Development of SupeR BEAT with EBM

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Collaborative Value Creation with EBM Corporation on SupeR BEAT Development

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Summary

This article outlines the joint development of SupeR BEAT, an OFF-JT device for cardiovascular surgery. It describes the initial encounter between EBM and Toyoda Gosei, directions in product development, and speed prototyping driven by pared-back simplicity. It also considers the intrinsic value of collaborative development, including interactions and bridging activities with the medical community that transcend the simple relations of manufacturing to provide an example of open innovation.

1. First Meeting and Concept Building

The encounter between Toyoda Gosei and President & CEO Young-Kwang Park of EBM Corporation (named for "Engineering Based Medicine")[1), 2)] started with a single email in June 2017, and has since driven innovation in equipment development and surgical training services.

At Toyoda Gosei, we are convinced that e-Rubber is "the ultimate bio-mimetic," stemming from its unique characteristics and flexible qualities. In exploring possibilities, we had been researching medical simulators both in Japan and overseas when we were attracted to a company website that seemed a little different, and we asked to meet with President Park.

The 90-minute conversation at our first meeting touched on a shared sense of values inspired by the behavior (like a living organism) of the eR diaphragm actuator (Fig. 1), our mutual desire to use e-Rubber to help the world, Park's research experience, and a discussion of our attitudes to business. The basic concept for development of the next-generation model of EBM's current device (BEAT; described later) was decided at that time.

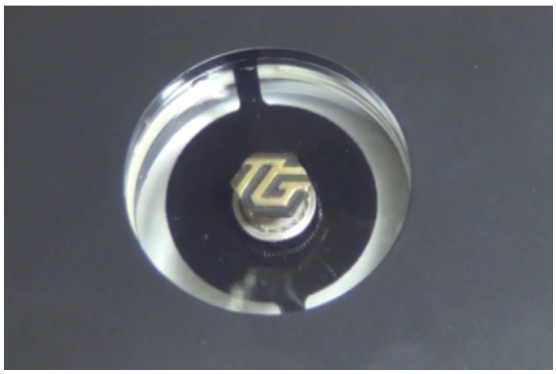

Fig. 1 eR Diaphragm Actuator

Toyoda Gosei knew President Park's history—he had won the Waseda University Campus Venture Grand Prix Award in 2006 and founded his company in the same year, which had become stable after considerable initial hardships. He had been chosen as one the young members (Global Shapers) of the World Economic Forum (Davos Conference). We also knew he was ambitious and was building relationships with those in political and financial circles. It was not until later that we learned that he also had a pilot's license, so he was no stranger to a world in which mistakes have direct consequences for physical safety[3), 4), 11)]. However, more than anything, we quickly recognized his dedication and energy toward accomplishing his goals of improving the skills of young doctors through surgical training, quantitative evaluation of surgical procedures, construction of an assessment platform, and international standardization driven by Japan. This was the catalyst for cooperation with the e-Rubber development team.

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2. OPCAB and BEAT, and then to SupeR BEAT

In the field of cardiac surgery, procedures have a direct bearing on the life of the patient, yet young doctors actually have little opportunity to train in surgery. As the number of patients increases, safely training and improving the technical skills of physicians is an increasingly important issue.

Among the treatments for ischemic heart disease resulting from stenosis or obstruction of the coronary artery, which carries essential nutrients and oxygen to the cardiac muscle, coronary artery bypass grafting (CABG) (Fig. 2) is well known as an effective surgical approach. Of the various methods, the method of stopping the heart while using an artificial heart-lung machine is called the "on-pump" method, while performing the operation without the use an artificial heart-lung machine and not stopping the heart is called the "off-pump" CABG (OPCAB) method[5), 6)].

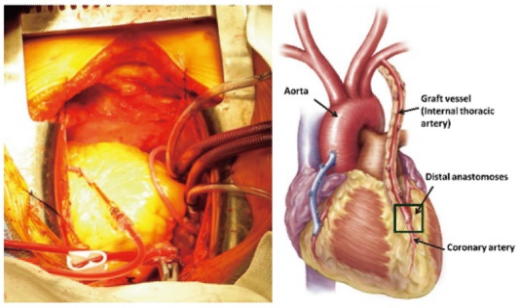

Fig. 2 Coronary artery bypass surgery (left), post-operative image (right)

President Park understood the clinical needs of cardiac surgery and developed the beating-heart coronary artery bypass surgery training simulator BEAT and the coronary artery model YOUCAN (Fig. 3), which have gained a reputation for reliability. The YOUCAN device, which mimics the coronary artery on the myocardium, is placed on the motion platform of the BEAT beating-heart device. It is used for self-training in vascular suturing (anastomosis).

Based on conversations with 1,000 doctors, and in line with the notion that training simulators are meaningless if not used, gimmicks that added no real value were abolished and "simple but sufficient" functionality was realized. This machine is currently being introduced in many hospitals offering cardiovascular surgery, both in Japan and abroad, and there is little doubt as to its value.

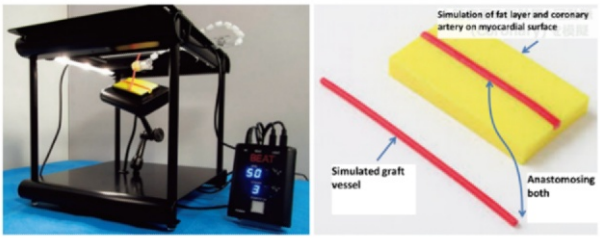

Fig. 3 BEAT beating-heart coronary artery bypass surgical training simulator (left). YOUCAN coronary artery model (right)

As the next step in increasing the value of non-hysteretic e-Rubber artificial muscle, we are seeking to add training in situations of greater stress, random environments, and dynamic environments.

Many people know that training to improve the skills of professional athletes can be broadly divided into two types: "closed skills" and "open skills"[7)]. In soccer, for example, dribbling and passing drills are performed in a stable and repetitive fashion to improve a player's sense of ball touch, leading to accurate reproduction during play. Such "closed skill" training is used for the game's fundamentals. On the other hand, "open skill" training aims to build accurate judgment and behavior in selecting the most suitable play for the constantly changing environment—for example, the game situation and the opposing side's tactics—as well as training to build automatic behavior loops.

The current BEAT is a first-class training device to improve fundamental closed skill areas by providing a high-load environment apart from actual on-site anastomosis. Next-generation devices utilizing e-Rubber will be able to offer situation-based case study training with more dynamic myocardial movement that has broader bandwidth and flexibility. These devices will be able to present random environments (such as heart rates and patterns changing from moment to moment, unexpected condition changes, etc.) with precise control.

The true value of the new SupeR BEAT product (Fig. 4) is its function as a higher-end version of the current BEAT device.

We are currently further developing both the software and hardware as we head toward the commercial release of SupeR BEAT in fall 2019. We are committed to doing our utmost to contribute to the improvement of surgical procedures for physicians.

Fig. 4 SupeR BEAT

3. Bridging activities with the medical industry

In November 2017, EBM and Toyoda Gosei signed an agreement for the collaborative development and dissemination of a surgical training simulator using e-Rubber. Here, "collaborative" means simply working together to produce value.

The development of e-Rubber is highly promising for the medical industry, although Toyoda Gosei lacks experience and specialist expertise in that field. EBM will guide Toyoda Gosei in this unfamiliar area, leveraging its network of connections to help Toyoda Gosei build its knowledge and expertise in this field. As it learns about the medical industry, Toyoda Gosei will also build its business launch skills in the field.

The first opportunity was attending the 1st Off-JT Boot Camp (Kobe MEDDEC) of the World Surgical Education Forum, which President Park founded and also serves as secretary, in December of 2018.

This training camp was a gathering of young cardiovascular surgeons who had graduated from medical school in the past several years. They underwent intensive training using BEAT devices while also meeting with veteran instructors who assessed their skills and gave meticulous advice. The strong desire for improvement of these serious young doctors was apparent as they worked stitch by stitch. Paired with the impressions of the veteran doctors watching over them, this was a site where the true value and significance of Off-JT surgical procedures could be recognized (Fig. 5).

Fig. 5 The 1st Off-JT Boot Camp

Toyoda Gosei was also honored by the presence of Emeritus Professor Hikaru Matsuda of Osaka University, a preeminent authority who pioneered heart transplant techniques in Japan, and Professor Hitoshi Yokoyama of Fukushima Medical University (appointed President of the Japanese Society for Cardiovascular Surgery in February 2018).

The high expectations and words of encouragement for e-Rubber from these respected figures in the medical field were very encouraging for Toyoda Gosei. E-Rubber was given a rare opportunity at this forum, and we are committed to sparing no effort in pursuit of its goals.

In terms of the possible scope of sale for SupeR BEAT in the medical equipment market, the US is the largest potential market, followed by Europe and Japan.

For any manufacturer of medical equipment, the academic societies and conferences in the United States are of paramount importance. These sites bring together the world's most advanced and developed products, as well as influential physicians from all over the world. At EBM Corporation’s exhibition at the meeting of the Society of Thoracic Surgeons (STS[8)]) in January 2018, Toyoda Gosei introduced the current model of BEAT to visitors, as well as greeting doctors from Japan and other countries and visiting the booths of leading medical equipment manufacturers. These conferences have allowed us to close the psychological distance between potential business partners with whom we previously knew only via magazines or online (Fig. 6).

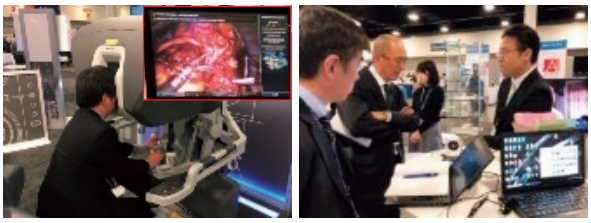

Fig. 6 STS 2018 (Society of Thoracic Surgeons, USA)

Just as in the development of the current model BEAT, discussions with doctors are of great importance in the design considerations of SupeR BEAT. The value concept for e-Rubber was presented with the announcement by EBM and Toyoda Gosei of the new SupeR BEAT product. The tension and relief felt when we first presented this device Professor Yokoyama of Fukushima Medical University and other doctors, as well as each of the many opinions obtained at that time, were an essential part of the process as SupeR BEAT moves towards commercialization. We also obtained good design feedback from the many doctors who practiced with the SupeR BEAT at the exhibition of the Wakayama Association for Coronary Artery Surgery[9)] (on-site Off-JT) in July (Fig. 7).

We are now fine-tuning the specifications through events for product development and commercialization, such as conferences held by the Japanese Society for Artificial Organs[10)] (November 2018) and STS (January 2019).

Fig. 7 Demonstration of anastomosis by Fukushima doctors (at left); Surgical trial by Wakayama Association for Coronary Artery Surgery (right)

4. EBM and Toyoda Gosei: Full speed toward manufacturing

Toyoda Gosei and EBM share a common value: "Finalization of a concept is meaningless if you don't make the product, so you have to move full speed ahead." For the SupeR BEAT prototype, the functional concept and design were worked on with the same speed in Fukushima and Aichi by the people in charge at EBM and Toyoda Gosei. The parties also met together at Fukushima FIST to work intensely for production while taking in abundant user input. Proposed improvements written on the whiteboard were input into 3D data on the spot. These data were converted and processed immediately, with DR carried out the very next day on actual prototypes. Just a few days of this camp led to real improvements. We call this process "crunch-mode manufacturing."

The emphasis on the prototyping process by the e-Rubber application development team was based on the question: "How can we conduct meaningful trial and error at high speed?" Production without clear goals is obviously pointless, and the process did not neglect academic and theoretical approaches. E-Rubber can provide entirely new value, but we need to continue acquiring intelligence and ideas while acting at high speed.

"Creative destruction" is perhaps an exaggeration, but when testing using a heuristic approach[11], iteration speed is essential.

Toyoda Gosei and EBM have reached a point of unspoken communication with a shared sense of values, are our movements are syncing in surprising ways.

In this process of "crunch-mode manufacturing," one of the major outcomes of collaboration is the emergence of mutual outcomes in shared approaches to manufacturing and quality. For Toyoda Gosei, which has no direct connection with the medical industry, the authenticity and tension gained through the manufacture of SupeR BEAT are valuable assets in searching for the right approach to collaboration with the medical industry.

5. Towards the future

Opportunities for actual surgical practice are decreasing for young surgeons and less time is devoted to educational guidance. Increasing the training time for surgical procedures and skills is a challenge, and the Japanese Board of Cardiovascular Surgery has made the use of simulators to perform Off-the-Job Training (OFF-JT) mandatory since 2017. This training seeks to improve the technical performance and cognitive judgment of young surgeons to approach veteran levels by virtue of planned experience using OFF-JT simulators, rather than through surgical experience (incidental experience) obtained in actual patient cases. The concept that underpins this training method design is "deliberate practice" (intentional practice, planned practice, marginal practice)[12]. We hear that in the future, academic associations will also assist in the systematic development of OFF-JT. In addition to technical skill training, we intend to learn from on-site issues and past troubles to develop better movement and training. This will contribute to SupeR BEAT as material for deliberate case studies to test both knowledge and judgment.

Toward that end, Toyoda Gosei will apply the dedication that we have accumulated on the front lines of manufacturing life-critical components such as brake hoses, as well as human development. There will be no greater pleasure for us than to help drive medical collaboration.

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