan, Da Vincis were introduced for clinical tests in two university hospitals in 2000. Though the tests were finished in June 2002, the applications for approval have not been submitted. Usually in Japan, it takes a long time before approval for medical equipment is given, especially if the appropriate applicable provision is not defined in the Medicine Act. For this reason, only two Da Vincis and five Zeuses have been introduced into the country, and the number of trial operations remains at a level of about 100 cases.

Retracing the historical development stages of robotic surgical systems in the U.S., as described in the following section, these systems were being steadily improved so as to achieve the performance of medical equipments in 1990's. Robotic surgical systems with high quality such as Da Vinci and Zeus did not just suddenly appear. They are the fruits of the great efforts. The robotic surgical systems are often misunderstood in Japan in that; it is considered that the development of the robotics has only brought precision-improved manipulators and the performances of these systems are inferior to human's, or autonomy type of robots will perform operations at their discretion without respect to the operator's intention.

It seems that in the 1990s, the international flow of medical engineering technology has been overlooked or considered less serious in Japan. According to the 7th Technology Foresight[25] conducted by NISTEP in 2000, any keywords concerning this technology were omitted from the Delphi subjects in medical/health and manufacturing fields. Concerning the life science field, there was one subject, "minimally invasive surgery applying a micro machine or robot will make up most of surgical operations". The average of answers by all the respondents to the question "When will it be realized?" was 2016 to 2017, and that of specialists saying 2014. They both forecast that the moment to realize it will come late. This means that even Japanese specialists could not sufficiently grasp the overseas trends at the point of 2000. Or if so, they considered that minimally invasive surgery using a macro machine or robot would be introduced quite late because of particular circumstances in Japan.

Since none of the robotic surgical systems mentioned above have been approved as medical equipment in Japan, surgical operations using these systems are confined to clinical tests and the total cost including hospital charges relies on surgeons' research expenses. For this reason, the number of domestic operations totals only about 100 cases. However, the first application which may break through this deadlock in Japan has stepped forward. It has proposed in the provision of the Special Zones for Structural Reform established in 2003[43]. Fukuoka and Kitakyushu City Governments jointly proposed to be "robot development/demonstration test special area" and has just approved. They are trying to add the demonstration tests of operations using robotic surgical systems to the proposal. If this application is accepted, as part of the Special Healthcare Expenditure, a budget will be allotted to operations using these systems as a special case under the provision of the Health Insurance Act. It may result in an increase in the number of robotic surgical operations in this area.

2.6 Venture companies which developed robotic surgical systems

American venture companies, which developed two typical robotic surgical systems, had been closely related to the research and development activities in universities.

Computer Motion Inc., which has developed Zeus, was founded by a researcher of the Development of Electrical Engineering, University of California, Santa Barbara in 1989. The history of this company's development[26] is instructive for us. This company first received approval for Aesop 1000, which was an endoscopic operation system, by the FDA in 1994. In the period of 1991 to 1994, the voice recognition function was researched in a project style, resulting in Hermes, a system that behaved as instructed by the surgical operator's voice. Developed on the basis of this result, Aesop 2000 with voice recognition (1996) and Aesop 3000 with increased freedom of the robot arm axes (1998) were approved by the FDA, respectively. In addition, a system called Socrates was devised, which gave operational advices to the surgical operators at the remote site like a TV conference. As a result, Aesop was incorporated this remote-controlling system to be Zeus, which was approved in 2001.

On the other hand, Intuitive Surgical Inc., which has developed Da Vinci, was founded in 1995 as the foundation of technologies cultivated in the Stanford Research Institute (currently SRI International) affiliated with Stanford University. Getting behind, the company initially aimed at a high-quality, large-scaled robotic surgical system. It was required a short time period of only five years from starting up the company to FDA approval for Da Vinci. It is reported that about 20 billion dollars of research expenditures and 100 or more PhD researchers were totaled up for the research and development of Da Vinci.

Both of the original robotic surgical systems do not perfectly satisfy the surgical operators. However, they are being satisfactorily accepted by the surgeons in many countries, because of sufficiently taking the need of the operators, who perform operations at the actual operating scenes, into account and improving them in rapid response to these needs. The reason that these systems were approved at a relatively early stage seems mainly to be in the initial establishment of the total concept and framework of them. Enabling technologies for detailed parts could be improved at a later stage. These technologies include many Japanese technologies with and without patents reserved.

Note that the two companies mentioned above, which had been patent-competitors so far, but they were merged together at the end of June 2003. In the near future, the technologies cultivated in these companies will be integrated to create a new system. The new company has several technical contracts with many companies including Japanese ones[27].

3 Positioning of medical robots in the Japanese robotic researches

3.1 History of robotic researches in Japan

Robot researches of Japan are based on the prosperity of industrial robots starting from the 1960s. About 60% of the total industrial robots in the world are being operated in Japan. Meanwhile, research on humanoid robots, is constituted another trend of robot development[5]. It was said to have started from WABOT, which was developed in the Ichiro Kato research laboratory of Waseda University from the 1960s. The Robot Contest[28] ,which was first targeted mainly at the students of technical schools, has spread into the world. At present, robotics is one of the attractive research subjects for Japanese students of engineering departments. Nevertheless, the Robotics Society of Japan fell unexpectedly behind in its establishment in 1983. This year is just the 20-year anniversary.

The development of alternatives for biological functions is a universal research subject in the world medical engineering field. Japanese engineering researchers have also been attempted the application to medical treatments [17]. On the other hand, research toward the improvement of humanoid has not been eagerly conducted in any country of the world except Japan. Overseas researchers tend to psychologically keep a distance from it. It is said that the reasons why the research on humanoid robots has prevailed in Japan include; the national character with no religious allergy to robots, and the attractive impression “robots are dependable friends” given by robots including Astro Boy, which was TV broadcasted as the first video animation in Japan. Strictly defining of robot is not easy. Instead of the definition, considering from an aspect of the comparison between the researches in Japan and foreign countries may help us to understand them. The Japanese researches are characterized in that they adhere to the development of autonomous movement such as bipedal technology and of intelligence technologies for understanding and learning.

In actuality, the perspective of robot researches expected at this point of the 2000s is not so different from that used to in 1980. The theses of many projects for developing robotics were to apply the technologies cultivated in the development of industrial robots to future robots, which could work under extreme conditions, for example in nuclear reactors, in space and at the bottom of the sea, and which could supply such services as housekeeping, nursing/medical assistance, emergency medical treatment and security. Most of these Japanese robot researches are not practical technologies at present[5], which are still seeking for the future technologies. From the aspect of the 1980s viewpoint, the robots include pet robots for entertainment and healing are attracting greater attention than expected. They are expected to be developed to a level higher than that of only playing tools, for example healing and health-caring of the elder living alone and the child staying home alone, of which numbers are increasingly growing due to a decrease in the number of children[3]. In Japan, autonomous movement functions and mock intelligence tend to be required in even toy robots.

3.2 Robotic surgical systems viewed from the aspect of the history of Japanese robot researches

As mentioned in 2-1, in the U.S. and Europe, surgical operations using a robotic surgical system are considered to be meaningful as "telesurgery" using the robotics. So, it may be difficult to apply this concept directly to Japanese robotics. At present, however, existing types of curative equipments for supporting surgery are called as "robotic" surgical systems. They are developed definitely by the researchers in the robotic field in Japan. Thus, the characteristics of the robotic surgical systems are described below from the aspect of typical robotics in Japan.

As known from Table 1, the robotic surgical systems have been developed focusing on enabling technologies for simulating the functions of human eyes and hands, while those for simulating the functions of feet (movement) are less emphasized. From this viewpoint, it can be said that these surgical systems are on the extension of the industrial robot technologies, which have been thoroughly cultivated in Japan. It is in another flow than Japanese current robot researches centering on movement and bipedal functions. Here, another example in medical robotics, that is easier to distinguish, is introduced. Robodoc is orthopedic surgery-supporting system for implant arthroplasty. It is an equipment that can grind down into the bone safely at a higher level of precision with good reproducibility, eliminates the need for blood transfusion, and enables the patients to start the training of standing on day 2-3 after the operation. It more closely resembles industrial robots. It was developed by a spin-off venture, Integrated Surgical System Inc.[29] and several units have been imported into Japan.

Another noteworthy point is that the surgeons do not desire the autonomous robots to perform operations by themselves. They pay greatest attentions for this point in considering medical robots. It is important for the surgeons that the individual behaviors of the robotic surgical system should surely reflect the determinations made by the operator throughout the operation. It is a cardinal rule that the surgical operators taking the responsibility for the operation perform it at their own discretion even if it is in far distant place. For this reason, precedence was given to remote-operability rather than independency of robots. Namely, the researches on the robotic surgical systems neither aim at the alternatives for human operators nor require the robots to have autonomous intelligence. This point is the largest difference from Japanese current robot researches seeking for autonomous robots.

Although it is said that the Japanese have less allergy to robot researches, they have a resistance to the introduction of robots into the medical and nursing fields, compared with foreigners. These fields are strongly related to themselves. The Japanese tend to want any nurses or assistants being a part of their family rather than others, and being female rather than male. Concerning this point, the face-to-face endoscopic technologies and diagnostic technologies are far different from the images of robot technologies the Japanese have. It may be only said that some functions developed in robotics were taken in the medical field. Since the Japanese have less resistance to them, they must be more increasingly introduced into this field in the future, if even a problem of approval as medical equipment is solved.

Thus, the robotic surgical system has advanced in a different way from that of robot researches prevailing in Japan. It is far from the common images of robots which the most Japanese have, being a rather modest technology. Some Japanese consider that technologies, which do not seek for autonomous movements or intelligence, are those for enabling simple mechanical works but not for robot technologies. This difference in images is one of the major reasons why this system has not attracted great attention in conducting the researches and developments of robots in Japan.

3.3 Researches for medical robotics in Japan

As an output from robotics, the medical and welfare application has an impact on the society in that it is useful for human beings. And it also can enjoy a great economic effect. The Robotics Society of Japan has recently paid attention proactively to the medical and welfare field.

Table 3:Past and present projects in medical robotics

middle or large	Japan Society for the Promotion of Science	JSPS Research for the Future Program “Development of surgical robotic system”[30]
	Ministry of Economy, Trade and Industry	NEDO project “Less-invasive advanced surgical supporting system using endoscope”[26] (continued of “System for supporting cephalophyma operation”)
small scale	Ministry of Education, Culture, Sports, S&T	15 studies on the medical treatment supporting robotics under S&T Research Grant (1984 - 2000)
	Ministry of Health, Labor and Welfare	9 studies on the less-invasive surgical supporting system (1997 - 2001)

Besides, “Development of body functional analytical/supportive/substitutive devices” was launched from 2003 by Ministry of Health, Labor and Welfare

It held its robotics seminar “Medical robotics entering the practical stage” in November 2002. It suggested that these technologies are being put into practical use and do not aim at the far future.

Some universities and institutes in Japan have medical robot technologies as the subjects of researches. They have conducted a significant number of the projects on these technologies so far (Table 3). Note that the total budget allotted to all the projects listed in the figure is less than 3 billion yen. It is one-digit less than those invested in the developments of Da Vinci or Zeus mentioned above. This indicates the fact that the Japanese researches and projects on medical robotics are small scaled and too distributed, implying that only enabling technologies are output. In Japan, moreover, some of the researchers from industrial robotics have not paid attention to the medical and welfare field until just recently, for example the first remote-controlled surgical trial had not performed on experimental animals until 2002, using the results of the project “Development of Surgical Robotic System” [30] described in Table 3.

Unfortunately, in Japan, no large change may be found in the system where the distributed researches are conducted. It is important that the results of these projects are not only presented in journals or meetings but also led to realistic results, namely the picture of where equipment surgical operators can use conveniently. Even from the distributed researches, a system with reasonable cost for small-scaled hospitals can be built up as an output. In addition, some operations requiring more precise works cannot be treated by any existing robotic surgical system such as in the brain surgery and some orthopedic surgery fields. It is meaningful that researches and developments are conducted to enable the surgical operators to perform microsurgery in vivo using precise instruments and radio communication technologies including MEMS and micro machines, for which Japan is said to be superior to other countries. If the projects are strengthened to address a relatively large-scaled robotic surgical system in Japan, it may be significant to build up the medical system integrating curatives and diagnosis[30].

4 Perspective of medical engineering researches in Japan

4.1 Change in the environment surrounding medical engineering researches

Many complicated problems have been pointed out in the Japanese medical and welfare system and the Government is strongly requested to change its direction[2, 31, 32], omitting the detailed descriptions of these problems here. The largest change in the environment is that in demographic percent distribution, namely extremely high increasing rate of the elder (e.g., 17.4% in 2000). Japan must proactively bring some qualitative changes, which could be countermeasures against this large quantitative change in the near future. Variety in the requirement for medical care by the Japanese would make the quantitative problem more serious. The younger Japanese tend to require world leading technologies in the infant or in incurable disease treatment and to require day surgery and a reduction in health care cost in adult disease treatment, while the elders often require humanistic health care services rather than advanced medical treatments. The attempt to respond to such a variety in user’s requirement in the existing medical system will certainly lead to a shortage in the number of healthcare professionals and an increase in the number of errors in medical treatment. Some kinds of rationality must be necessary to respond the variety in the near future.

Meanwhile, turning the viewpoint, the medical business field is expected to have a great perspective in Japan where the elders have occupied a large percentage of the population. It constitutes the background for large expectations to bio technologies.

On the other hand, not so clearly being aware of it as mentioned at the beginning of this paper, Japan has not been gradually considered to be a leading country where advanced medical treatment can be undergone among the countries of the world. At present, since the fairness and provisions of medical treatments are too strictly defined in Japan, it has been strongly insisted that these shackles disturb the development of advanced medical treatments[2, 31, 32]. Some problems have always been raised until any new equipment reaches the level at which it can be introduced into the actual medical fields. To identify and solve them, no other ways have been provided than clinical tests (Clause 7, Article 2 of Medicine Act). Such a system is required that an attempt to apply any new treatment made even with the burden of a minor risk, "freedom for the patient to select the treatment method by him-herself", can be accepted. And all the surgical operators, manufacturers, and patients should be sufficiently protected against possible damages, for example, with the application of social or private insurance. It goes without saying that all the medical treatments require prudent attitudes. However, the weak examination system should not disturb them, meaning that clear standards must be made as soon as possible. With the very nature of the problem being left ambiguous, on the other hand, with the overconsciousness to the manufacturer's responsibility defined in PL Law (Product Liability Law) and to the surgeon's responsibility in conducting medical treatments, it is impossible to introduce Japanese new technologies into the practical medical fields. Unless a social environment where advanced medical treatments are proactively accepted is established in Japan, any advanced medical equipments developed in this country would remain at their research stages.

Note that as intellectual property rights, such as patents, concerning advanced drugs and medical equipments are widely interpreted for their use in foreign countries. It gives one strong incentives for launching a new venture business. It is being discussed whether patent rights should be admitted in Japan as well[44], concerning their activities for the practical use. Some Japanese surgeons are still worry about the restrictions on medical treatments by the patents. However, medical practices themselves are excluded from the violation of the patents in many countries. Attention is being paid to the future direction of this discussion in Japan.

4.2 Engineering approaches to medical fields

(1) Translational engineering researches

The medical services cannot rely only on medical science[33]. The research field of medical engineering was set out starting at the researches on medical sensors and others in about the 1940s in Japan[17]. The Japan ME Society (Japanese Society for Medical and Biological Engineering) founded in 1962 has a history of 40 years. In fact, manipulation technologies and medical sensor technologies developed in Japan have been appreciated by researchers in foreign countries. The problem being left unsolved includes a deficiency in the translational engineering approach. These excellent enabling technologies developed in Japan have not reached to build up and bring a total medical system into the practical medical scenes. Even if science has advanced, technologies do not make progress by themselves[33]. Further efforts made by more engineers are required to return the result of a research conducted by one scientist as social profits. For example, to put regenerative biotechnologies into practical use, some associated medical equipments have to be developed together.

Under the initiative of the medical equipment industry, the Medical Engineering Technology Industrial Strategy Consortium (METIS) was founded in March 2001[34]. Such a suggestion "the most useful method is to induce engineering researchers to participate in the medical translational researches" was made in the consortium. Nevertheless, turning the view onto the broad outline of Biotechnology Strategy Council[35], the descriptions of the 3-year plan for activating nationwide trial tests[36] that is one of the practical measures for the strategy, and the theme of 21st Center of Excellence (COE) in the adopted universities, almost no draft have been described about concrete measures for practical translational engineering researches.

Note that even in the U.S., which seems to be a leading country compared with Japan,

"Medical scientists and public health policy makers are increasingly concerned that the scientific discoveries of the past generation are falling to be translated efficiently into tangible human benefit." [38] Participatory discussions are being made about who among stakeholders should do what to solve this problem.

(2) Medical - engineering collaboration in universities

A keyword "collaboration between medical and engineering fields" has been picked up in some 21st COE programs[37] and other materials. They described the importance of interchange among researchers from different fields. All the researches on medical services require the knowledge of actual medical scenes. It is necessary to provide the research environment where the engineering researches frequently visit the campus of the medical school from the initial stage of the researches, and to realize actual measures such as personnel changes of students and faculties between the two departments. The medical-engineering collaboration system should play roles other than only as a joint meeting among research laboratories. Recently, computer-based surgical technologies have been introduced into the medical schools[39] . And the departments of advanced medicine, life science and innovative technology have been established in several universities[23]. These facilities may serve as portals for the engineering researchers to enter easily.

One example of the significances of engineering researchers' participation in the actual surgical operation is given below. A streamlined method of angiotomy, where a blood vessel is pinched, ultrasound energy is used to stop and coagulate bleeding, the cut is stitched up, and finally the vessel is cut off, has been developed. If a developer with no deep knowledge of this method makes an attempt to develop a robot only by leaning tell of the detailed information on the operator's behavior, he/she would make the best efforts in achieving a robot capable of performing correctly the technique for stopping blooding by knotting the vessel as done by the operator. The important consideration in conducting researches and developments is to exactly understand the objective to be attained by the robot but not to simulate the operator's behavior. That is just the reason why the engineering researchers need to participate in the actual medical fields. The success in the development depends largely on the idea of implementation envisioned by the engineering researchers. The surgeons have pointed out that many rooms for creating new ideas are being left free. For example, existing robotic surgical systems are the intuitive embodiments of fantastic stories such as "Fantastic Voyage, 1966" where the surgeons whose body sizes were reduced to the micro size entered the patient's body for curatives, though the surgeons practically perform the operations from outside of the patient's body or from far away.

Most new medical equipment have been developed mainly by an engineering developer working at a company and brought into hospitals. Even products developed by companies specialized in the medical field are often unsuitable for the surgical operators to use at the actual medical scenes. For example, many problems have been pointed out such that; some medical equipments are not so clean, some have a risk of any effects on biological bodies such as immune response, and the others neglect surgeon's operability. The introduction of advanced medical equipments may incur an increase in health care cost. Even technically advanced products are not put into practical use if they do not totally have an advantage in the actual medical scenes. These problems should be discussed together in medical and engineering departments, in cooperation with department of economics. These considerations would also be important in the research and developments of future nursing tools.

(3) Relationship between the medical equipment industry and medical engineering researches in Japan

In the near future in Japan, inevitably, information on the evaluation of medical institutions will be widely provided to citizens via the Internet[41] and a principle of market mechanism will be brought into the field of health care services. Until now, there is a vicious circle in Japan as follows. Only several units of advanced medical equipments have been introduced for making clinical tests. Since the domestic market have been small in spite of the potential market being large, the companies have input less energy into the development of them. It has led to confine the Japanese equipments at the research stages, remaining at a low practical level. According to statistics[3], at present, the medical equipments, especially curatives, are excessively imported. Diagnostic equipments, of which sales performance has been superior to that of foreign countries, have reduced their shares. It was taken up in a meeting for discussing the vision of the medical equipment industry under the leadership of the Ministry of Health, Labour and Welfare[40]. It is worried that the excess of imports would be expanded after introducing more smooth examines for approval of the medical equipments.

Today, however, globalization has advanced for most of manufacturing. It is required for the medical equipment industry to have an internationally competitive power to open to the worldwide market rather than being closed within the domestic market. Focus only on the domestic market narrows our horizon. The market for the medical equipments has been uneven in the world. Now, only the North American, Japan and European countries, of which population in total occupies only about 12% of the world population, occupy 83% of the medical equipment market. However, the worldwide market should be largely changed in a future few years because some other countries including China have proactively participated in trial tests. China has also begun to invest subsidies in introducing the advanced medical equipments into hospitals.

In the near future, the results of most Japanese projects may be meant to compete with the products developed by overseas venture companies in the medical service market. If Japan takes overprotective scientific and technological measures, it is expected that the difference in the development of products from the U.S. and European countries, where the performance at the clinical trial stage is centered on, will become larger. Considering the total vision including the expansibility of new medical service businesses and education and training systems, protective policies taken for promoting the development of medical equipments may offer a demerit. Neglecting the actual situation may lead to a loss of the succeeding opportunity. Essentially, protective policies should not be taken to the medical and welfare industry from the aspect of potential for huge benefit to the citizens.

5 Conclusion

The technologies of robotic surgical systems have offered new qualitative effects such as less-invasive curatives and remote operability, which have a large potential for progress of the entire medical system in Japan. These effects are not on an extension of the conventional industrial robotics which have aimed at precise works and substitution of humanities. As the percentage of the elders in the national population is rapidly increasing in Japan, the future picture of medical services would become to discuss more earnestly. Progressing in information society, many Japanese must be aware of a difference in medical service between Japan and the other advanced countries. If the robot technologies, of which Japan has been proud, neither appear on the actual medical stages nor contribute to the Japanese medical and welfare industries, it is really a loss.

To start new innovation of medical equipments from Japan, it is essential to establish clear responsible objectives that cover translational engineering researches with strong medical-engineering collaboration, which are integration of individual enabling technologies into a total medical system for bringing into the actual medical scenes. To improve the research environment, it is required that rooms for choice by the operators and the patients to attempt new technologies should be left, supporting with some insuring systems. As the approval institutions and the intellectual property rights related to medical services also have large influences, great attentions are being paid to their discussions.

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