Development of Medical Robot Systems

Medicaroid Corporation was founded with the corporate vision of "By creating our medical robots, we support an aging society in which everyone can live in peace."

Making use of the machine control technologies that have been built up in the field of robotics, Medicaroid Corporation has developed a robotic operating table for hybrid operating rooms, which enables the simultaneous provision of endovascular treatment and surgery. It is also working for commercialization of robots that assist laparoscopic surgery.

Introduction

The application of robotics is increasingly expected in recent years as needs are becoming more sophisticated and diversified in the medical field in line with the progress of Japan's aging society.

1 Background

In 2013, Medicaroid Corporation was jointly established by Kawasaki Heavy Industries, Ltd., a leading company in the field of industrial robots, and Sysmex Corporation, which has inspection and diagnostic technologies and a large network in the medical sector.

2 Activities of Medicaroid

Since its foundation, Medicaroid's marketing activities have been in the inspection, diagnostics, and treatment areas, and it has focused its efforts on meeting specific demands from medical professionals. After FY 2015, we have developed products that embody new robot systems based on demands collected in these areas.

As shown in **Fig. 1**, Medicaroid is not aiming to create robots that replace human beings, but that serve and support them. Our corporate mission is to create robots to support an abundant aging society in which everyone including patients, medical professionals and family members can live in peace.

Medicaroid set up an open platform system for commercialization. In 2016, we founded Medicaroid, Inc. in Silicon Valley in the United States and have aimed to deploy products by making use of the latest findings and many different technologies through collaboration between Japanese and U.S. offices in cooperation with other parties including public, academic and medical organizations as well as private corporations.

Medicaroid addresses two main commercialization targets. Their timeline is shown in **Fig. 2**. One of the targets is the applied robot project which aims to apply industrial robots to the medical and pharmaceutical sectors. An example of results from this project is the operating table with robotics that was commercialized in FY 2016. The other target is the robotic assisted surgery project aiming to develop robots that support surgeons. The first launch of such a robot is scheduled in FY 2019.

Fig. 1 Corporate mission of Medicaroid

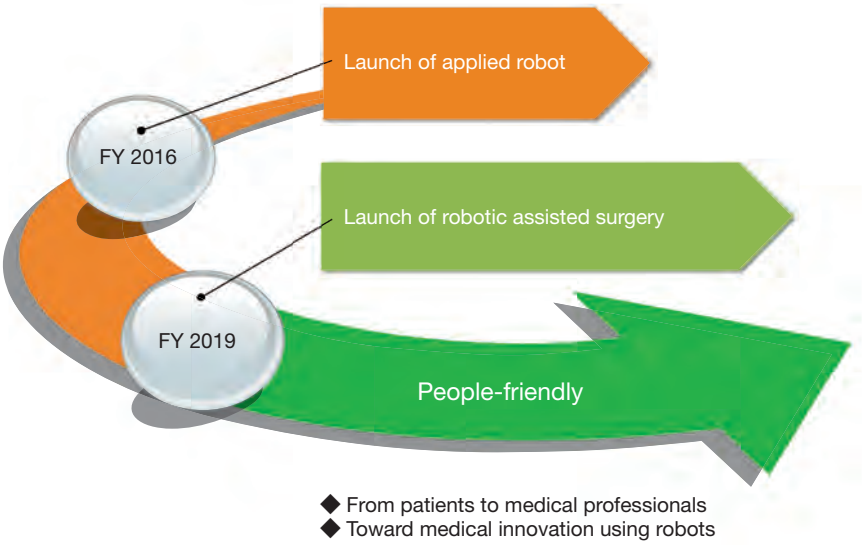


Fig. 2 Product timeline

3 Applied robots

We developed a robotic operating table for a hybrid operating room as one of our applied robots.

As shown in **Fig. 3**, an X-ray fluoroscopic imaging apparatus for angiography and a special surgical bed are installed in the hybrid operating room. The hybrid operating room enables the surgeon to perform endovascular treatment that would have been performed in an angiography room and surgery that would have been performed in an operating room at the same time.

Leveraging X-ray fluoroscopic image information allows for far more sophisticated and precise surgery to be performed as well as treatment that places less burden on patients' bodies by, for example, reducing the operating time, the amount of bleeding, and length of hospitalization. Safer and more reliable treatments can be provided because additional surgical procedures can be seamlessly performed if endovascular treatment is not enough to address the situation.

The hybrid operating room is expected to be used in many areas such as cardiovascular surgery, cardiology, spinal surgery, neurosurgery, orthopedic surgery, and respiratory surgery. More efficient and safer advanced

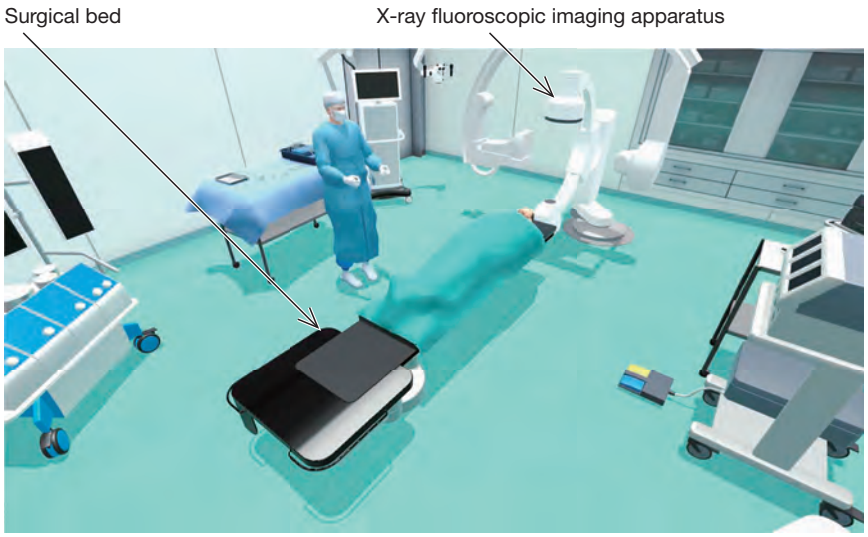


Fig. 3 Image of hybrid operating room

medical care than the conventional treatment system can be provided in the hybrid operating room. In fact, better performance in surgery has been recognized in the hybrid operating room.

To benefit from these advantages of the hybrid operating room, we considered a robotic operating table that makes use of the machine control technologies that have been built up in the field of robotics.

Because this was our first attempt at developing a product to be used in surgery, we had to precisely understand specific user needs and develop a product that exactly meets those needs. Therefore, with "the human-centered design method," we hypothesized user needs and created a full-scale product mock-up conceived from the hypotheses. Then, we demonstrated actions usually performed during surgery using this mock-up in front of nurses, anesthesiologists and neurosurgeons who actually use the product and listened to their opinions about the product concept, foreseeable challenges and their solutions. We improved the mock-up by repeatedly reflecting additionally identified needs in the next series of evaluations.

Using specific user needs obtained from these efforts as design input, we developed the robotic operating table shown in **Fig. 4**, the "Vercia SOT-100." In addition, we developed two types of dedicated controllers shown in **Fig. 5** by listening to users and focusing on the operation procedures.

The robotic operating table thus developed by applying robotics to the treatment table used in neurosurgery can be used to freely move the patient without placing a burden on them or medical professionals and save space in the operating room. The introduction cost of the equipment can also be reduced by moving the operating table rather than large equipment such as the X-ray fluoroscopic imaging apparatus. In addition, remote maintenance via network and other measures allow us to provide quick support.

Fig. 4 Robotic operating table

Fig. 5 Controllers

The regulatory application for the developed operating table was completed in March 2017. We believe that the hybrid operating room will spread with the development of the robotic operating table, providing minimally invasive treatment for more patients and accelerating improvement of QOL (Quality of Life).

4 Robotic assisted surgery

As the safety and effectiveness of robotic assisted surgery developed in the United States in the 1990s have been demonstrated in many different clinical studies and tests, their range of application is rapidly spreading. The global robotic assisted surgery market is expected to expand at an average annual growth rate of 30% and reach 20 billion USD in 2019 as shown in **Fig. 6**.

(1) Robotic assisted laparoscopic surgical system

Laparoscopic surgery is a minimally invasive surgical technique that places less burden on the patient and is popular because surgical wounds are smaller than those in conventional laparotomies or thoracotomies and hospitalization after the surgery can be reduced. However, because this surgery is performed by running the camera and surgical instruments through small holes in the patient's body unlike a laparotomy, there are disadvantages such as the difficulty of operating surgical instruments due to the small field of view and the techniques not being intuitive and so requiring a long time to learn.

Even so, about 2,500 robotic assisted laparoscopic surgical systems operate in the United States. This system was also authorized as a medical device in Japan in 2009 and its application to surgery for prostate cancer and other diseases started. The number of cases in which it is used is expected to increase in the future.

A conceptual image of the robotic assisted laparoscopic surgical system developed by Medicaroid is shown in **Fig. 7**. The forceps, which were difficult to manually operate, can be easily operated through the robot. As the growth of robotic assisted surgery is the most anticipated,

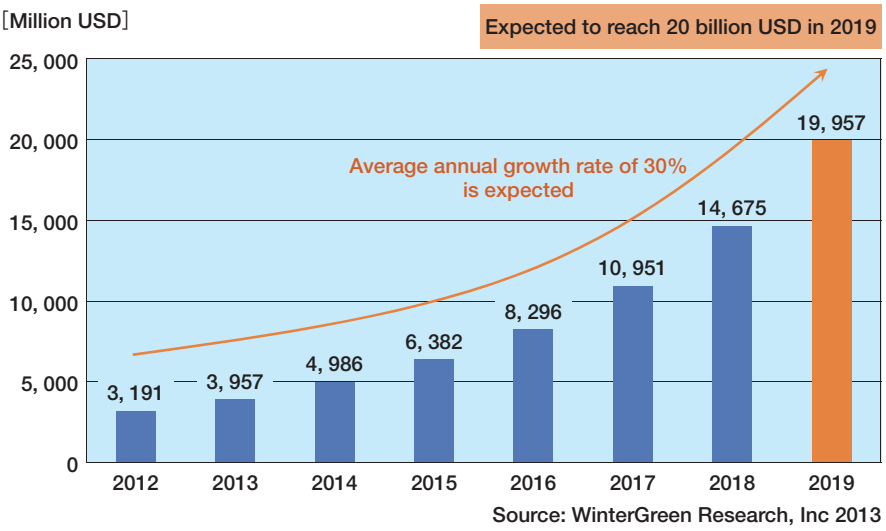


Fig. 6 Market forecast for robotic assisted surgery

Fig. 7 Image of robotic assisted laparoscopic surgical system

we will develop medical robots with new added values as our core products under the design concept shown in **Fig. 8**. We aim to improve the economic efficiency of equipment, running and other costs while reducing the setup time and size in comparison with existing robotic assisted laparoscopic surgical systems. We are also aiming for medical innovations using robots by realizing high safety and reliability and reducing medical risks based on the robotic technologies we have accumulated so far.

In developing this system, we will also repeatedly prototype functions such as a surgery robot that is equipped with forceps with multiple degrees of freedom and operation consoles with the human-centered design method, ask domestic and overseas surgeons to evaluate them, and make further improvements based on their feedback toward commercialization.

(2) Robotic assisted flexible endoscopic surgical system

Peering even further into the future, we are developing a robotic assisted flexible endoscopic surgical system, which is an even greater challenge.

For a high level of safety, more minimal invasiveness and for difficult treatments, we joined the "Flexible Endoscopic Surgery System" project commissioned by the Japan Agency for Medical Research and Development with Kawasaki Heavy Industries, Ltd.

Although the surgery became less invasive and more precise with the advent of the robotic assisted laparoscopic surgical system, it is often too difficult to treat pancreatic cancer or other diseases with laparoscope and endoscope surgery and so laparotomy is still the mainstream. In addition, the assisted flexible endoscopic

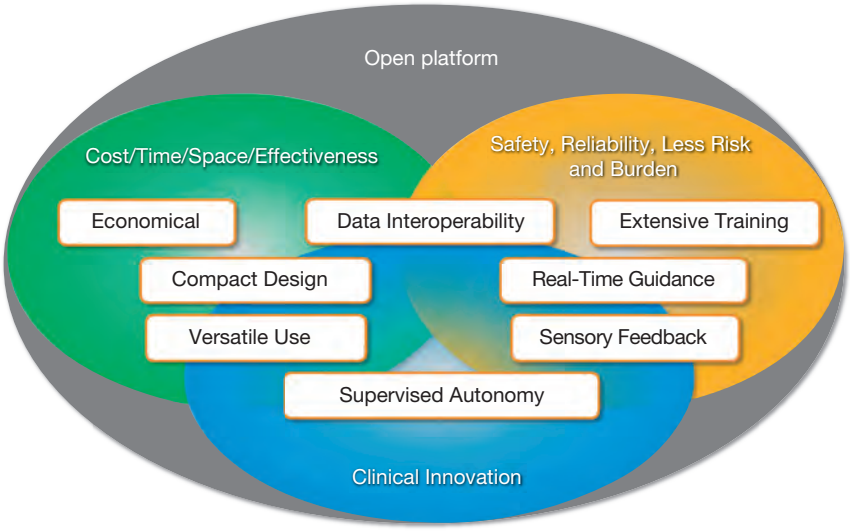
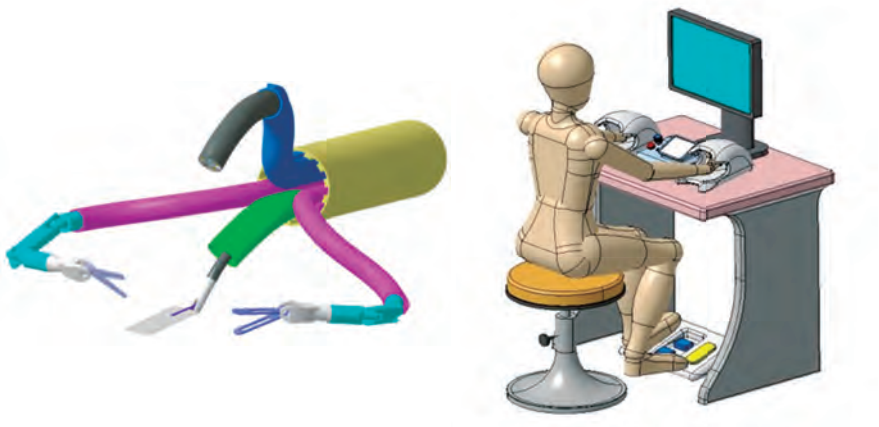


Fig. 8 Design concept



(a) Robotic flexible forceps (b) Operation console

Fig. 9 Image of robotic assisted flexible endoscopic surgical system

surgical system developed as an extension of gastrointestinal endoscopy is not widespread because an extremely high level of skill is required to operate the forceps.

In this context, we are developing a new assisted flexible endoscopic surgical system that the surgeon can intuitively operate while looking down at the surgical field by integrating the flexible endoscope and robotics, which Japan is good at. A conceptual image of robotic assisted flexible endoscopic surgical system is shown in **Fig. 9**. We are currently developing the flexible robotic forceps, which supports a variety of surgery methods with a wide operating range and a high gripping force, and the operation console, which allows for intuitive operations of the flexible robotic forceps.

Conclusion

Medicaroid Corporation is developing medical and pharmaceutical robot systems. We will develop, manufacture, and sell these systems based on the results of thorough marketing activities. Then, we will commercialize robot systems that contribute to the development of the medical and pharmaceutical industry of the world and support an aging society in which everyone can live in peace through these products.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