Chronic Trial of an Artificial Myocardium in Goats and Preliminary Modelling of Diseased Heart

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As for the GCOE project, we focused on two major research. These two, 'artificial organ research and simulation' as one of the core research topics, are performed through the following projects:

1) development and long term examination for hemodynamic effect,

2) mechanical modelling of the ventricle of patient's with heart failure.

In addition to the pathophysiological study, we contribute to the effective implementation of research at clinical and biomedical engineering levels and the creation of a network among surgeons, physicians and biomedical engineers through strategic treatment, and integration and support of technologies for patients' QOL.

The results of these activities are made available not only for other surgical treatment for severe heart failure but also for the general understanding of pathophysiology of cardiac failure from the patients' point of view. Some of the main topics obtained by our activities in 2008 are introduced below.

Summary of the development and hemodynamic examination of an artificial myocardium

Thromboembolic and haemorrhagic complications are the primary causes of mortality and morbidity in patients with artificial hearts, which are known to be induced by the interactions between blood flow and artificial material surfaces. The authors have been developing a new mechanical artificial myocardial assist device by using a sophisticated shape memory alloy fibre in order to achieve the mechanical cardiac support from outside of the heart without a direct blood contacting surface. The original material employed as the actuator of artificial myocardial assist devices was 100um fibred-shaped, which was composed of covalent and metallic bonding structure and designed to generate 4-7 % shortening by Joule heating induced by the electric current input. Prior to the experiment, the myocardial streamlines were investigated by using a MDCT, and the design of artificial myocardial assist devices were refined based on the concept of Torrent-Guasp's myocardial band theory. As the hydrodynamic or hemodynamic examination exhibited the remarkable increase of cardiac systolic work by the assistance of the artificial myocardial contraction in the originally designed mock circulatory system as well as in the acute animal experiments, the chronic animal test has been started in a goat. Total weight of the device including the actuator was around 150g, and the electric power was supplied percutaneously. The device could be successfully installed into thoracic cavity, which was able to be girdling the left ventricle. In the chronic animal trial, the complication in respect to the diastolic dysfunction by the artificial myocardial compression was not observed.

Summary of the modelling of diseased heart

Endoventricular patch plasty, called the Dor procedure, is performed as a heart reconstruction for the surgical treatment of the patients with severe heart failure associated with anteroapical large myocardial infarction. The authors have been establishing a new engineering method for the individual simulation of operational procedure in order to determine the optimal left ventricular size and shape and to estimate the volumetric reduction after the surgical ventricular restoration in each patient. In this study, three individual ventricular shapes were fabricated by numerically resampled data which were obtained from the diagnostic magnetic resonance imaging in each subject. Prior to the fabrication of the models, epi- or endocardial envelope curve was outlined without papillary muscles or tendinous cords in each end-diastolic and end-systolic phase for the compatible reference in echocardiogram, computed tomography or magnetic resonance imaging investigations. And the mechanical silicone rubber models were made by the use of female moulding for the discussion of each subject among surgeons. In this paper, we examined a methodology for the simulation of ventriculoplasty by using a silicone rubber model and evaluated the capability of quantitative expression of ejection fraction.

I. Artificial Myocardium
1. Introduction

Chronic heart failure (CHF) is functionally and structurally characterized by pathophysiological remodeling of the ventricle. In general, ventricular assist devices (VADs), such as artificial hearts, are used for the surgical treatment of the patients with the final stage of severe heart failure [1-5]. However, thromboembolic and haemorrhagic complications are still the primary causes of mortality and morbidity in patients with VADs, which are known to be induced by the interactions between blood flow and artificial material surfaces. Several concepts of the mechanical assistance from outside of the ventricle have been presented so far, such as Anstadt's ventricular cup, providing a solution to these problems without direct contacting surfaces against blood [6-13]. And also some new devices, such as Myosprint, demonstrated improvements in eliminating mitral regurgitation in dysfunctional left ventricle as well as in preventing the ventricular enlargement which was to compensate for the reduction in cardiac function [14-15]. Although the passive implantable devices, which are girdling the ventricle from the outside, have been already applied for clinical trials in patients with chronic congestive heart failure for the passive assistance as well as for the prevention of enlargement of the left ventricle to compensate for the reduction in cardiac function, there might be a limitation to passive assistance in the case of sudden changes of cardiac contractile function, such as angina of effort. We have been developing an artificial myocardial assist device by using a covalent type nano-tech shape memory alloy fibre, which is capable of assisting natural cardiac contraction from outside of the ventricular wall as shown in Figs. 1 and 2. The purpose of this study was to examine the function of the artificial myocardium, which was designed to assist the heart synchronously with native contraction, and its feasibility in chronic animal experiments.

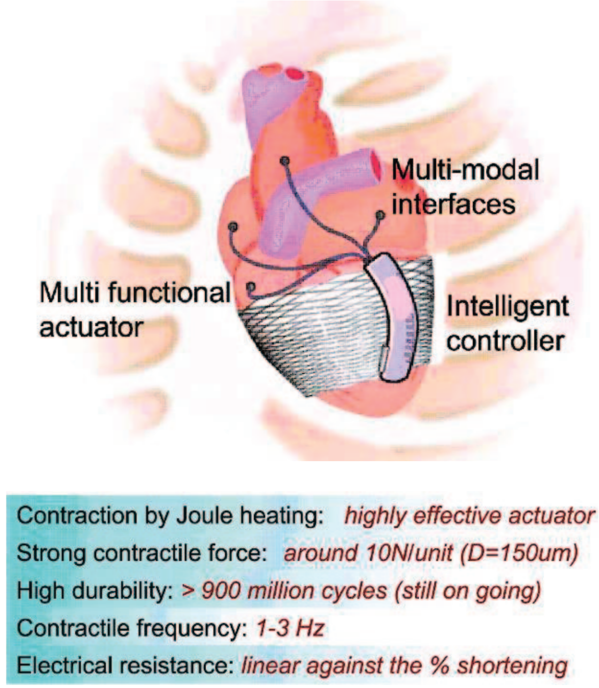


Fig. 1. Schematic illustration of a concept for the sophisticated mechanical contractile assistance by using the artificial myocardium with shape memory alloy fibre (upper), and the special features of the covalent structured shape memory alloy material (bottom).

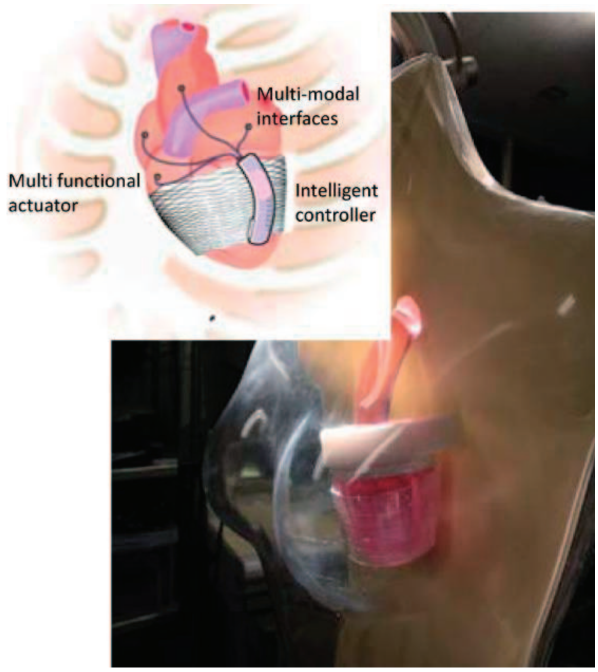


Fig. 2. Mock representation of the installation of the artificial myocardium using shape memory alloy fibres attached on the silicone left ventricular model.

2. Materials and Methods

2.1. Myocardial assist device description

The artificial myocardium consists of ten shape memory alloy fibres which were covered by silicone rubber as shown in Figs. 3 and 4. Special features of the shape memory alloy fibre material (Biometal®) which was to be employed as the actuator of the artificial myocardium were as follows: a) composition of covalent and metallic bonding structure, b) 4-7 % shortening by Joule heating induced by the electric current input, c) linear characteristics of electric resistance against shortening, d) strong maximum contractile force of 10N with 100um-fibre, e) high durability of over one billion cycles, f) contractile frequent response by 1-3 Hz, g) select-able maltensitic temperature by fabrication processing from 45 to 70 Celsius, and h) elective diameter size smaller than 30um [16-18]. The contraction of the device can be con-trolled by an originally-designed microcomputer system. The device is controlled and performed by electrical signal input, which is supplied percutaneously. Each signal for the contraction is regulated by the controller and synchronized with native electrocardiogram (Figs. 5 and 6). Originally-designed ladder-shaped hinges were constructed on the parallelly-linked shape memory alloy fibres belt, specifical-ly on the surface attaching to the left ventricular free wall in order to simulate the wall-thickening effect as well as to promote the mechanical shortening perpendicularly to the left ventricular long axis.

2.2. Mechanical design of the device based on the anatomical examination of native heart

Myocardial streamline was confirmed by the MDCT in-vestigation in a healthy goat heart which was extracted and unfolded based on the Torrent-Guasp's myocardial band concept as shown in Fig. 7 [19-22]. The orientation of the device contraction might promote native systolic function while avoiding both the external and internal critical struc-tures of the heart. The myocardial streamline was detected from the data with plastic markers plot by MDCT, and the angular configuration to the left ventricular long axis was calculated.

2.3. Experimental procedure

The chronic animal experiments were performed in healthy female adult Japanese Saanen goats (n=2), which weighed 45 kg. Implantation of the device was performed as part of an open-chest cardiac procedure on a beating heart under the normal inhalation and anesthesia followed by endotracheal intubation using 2.5% halothane. The band-shaped myocardial assist device was installed into the thoracic cavity girdling from the apex to the base and one of the ends was parallel to the left ventricular

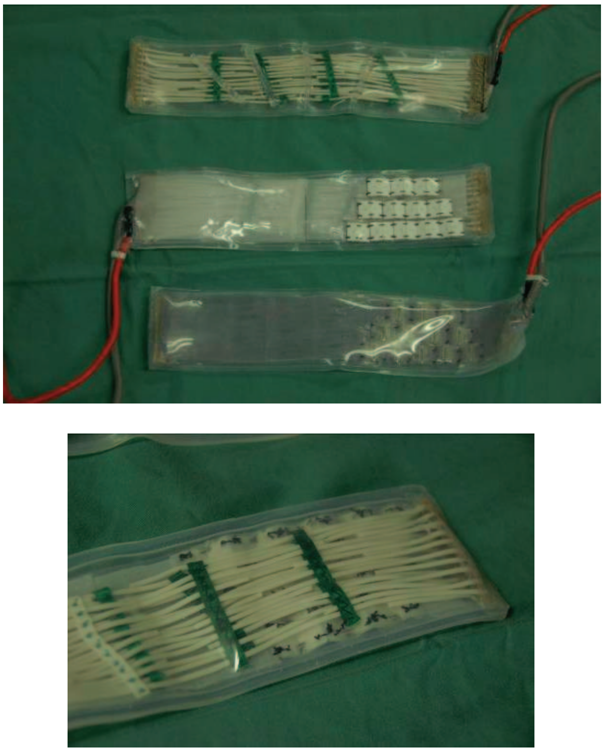


Fig. 3. Several types of myocardial assist device developed for the feasibility study in chronic animal experiments (top), and the details of the connection of shape memory alloy fibres covered with silicone membrane (bottom).

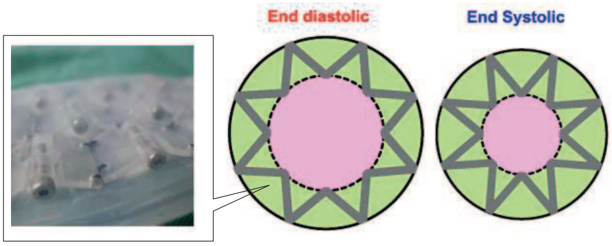


Fig. 4. Structural design of the sophisticated myocardial assist system implemented onto the surface of the myocardial band, which is simulating the native "wall-thickening effect".

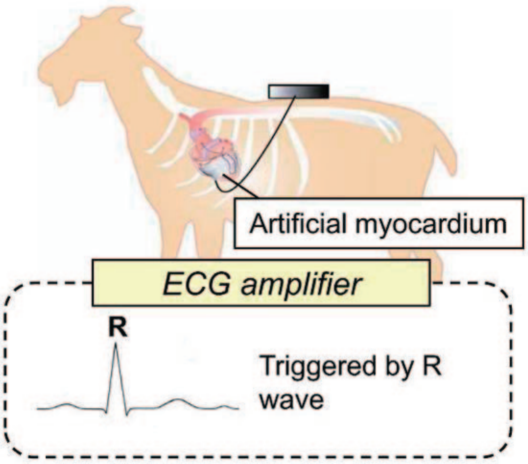


Fig. 5. Schematic illustration of the signal connection for the control of myocardial contraction

long axis myocardial streamline on its free wall side. Coronary vasculature was visually identified and avoided on the exterior of the heart during the implantation. There was no direct suture on the tissue or muscles with the device. Prior to the measurement, postoperative care without mechanical assistance was carried out for one week. These animal trials were electively terminated after postoperative one month.

The chronic animal experiments were performed in healthy female adult Japanese Saanen goats (n=2), which weighed 45 kg. Implantation of the device was performed as part of an open-chest cardiac procedure

All animals received humane care in accordance with "the Guideline for the Care and Use of Laboratory Animals" published by the National Institute of Health (NIH publication 85-23, revised 1985) as well as with "the Guidelines for Proper Conduct of Animal Experiments" formulated by Science Council of Japan (2006) and the guidelines determined by the Institutional Animal Care and Use Committee of Tohoku University.

3. Results and Discussion

3.1. Adverse events

There were no serious infections and surgical procedural failures in the implantation of the device from the beginning and throughout the study in all cases (Fig. 8). And the unanticipated complication in respect to the device-related diastolic dysfunction by the artificial myocardial compression was not observed. Several mechanical structural device failures could be investigated after the extraction of them.

3.2. Hemodynamic effects

Left ventricular and aortic pressures were obtained and remarkably increased by the mechanical assistance as shown in Fig. 7. Each waveform was calculated as the average of the data in the period of 90sec. ‘Control’ indi-cates the waveforms taken without assistance, while ‘As-sisted’ were with mechanical contraction. There were no significant changes in the left ventricular end diastolic pres-sure, so that it was suggested that there might not be any diastolic dysfunction during the mechanical assistance using the artificial myocardium. As a result, left ventricular systolic pressure was increased from 110 to 118 mmHg (7%), and assisted flow rate was elevated for 70msec, which was equivalent of the mechanical contractile duration, from the data calculated (Fig. 9). Consequently, the assistive effect on cardiac output during the assistance was calculated to be 3% higher than the control condition without mechanical contraction.

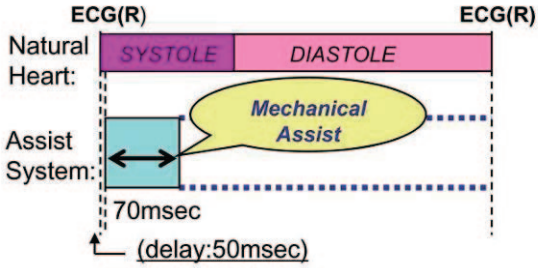


Fig. 6. Schematic drawing of the contraction signal input for the artificial myocardium synchronized with electrocardiogram (ECG-R).

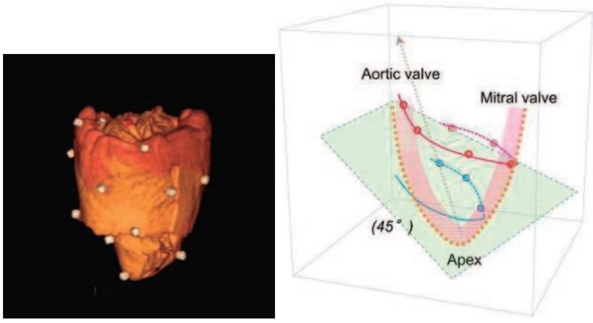


Fig. 7. MDCT examination of the healthy goat heart unfolded by the Torrent-Guasp’s concept and reconstructed with plastic markers (left), and the native myocardial streamline orientation calculated from the data as the reference of implantation of the artificial myocardium (right).

Fig. 8. Successful implantation of the artificial myocardium without unanticipated complications in relation to infections or surgical procedural failures.

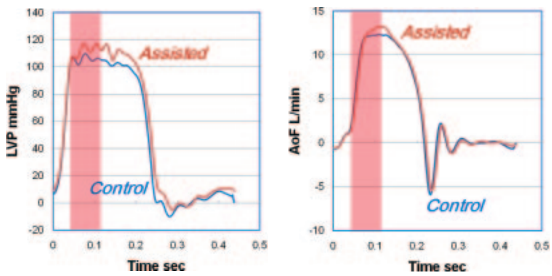


Fig. 9. An example of the changes in hemodynamic waveforms obtained at the goat with myocardial assist device.

4. Conclusions

The first animal trials of the artificial myocardium using shape memory alloy fibre demonstrated both feasibility and efficacy in healthy adult goats. The result indicated the development of the active ventricular assist device was useful because of its ability to consistently reduce or eliminate the complications in relation to thrombosis or hemolysis along with simple mechanism for the effective actuation.

II. Mechanical Modelling of the Failing Heart
1. Introduction

Ventricular aneurysm is one of the cause of severe heart failure. Surgical procedures such as Dor's operation are applied for the reconstruction of shape as well as cardiac function to the patients with the disease [23-4]. In general, these surgical procedures and the way to reconstruct the hearts are clinically decided by the diagnostic information which is provided by 2D/3D echocardiography, computed tomography (CT), or magnetic resonance imaging (MRI). However, as those imaging technologies indicate the virtual pictures, it is difficult to estimate the postoperative function as well as the structure [25].

Moreover, the ventriculoplasty implies not only the volumetric reduction at the lesion of the aneurysm but also the reconstruction of the internal structure such as papillary muscle positions against the mitral valve. Therefore it is anticipated that the excessive ventricular configuration reconstitution may cause degradation of cardiac function as postoperative complication, and also the effective volumetric reduction cannot be achieved due to patching insufficiency.

The purpose of this study was to reproduce and provide the tangible diseased ventricular model, which was identical to each patient's heart and could simulate physical images of those surgical procedures quantitatively. In this study, we established a new rapid prototyping method for the fabrication of the elastic diseased ventricular model, and examined its reproducibility on the parameter of ejection fraction.

2. Materials and Methods
2.1. Ventricular aneurysm and ventriculoplasty

Figure 10(A) indicated the sagittal chest view of a patient with severe aneurysm. The wall thickness of the left ventricle at the lesion was less than 6mm, and the akinetic or dyskinetic properties could be seen by MRI investigation. Then the ventriculoplaty was to be designed to make a patch for covering the extended epicardial portion as shown in Fig. 10(B). Ejection fraction of the subject was 22.6% by Teichholz method from the measurement of diameters in MRI figures (Fig. 11) [4]. These

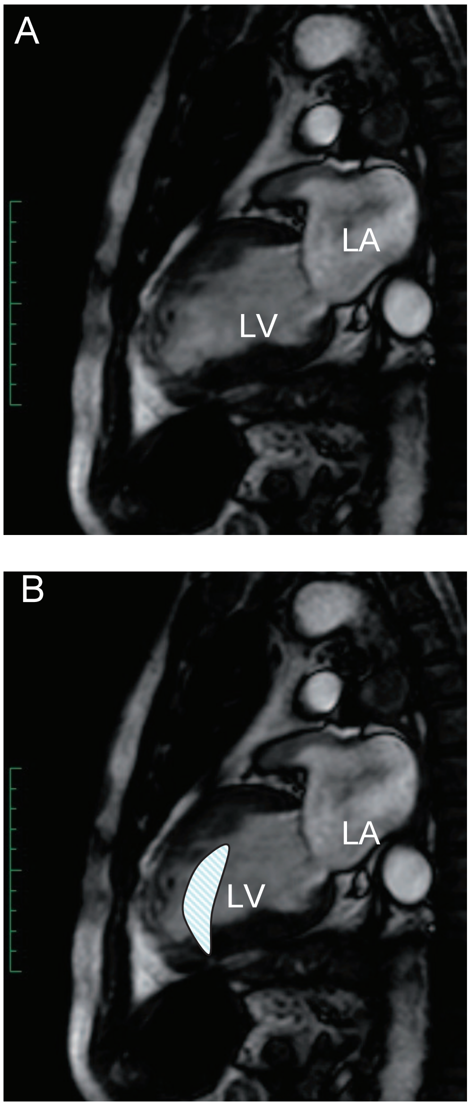


Fig. 10. Sgittal plane view of a patients's heart with ventricular aneurysm taken by magnetic resonance imaging; Figure A (top) indicated the preoperative patient's heart, and the hatched area in Figure B (bottom) was the image of the region to be patched by surgical treatment using "Dor procerdure".

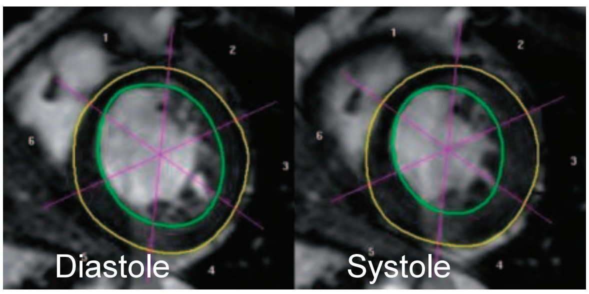


Fig. 11. Cross sectional view for preoperative diagnostic evaluation of the patient's ventricular shape at the mitral cord—papillary muscle position; the inside (endocardial) or outside (epicardial) lines were defined by surgeons for the evaluation of ejection fraction in MRI workstation.

morphological characteristics in the lesion were diagnosed by 3D echocardiography (Philips, Sonos, QLAB) as shown in Fig. 12.

The surgical treatment so called modified Dor procedure for volume reduction was to be applied for the lesion by using an ePTFE patch.

2.2. Measurement of ventricular dimensions

Based on the measurement of ventricular configuration and motions, we extracted the two phases of the contraction; end diastolic and end systolic shapes. The MRI data were obtained every 7–8 mm in short axis view, and around twelve layers were extracted for the reconstruction. Inside and outside edges were determined and these envelops were outlined as shown in Fig. 13 (left). Each shape of the lines was decided by the discussions with surgeons, and the bulging portion at the papillary muscles and tendinous cords was excluded for more sophisticated surgical investigations synchronizing with the images of the operator.

2.3. Numerical and mechanical reconstruction of ventricular shape

All the configuration data were imported to 3D NURBS modelling software (McNeel North America, Rhinoceros) for the numerical reconstruction. Each layered data was repositioned at appropriate distance as shown in Fig. 13 (right). Then the smoothed surfaces were formed approximately. In every stages of calculation, we compared the result and original MR images in order to prove to be the fusion of the configurations in the process.

Then the recalculated lumens were obtained as shown in Fig. 15 (a), and the data was transported to CAM (Mimaki & Toki Corp, NC-5 Machining Star) for the cutting process. Each layer was cut out from a plastic plate of 2–5 mm in thickness. And the apex portion was carved out by 1mm thickness contour. The plates were integrated and laminated accurately, and the male moulds of end-diastolic or end-systolic forms had been constructed (Figs. 15 and 16). Elastic tangible ventricular model of each patient could be casted by silicone rubber (Shin-etsu, KE-1300T) by using the female moulds, and the elasticity of each model was arranged according to the surgeons' request.

Figure 16 illustrates the fabrication process including the cutting plastic plate in 2mm thickness and the layer-building for male mould as endocardial shape and for female one as epicardial chamber. Each mould was fabricated separately and assembled for casting after the layer-building. Internal surfaces of the epicardial female mould was smoothly ground in order to achieve the sophisticated representation of native ventricular surface as well as to eliminate the cutting margin.

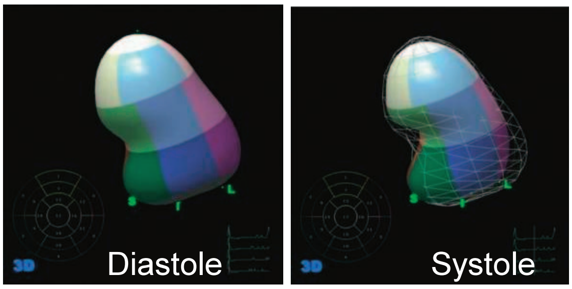


Fig. 12. Abnormal left ventricular cavity reconstructed by 3-D measurement of echocardiography in the subject shown in Figure 10 and 11.

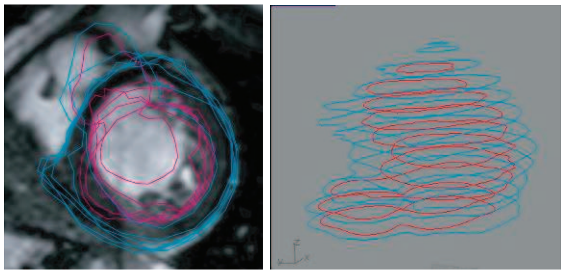


Fig. 13. An example of a short axis view of the patient heart with the lines of internal or external edges of ventricular wall for the 3D tangible modeling (left); the ventricular walls were outlined as vector data, and the data were transferred to be smoothed DXF format. The distance between layers in the patient's MRI data was 7.69mm. And a schematic illustration of the patient heart configuration (end-diastolic phase) by the reconstruction in the 3D CAD software (right).

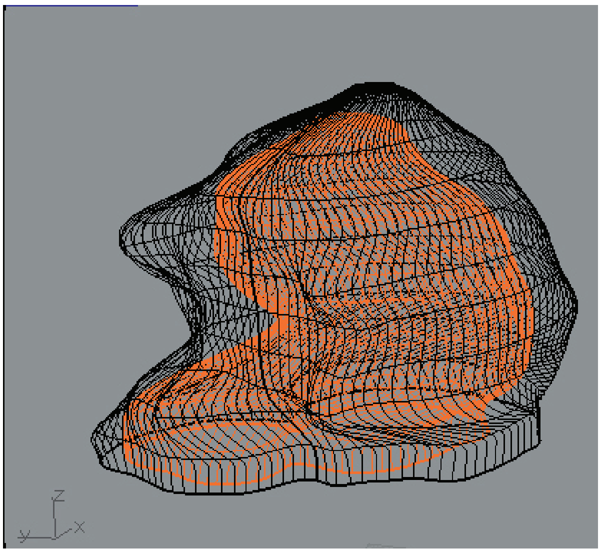
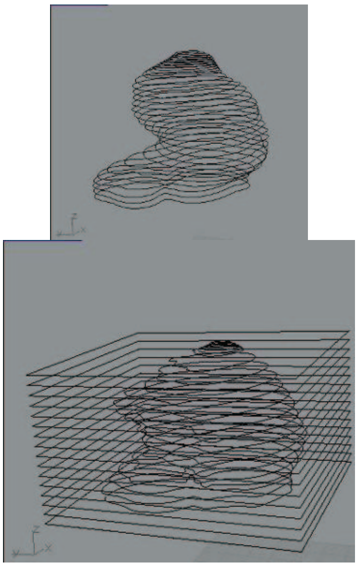
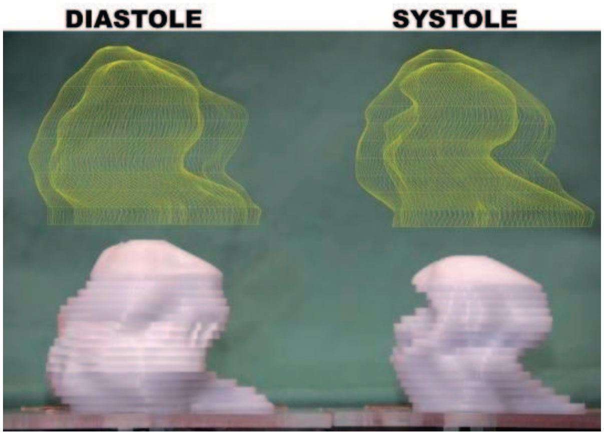


Fig. 14. An example of the surfaces representing the patient's endocardial and epicardial shapes which is formed by 3D interpolation; these data were calculated by the interpolation of the measured data obtained in MR images.



(a) End-diastolic lumen (left) and contours (right) for cutting layers



(b) Contour shapes and the male moulds

Fig. 15. Schematic illustrations of CAD/CAM data for cutting (a), the male moulds for end-diastolic and end-systolic shapes (b).

Fig. 17. Female mould of the patient's heart; the internal and external profiles consisted of integrated layered plastic plates, and the silicone elastic models were able to be moulded.

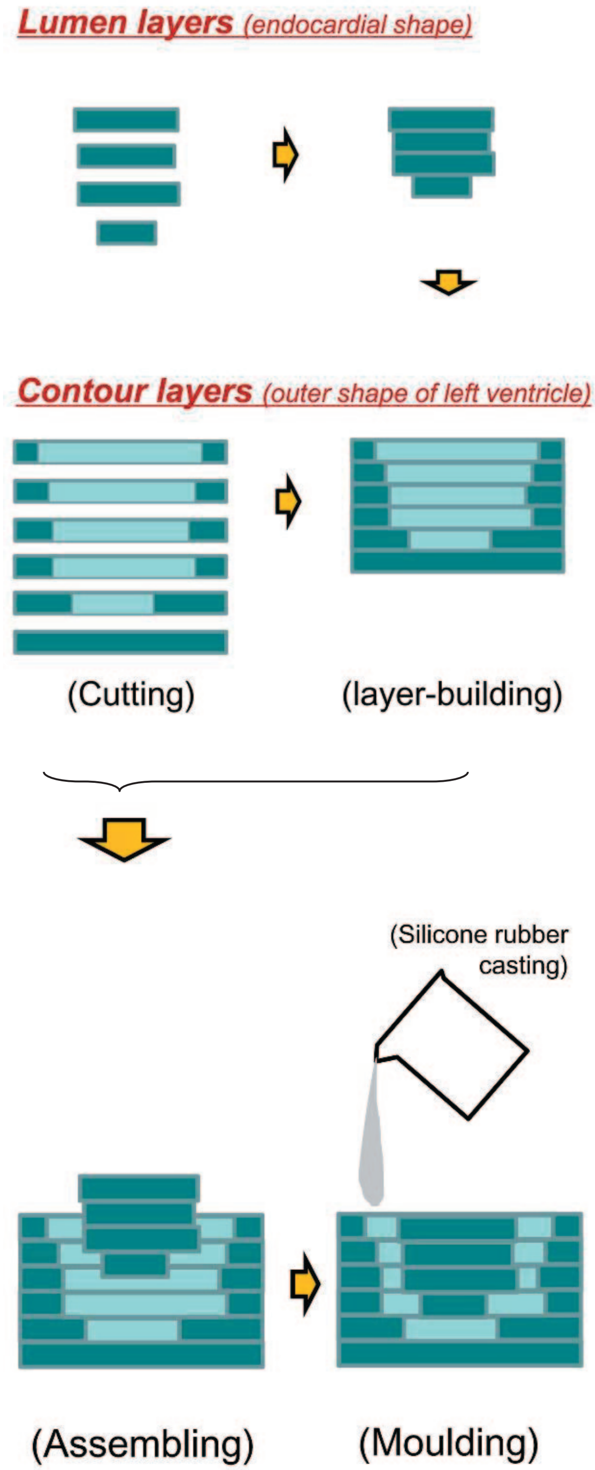


Fig. 16. Typical fabrication process developed and performed in the study for the precise mechanical modelling of the failing heart of each patient.

3. Results and Discussion

3.1. Tangible diseased heart

Figure 18 indicated the examples of the patient's heart with ventricular aneurysm. The lesion of the silicone models was investigated and it could represent the similar features of the information given by echocardiography or CT, MR imaging. Furthermore, the surgeons could examine their techniques on the same elastic models, which could be casted by same moulds, by using scissors and needles several times. And consequently, the total processing time from the data calculation to fabrication was around 72hours.

And the model was also useful for the pathophysiological and surgical explanation to patients by using their own tangible disease.

3.2. Preoperative investigation by using the model

These models seemed to be useful for the preoperative quantitative investigation. A patient's results of the volumetric investigations by MRI or the model, which was indicated in Fig. 18, were shown in Fig. 19. End-diastolic and end-systolic blood volumes were 172.5, 133.6 mL by Teichholz method respectively, whereas the values of the silicone model measured by water weighing method were 133.0 and 88.5 mL. The ejection fraction which was derived from MRI was 23%, and that obtained from the model was 33% [26].

Although the structural changes in the contractile process of the diseased left ventricle was so complicated, the silicone model was useful for more quantitative examination of reconstructive surgery before the operation.

It is well known that the balance between volume reduction and surgical effect as cardiac output by the application of Dor procedure as shown in Fig. 20. Recently the operational technique is widely used for the reconstructive surgery for ventricular aneurysms.

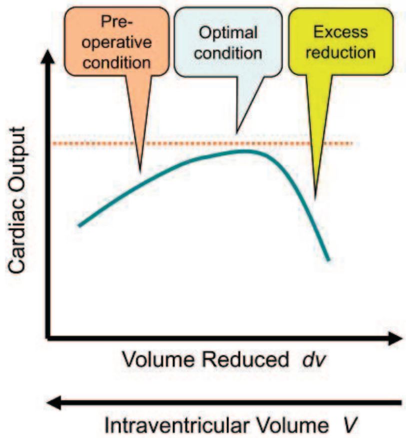
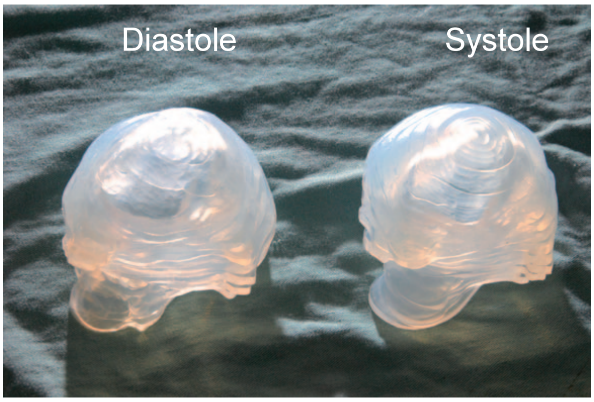
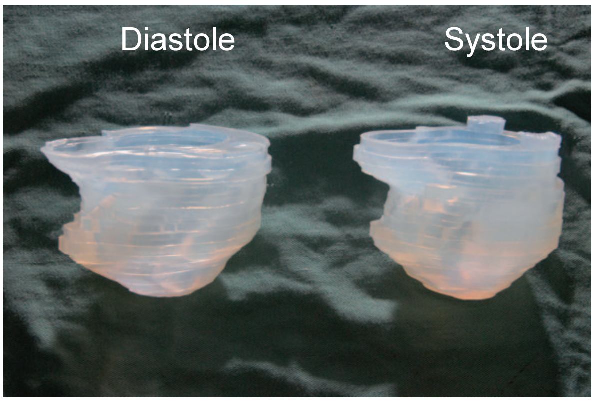


Fig. 20. Relationships between cardiac output and volume reduction after the surgery by Dor's operation for ventricular aneurysm



(a) Septal–apical view of the models



(b) Frontal view of the models

Fig. 18. End-diastolic (left) and end-systolic (right) silicone models moulded for the reproduction and surgical simulation of the patient's failing heart with ventricular aneurysm.

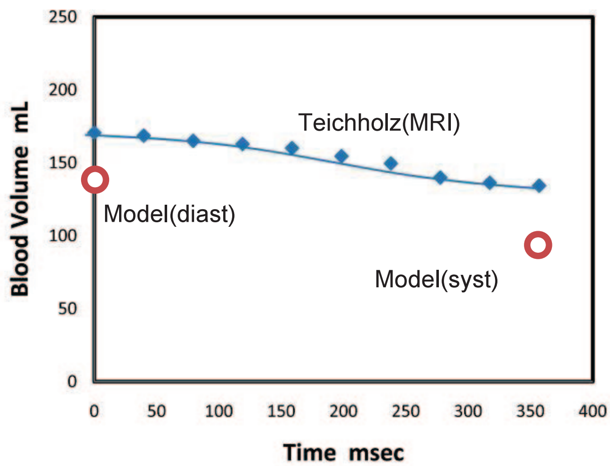


Fig. 19. Comparison of the changes obtained from a subject in ventricular blood volume calculated by Teichholz method by using the MRI workstation and by the elastic models fabricated in this study.

Volumetric reduction might be effective for the excess enlargement of end diastolic diameter with alternative morphogenesis due to histological alteration. As shown in Fig. 20, however, it is anticipated that the excess reduction might also decrease cardiac function rather than improvement. Spatial reposition of anatomical components in ventricular cavity, such as the displacement between mitral valve and papillary muscles, can be suggested by the use of our mechanical model quantitatively.

4. Conclusions

A sophisticated method of the rapid prototyping of tangible diseased heart was established. The model fabricated in this study was applied for three clinical cases for the preoperative investigation of modified Dor Procedure. As a result, this modelling method was useful for the surgical planning based on quantitative evidence, as well as the clinical explanation to patients.

III. Project Perspective

Those two projects will be tightly connected in the alternative aim of pathophysiological cardiovascular research across subject areas in anatomically identical reconstruction of the artificial myocardial assist device in analyses and examination of mechanical interactions between native properties with heart failure and circulatory assist devices. As shown in Fig. 21, the modelling and simulation method is useful for more sophisticated design and control of the artificial myocardium using shape memory alloy fibres. The mechanical modelling was effective for the evaluation study of surgical planning in Dor procedure before the operations. And also it will be necessary to achieve the identical shape design of myocardial assist device for optimised partial and effective cardiac support in each patient as well as in each lesion.

We represent a challenge to both clinical and biomedical engineering technology-enhanced examination environments, and this promising field has not been adequately investigated to date. Effective evaluation of those developmental study based on anatomical analyses concepts in the new technology in artificial organ research as well as surgical simulation can only be achieved through interdisciplinary study involving materials science, cyber science, medical engineering, and other educational disciplines. The projects are primarily concerned with research and development of approaches and solutions which address the personalisation of evaluation in cardiovascular functions and examination for identical modelling, and as such may offer the basis for human-centred activities that promote autonomic nervous activity, hemodynamic regulation and physiological response in inevitable super aging society.

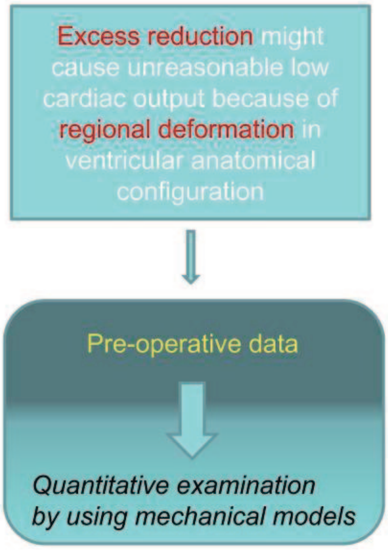


Fig. 21. Strategic concept of the application of modelling methodology for the future development of artificial myocardium and surgical planning

Acknowledgements

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