



# Aortic Valve Reconstruction to Treat Aortic Stenosis Using Autologous Pericardium: Ozaki Procedure

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## 26.1 Introduction

Tremendous advances have been made in the treatment of valvular disorders in recent years. Due to the development of new biological and mechanical valves and the evolution of valve-preserving surgical techniques, the search is on for surgical techniques that will not only improve curability but also lead to a higher quality of life. In recent years, the valvuloplasty techniques developed for mitral valves have also been used to treat aortic insufficiency (also known as aortic regurgitation or AR). However, there are still no established forms of valvuloplasty to treat aortic stenosis (AS). In our department, we perform aortic valve neo-cuspidization using autologous pericardium. This surgical technique was first used in April 2007, and by the end of December 2015, 850 patients had undergone the procedure at our hospital with extremely favorable outcomes [1–12].

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## 26.2 Changes in Surgical Technique

An examination of the history of aortic valvuloplasty to treat AS shows that the Cavitron ultrasonic aspirator (CUSA) was used to remove calcifications from calcified cusps from the latter half of the 1980s until the 1990s. There was obvious improvement in cusp mobility, the pressure gradient across the aortic valve decreased, and the valve opening area was enlarged. However, AR worsened 2 years postoperatively, and CUSA was withdrawn from use. This device is no longer used to remove calcifications from valve cusps in patients with AS [13] unless the valve is replaced.

Aortic cusp extension is another technique that has increasingly been used to correct AR, and there have been several reports of favorable mid- and long-term outcomes. Although the technique had not been used to treat AS, Duran et al. began to use it to treat AS from the latter half of the 1980s [14]. This procedure involved the transplantation of a pericardial strip onto the leaflet after resection to achieve more complete coaptation. However, if this pericardial strip was too large, it could inadvertently occlude the coronary artery ostia, which in turn would potentially cause myocardial ischemia. For these reasons, Duran et al. withdrew the aortic cusp extension technique from use and began using a technique that involved replacing all valve leaflets with pericardium [15]. However, this technique

was only indicated for cases in which each commissure could be evenly located during the sizing stage because the size of all three leaflets created with pericardium had to be the same. This technique was therefore not indicated for bicuspid valves.

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### 26.3 Advantages and Disadvantages

The biggest advantage of this technique is biocompatibility. No transplantation of a foreign body in the form of a prosthetic valve is required, so there are no rejection reactions, and the risk of cerebral infarction is also considered to be low.

1. No need to administer anticoagulants such as warfarin: The only oral postoperative antiplatelet agent used is aspirin, and there have been no actual cases of postoperative cerebral infarction.
2. Low pressure gradient across the aortic valve: Unlike with prosthetic valves, the effective valve opening area becomes equal to the aortic annulus; therefore, as mentioned previously, there is virtually no pressure gradient at all across the valve, even in patients with a narrow aortic annulus.
3. Saving medical resources: Autologous tissues are used during this procedure, so there are economic benefits associated with not using prosthetic valves.
4. Safety: No artificial materials are used, so there is a high level of resistance to infection.
5. Facilitation of redo surgery: There is no need to excise a firmly adherent prosthetic valve when repeat surgery is performed. Repeat surgery merely involves resection of the autologous pericardial valve.

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### 26.4 Practical Surgical Techniques (Figs. 26.1, 26.2, 26.3, and 26.4)

The surgical technique that we use involves the resection of autologous pericardium, at least 7 × 8 cm in size, which is then processed with 0.6%

glutaraldehyde for 10 min (Fig. 26.1). After resecting the calcified leaflets, calcified areas of the annulus are removed using a CUSA. Next, we use our original cusp sizer to measure the circumferential distance between each commissure (Fig. 26.1). Using our original template, glutaraldehyde-treated autologous pericardium is used to create cusps that correspond to these measured values (Fig. 26.2). During this process, 5-mm wing extensions are created at both edges of the leaflets (Fig. 26.2).

The leaflets are sutured directly to the annulus using a 4-0 polypropylene suture with 13-mm 1/2 circle needle as shown in Fig. 26.3. Finally, the wing extensions are fixed to 5 × 10-mm pledgets on the external aorta using a 4-0 polypropylene suture with 17-mm 1/2 circle needle (Fig. 26.4).

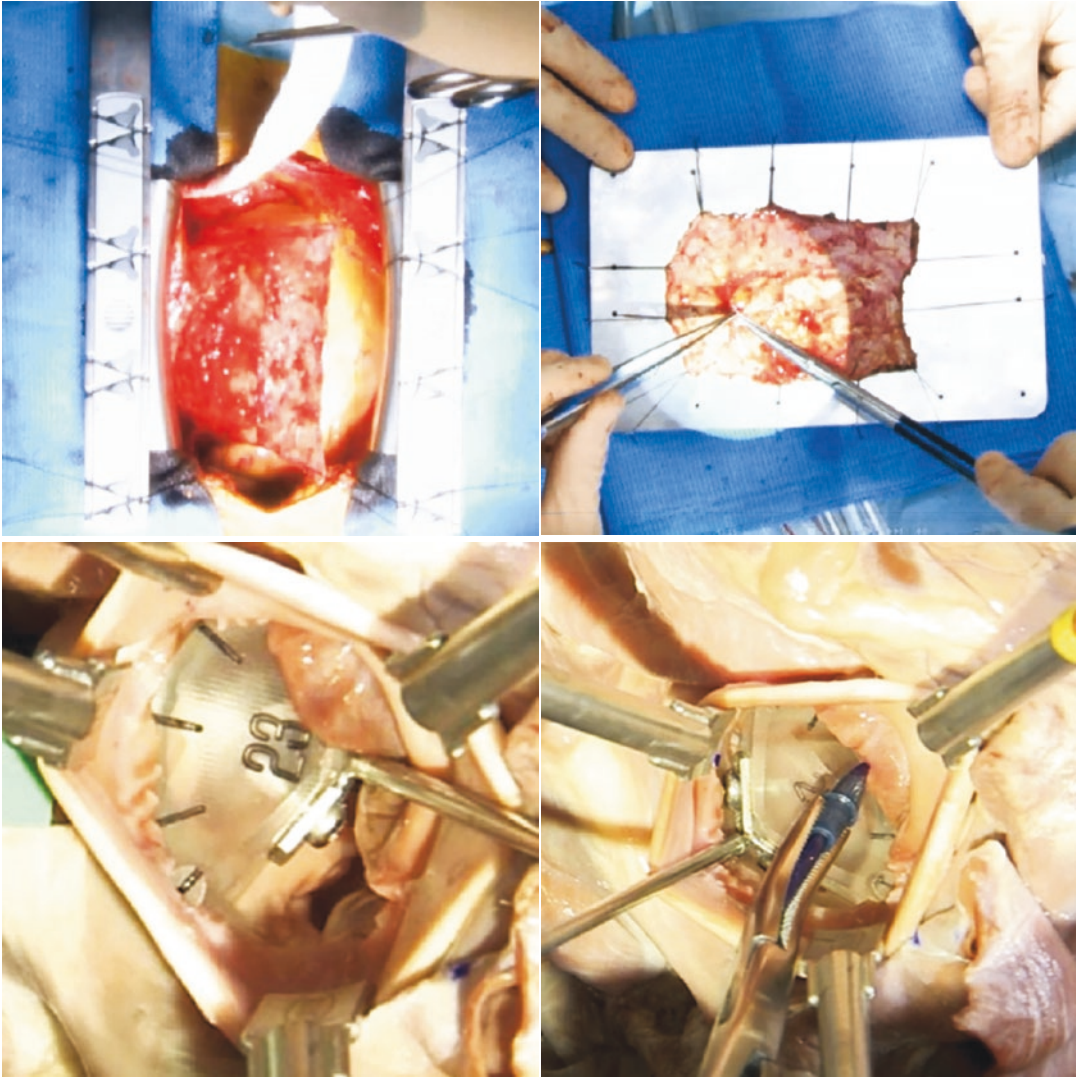
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### 26.5 Personal Tips

Cusps of the same size will always be created when following the approach of Duran et al. He estimated the cusp free-edge length from the annulus diameter during valvuloplasty using pericardium [15, 16]. However, based on personal experience [4], the intercommissural distance was the same for all three cusps in 13% of cases, for two leaflets alone in 57% of cases, and every distance was different in 30% of cases. Based on this knowledge, it is doubtful that three cusps of identical size can be sutured to three native cusp insertion lines of different lengths. In addition, as shown in Fig. 26.5, the cusp contact point is lower than the vertical position of the commissure, and there are individual differences in height. Thus, if the cusp contact point is low, then the cusp free-edge length will increase, and when the cusp contact point is high, then the cusp free-edge length will shorten. It is quite difficult to derive the cusp free-edge length when taking everything from the annulus diameter to these factors into consideration.

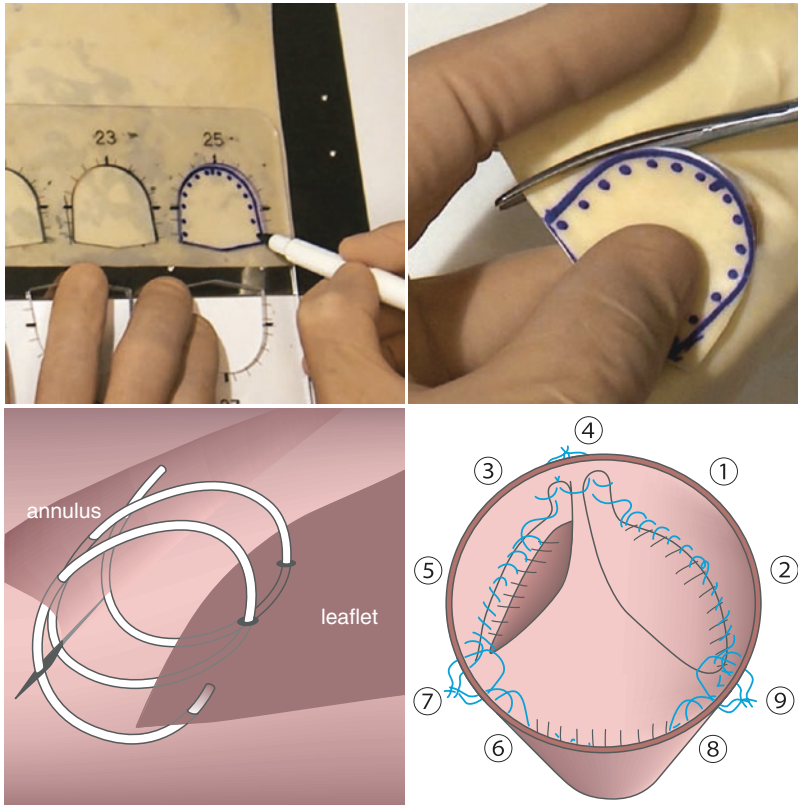
Our method includes two essential points:

1. It is possible to derive the cusp free-edge length from each intercommissural distance.
2. The new pericardial cusp contact point is elevated to the height of a line connecting the commissures.



**Fig. 26.1** Harvesting of the autologous pericardium and measurement of the intercommissural distance. Upper column: (1) The autologous pericardium is harvested at a size of at least  $7 \times 8$  cm. (2) Before harvesting the pericardium, excess adipose tissue is removed using an ultrasound scalpel. (3) When harvesting the pericardium, gauze is placed between the pericardium and the heart to prevent myocardial injury. (4) The pericardium is fixed to a plate with sutures to prevent it from shrinking during the glutaraldehyde treatment. (5) The pericardium should always be fixed in such a way that the rough surface is facing upward during this process. (6) The shape of the pericardium is drawn onto a piece of paper, which is used

at the end of surgery to cut a piece from a sheet of expanded polytetrafluoroethylene for repair of the pericardial defect. Lower column: (1) The intercommissural distance is measured, and at this time, the circumferential length connecting the commissures, and not the length of the annulus, is measured. (2) First, one part of the sizer is firmly attached to the commissures on one side, and another part of the sizer is used to confirm whether it will reach the contralateral commissure. (3) This is repeated until the appropriate size is measured. (4) If the measured value falls between two sizes, then we use the larger size. (5) Once the size has been determined, the midpoint of each annulus is marked



**Fig. 26.2** Preparation and suturing of the autologous pericardial valve. Upper column: (1) After treatment, moisture is removed from the pericardium, and it is placed onto a plate with the smooth surface facing upward because it is not possible to draw on the rough surface. (2) A surgical skin marker is used to draw the leaflet along the window used for the template, and dots are also marked. (3) There are holes on both sides of the template for a 5-mm wing extension, which are also marked. (4) Large cusps are created from the thick pericardium facing the

diaphragm. (5) The pericardium is easier to cut if it is glued to the paper protecting it. (6) The cusp is cut along the outside of the line that has been drawn. (7) A 5-mm wing extension is created on both edges of the valve cusp. Lower column: (1) The cusp is sutured in such a way that it is adherent to the annulus inferiorly. (2) The needle is usually passed from a superior to an inferior direction through the cusp, and from an inferior to superior direction through the annulus. (3) Each cusp is sutured in the sequence shown in the diagram

These points offer three advantages.

1. Enlargement of the coaptation zone.
2. The cusp contact point and each commissure will be in the same plane, there will be a 1:1 match between the intercommissural distance and the cusp free-edge length, and it is easy to derive the cusp free-edge length.
3. With the cusp contact point and each commissure in the same plane, when the leaflets are closed, they will support one another at the height of the commissure,

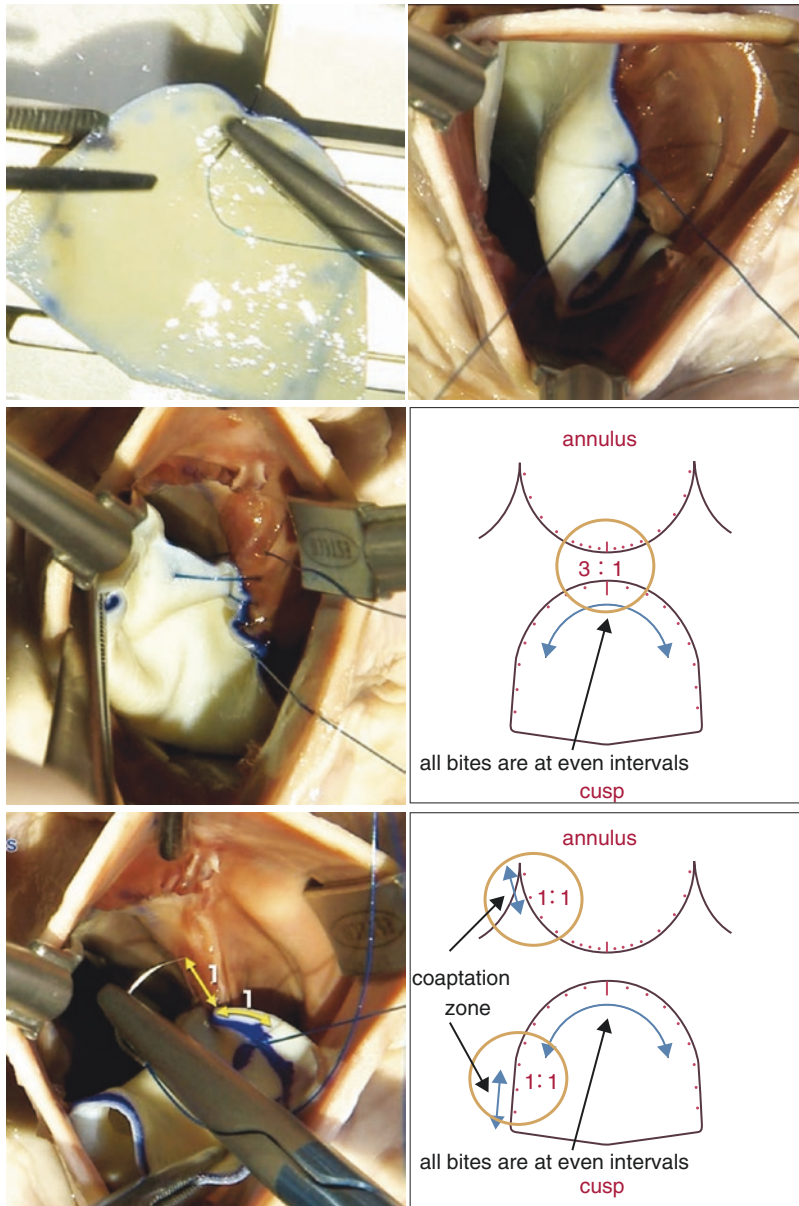
which reduces the stress placed on the commissure.

Based on the above, the intercommissural distance is believed to define the cusp free-edge length, and a method was devised to create cusps based on the measured values [4].

## 26.6 Outcomes of Aortic Reconstruction to Date

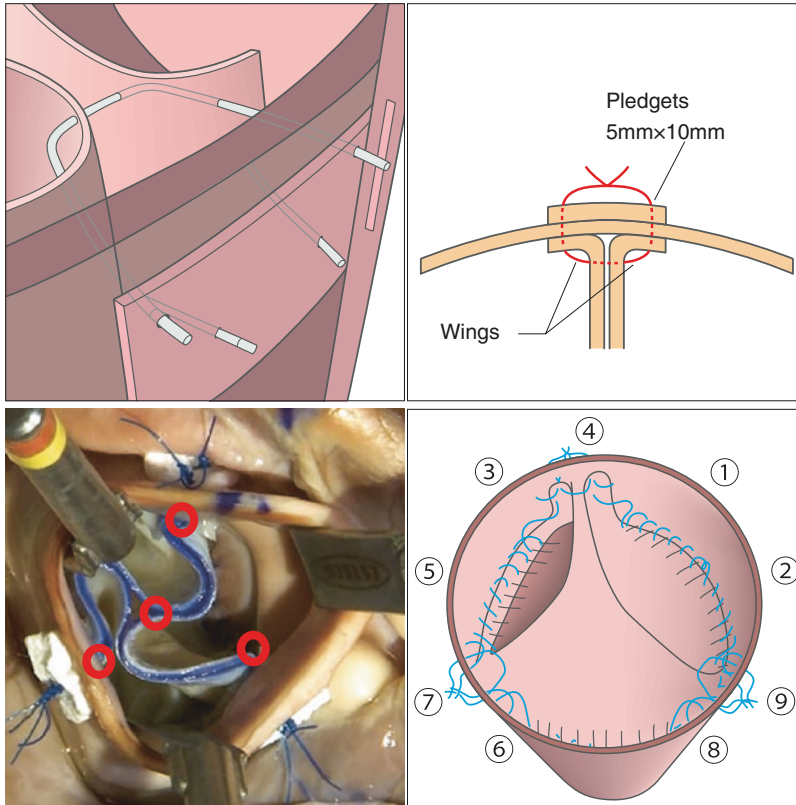
Outcomes of aortic reconstruction to treat aortic valve disorders in our institution (Fig. 26.6).





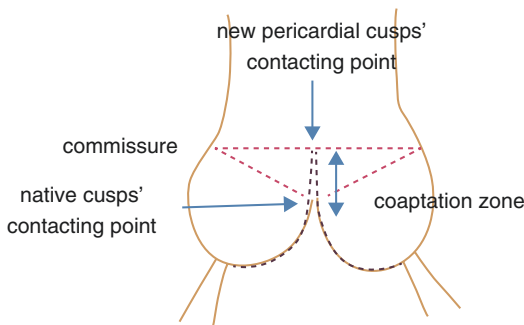
**Fig. 26.3** Sequence of suturing the cusps. Upper column: (1) The cusps are sutured using a 4-0 polypropylene suture with a 13-mm 1/2 circle needle. (2) The smooth surface of the leaflet faces the left ventricle. The surface with the dots and lines drawn onto it will become part of the left ventricle. (3) First, the needle is passed through the center point of the cusp and the corresponding center point of the annulus. Then, after the cusp has descended into the left ventricle, three knots are created. Middle column: (1) The suturing continues as shown in the diagram. (2) Suturing is performed at equivalent intervals that correspond to the dotted line on the side facing the cusp. (3) The suture intervals on the side facing the cusp are created close to the base of the annulus and in such a way that they are 1/3 (1:3) of the intervals between the cusp sutures. (4) It is important to

suture in such a way that the leaflet is firmly gathered close to the base of the annulus. Lower column: (1) The remaining cusp length is confirmed after some suturing has been performed at a ratio of 1:3. (2) During the part of the procedure when the remaining cusp length is either equal or slightly longer than the remaining annulus, the suture interval along the annulus is the same as that along the cusp. (3) The final point of suture insertion into the cusp is always 5 mm away from the margin. (4) If the dots have been marked within 5 mm of the margin, this should be ignored and the suture should be passed through the cusp at 5 mm from the margin. (5) After the final suture insertion point has been passed, the needle is straightened and used to pass through the aortic wall. The point at which the needle enters is 2–3 mm inferior to the commissure



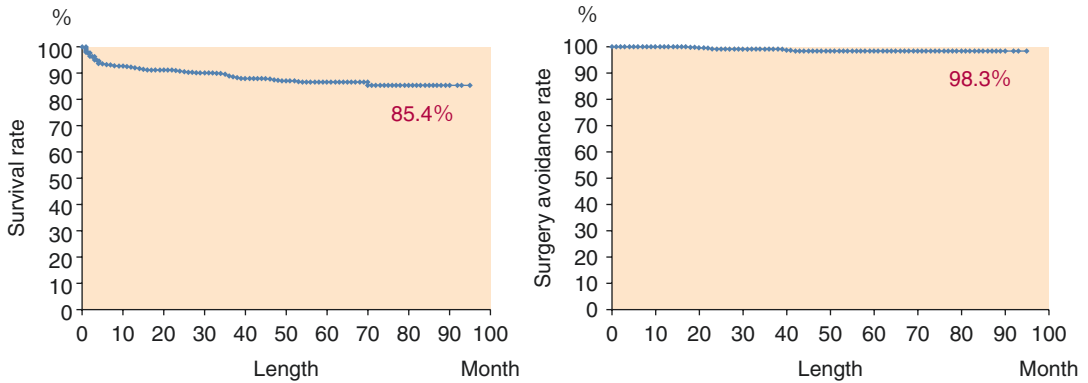
**Fig. 26.4** Creating the commissures and the final design. Upper column: (1) A 4-0 polypropylene suture with a 17-mm 1/2 circle needle is used to create the commissures. (2) A new suture is passed as shown in the diagram. (3) This suture is passed at a middle height between the cusp margin and the final insertion point above the cusp. This is approximately 2.5 mm above the margin. (4) When the above-mentioned suture is used to pass through the aortic wall, four sutures will exit the external aortic wall.

These four sutures are passed through 5 × 10 mm pledgets and ligated at the external aortic wall. Lower column: (1) The three commissures are created in the sequence shown in the diagram on the right (right coronary cusp—left coronary cusp—non-coronary cusp). (2) The three cusps are adjusted before closure of the aortic wall to form a windmill shape. (3) The three commissures and the middle contact point of the three leaflets are adjusted to lie in the same plane



**Fig. 26.5** Basic idea of aortic valve reconstruction

1. Period: From April 2007 to December 2015
2. There were 534 patients with aortic stenosis (AS), 254 with aortic regurgitation (AR), 61 with ASR, 19 with infective endocarditis, and five with a prior aortic valve procedure (including 444 men and 406 women). Among these patients, 224 valves were bicuspid, 28 were unicuspid, and two were quadricuspid.
3. Median patient age: 71 (range 13–90) years.
4. Mean preoperative annulus diameter:  $20.9 \pm 3.3$  mm.



**Fig. 26.6** Outcomes of aortic reconstruction to treat aortic valve disorders in our institution

5. Mean aortic cross-clamping time:  $106.8 \pm 27.5$  min, mean cardiopulmonary bypass time:  $150.4 \pm 30.4$  min.
6. Survival at 118 months: 85.9%, Freedom from reoperation at 118 months: 95.8%.

## 26.7 Conclusion

We have accumulated 10 years of experience with autologous pericardial aortic neo-cuspidization since April 2007. The freedom from reoperation rate is extremely favorable at 95.8%. There is no need for a prosthetic valve or for anticoagulants, which means infrequent onset of complications such as cerebral infarction. This surgical technique can also save medical resources. For these reasons, this surgery has been performed in all Asian countries (including China, Malaysia, Vietnam, South Korea, India, Thailand, and Turkey), Europe (UK, Germany, Italy, Belgium, Switzerland, Poland, Russia, and Ukraine), and the US (including at the Cleveland Clinic, Columbia University, the University of Pittsburgh, Boston Children's Hospital, UPMC, DeBakey VA Houston, etc.). It has received a high degree of interest from around the world, and there will be initiatives to develop more durable materials and continued communication from Japan to the rest of the world.

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