

CDX)により取得した。麻酔開胸下で心膜を切開し、心臓外壁にシリコンでコーティングを施したシステムを装着した。アクチュエータを駆動するための電力供給は経皮貫通ケーブルで行ったが、人工心臓の埋込時に必要な心臓や大動脈への侵襲がないため、装着にかかる時間は短く、出血もない。図4中矢印に示すがごとく、デバイスによる補助を行った心拍中の大動脈血流量は非補助時に比べて約15%、左心室収縮期圧は約7%の高値をとった。心臓全体を取り囲む構造のため、装置による冠動脈の圧迫や心筋組織への血流障害が懸念されたが、数時間にわたる

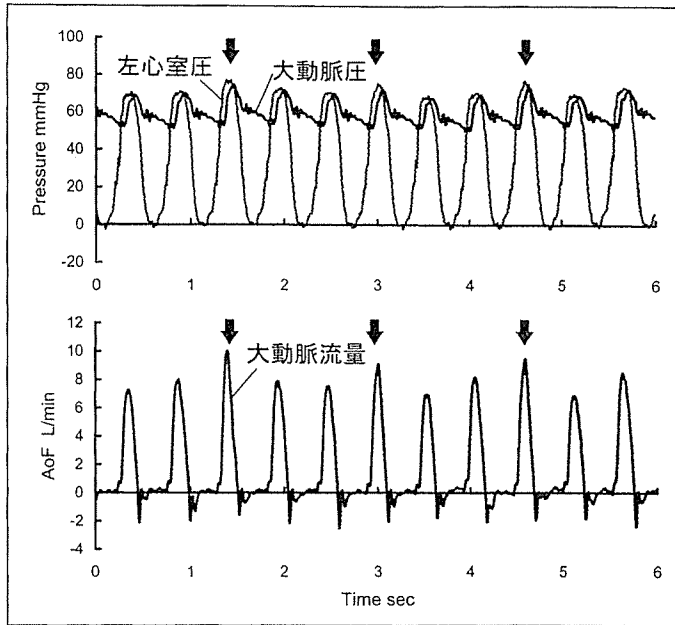


図4 成山羊を用いた動物実験における人工心筋駆動時の血行力学的効果
矢印は心電図同期による力学的な収縮補助を行った心拍を示し、この実験では自然心拍3回に対する1回の補助を行っている

人工的補助では、これらの冠循環不全に起因すると思われる心機能低下はみられず、したがって適切な初期張力を選択することで、機械式人工心筋によってこのように有効な収縮支援をなすことが示されつつある。

システムが具現化すれば、高度な社会活動に復帰し適応することが容易になりうる。

ただし、これらの医工学的技術の応用に際しては、マルチモーダルなインターフェース活用することで、機械的なサポートを受ける側の自由度を任意に設定でき、それを限定もしくは低減させないことが重要である。

4 まとめ

来るべき近い将来、超高齢社会が不可避的に到来するにあたって、人間機械論に基づいて、内臓機能だけでなく日々の生活や運動の支援システムが数多く提案され、実用化される段階にきている。ここで述べたように最新の工学技術を応用することで、ここに述べた微小システムとしての人工心筋を実現することが可能となった。近年、高齢者数の増加に伴って、心臓血管疾患の患者数が増えつつある。たとえば労作性の心不全に対して、共生自律的に心臓の収縮を支援し、循環を人工的に補助することができる

参考文献

- 1) Zipes D.P, et al: Braunwald's Heart Disease, W.B Saunders, 2005.
- 2) http://www.yomiuri.co.jp/ryou/news/ryou_news/20060207k08.htm
- 3) Perez-Tamayo RA, Anstadt MP, et al: ASAIO J. 1995 41 (3): M512-517
- 4) Sabbah HN, et al: Circulation 1999;100 (Suppl): 439.
- 5) McCarthy PM, et al: J Thorac Cardiovasc Surg 2001;122:482-490.
- 6) Miyagawa S, Sawa Y, Shimizu T, Okano T, et al: Transplantation 2005;80 (11): 1586-1595
- 7) Yambe T, Shiraiishi Y, et al: Biomed Pharmacother. 2003 57 Suppl 1:122s-125s.
- 8) Homma D, et al: Proc 25th Japan Congress on Materials Res, 1982.
- 9) Uematsu M, Shiraiishi Y, et al: Proc IEEE-EMBS, 2005.

DEVELOPMENT OF AN ARTIFICIAL MYOCARDIAL ASSIST SYSTEM

Y. Shiraishi¹, T. Yambe¹, E. Okamoto², Y. Saijo¹, K. Sekine¹, Y. Hori³, T. Kuwayama¹,
S. Nitta¹, F. Sato⁴, D. Ogawa⁴, P. Olegario⁴, A. Tanaka⁴, M. Yoshizawa⁵, Q. Wang¹,
X. Duan¹, H. Liu¹, H. Aoki⁶, J. Nagatoshi⁶, S. Ito⁶, M. Umezu⁶, T. Fujimoto⁷, N. Masumoto⁸
K. Tabayashi⁹, H. Sasada¹⁰

¹ Institute of Development, Aging and Cancer, Tohoku University, Sendai, Japan

² Faculty of Engineering, Hokkaido-Tokai University, Sapporo, Japan

³ TUBERO, Tohoku University, Sendai, Japan

⁴ Graduate School of Engineering, Tohoku University, Sendai, Japan

⁵ Information Synergy Center, Tohoku University, Sendai, Japan

⁶ Graduate School of Science and Engineering, Waseda University, Tokyo, Japan

⁷ Department of Engineering, Shibaura Institute of Technology, Tokyo, Japan

⁸ Department of Engineering, Nippon Institute of Technology, Saitama, Japan

⁹ Graduate School of Medicine, Tohoku University, Sendai, Japan

¹⁰ Graduate School of Agriculture, Tohoku University, Sendai, Japan

Abstract

The authors have been developing a newly-designed totally-implantable myocardial assist system, which is attached onto the ventricular wall and is also capable of supporting the natural ventricular contraction. This system consists of a mechanical actuator and a contraction assistive device, which is made of polyurethane and covered by the acrylic casing. The weight of the actuator is 550g, and the shape of it (W: 70mm, H: 59mm, L: 110mm) was designed to be installed into the intercostal space in the thoracic cavity. Its functional requirements are not only to be totally implantable but also to be able to assist the diseased heart function effectively according to the physiological demand. In this study, the totally-implantable electrohydraulic myocardial assist device was installed into the intercostals space of goats, and the preliminary hemodynamic performance of the device was examined. And the effects of the synchronous mechanical contraction generated by the electrohydraulic actuator on the cardiovascular function was also evaluated.

1. Introduction

Recently, the heart disease has been the second cause of death in Japan that follows malignant tumours. And it is anticipated that an increase in the number of death by the cardiac failure might become a serious problem aiming at the super-aging society.

Artificial organs such as ventricular assist systems or blood pumps are generally and successively applied in the treatment of severe heart failure. However, the artificial materials might cause hemolysis or thrombus formation on the blood contacting surface.

The authors have been developing a miniature artificial myocardial assist device (so called 'artificial myocardium'), which is capable of supporting the cardiac contractile function from outside the ventricular wall. The methodologies of the direct ventricular support systems were already reported as direct mechanical ventricular assistance (DVMA) by Anstadt's or other

groups, as well as the right ventricular assist device which was invented and reported at IDAC, Tohoku University [1-8].

The purpose of this study was to develop a totally-implantable electrohydraulic myocardial assist system, and the design image was shown in Figure 1[9]. The diaphragm assisting ventricular motion is driven by an electrohydraulic actuator, which is controlled by an embedded system. The transcutaneous electric transfer system, which has been developed at Tohoku University, can be applied for the system, and used to transmit the information of the system parameters not only of the mechanical system, but also of natural cardiovascular systems.

In this study, the development of a totally-implantable myocardial assist device could be achieved and we examined the hemodynamic performance of the device, and evaluated the effect of the motion of the system on cardiac functions in goats.

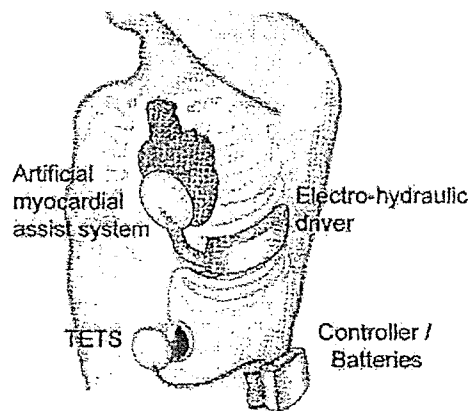


Fig. 1. Schematic illustration of an image of the electrohydraulic myocardial assist system. The portion of the driver will be installed into the intercostal space

2. Materials and Methods

2.1. Mechanical myocardial assist system

The newly-developed electrohydraulic myocardial assist system consisted of the following mechanical components: a) a fluid-filled chamber; a fluid-filled polyurethane diaphragm with disc shaped acrylic casing (D:52 mm x H:14 mm), in which the amount of change in the internal volume is 50 mL, and b) an originally-designed electrohydraulic cylindrical actuator, which was controlled by an originally-designed micro-computer. The fluid-filled chamber, which was shown in Figure 2, was fixed to the heart by a fibreglass belt as shown in Figure 3. And its mechanical contraction was synchronized with the ECG.

Several prototype models were developed in order to be installed into the intercostal space while the feasible performance could be demonstrated. The actuator was covered by the acrylic casing, and the size was W: 70mm, H: 59mm, L: 110mm, which was designed to be fit the curvature of costae. The weight of it was 550g. In this study, the embedded controllers or TETS were set up outside of the body and connected to the actuator transcutaneously.

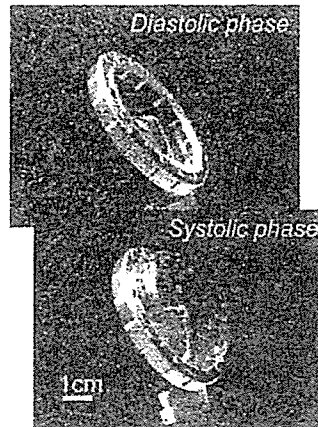


Fig. 2. Discomposed illustration of the contractile motion of the device, which was to be attached onto the ventricular wall

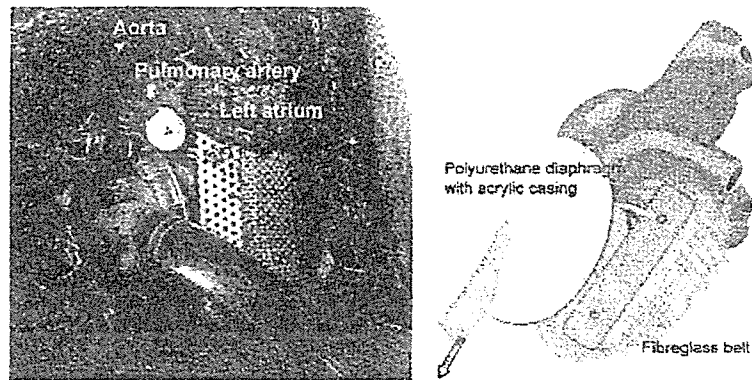


Fig. 3. Device attached onto the ventricle (left) and a schematic drawing of it joined with a fibreglass belt (right)

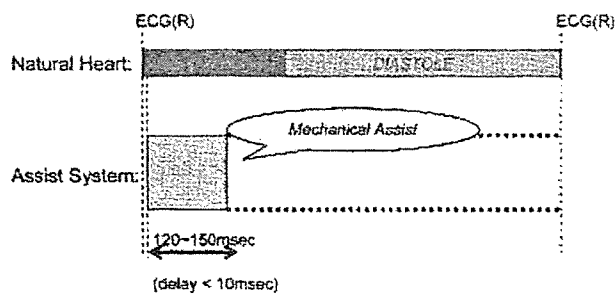


Fig. 4. Schematic chart of an example of the systolic contraction by the mechanical myocardial assist device. It was concluded that it is necessary to complete the mechanical contraction by the end of natural ventricular systolic duration, so as not to disturb the natural cardiac functions

The contractile duration was set at 120–150 msec so as not to disrupt the natural cardiac diastolic function, and the actual time delay from the input of 'R' pulse of the ECG signal to the effective contractile motion generated by the actuator was around 50 msec in that contraction. Figure 4 shows the schematic drawing of the mechanism and the illustration of the control diagram of the device.

2.2. Hemodynamic performance in goat

Prior to the measurement, the myocardial assist device was installed in the thoracic cavity and anchored on the surface of the heart by a belt under general anesthetising procedure. The hemodynamic waveforms were obtained from healthy goats. Pulmonary and aortic blood pressures were measured by pressure sensors and amplified with a polygraph (Fukuda Denshi, CM-5001), and aortic pressure was also monitored by using the catheter-tip transducer (Millar, SPC-464D). Myocardial perfusion was obtained by the laser-doppler flowmeter (Omegaflow, FLO-C1BV), and cardiac output was also measured at the main trunk of the pulmonary artery by an ultrasonic flowmeter (Transonic Systems, TS420). Each data was digitally recorded with a data recorder (TEAC, LX-10) by the sampling frequency of 1.5kHz. All the animal experiments related to this study were performed under the consent of the ethical review boards on animal experiment of the Department of Medicine, Tohoku University, and also of the Institute of Development, Aging and Cancer, Tohoku University, 2002-2005.

3. Results and Discussion

3.1. Mechanical design of the myocardial assist actuator

Figure 5 and 6 shows the prototype model of the electrohydraulic myocardial assist system, which was to be installed into intercostal space. For the installation of the former model (Figure 5, type No.2), it was necessary to remove the fourth and fifth and a part of sixth costae to make enough room to be fitted in the thoracic cavity, but any complications which might have been caused by the operation were not confirmed in goats.

The revised model, which was optimised for the thoracic cavity, was also developed as shown in Figure 6, and consequently the procedure of closing chest found to become much easier.

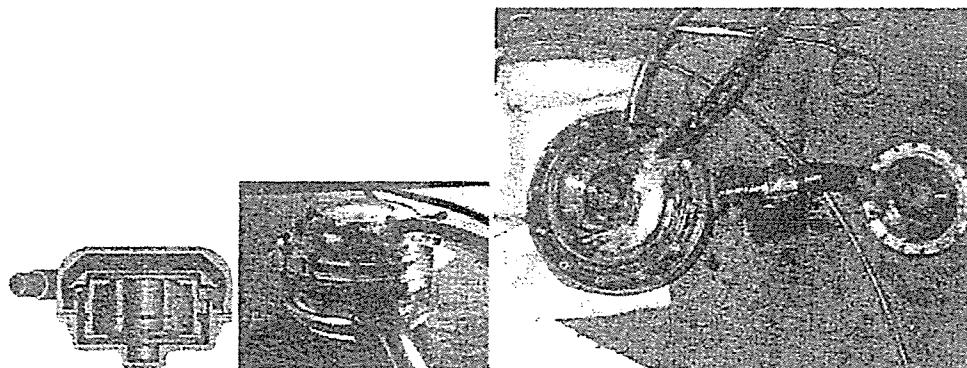


Fig. 5. Schematic illustration of the prototype model (No.2) of the totally-implantable electromyocardial assist system (left). The originally-developed linear actuator was covered by the acrylic casing (centre), and the hydraulic port was connected to the device which was attached onto the ventricle (right)

3.2. Hemodynamic examination in goat

Assistance was made by the actuator synchronously with natural heart once against every two beats of systolic contraction. The period of the assistance duration was set to around two hours a day, and the hemodynamic effects were obtained as shown in Figure 7. Then it was indicated that the increase of aortic pressure as well as the cardiac output could be achieved by the mechanical assistance by using this system.

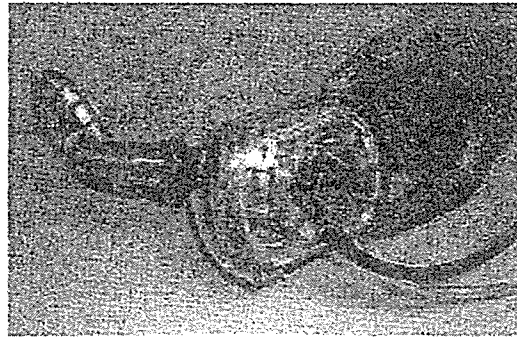


Fig. 6. Revised model (No.3) which was to be easier to be installed into 4-5 intercostal space, and the size of which was W: 70mm, H: 59mm, L: 110mm

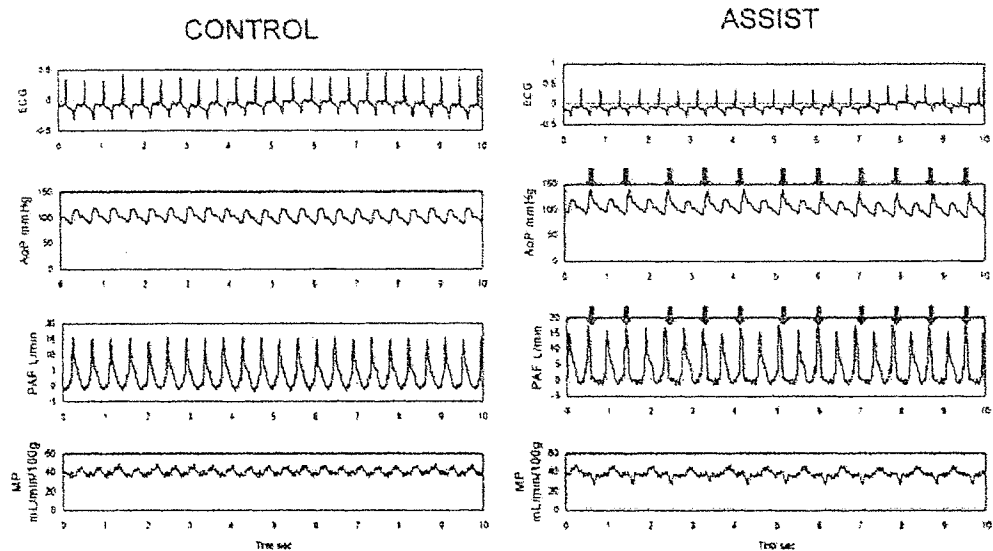


Fig. 7. Changes in hemodynamic waveforms obtained from a goat under standing condition. 'control' indicated the insensitive condition of the actuator (left). Red arrows pointed out the 'assistance' by the electrohydraulic device (right). 'AoP': aortic pressure, 'PAF': pulmonary arterial flow, and 'MP': myocardial perfusion obtained by the laser-doppler flowmeter which was attached on the left ventricular wall inside the fibreglass belt

However, different effects were caused by the portion of ventricle where the device was installed in. Therefore, it was suggested that the optimized installation of the device might improve the mortality of the patient, though it was pointed out that there might be some problems in long-term use of the reconstructive surgery by using artificial devices for the treatment of congestive heart failure [10]. Also the trade-off between the damage on the myocardial tissue and the strength of mechanical assistance should be examined further. And as the heart rate might have been decreased during the assistance from the outside, further investigation should be carried out from the physiological point of view focusing on the influence on autonomic nervous systems.

It is also necessary to optimise the driving efficiency on the electrohydraulic systems, because the efficiency in the transcutaneous energy transmission system will become important, too, when it is employed.

4. Conclusion

Newly-designed myocardial assist system was developed, which was capable to be installed into the intercostal space. It was easy to attach the device onto the ventricular wall and to fix the electrohydraulic actuator into the thoracic cavity. And also preliminary examination of the performance of the device was conducted in goat experiments. The elevation of the cardiac functions followed the changes in vascular hemodynamics were investigated by the mechanical assist. Then it was confirmed that the newly-developed artificial myocardium might be useful and effective to improve and support the ventricular systolic function. As our system could assist natural ventricular functions with physiological demand, it might be applied in patients with exertional heart stroke, as well as the cardiac massage at lifesaving emergency for the recovery from ventricular fibrillation.

Acknowledgements

The authors would like to extend their appreciation to Mr Kimio Kikuchi for his cooperation in the animal experiments.

This study was supported by the Grant-in-Aid for Scientific Research of Ministry of Health, Labour and Welfare (H14-Nano-020, H17-Nano-009), and of Ministry of Education, Culture and Sports, Science and Technology (14657315, 17789838). And it was partly supported by the Program for Promotion of Fundamental Studies in Health Sciences of the Organization for Pharmaceutical Safety and Research of Japan.

References

1. Anstadt G.L., et al.: A new instrument for prolonged mechanical massage, *Circulation*, 1965, 31(Suppl. II), 43.
2. Anstadt M., et al.: Direct mechanical ventricular actuator, *Resuscitation*, 1999, 21, 7-23.
3. Kawaguchi O., et al.: Dynamic cardiac compression improves contractile efficiency of the heart, *J. Thorac Cardiovasc. Surg.*, 1993, 113, 923-31.
4. Yambe T., et al.: Recent progress in artificial organ research at Tohoku University, *Artif. Organs*, 2003, 27, 2-7.

5. Lowe J.E., et al: First successful bridge to cardiac transplantation using direct mechanical ventricular actuation, *Ann. Thorac Surg.*, 1991, 52, 1237-43.
6. Mitsumaru A., et al.: Experimental study of combination of extraaortic balloon counterpulsation and ventricular assist cup to acute heart failure in dogs, *ASAIO J.*, 1997, 43, 3, 187-92.
7. Perez-Tamayo R.A., et al.: Prolonged total circulatory support using direct mechanical ventricular actuation, *ASAIO J.*, 1995, 41, M512-7.
8. Nitta S, et al.: Right ventricular reconstruction by RV device, *Heart*, 1978, 10, 1, 88-90 (in Japanese).
9. Wang Q., et al.: An artificial myocardium assist system: electrohydraulic ventricular actuation improves myocardial tissue perfusion in goats, *Artif. Organs*, 2004, 28, 9, 853-857.
10. Lee R., Hoercher K.J., McCarthy P.M.: Ventricular reconstruction surgery for congestive heart failure, *Cardiology*, 2004, 101, 61-71.

BIOMEDICAL ENGINEERING ANALYSIS ON THE EFFECTIVENESS OF CARDIOVASCULAR SURGERY: ANASTOMOSIS METHODS FOR CORONARY ARTERY BYPASS GRAFTING

M.Umezu, J.Kawai, J.Suehiro, M.Arita*, Y.Shiraishi*,
K.Iwasaki, T.Tanaka*, T.Akutsu*, H.Niinami**

Integrative Bioscience and Biomedical Engineering, Graduate School of WASEDA
University, Tokyo, Japan

*Advanced Research Institute of Science and Engineering, Waseda University, Tokyo, Japan

**Cardiovascular Surgery, Juntendo Medical University, Tokyo, Japan

Abstract

There are two types of coronary artery bypass grafting (CABG) anastomosis methods: end-to-side anastomosis (ESAs) and side-to-side anastomosis (SSAs). The selection of these methods is determined by surgeons' favor because of no experimental information to select them. The ultimate purpose of this study is to provide new information with surgeons to select anastomosis methods through both *in-vivo* and *in-vitro* tests on ESAs. The *in-vivo* tests have been performed in pigs and energy loss at anastomosis was calculated and compared the value between ESAs with SSAs. The *in-vitro* tests have been conducted in the newly-developed system to evaluate CABG anastomosis methods. This system is composed of the mock circulatory system and the coronary simulator, which has been originally designed to reproduce various types of coronary hemodynamics. Both *in-vivo* and *in-vitro* tests resulted in the same tendency of energy loss: SSAs had lower energy loss than ESAs under the particular conditions. These were caused by a difference in local flow at the anastomosis between ESAs and SSAs. Consequently, it is suggested that SSAs is a more favorable anastomosis method than ESAs.

1. Introduction

Coronary artery bypass grafting (CABG) is widely employed as one of the effective treatments for ischemic heart diseases. They generally bring favorable outcome to the patients, even though the restenosis and reocclusions sometimes occur due to graft failures.

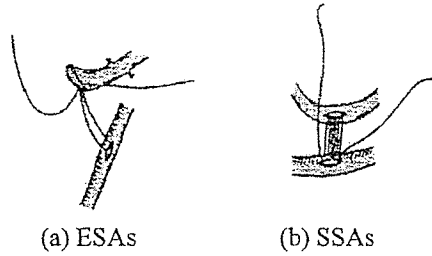


Fig.1. Schematic drawings of two types of anastomosis methods for coronary artery bypass grafting.

At present, there are two types of the anastomosis methods: end-to-side anastomosis (ESAs) and side-to-side anastomosis (SSAs) as shown in Fig.1. Though ESAs methods are conventionally used in Japan, their configurations have a tendency to deform in the narrow space of thoracic cavity. On the other hand, SSAs methods' configurations are more stable because the grafts are anastomosed parallel to the native coronary artery. As there is no experimental and no theoretical information to select them, anastomosis method is chosen by surgeons' favor. In this study, the *in-vivo* and *in-vitro* tests have been conducted on ESAs and SSAs to make clear the effectiveness of two anastomosis methods. The ultimate purpose is to provide new information with surgeons to decide the anastomosis methods, considering individual difference of the patients condition.

2. Materials and Methods

2.1. In-vivo test methods

Pigs with a weight between 40 and 50kg were served for the acute experiments. Coronary artery bypass grafting surgeries were performed using mammary arteries as grafts. Right and left internal mammary arteries were anastomosed to the right coronary artery to compare ESAs with SSAs under the same condition as shown in Fig.2. Pressure and flow rate were measured at inlet and outlet anastomosis and energy loss was calculated by equation (1), using the following parameters: pressure gradient ΔP and flow rate Q .

$$E_{loss} = \int \Delta P \times Q dt \quad (1)$$

A dog was served for making silicone anastomosis molds to determine configurations of each anastomosis method. Coronary artery bypass grafting was performed as mentioned above. After sacrificed, silicone (TSE352, GE Toshiba silicone) was injected to coronary artery under the 100mmHg pressure condition. The silicone-injected coronary artery was submerged in aqueous sodium hydroxide at appropriate concentration to remove the whole tissue.

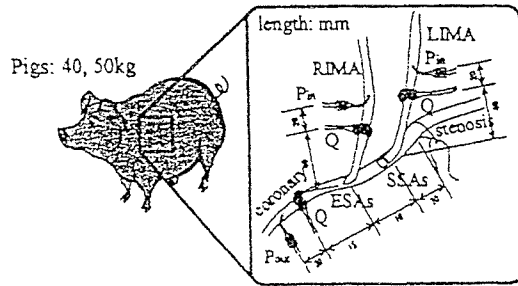


Fig.2. Schematic drawing of the coronary artery bypass grafting method for the acute animal experiments. RIMA and LIMA were anastomosed to coronary artery, indicated as ESAs and SSAs. Right and left internal mammary arteries

2.2. In-vitro test methods

The new evaluation system has been developed for investigate ESAs and SSAs as shown in Fig.3. It is composed of the original mock circulatory system and the newly-developed coronary simulator. The coronary simulator, driven by linear actuator composed of stepping motor, has been designed to reproduce natural coronary hemodynamics. For investigating anastomosis methods, CABG anastomosis models were aligned between the mock circulatory system and the coronary simulator. Pressure and flow rate were measured at the inlet and outlet models and energy loss was calculated by equation (1).

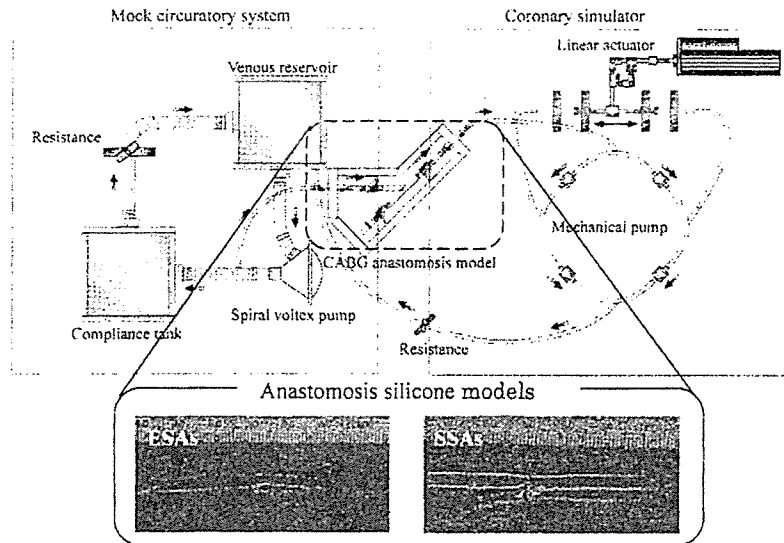


Fig.3. The newly-developed mock circulatory system to evaluate anastomosis methods of CABG

The *in-vitro* tests using this system were conducted under the following conditions: aortic pressure of 90/50mmHg (Hypotension), 120/80mmHg (Normotension) and 160/120mmHg (Hypertension), while coronary flow of 50 mL/min and 30mL/min. By using this system, flow visualization tests were conducted using particle tracer method. Commercial software Dipp95 (Direct) was used for the flow analysis.

3. Results and discussion

3.1. *In-vivo* test results

The acute animal experiments resulted in a difference in energy loss between ESAs and SSAs as summarized in Fig.4. The energy loss for SSAs was lower than that for ESAs by 25% and 48% under the normotensive and hypotensive conditions, respectively.

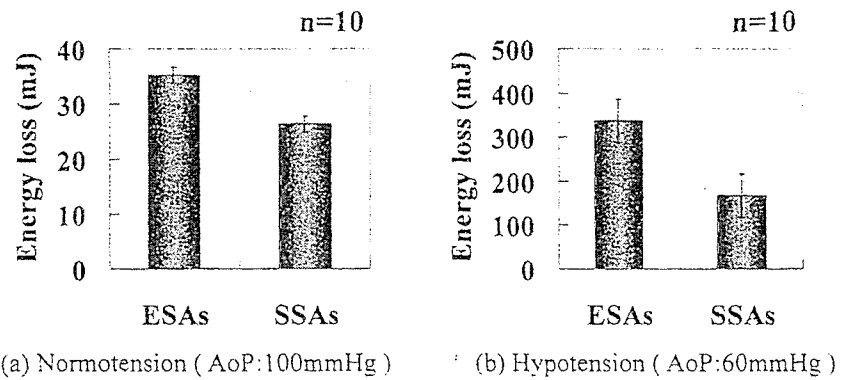


Fig.4. Energy loss for ESAs and SSAs at the acute animal experiments under following two conditions: aortic pressure (AoP) is around 100 and 60 mmHg

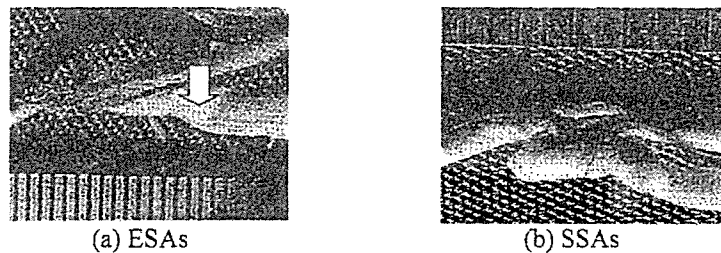


Fig.5. Silicone molds of two types of CABG anastomosis methods. The narrow configuration at ESAs is indicated as a white arrow

By making silicone molds of the real anastomosis shown in Fig.5, it was confirmed that configurations of molds were anatomically similar to those of silicone models used for *in-vitro* tests. Moreover, orifice areas of the configurations were calculated as summarized in Table 1. These comparative data suggested that resistance of SSAs was lower than that for ESAs under the same conditions

Table 1. Anastomosis areas of ESAs and SSAs

Anastomosis method	Anastomosis Area mm ²
ESAs	1.49
SSAs	2.04

3.2. *In-vitro* test results

Typical waveforms of natural coronary artery and simulator were shown in Fig 6.

It was confirmed that flow waveforms reproduced by coronary simulator were similar to those in natural coronary artery under the standard condition (normotension with high flow).

The only two tests exhibited a difference in energy loss between ESAs and SSAs as summarized in Fig.7. The energy loss for SSAs was lower than that for ESAs by 18% and 24% under the normotension with high flow and hypotension with low flow, respectively.

Flow visualization tests under the two conditions indicated a difference in local flow between ESAs and SSAs. There were strong collisions to coronary wall due to the narrow configuration at ESAs indicated in Fig.8. Moreover, the flow velocity at ESAs increased after passing through the anastomosis as summarized in Table 2 and 3. These were consistent with higher energy loss for ESAs under the two conditions.

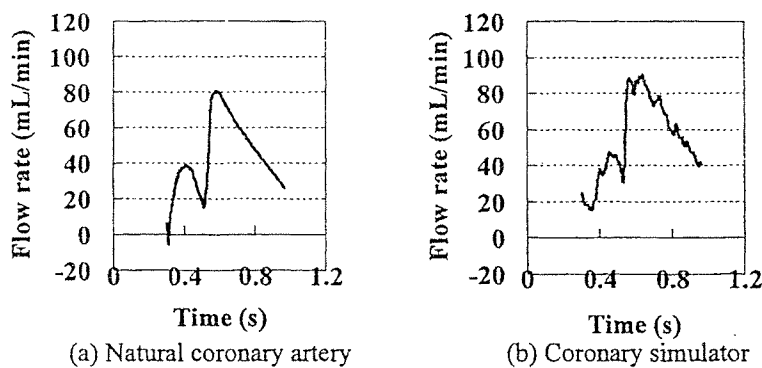


Fig.6. Flow waveforms in natural coronary artery and coronary simulator

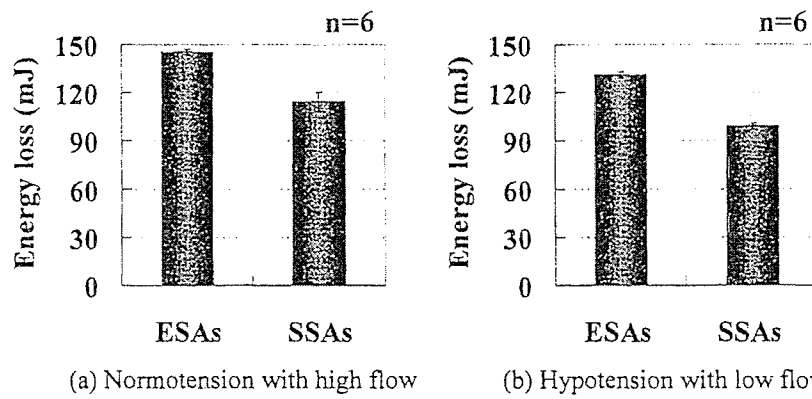


Fig.7. Energy loss for ESAs and SSAs at mock *in-vitro* tests under the two conditions

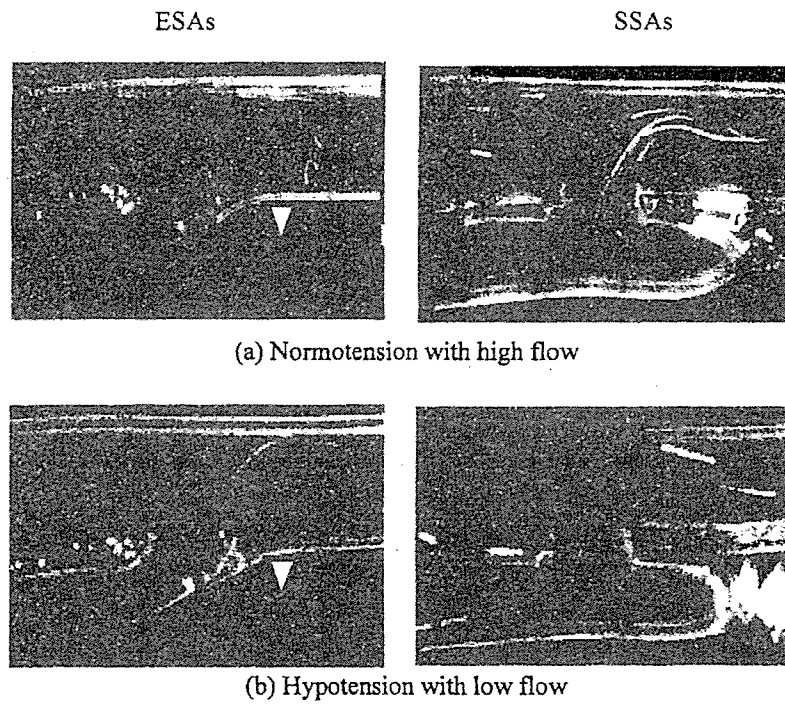


Fig.8. Flow visualization test results under the two conditions. The strong flow collision at coronary wall is indicated as the white arrow heads

Table 2. Changes in velocity at normotension with high flow

	ESAs	SSAs
Inlet velocity (mm/s)	139	239
Outlet velocity (mm/s)	172	118

Table.3. Changes in velocity at hypotension with low flow

	ESAs	SSAs
Inlet velocity (mm/s)	631	296
Outlet velocity (mm/s)	666	188

4. Conclusion

Throughout both experiments of *in vitro* and *in vivo*, it was found that SSAs had lower energy loss than ESAs. This was mainly caused by a difference in local flow due to a change of anastomosis configurations when they swelled under the arterial pressure. Therefore, considering the local flow influenced by the anastomosis configuration, it is suggested to select SSAs rather than ESAs for a favorable anastomosis method of CABG.


Acknowledgements

This research was supported by the program for promotion of Fundamental Studies in Health Sciences of the Organization for Pharmaceuticals and Medical Devices Agency. (ID: 02-01). Also, supported by "Frontier Advanced Research Fund for private university (No.2001-F1) from the Ministry of Education, Culture, Sports, Science and Technology

References

1. J.Kawai, J.Suehiro, M.Umezu, et al.: *In vitro* characteristic of coronary arterial anastomosis methods, Proc. of 3rd Japan-Australia Cardiovascular Bioengineering Symposium: 34/35, 2001

早稲田大学人間総合研究センター 監修

ヒューマンサイエンスシリーズ 

人工臓器で幸せですか？

梅津 光生 編著

山口社

まえがき

まずはじめに、「人工臓器で幸せですか？」という本をなぜ企画したかということに関して私のいままでの経歴を中心に説明してみたいと思います。

私のバックグラウンドは機械工学です。ところが私のように生物、生体、医学領域を対象とするエンジニアはバイオエンジニアと呼ばれています。私はバイオエンジニアとして三〇年間、おもに人工臓器に関する研究を行って参りました。早稲田大学の大学院生のときに、東京女子医科大学と共同研究を行いました。そのときのテーマは、『心臓がドキドキすることは、身体のいろいろな部分に対してどういう意味があるのか』という内容であり、そのことを心臓手術のときに使う人工心肺装置を造りながら調べる研究を行いました。

それから一九七九年に大阪の国立循環器病センター研究所の開設のために、大阪に行きまして、
ま
き
そこの研究所では人工心臓、特に補助心臓の開発研究、ならびに人工肺や人工弁など、いわゆる人
が
工臓器の性能評価研究も行いました。当時のグループの共同研究成果は、その後企業化され、補助
え
人工心臓は世界で初めて認可されました。いまは心臓移植を待っている患者様にその国産人工心臓
ま
が広く使われているのです。

i

八〇年代の後半から九〇年代の初めにかけて、オーストラリア・シドニーのセントビンセント病院で、当時、建国二百年の記念プロジェクトとしてスタートしたオーストラリア人工心臓プロジェクトの初代リーダーを担当しました。

それから、早稲田大学に移りまして、人工臓器の研究をさらに進めるとともに、最近ではティッシュエンジニアリング（再生医療）という分野にも研究を拡大しています。その三〇年間という中で、一生懸命にやっただけには患者様には直接役に立つものがそんなに多く造れなかったなあという印象を持っています。

今回「人工臓器で幸せですか？」という本を企画するにあたり、どうすればもっと患者様に使用される人工臓器ができるのかを考え始め、まず考えたことは、医療機器は一般的な家庭用品などとは違ったプロセスで生まれてくるのではないかという点です。一般に企業が製品を出すというときには消費者の声を正確にとらえてニーズをちゃんと確かめることを行っていると思います。ところが、医療機器の場合はどうかというと、医療機器を造るにあたって、多くの場合は、直接それを使う医師の意見が反映されてモノができてくるということが多いのではないかと思います。

すなわち、人工臓器の場合は、患者様がそれを使うのですが、患者様の声というよりはむしろ医師の声ばかりが聞こえてくる。表現を替えれば一般の製品で消費者の声より販売店の方々の声が多く反映されているのではないかと思います。

一般の家庭の製品では、消費者と販売店という消費者のほうはかなり強い立場にあると思います。ところが、医療機器を使うということになりますと、どうしても治療をしてもらおうという感覚が働きますから、患者様よりは医師のほう立場が強い。一般的にモノをつくる時には立場の強い人の意見が大きく反映されていくと思います。

そこで今回、人工臓器の恩恵を本当に受けている方々が、実際に人工臓器による治療をどう考えておられるのかについての生の声を直接聞いてみたいと思いました。それこそが新しい人工臓器の開発なり、従来の人工臓器の改良の方向なりを定める上で非常に有効ではないかと考えました。それと同時に、現在人工臓器を使って生活されている、または使ったという経験をお持ちの方がその経験をお話しくだされば、一般の方々やこれから先に人工臓器を使おうと考えておられる方々に有益な情報を提供できるのではないかと考えた次第です。

最近、大学では生き残りをかけて、大学の特徴や入試に関する説明を高校や予備校でする機会が多くなって参りました。私も人工臓器の生体工学など将来の医療に関わるテーマに関して、模擬講義や講演を依頼されることが多くあります。人工臓器の開発研究というのは、一般の方々には医学部で研究しているのだらうと思われているのではないのでしょうか。しかし、いかに理工学がこういう分野に進出して、理工学・医学が融合しながらいわゆる学際領域の研究を展開しているのかを説明しますと、なるほどなあどわかってくださる方が多くおられます。したがって、このような本を通

じて、理工学者がどのようにこの分野に関与して貢献しているのかということも、理解していただけたらと思います。

iv

ここでこの本の特徴をいくつか述べたいと思います。まず、三種類の人工臓器を取り上げて、それを使っていらっしゃる方々に直接インタビューをするという形式をとりました。ペースメーカー、人工弁、人工血管という代表的な人工臓器に関しまして、使用している方の声を聞くというのが第一の大きな特徴であります。

二つ目は、インタビューをしたそれぞれの人工臓器に関して、その歴史と現状、そして将来どうなるかという解説の記事を載せました。

一般にこのような解説は医師が書くことが多いのですが、この本では、すべてバイオエンジニアが執筆いたしました。したがって、臓器を機械で置き換えた場合、その機械がどのような性能になっているのかとか、どういう設計思想で造ってきたのか、という少し違った視点でのとらえ方もこの本から理解していただけるのではないかと思います。

それから三つ目の特徴としては、人工臓器を使っていらっしゃる方々の声と解説記事を、ともにインタビューという方法をとってまとめたことです。このインタビューは、専門の方ではなく、この分野から離れた一般の方にインタビューをお願いしました。そうすることで自然にわれわれの知らないこと、知りたいことを自由に聞いてもらうことができ、それをわかりやすくまとめたという

こともこの本の特徴になっていると思います。インタビューを行い、さらにそのやりとりをまとめて下さった小島裕子さんに心より謝意を表したいと思います。

なお、インタビューの内容に関しましては、人工弁の患者様をご紹介くださりました北村信夫先生（京都府立医科大学教授・当時）と、人工弁の部分をご校閲くださりました夜久均先生（京都府立医科大学教授）に感謝致します。また人工血管の患者様をご紹介くださりました岩村弘志先生（湘南鎌倉総合病院・当時）には、内容の校閲もしていただきました。ここに厚く御礼申し上げます。なお、ペースメーカーに関しましては、インタビューを受けてくださりました阿久津哲造先生は、医師でもあります。また、ペースメーカーの解説記事を書いてくださりました藤本哲男先生（芝浦工業大学教授）は、バイオエンジニアでもあり、医師でもありますので、この部分はお二人自身にも校閲をしていただきました。このお二人にも厚く御礼申し上げます。

この本を通じて、人工臓器の使用者の生の声を聞き、バイオエンジニアによる解説を知っていただくことで、一人でも多くの方々が人工臓器による治療の意味をご理解いただければ幸甚に存じます。

二〇〇五年八月

編者 梅津 光生

v

心臓から拍出される血液を全身に送り届け、また体内の臓器から心臓へと血液を戻す管路の役割を果たすものが血管です。この血管の代用となるものが人工血管と呼ばれ、体内の複雑な血管のかたち合うように、いろいろな材料と製法で造られています。

十九世紀末に盛んになった血管の外科手術方法の研究の発達に伴って、人工血管の開発が数多く試みられました。現在の人工血管とはほぼ同等の形となったのは、二〇世紀半ばになってからです。その後、化学工学や組織工学、遺伝子工学などの科学技術の進歩によって、新しい材料や作成技術を応用した人工血管が登場しています。

多くの人工血管は、ポリエステルを材料とした布製のもので、日本国内でも年間四万本以上が使われています。相対性理論で有名なアインシュタイン博士は、医師に勧められても人工血管置換手術を受けず、一九五五年に腹部大動脈の動脈瘤破裂をきたしたことが知られています。人工血管を使った治療が必要となる病気には、血管構造が弱くなって血管がふくれあがる大動脈瘤や解離といったものや、血管の内腔が狭くなって血液が流れにくくなる狭窄などがあり、人工血管はそれぞれ血管壁の支えとなる役割、あるいは血流をバイパスする役割を果たします。

また、血管自体の病気だけでなく、腎臓の病気で人工透析が必要となった場合にも、透析装置へ血液を循環させる出入口に人工血管が植え込まれて使われます。可動部もなく、外からは直接見ることができない人工血管は、手術後に人工物が体内に存在するという感覚をあまり生じさせない人工臓器なのかもしれません。

対談者の戸田さんを紹介してくださった先生は、岩村弘志湘南鎌倉総合病院心臓血管外科部長（当時）です。

〈岩村先生のプロフィール〉

湘南鎌倉総合病院心臓血管外科部長（当時）。

日本外科学会専門医でもあり、人工血管置換手術に関して、インタビューを行った戸田さんの紹介者。戸田さんに対しては、前任の須磨久善先生が手術をされたが、須磨先生が転出された後のケアを引き継ぎ湘南鎌倉総合病院で行っていた。個人的には、岩村先生のアイデアによる新しい分岐人工血管の性能を早稲田大学のシミュレーターで調べる実験を行っているところである。

(1) 臨死体験からの生還

—対談者（患者） 戸田道男さん—

〈戸田さんのプロフィール〉

鎌倉市在住。証券会社を退職後、一九九八年の十二月、自宅の落ち葉を掃除中に突然激しい胸の痛みに見舞われ、救急車で近くの湘南鎌倉総合病院へ搬送された。

解離性大動脈との診断で、須磨久善病院長（当時）によって人工血管移植の緊急手術を受けた。

現在は経過良好で、インタビューは手術の五年後に、湘南鎌倉総合病院において岩村弘志先生の立ち会いのもとに行われた。

二〇〇三年七月インタビュー。