Keynote Lecture Series

Embracing industry in the development of robotic coronary bypass grafting—the sun rises in the East

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The introduction of robotic surgical devices nearly two decades ago led to a significant reduction in the invasiveness of cardiac procedures. The further worldwide implementation of robotic surgical devices in cardiac surgery, especially coronary artery bypass grafting and mitral valve repair or replacement, has, however, been stalled by numerous challenges. First, there is the high complexity of the procedures that involve a significant learning curve; second, there is the significant cost of robotic surgical devices. Furthermore, significant changes in the medical device regulation have occurred in recent years, hindering further technological development and the emergence of new players on the market. Finally, clinical evidence regarding the benefits of robotic-cardiac procedures remains scarce at this time. We invited all players active in or planning to throw themselves into robotic-assisted cardiac surgery to discuss these challenges in a semi-structured interview. Two promising and ambitious companies showed interest in participating in this project: Medicaroid and SS Innovations. The main conclusions from the interview are that both companies aim (I) to launch an affordable alternative compared to the current robotic surgical devices, (II) to further develop their robotic devices based on the opinion of physicians, and (III) to engage in overcoming the steep learning curve correlated with robotic-assisted cardiac procedures.

Keywords: Robotic cardiac surgery; medical industry; surgical education

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Introduction

The implementation of robotic surgical systems has changed the invasive nature of several cardiac surgical procedures over recent decades. Traditionally, coronary artery bypass grafting (CABG) and mitral valve repair (MVR) could only be performed by the conventional sternotomy approach. Attempts have been made to reduce these procedures' invasiveness; however, the rise of robotic surgical systems has proved to be the real game-changer (1).

In the 1990s, pioneering robotic surgical systems were introduced for the first time in cardiac surgery, with the da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA, USA) being approved for use in 2000 by the Food and Drug Administration (FDA). European surgeons were among the first worldwide to adopt robotics into various aspects of cardiac surgery, including the previously mentioned MVR and replacement and CABG, as well as cardiac tumor resection and atrial septal defect closure. The widespread implementation of robotic surgical systems, however, has been stalled due to the complex nature of the procedures, the associated need for training, recent changes in medical device regulations (MDRs), significant costs, the lack of robust clinical data on robotic-assisted cardiac procedures, and a declining interest from medical industries due to the aforementioned reasons (2-4).

Further development of robotic surgical technology,

Figure 1 Tetsuya Nakanishi—General Manager of Medicaroid Europe, courtesy of Medicaroid.

including the availability of second- and third-generation machines, has sparked a renewed interest in the use of robotic surgical devices in cardiac surgery. Furthermore, the success of robotic cardiac surgery in the USA, as demonstrated in a recent study on robotic MVR by Mori and associates, has shown that the robotic approach is associated with a lower rate of conversion to mitral valve replacement, shorter length of stay, and lower readmission rates compared with thoracotomy or sternotomy approaches. Additionally, there is emerging clinical evidence showing the benefits of robotic CABG in reducing postoperative complications over conventional CABG (e.g., pneumonia and postoperative pain) and a reduction in recovery time (3,5,6).

We discussed these challenges among other burning topics concerning robotic-assisted cardiac surgery, with representatives of the leading medical corporations in the field, since a partnership with these corporations will be key for the further advancement of robotic-assisted cardiac procedures, particularly robotic coronary bypass grafting.

Involved parties

We invited all corporations involved in the field of robotic-assisted cardiac surgery to join our semi-structured interview. A brief introduction of the stakeholders who accepted our invitation will be provided below, followed by the interview, which we structured by first introducing the question, followed by the corporations' answers.

Medicaroid ('M' in the interview)

Representative: Tetsuya Nakanishi—General Manager of Medicaroid Europe (*Figure 1*).

Medicaroid was founded by Kawasaki Heavy Industries Ltd. and Sysmex Corporation in 2013. Their robotic device, the hinotori™ Surgical Robot System, was originally developed and manufactured in Japan and was first used in clinical practice in 2020. The direct translation for 'hinotori' is 'firebird', which means phoenix. It comprises four operation arms, a high-resolution visual system, and an ergonomic cockpit (*Figure 2*). Although the company was only recently founded, it has significant industrial backing and experience from Kawasaki Heavy Industries in industrial robotics.

SS Innovations ('I' in the interview)

Representative: Sudhir Srivastava—Founder, Chairman and Chief Executive Officer (CEO) of SS Innovations (*Figure 3*) and Vishwa Srivastava—President and Chief Operating Officer (COO) of SS Innovations South Asia (*Figure 4*).

The roots of SS Innovations can be traced back to India, where the SSi Mantra (*Figures 5,6*) has been in clinical use since August 2022. Their current Chairman and CEO, Sudhir Srivastava, is considered a pioneer in robotic cardiac surgery and performs a large variety of procedures, including robotic-assisted minimally invasive direct coronary artery bypass, totally endoscopic coronary artery bypass, and atrial septal defect repair. Previous trials successfully validated its safety, feasibility, and efficacy. Currently, only two installations are outside of India, with one being in Dubai, United Arab Emirates, and one at the laboratory at Johns Hopkins Hospital, United States for training in minimally invasive procedures.

The questions posed in the interview focused on the training of surgical novices, the challenges regarding MDRs, and future perspectives. We will discuss each topic separately and provide the answers from the interviewed corporations.

Differences regarding existing robotic surgical systems

Can you briefly outline what you think is a unique feature that sets your robotic surgical system apart from others?

M: the main advantage of the hinotori™ Surgical Robot System is that it imitates the movements of a human arm. While most companies focus on laparoscopic procedures, the application of our robot remains broader, with a special

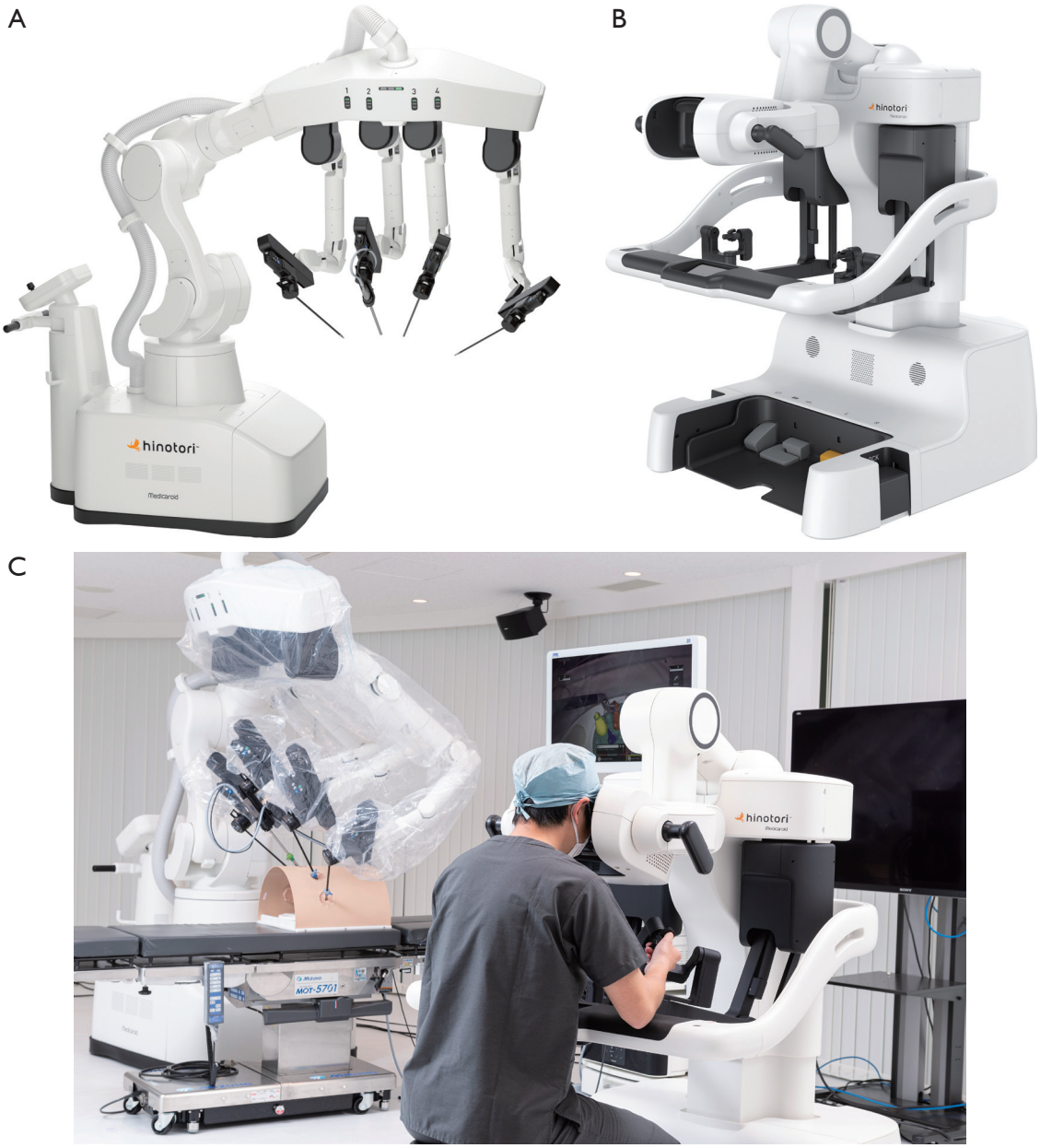

Figure 2 The hinotori™ Surgical Robot System, courtesy of Medicaroid. (A) hinotori™ operation unit. (B) hinotori™ surgeons' cockpit. (C) hinotori™ robotic assisted surgery system.

interest in robotic-assisted cardiac procedures. Further deploying our robotic surgical system in the latter surgical field remains one of our main objectives, since cardiac surgery is considered one of the most studied and controlled surgical disciplines.

I: the focus of our platform is on usability on the one hand, and on the other hand, we want to commit to sustainability and affordability without sacrificing quality compared to the existing platforms. We are proud to inform you that currently, more than 500 clinical cases have been completed with our platform in various disciplines, including cardiac surgery with one case of totally endoscopic coronary bypass without device-related complications.

From the beginning, we have received interest from low-income countries. This is a market that is currently still being overlooked but where there is also a growing need for

Figure 3 Sudhir Srivastava—Founder, Chairman and Chief Executive Officer of SS Innovations, courtesy of SS Innovations.

Figure 4 Vishwa Srivastava—President and Chief Operating Officer of SS Innovations South Asia, courtesy of SS Innovations.

Figure 5 The SSi Mantra Surgical Robotic System courtesy of SS Innovations. (A) Arm carts, (B) surgeon command centre, (C) the SSi Mantra set-up.

Figure 6 Images of the SSi Mantra in operation, courtesy of SS Innovations.

and interest in this technology. However, these countries face the same challenges as India, mainly in terms of financial capacity to further roll out this technology. Thus, we are currently dealing with this situation not only in India but also in these other low-income countries.

Acquisition and dispersion of robotic surgical skills

Several studies have pointed out that training significantly influences clinical outcomes. There is no uniform curriculum for robotic CABG or robotic cardiac surgery in Europe at the moment. Robotic surgical skills are primarily taught outside the existing curriculum and provided by individual proctors on a diverse spectrum of robots.

How do you plan to train surgeons on your robotic surgical device?

I: there are several ways in which we work toward this challenge. Since there is a decline in cardiac procedures worldwide, that also means that interest in this market from existing companies is also declining. This, in turn, makes it difficult to continue the development of an 'all-round' cardiac robotic surgical device. There remains a huge gap between what is being done and what can be done. With the experience we have gained over the past decades, we have established a training platform in India. The goal is to formalize training by establishing a curriculum for robot-assisted cardiac surgery. This curriculum could then be taught locally but will be accessible internationally.

A second major step is to build our teleproctoring and telesurgery plans. Since a small number of surgeons are fully proficient with robotic cardiac procedures and it is not time- and cost-efficient to fly halfway around the world, these concepts could prove useful. When a trainee surgeon encounters a challenge, the proctor can provide a way out from a distance.

Third, the further development of virtual platforms is important. We currently have a department called 'Maya' that is working on virtual reality. Here, the goal is to reach certain levels of proficiency as quickly as possible through

assignments with graduated levels of difficulty. We start from the absolute beginning and do not assume any prior knowledge of robotic surgical devices.

Additionally, today we can also take advantage of available 3D imaging to virtually bring the patient, in preparation for the surgery, to life. This allows the surgeon to go through the operation, with all its facets, even before the first real incision is made. As such, the 'unknown' about the operation disappears, making it safer and leading to more stable and efficient outcomes.

A potential game-changer for the further development of robotic training might be the construction of a global cardiac surgery registry. The information we could glean from this to further improve clinical practice would be virtually endless.

What is your opinion about a potential collaboration between medical companies and overarching medical organizations (e.g., the European Association of Cardio-Thoracic Surgery) regarding the acquisition of robotic surgical skills?

M: cooperation between industry and the overarching medical organizations is key and could be beneficial for both sides. On one hand, these organizations' role may be to establish guidelines and certification processes for training programs and to promote further training. Although the issues are completely different, a parallel can be drawn to driver's licenses, where the government exercises control over the fitness to drive. Following this logic, therefore, only certificate holders would be deemed competent to perform a robotic-related procedure, which can only benefit safety and clinical outcomes. On the other hand, such collaboration will inseparably lead to an exchange of information and experiences that will, in turn, be important for the further development of robotic surgical devices.

I: training on robotic surgical devices should be provided by both industry and international or national societies. The main hurdle remains the decreased interest of existing companies regarding cardiac surgery in general. Secondly, companies active in cardiac surgery are focused mostly on intracardiac procedures.

We have already discussed our personal ideas to improve training in the answer to the previous question, and we will continue to work on them. However, it will require collaboration at a higher level to make them a reality. We are convinced that an advisory group is needed to further elaborate on the ideas brought forward by clinicians, industry, and international organizations.

Who do you think should oversee the robotic surgical training?

M: in general, the overarching organizations, in collaboration with the different universities, are best suited for this task. However, since there can be many differences between universities and their collaborations with overarching organizations, proctors are indispensable. The proctorship can, again, be certified, as discussed in the previous question, guaranteeing state-of-the-art education in robotic surgery.

Does your device currently allow you to track the progress of surgical skill development?

M: yes, the hinotori™ Surgical Robot System is currently equipped with a feature to record and collect data, including the endoscopic view, motion data, and manipulation of instruments. These data are already being analyzed. The goal is to apply the results in the training process to further optimize robotic cardiac procedures.

MDR

I: semi-recently, a new MDR (2017/745) was created by the European Union in the wake of a series of scandals in the early 2010s. Previously, the regulation of medical devices was less strict than for drugs, and approvals could be granted in cases of limited evidence. This new MDR imposes stricter obligations for pre-marketing testing, certification, and post-marketing surveillance. While these stricter obligations aim at patient safety, they also bring with them challenges, including increasing development costs, and drawbacks, such as restraining innovation (7).

What is your current view on MDR, and what impact does it have on your activities?

M: first, the regulation is important regarding patient safety, but going through the steps to finally obtain certification is a detailed process, which slows market speed. In Europe, we are working toward Conformite Europeenne (CE)-mark conformity according to the current MDR for urology, general surgery, and gynecology, and this is foreseen in

the forthcoming future. After receiving approval for these specialties, we plan to apply for cardiac surgery.

In 2020, we received approval for urology in Japan, and this was expanded to general surgery and gynecology in 2022. Next will be thoracic surgery, and its approval in Japan is coming up soon. At the moment, we do not hold approval for cardiothoracic surgery. However, we are thinking about this as a future step.

I: in India and many other jurisdictions that do not require Food and Drug Administration (FDA) approval or CE accreditation, we are allowed to perform any procedure involving soft tissues, including cardiac surgical procedures, and we have already done them too. Our installations today are, with all the required instrumentation, completely capable of being used in valve repairs or replacements.

Approval by FDA or obtaining CE accreditation has become particularly important and, of course, has a major impact on market access. However, it cannot prevent things from going wrong afterward. Approval by these organizations is relative, and robust training on robotic-assisted cardiac procedures is equally important.

We have a very systematic approach to launching our robotic surgical systems. Basically, we install robotic surgical systems, and tutoring will then be provided in an incremental approach.

Regarding FDA, next month (note: this interview took place at the end of 2023), we have a presubmission meeting with them. As most companies do, we are starting off with abdominal indications. However, we wish to commence with cardiac indications in the short term. A similar approach will be followed for Europe.

Obtaining accreditation in Europe as well as in the United States is a time-consuming process. If surgeons still wish to perform robotic coronary bypass in the meantime, one option would be to make our stabilizer available on an existing system. We must be creative until we receive our approvals.

Future perspectives

What does your long-term vision consist of?

M: we have developed a robot that assists the surgeon and allows to perform a diverse range of procedures without replacing the surgeon. To achieve the long-term goal of continuously expanding the range of procedures, including cardiac in the future, we need to identify current challenges, and continuous communication with surgeons is, therefore, indispensable.

This journey is never-ending, and we must keep optimizing our robotic surgical device. In fact, our key opinion leaders are always surprised by how fast we realize and implement the optimizations suggested by them. We are always updating our robot to the needs of the clinicians and surgeons, making this one of our core competencies.

I: we proceed step by step. First, we developed all the instruments necessary for cardiac surgery, ranging from coronary bypass surgery to valve repair. Currently, we are working on a prototype of a 'smart' connector that we will call 'NARDY', which can automatically complete coronary anastomoses. Another development in progress is a 'multi-fire clip applier', which can be paired to a fifth robotic arm and will be available soon—another feature that sets our robot apart from the others.

Aside from the projects described earlier, we also aim to partner up with cardiologists on implantable technologies. We think that if you could combine robotic surgical systems with these implantable, 'percutaneous' technologies, we could provide better treatment options for patients and 'revive' the surgical community.

Conclusions

The further implementation of robotic cardiac surgery worldwide is at a crossroads. On the one hand, clinicians are dealing with several previously described challenges, and interest of established companies is shifting to other surgical fields. On the other hand, new companies are emerging, and the constant drive for improvement never stops, resulting in an ally to meet these challenges. Along with beneficial clinical evidence regarding the use of robotic surgical devices, this has sparked a new interest in robotic cardiac surgery.

As coincidental as it may seem that both companies interviewed are from Asia, this comes as no surprise. Firstly, the Asian market, and certainly low-income countries, have long been overlooked by the major players within robotic cardiac surgery, especially regarding the high price tags. Both Medicaroid and SS Innovations are trying to bring an affordable alternative to the market in these countries with their devices.

Their ambition, however, extends further, as they wish not only to develop a product that performs as well as existing devices but one that can surpass them. To achieve this goal, both companies use their networks. In the case

of Medicaroid, this involves the technical know-how of Kawasaki Heavy Industries Ltd. and Sysmex Corporation. SS Innovations, on the other hand, uses the surgical experience of their leading surgeons in robotic cardiac surgery.

Both companies agree that a formal training curriculum will be beneficial for the further development of robotic cardiac surgery. A collaboration between the industry and overarching medical organizations can play a major part in this. Concrete proposals for improving training include the use of virtual reality and the processing of data acquired by the robotic surgical devices. The most important role, however, will be for (tele)proctoring.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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