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Development of a New Pulsatile Ventricular Assist Device

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ABSTRACT

We developed a small, lightweight, low-cost implantable ventricular assist device (VAD) for use in smaller Japanese subjects. The major advantage of this pump is the simplicity of its fabrication. Most parts of the pump were shaped from a transparent acrylic block by a turning process, and the diaphragm was made from a silicon sheet. Since this method of construction did not require any complex processes, we could manufacture many pumps of various shapes. We determined the most efficient shape for the Ebacor VAD using the flow visualization technique. The pump showed an output above 6 liters/min under a driving pressure of 300/–100 mmHg. The pump performance of current VADs is superior to that of the Ebacor VAD, because these pumps are larger. Since the Ebacor VAD is small in size, it can be driven by the driving system of a normal IABP control unit, which many hospitals already have in place. During a 30-day continuous driving performance test of this pump, no problems like performance decrements or water and air leakage were observed.

Key words: *Ventricular assist device, Low cost, Flow visualization*

Heart transplantation was restarted in Japan in 1997[5], but the number of recipients is small because brain death has occurred in a few cases. Patients with end-stage cardiac failure who require heart transplantation are typically waiting with a ventricular assist device (VAD) for an extended period[6]. Since VADs are also used for permanent implantation as a destination therapy, as a bridge-to-recovery, or as a bridge-to-therapy in patients who are not indicated for heart transplantation due to their age or complications[3], the number of patients who require a VAD is growing[15]. In Japan, there are two types of Japanese VADs available: the Toyobo VAD and the Zeon VAD[14]. Both are paracorporeal, pneumatic VADs. US-made implantable VADs such as the Novacor VAD and the Heart Mate VAD are imported and implanted in some Japanese cases[4,12]. These US-made devices, however, are too large for many Japanese patients because the devices require a body surface area (BSA) greater than 1.5 m^2. In addition, the price of the device is extremely high. Thus, the development of a small and inexpensive implantable VAD is very important for Japan.

We studied various types of artificial hearts[2,7,13,16], and devised a pneumatic VAD that was easily fabricated, small, and inexpensive. This pump was manufactured by Eba Kousakusho Ltd., and was named the "Ebacor VAD". We designed many pumps of various shapes, and investigated the most efficient shape for the Ebacor VAD. In the present study, we determined the best shape of the Ebacor VAD using flow visualization techniques. Furthermore, the performance of the Ebacor VAD was compared to that of other VADs, and its durability was investigated through a continuous driving performance test.

MATERIALS AND METHODS

1. Materials and fabrication of the Ebacor VAD

Figure 1 shows the structure and parts of the typical Ebacor VAD. The Ebacor VAD consists of only six parts: an air chamber, blood chamber, inlet valve, outlet valve, diaphragm, and drive line. The air chamber and blood chamber are shaped from an acrylic block by a simple turning process. The manufacture and processing of each part is very simple. Silicon ball valves are used as inlet and outlet valves. The diaphragm is made of silicon. As a driving line, a 6 mm silicon tube is used.

The air and blood chambers are transparent, and the internal flow can be inspected from outside. This allowed us to observe and evaluate the flow inside pumps of various shapes in this study. The air and blood chambers have thread grooves

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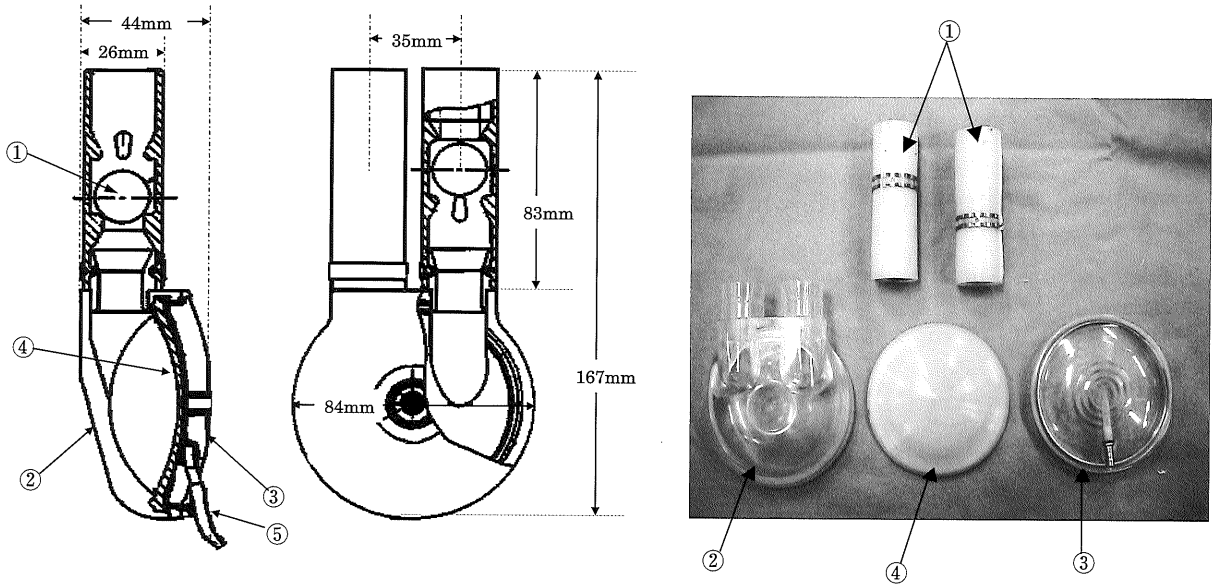

Fig. 1. Structure and parts of a typical Ebacor VAD are shown. The Ebacor VAD consists of only six parts. Two silicon ball valves are used as the inlet and outlet valves (1), the air chamber and blood chamber are shaped from an acrylic block (2) (3), the diaphragm is made of silicon (4). As a driving line, 6 mm silicon tube is used (5).

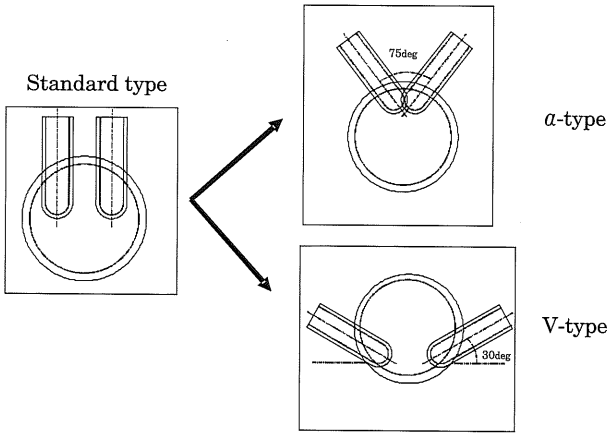

Fig. 2. Schemata of three different types of Ebacor VAD are shown. The inlet is placed parallel to the outlet in the standard type, the inlet and the outlet are crossed in the α type, and the inlet and the outlet are placed linearly near the circumference in the V type.

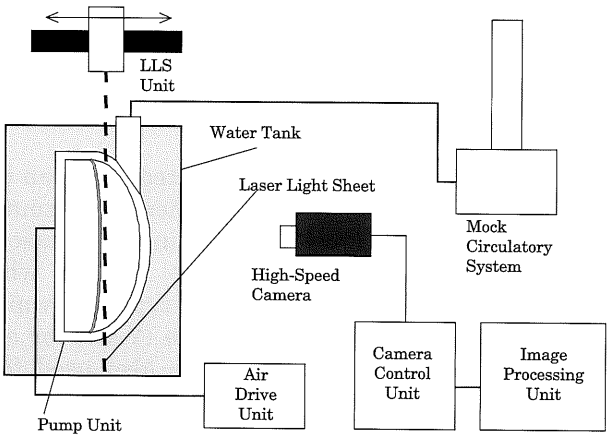

Fig. 3. The system of flow visualization is shown.

in their joints, and are easily assembled by screw type mounting and dismounting. Therefore, it can also be easily dismantled. This will allow us to observe the interior of each part in detail after durability tests or animal examinations in the future. The diaphragm is interleaved and fixed between the air chamber and blood chambers. The artificial valves are encased into the body of this pump.

2. Selection of the pump shape

A ventricular assist device should have a shape which causes no thrombosis, and in which the blood flows without stalling. To determine the best shape of the Ebacor VAD, we used a visualization analysis method for the flow field in the pump. In this study, we evaluated the internal flow field in three models of the Ebacor VAD in which the positions of the inlet and outlet were changed to investigate the optimal shape. Figure 2 shows the different shapes of the three models. The inlet was placed parallel to the outlet in the standard type model, the inlet and the outlet were crossed in the α type model, and the inlet and the outlet were placed linearly near the circumference in the V type model.

Figure 3 shows the system of flow visualization. As a light source, a 35 mW He-Ne Laser Light Sheet (LLS) was used. The tracer tracking method was used to estimate the internal flow field. Polystyrene beads of 200–400 μm were used as tracers. The entire pump was submerged under

water to prevent scattering of the laser beam, the pump was exposed to the LLS from the side, and the internal flow field was recorded by a Charge-Coupled Device (CCD) camera placed in front of the VAD. The CCD images were analyzed using Particle Imaging Velocimetry (PIV) processing techniques, and the streamline in the pump was estimated by Optical Flow Matching based on a normalized cross correlation method.

In addition, the washout performance was compared among the three models by a dye injection method. During diastole, 10 ml of condensed milk was injected, and the number of strokes necessary to wash it out was estimated by analyzing the brightness changes in the center of the pump.

Saline solution was used as the vehicle, and the pump was driven at 30 bpm to adjust for the Reynolds number of blood. The driving pressure and loading conditions were kept constant among the three models.

3. Performance test

The pumping performance of the typical Ebacor VAD was measured in an overflow-type mock circuit. As a control, the pumping performances of the Toyobo VAD and Zeon VAD were also measured under the same conditions. The Toyobo VAD was developed at the National Cardiovascular Center in Osaka, and is manufactured by Toyobo Co. Ltd, Osaka, Japan. The blood pump is paracorporeal, pneumatic, and diaphragm-type. The effective stroke volume is 70 ml, and the maximum output is 7.0 liters/min. The Zeon VAD was developed at Tokyo University and is produced by Nippon Zeon Co. Ltd. The blood pump is paracorporeal, pneumatic, and sac-type. The stroke volume is 40 ml, and the maximum flow is approximately 5.0 liters/min. Both pumps have two Bjork-Shiley valves as inlet and outlet valves.

The outputs of each VAD were measured while changing the stroke frequency from 40 to 120 bpm under driving pressures of 300/–100 mmHg in a driving device, the Corart C104 system (Aishin Seiki Co. Ltd, Kariya, Japan). Although the Corart C104 system was the driving device for the Zeon VAD, we used this system with all VADs to ensure uniform conditions. The preload and afterload were fixed at 10 mmHg and 120 mmHg, respectively. An electromagnetic blood flow meter (MFV-3200, Nihon Kohden Co., Japan) was used to measure the pump output. The outputs of each VAD were measured 10 times. All values were expressed as means ± standard deviation. The statistical differences were determined by a Student's paired t-test, and significance was set at a p value less than 0.05.

4. Durability test

Durability was estimated by a 30-day continuous driving performance test. The continuous driving was performed using an overflow-type mock circuit by fixing the preload and afterload at 10 mmHg and 120 mmHg, respectively, and by setting the driving pressure in the Corart C104 at 200/–50 mmHg. Pump performance and water and air leakage in the pump and tube were observed and then recorded daily. At the end of the 30-day test, the pump was dismantled to check for the presence of internal flaws and cracks.

5. Driving test by the normal IABP system.

The stroke volume of the Ebacor VAD was very small. The amount of air used to drive the Ebacor VAD was also 40 ml, which is almost equal to the capacity of a normal IABP balloon. We recognized that the Ebacor VAD could be driven by a normal IABP control system, which many hospitals already have in place. In this study, we drove the Ebacor VAD using a Corart BP-1v (Aishin Seiki Co. Ltd, Kariya, Japan) in IABP mode, and the output was compared with that of the Corart C104 system.

RESULTS

1. Features of the Ebacor VAD

The assembled pump is very small in size (volume: 135 ml, weight: 140 g, and stroke volume: approximately 40 ml), and fabrication was very easy. The size of the acrylic block used to manufacture the Ebacor VAD was 10 × 10 × 5 cm, and the time consumed shaping the Ebacor VAD with a lathe by hand was about twelve hours. The diaphragm and artificial valves were also fabricated easily. The assembly of the pump by means of threads was also easy and secure. The total cost excepting labor to manufacture the Ebacor VAD was less than 100 US dollars.

The air and blood chambers are transparent, and can be inspected from outside. Thus, we could

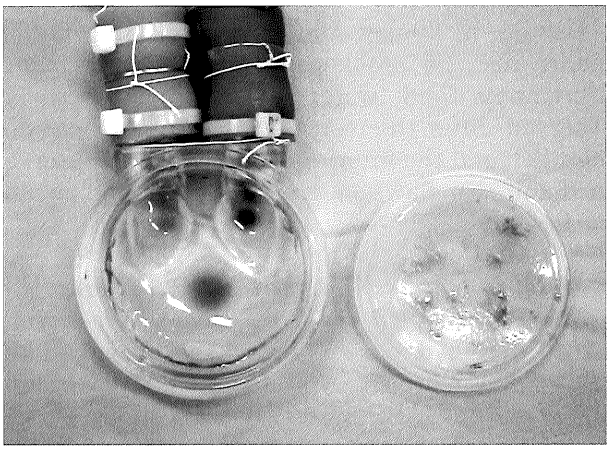

Fig. 4. Interior of the Ebacor VAD after animal examinations is shown. The appearance of adhesion thrombi was observed in detail.

observe and evaluate the flow inside the pump in many models in this study. The disassembly of the Ebacor VAD is also easy. We could observe the interior of each part in detail after a durability test or experimental animal examination (Fig. 4), and these results should contribute to this type of research in the future.

2. *Selection of the pump shape by visualization of the internal flow field*

Figures 5 and 6 show the flow fields in the pump during diastole and systole in all three types. Strong flow towards the center of the diaphragm during diastole, and strong flow from the entire diaphragm towards the outlet during systole, were observed in all types. The rectifying effect was the largest in the V type model, followed by the standard model and the α type model. In the washout test using dye injection, the injected condensed milk was washed out after 4 strokes in the V and standard types, and after 6 strokes in the α type model (Fig. 7). This indicated that the α type model had poorer washout performance than the V and standard types.

These results indicated that the V type model and standard type model were superior to the α type model. The standard type was selected for future study, since the V type required a larger space to be implanted and its washout performance was almost equal to that of the standard type model.

3. *Performance test*

Figure 8 shows the pump performance of each VAD in an overflow-type mock circuit. The Ebacor VAD showed pump outputs that ranged from 1.93 ± 0.1 to 6.66 ± 0.9 liters/min under a driving pressure of 300/–100 mmHg, while changing the stroke frequency from 40 to 120 bpm. The pump outputs of the Toyobo VAD and Zeon VAD were higher than that of the Ebacor VAD.

4. *Durability test*

During a 30-day continuous driving performance test, no problems, including performance decrements and water or air leakage, were observed. After the test, the Ebacor VAD was dismantled, and the interior of all parts was observed in detail. No flaws or cracks were found in any parts.

5. *Driving test by a normal IABP system.*

The Ebacor VAD could be driven by a normal IABP system. Figure 9 shows the output of the Ebacor VAD driven by the Corart C104 system and a normal IABP system (Corart BP-1v system on IABP mode).

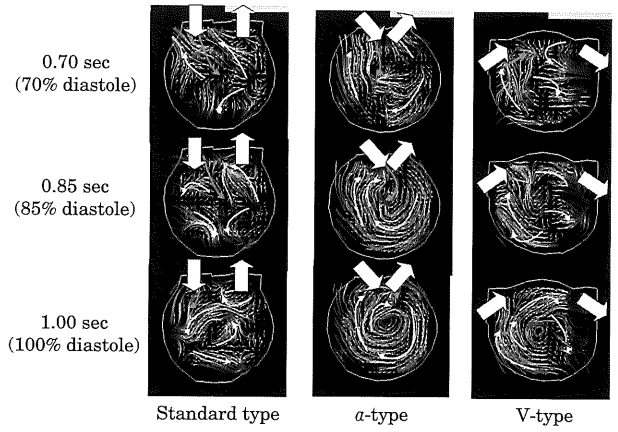

Fig. 5. Internal flow of three different types of Ebacor VAD in diastole is shown. Strong flow towards the center of the diaphragm was observed in all types.

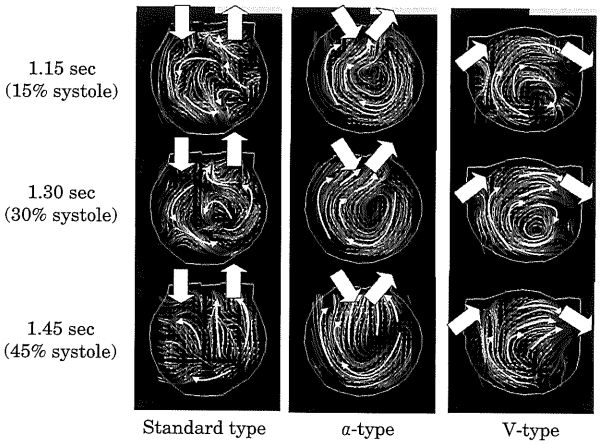

Fig. 6. Internal flow of three different types of Ebacor VAD in systole is shown. Strong flow from the entire diaphragm towards the outlet in systole was observed in all types.

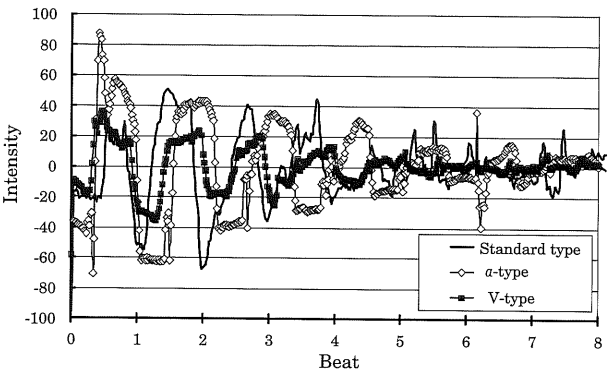

Fig. 7. Intensity changes of three models in the washout test are shown. The injected condensed milk was washed out after 4 strokes in the V and standard types, and after 6 strokes in the α type.

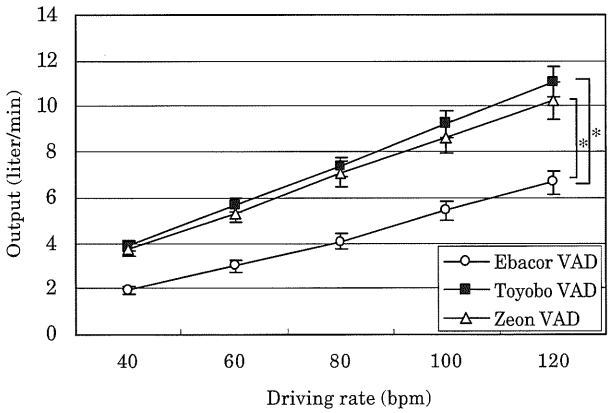

Fig. 8. The pump performance of the Ebacor VAD under a driving pressure of 300/–100 mmHg is shown. The pump outputs of the Toyobo VAD and Zeon VAD were higher than that of the Ebacor VAD. (*, $p < 0.05$)

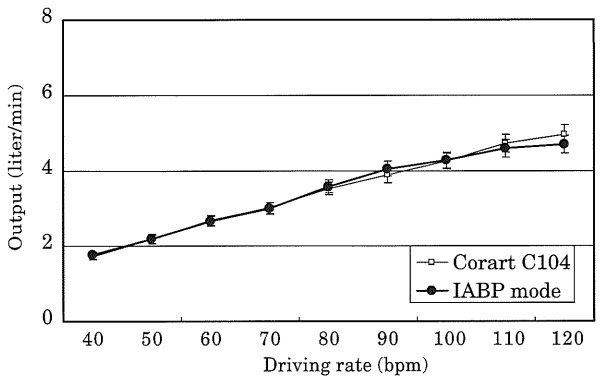

Fig. 9. Outputs of the Ebacor VAD driven by a Corart C104 system and normal IABP units (Corart BP-1v IABP mode) are shown. The Ebacor VAD could be driven by a normal IABP unit.

DISCUSSION

The greatest advantage of the Ebacor VAD is the simplicity of its fabrication. The air and blood chambers were shaped from an acrylic block by a simple turning process. The other parts were also easily fabricated. The air and blood chambers are transparent, and could be inspected from outside. We evaluated the flow inside the pump in many models in this study. Even when a new shape is proposed in the future, internal flow can be observed using this method.

Each part is assembled by screw type mounting and dismounting only, and complex processes such as mold making or welding of the parts are not required. This allows us to manufacture the Ebacor VAD easily and at a low cost. Another feature of the Ebacor VAD is the fact that it can be easily dismantled. This allowed us to observe the interior of every part in detail. This should be of use when the coating for anti-thrombotic activity in the Ebacor VAD is examined in the future.

The disadvantage of this prefabricated device was its durability, including the blood shield. However, the results of a 30-day continuous driving performance test showed that there were no problems in the durability of the Ebacor VAD over a short term. Currently, a long-term durability test is being conducted to investigate the long-term durability of the Ebacor VAD.

As an artificial valve, a silicon ball valve was used in the Ebacor VAD. The ball valve represents a first generation valve, and it is clear that the performance of the ball valve is inferior to that of Bjork-Shiley valves. However, the Bjork-Shiley valve is very expensive (about 10,000 US Dollars). We considerd that ball valve had sufficient performance and durability for use in our VAD. The ball valve has been used for 10 years or longer without any problems in clinical practice in many cases[8]. In addition, its structure is very simple, and it can be made inexpensively.

The diaphragm was made of silicon 5 mm in thickness, and we are now examining its shape and testing other materials which have greater durability than silicon.

As a driving line, a 6 mm silicon tube was used. This tube is very thin when compared with conventional pump tubes but, based on the results of our experiments, we confirmed that the VAD could be driven by this thin tube. This may reduce the risk of infection during implantation into the body, because the skin region perforated by the tube is small. By combining these features, our aim was to develop a ventricular assist device that had a five-year durability with a low cost.

The Ebacor VAD had pump outputs over 6 liters/min in the mock circuit, which indicated that it had sufficient performance as a VAD in small Japanese subjects. However, the pump performances of the Toyobo and Zeon VADs were superior to that of the Ebacor VAD, because the size of these pumps is larger and the stroke volumes are higher. Furthermore, these pumps also have two Bjork-Shiley valves as the inlet and outlet valves. Since we attached importance to reducing the size and cost of the VAD system, we decided that its pump flow was adequate.

The Ebacor VAD could be manufactured from acrylic and silicon only. Therefore, it could be made for less than 100 US Dollars. This is very inexpensive when compared with the cost of the Toyobo and Zeon VADs (about 30,000 US Dollars each), as well as US-made implantable VADs (over 140,000 US Dollars). However, like other VAD systems, the Ebacor VAD requires a separate driving device such as the Corart C104 system, and thus the cost of the system cannot be simply based on the cost of the pump alone. Nevertheless, the cost of the Ebacor VAD is still probably low when compared with other systems. Driving devices such as the Corart C104 system are very expen-

sive, and few hospitals have this device. In an emergency situation, the Ebacor VAD can be driven by a normal IABP system, which many hospitals already have in place. Currently, we are developing a small, lightweight, low-cost driving device, and the combination of the Ebacor VAD plus this driving device will produce a very low-cost VAD system in the future.

We previously mentioned the economical problems with VADs. In Japan, yearly increasing medical costs are now becoming a social problem. Therefore, when developing a VAD, its cost as well as its performance and durability are of importance. Many artificial hearts have been developed throughout the world. However, most of them emphasize performance and durability, and few investigators have commented on their economic efficiency. VADs are a very expensive treatment option even in Japan, where health care is provided to all citizens by the government. In countries where the health insurance system is not fully funded, the economic status of individuals directly affects their level of medical treatment. There are a few reports on cost efficiency in the field of assisted circulation[1,8,11,17], but cost is a serious and urgent problem that needs to be addressed in the future.

There are several limitations of the device that need to be improved, such as the durability of the pump, the anti-thrombogenicity of the materials, and a control system for on-demand circulation in this VAD. However, a small, lightweight, low-cost driving device as well as a low-cost assisted circulation system are feasible, and will be developed in the near future.

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We have applied for a patent for the Ebacor VAD in Japan, the USA, and Europe. We thank Mr. Shinsaku Kouguchi for his assistance in improving and processing the Ebacor VAD.

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