hinotori Surgical Robot System, the First Made-in-Japan Robotic-Assisted Surgery System

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In the medical field, where future development is anticipated, medical robots have been increasingly adopted in order to realize a safe and secure remotely-connected society.

Medicaroid Corporation developed the hinotori Surgical Robot System, based on the core concepts of compactness, safety, and high maneuverability. This system became the first robotic-assisted surgery system created in Japan to achieve Japanese regulatory approval in August 2020. The first human surgery with the system was successfully conducted in December 2020.

Introduction

In the medical field, which is expected to expand further in the future as society ages, medical robots have been increasingly adopted as part of efforts to establish a safe and secure remotely-connected society.

1 Background

In Japan, excess imports of medical devices totaled approximately 1.7 trillion yen in 2019. In particular, the da Vinci surgical system from US Intuitive Surgical has dominated the market for robotic-assisted surgery systems, which are large-scale medical devices. On the other hand, many Japanese companies develop, manufacture, and sell world-leading industrial robots, and these companies have been expected to create domestically-made robotic-assisted surgery systems by leveraging their technological capabilities.

The medical robot market is expanding by the year. Robotic-assisted surgery systems are likely to account for a large part of the global medical robot market, which is expected to exceed one trillion yen by 2025 [1)]. In addition, as US-based Intuitive Surgical's basic patents on its robotic-assisted surgery system expire, domestic and international companies have accelerated development to gain market share.

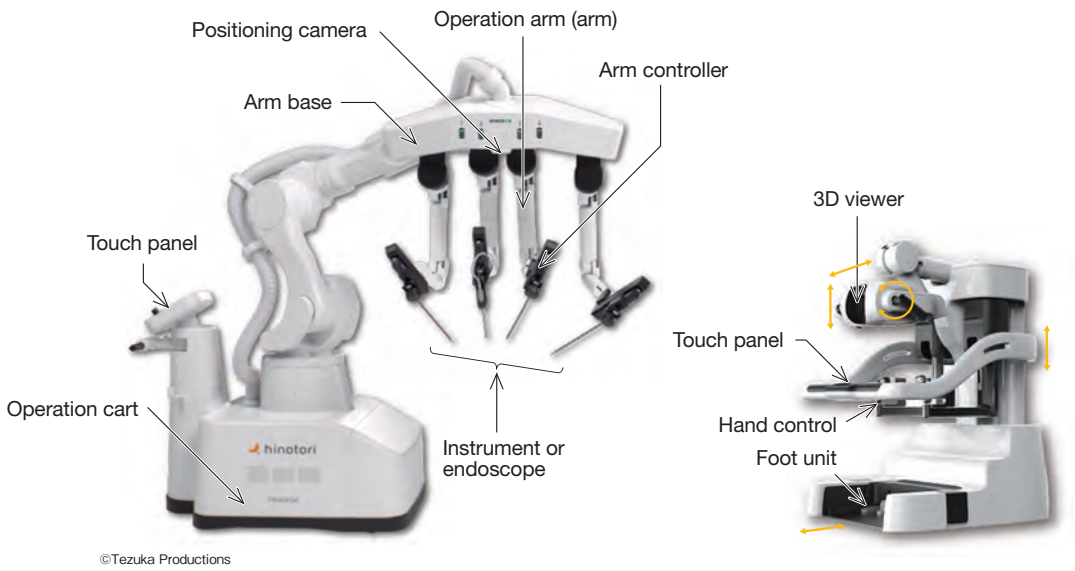
2 Development concept and history

We at Medicaroid developed this system based on the market-in approach. First, we asked domestic and international surgeons renowned for robotic-assisted surgery about current issues, defined the solutions to these issues to be needs, and created a prototype that satisfied such needs. Next, we asked surgeons to evaluate the prototype, after which we further improved the prototype by solving the new issues that were identified as a result of the evaluation. In this project, we executed this process annually for five years before completing the hinotori Surgical Robot System. The first prototype was created in 2015. For the first three years, we executed this process to solidify the concept; for the last two years, we executed the process to refine the product.

3 Concept

This product is a robot system to assist in laparoscopic surgery. As **Fig. 1** shows, surgical instruments (hereafter referred to as the "instruments") and endoscope attached to the operation unit are inserted through multiple ports (diameter: several millimeters) on the patient's abdominal wall, and the operating surgeon sitting at the surgical cockpit operates the hand control while watching a 3D video feed. This system enables the operating surgeon to perform surgical operations as if moving his or her hands within the body cavity and to perform minimally invasive surgery, which minimizes the burden on the patient.

What is important for surgical operations within the patient's body cavity is to minimize interferences among the operation arms while allowing the arms to move within the necessary range. In addition, in a small operating room,



(a) Operation unit

(b) Surgical cockpit

Fig. 1 System configuration

a small occupied volume is desirable to ensure handling and workflow lines. It is also important to reduce interferences with the patient and assistants around the bed and to ensure an ample work area for assistants.

Because this product is directly linked to human life, ensuring the robot is safe is vital. To this end, we decided to proactively adopt the technologies we have accumulated from the development of industrial robots.

In addition, because this system is a manipulated robot, the operator must be able to operate it comfortably in order to complete surgery smoothly and reliably. We must also consider usability by assistants and other staff members as well as the operating surgeon, who operates the system.

As described above, we designed the product by focusing on ① compactness, ② safety, and ③ maneuverability as important concepts during development. Furthermore, we strove to apply new technologies.

4 Details of development

(1) Compactness

(i) Compact arm structure that does not obstruct

For compactness, this product's combination of a motor and deceleration mechanism is designed to be suitable for movement during surgery. The main body of the robot to operate instruments has eight movable axes, each of which requires a different speed and torque. We identified the required speed and torque from simulated surgical operations and determined a motor size and speed reduction ratio that satisfied the conditions.

Also, by maintaining the pivot position through software control to eliminate the mechanism for retaining a tubular device called a trocar sleeve placed on the patient's abdominal wall, we secure a large workspace around assistant surgeon's hands as shown in **Fig. 2**.

(ii) Control to ensure a large working range while reducing arm interferences

Each operation arm is a redundant arm that has eight joints including a linear axis as shown in **Fig. 3 (a)**. Redundant control according to multiple constraints determined based on singular points and required working range reduces interferences among arms while ensuring the working range. The amount of lateral movement of the arm elbow is also constrained as shown in **Fig. 3 (b)** to restrain extension in the width direction in order to provide a large space for the assistants and nurses around the bed.

(2) Safety

(i) Mutual monitoring module to ensure safety

The technology of the functional safety operation monitoring unit Cubic-S [2)] that we have accumulated through the development of industrial robots is used to control the actuator and input/output. Safety is enhanced by a mutual monitoring module separate from the controller for motor control.

① Functions involving robot operation are permitted only when an enable switch on each arm or at the operation section at the rear of the operation cart is pressed, or when the operating surgeon looks into the 3D viewer and the Cubic-S redundantly confirms the sensor input. If movement of an arm that is not being operated is detected, such movement is

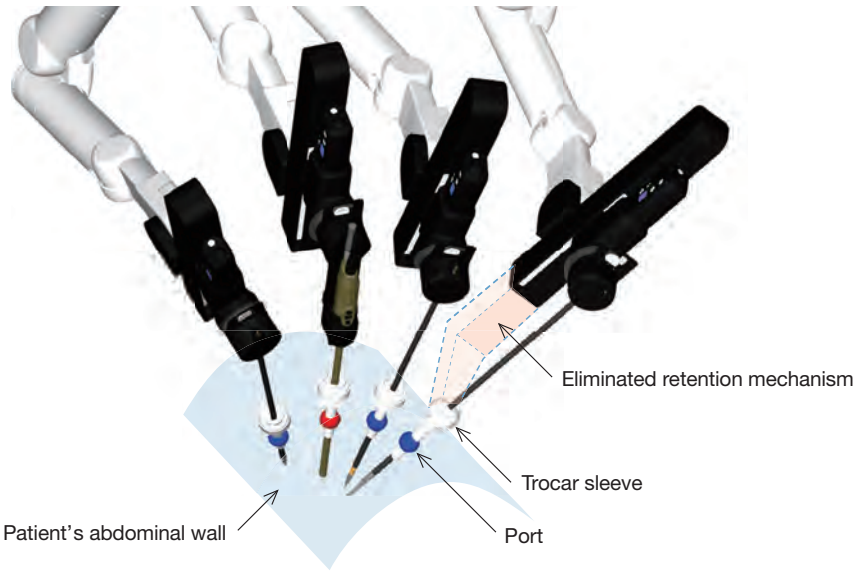
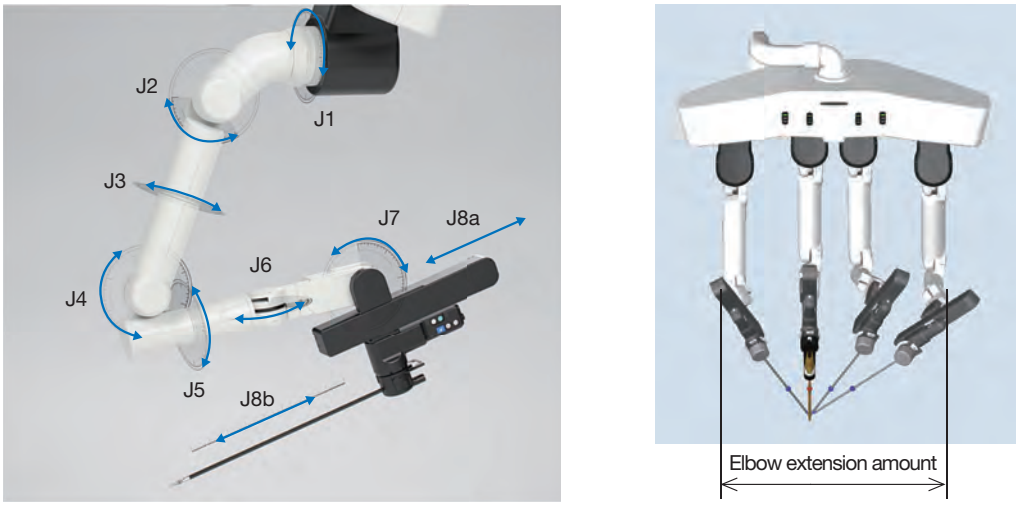


Fig. 2 Elimination of retention mechanism



(a) Placement of axes in the redundant arm

(b) Restraint of elbow extension amount

Fig. 3 Arm structure

immediately judged to be an error

② As described above, maintaining the pivot position through software control leads to ensuring a workspace for assistants. However, if the pivot position shifts, the patient's abdominal wall may be damaged. As shown in **Fig. 4**, when generating the position command, the primary controller confirms that the pivot position has not changed from the set value, and the Cubic-S also monitors and redundantly confirms the pivot position to improve safety.

(ii) Actuator control to reduce the risk of tissue damage

Endoscope vibration causes shaky video and hampers surgery. Instrument vibration may damage delicate body organs. Therefore, the system generates operation specification values that reduce vibration by applying a notch filter and various compensation to the operations inputted by the operating surgeon. In addition, because interferences between arms may generate large vibration at instrument tips and damage tissue, operation is restricted so that instruments do not move in the collision direction.

(3) Maneuverability

(i) Structure and compensated control for comfortable operability

What is important for smooth operations is not to

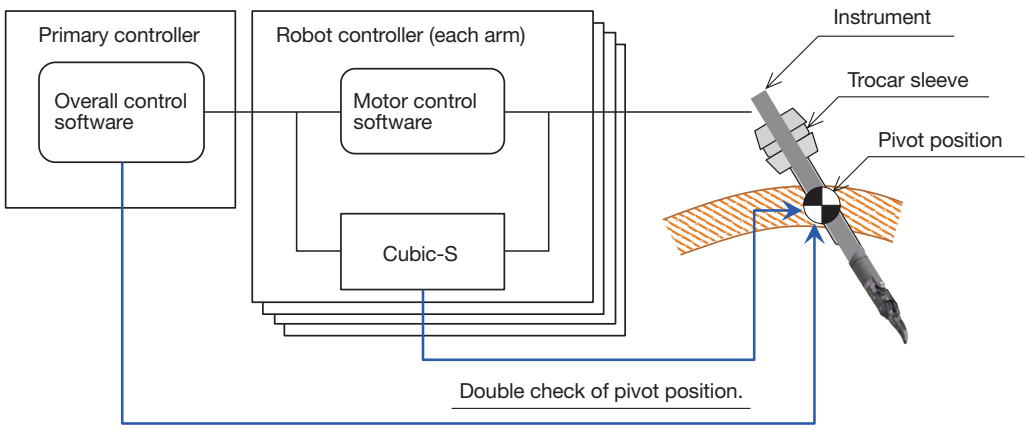


Fig. 4 Pivot position monitoring by Cubic-S

hamper the intended operations inputted. We developed a drive train that combines a high-power motor and a reduction gear that has a low reduction gear ratio with the arm on the operation input side to reduce the friction resulting from the reduction gear. We also designed the system to perform gravity, inertia, and friction compensation. Doing so achieved light, comfortable operability.

(ii) Adjustment mechanism to reduce fatigue

When operating a surgeon cockpit, a surgeon can take a forward leaning posture as if looking into the operative field during laparotomy, or a posture in which the upper body is raised to reduce a burden on the shoulder and neck. Adjustment mechanisms include armrest height adjustment and foot unit depth adjustment performed by touch panel operations, and manually operated 3D viewer position adjustment performed using an electromagnetic clutch equipped with an unlocking mechanism. The surgeon can fine-tune the system according to his or her body shape and preferences.

(iii) Operation input section for simple operations

The arm controller shown in **Fig. 5** is attached to each

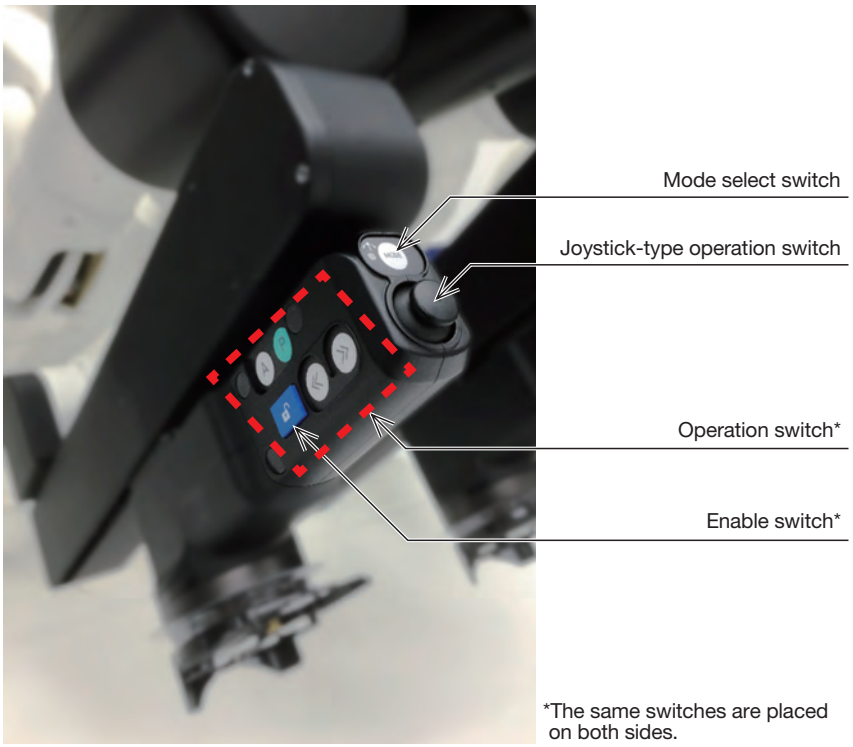


Fig. 5 Arm controller

arm on the patient side so that an assistant by the bed can change the posture when, for example, teaching the pivot position.

The simple joystick-type operation system has a bilaterally symmetric section, and the same switches are placed on both sides so that the system can be easily operated even when the direction to approach the bed is changed for reasons such as surgical site or flow lines.

Moreover, the positioning camera for acquiring an overall view is attached at the center of the arm base so that the relative positional relationship with the bed or patient can be adjusted while watching the video feed on the touch panel of the cart's rear section. This ensures maneuverability when the system approaches the bed.

(4) Striving to apply new technologies

(i) Instrument development

The instruments move inside the patient's body to perform necessary procedures, such as grasping or retraction of tissue, cutting and coagulation using an electrical cautery, and suture ligature using a suture and needle during surgery. Therefore, they require the highest level of functionality and performance for medical devices. Though Kawasaki did not have experience in designing and developing surgical devices, the company has gradually accumulated the required technologies and expertise by repeatedly developing elements.

Figure 6 shows the appearance of an instrument that has been designed with consideration given to the grasping force, tip shape, and ease of cleaning.

① Grasping force: The most important function of the instrument is to grasp and manipulate tissue or a needle. When the hand control grip is tightened to the specified angle, the tip of the jaw closes. When the grip is further tightened, the required grasping force is generated. When the wire in the drive transmission section inside the shaft is twisted as a result of shaft rotation, the wire tension changes, causing the grasping force to fluctuate. This product can maintain a certain amount of grasping force by performing compensation according to the shaft's rotation angle.

② Tip shape: Through repeated evaluation by surgeons, we have improved the instrument's tip shape to optimize it for application. For example, the needle holder, which holds and operates the needle, has been improved by attaching an anti-slip sheet to the grasping surface in order to reduce needle slippage, and by designing the tip round so as not to damage the thread during suturing. Because the grasping forceps adopt a jaw shape (i.e., the forceps are closed from the tip), leaving a gap at the base, they can stably grasp targets from thin membranes to thick tissue.

③ Ease of cleaning and sterilization: The instrument can be used 10 times by cleaning and sterilizing it each time. Therefore, we needed a structure that allows for cleaning and sterilization not only of the tip, where tissue and blood attach during surgery, but also the inside of the shaft and housing. To achieve ease of cleanliness, we analyzed where water accumulates by, for example, simulating the water flow inside the shaft and observing the interior when water passes using a transparent housing cover, and we realized a structure that inhibits contamination. Regarding ease of sterilization, we confirmed that autoclaving using a biological indicator sufficiently sterilizes germs.

(ii) Rulemaking strategies

As part of rulemaking strategies for commercialization, Medicaroid continues to participate in the development of international standards.

Because the regulatory authorities in each country are very concerned about the safety of medical electrical devices, each country has legislated technical

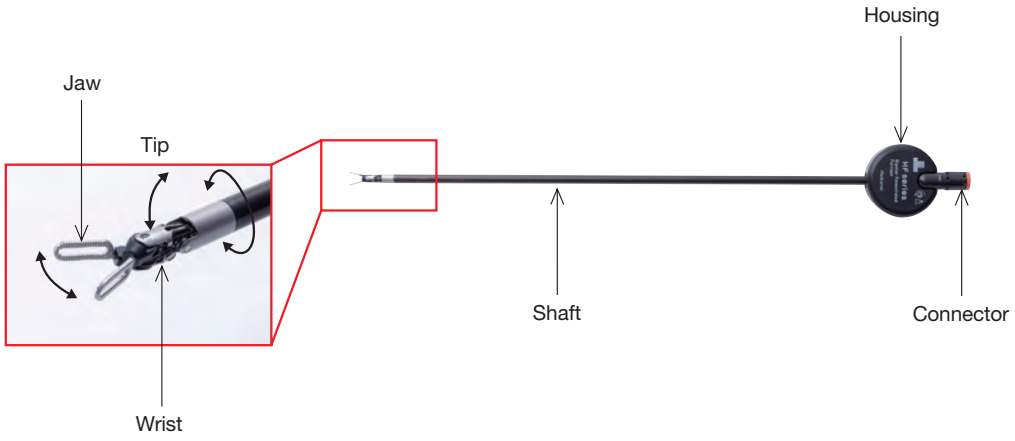


Fig. 6 Example of surgical instrument

requirements for medical electrical devices mainly based on the IEC 60601 series of standards issued by the International Electrotechnical Commission (IEC). However, when Medicaroid started to develop the hinotori Surgical Robot System, there were no safety standards for medical electrical devices using robotics technology.

To address this issue, the IEC has developed a standard that applies only to the robotic-assisted surgery system product group and issued it as IEC 80601-2-77:2019. During the development of this standard, Medicaroid participated in the writing of the standard as a member of the Japanese delegation and encouraged the introduction of safety technologies already in use in industrial robots. Many of the company's proposals were adopted.

Only six months after this standard was issued, Medicaroid completed conformity assessment with the standard and filed an application for pharmaceutical approval using conformity to this new standard as the basis of product safety. This quick application was possible because the technologies of Kawasaki are included in the standard, and some of us participated in the creation of the standard and are familiar with the requirements. We believe that this is one piece of evidence that our rulemaking strategies have borne fruit.

Conclusion

The hinotori Surgical Robot System is a completely new product that we plan to further grow and develop. We will first increase the range of target surgical procedures and expand the market by globally launching the product in the US, Europe, Asia, and other regions. Meanwhile, we plan to adopt many new technologies to make the product more attractive. In particular, by connecting digital information inside and outside the robot to a network and accumulating it in a database, we are focusing on efforts to make the information useful in providing guidance for more efficient surgery, in improving and transferring medical skills, and in providing support for remote robot surgery, in which a surgeon in a remote location supports surgery over a network.

Hiroaki Kitatsuji
Medicaroid Corporation

Hiroshi Ura
Strategic Safety Standardization Department,
Medicaroid Corporation

Takahiro Ueda
Development Department,
Medicaroid Corporation

Yu Usuki
Development Department,
Medicaroid Corporation

Tsuyoshi Tojo
Medical Robot Department,
Medical Robot Group, Robot Business Division,
Precision Machinery & Robot Company

Hirofumi Yamamori
Medical Robot Department,
Medical Robot Group, Robot Business Division,
Precision Machinery & Robot Company

Wataru Doi
Medical Robot Department,
Medical Robot Group, Robot Business Division,
Precision Machinery & Robot Company

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