13 ISMICS in Prague

June 13, 2013

A new suture device for distal coronary artery bypass surgery

Minoru Ono[1], Yoshifumi Itoda[1], Panthee Nirmal[1],
Takehiro Ando[2], Ichiro Sakuma[2]
1: Department of Cardiac Surgery, Faculty of Medicine,
2: Graduate School of Engineering
The university of Tokyo

1

Minimally Invasive cardiac surgery

Faster recovery

Cosmetic reasons

Introduction of minimally Invasive cardiac surgery

Endoscopic surgery

Robotically assisted surgery

da Vinci Surgical System

But, 1. Continuous suturing
2. Knot tying
are highly technically demanding.

Devices for distal coronary artery anastomosis

Ono et al — Evolving Technology

Early experience of coronary artery bypass grafting with a new self-closing clip device

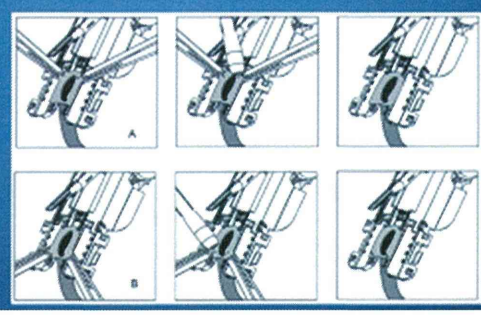
Minoru Ono, MD
Randall K. Wolf, MD
Dimitrios Angouras, MD
E. William Schneeberger, MD

J Thorac Cardiovasc Surg 2002;123:783-7

U-Clip

Withdrawn from the market

Cardica C-Port



3

New coronary artery anastomotic device

Features of new anastomotic device

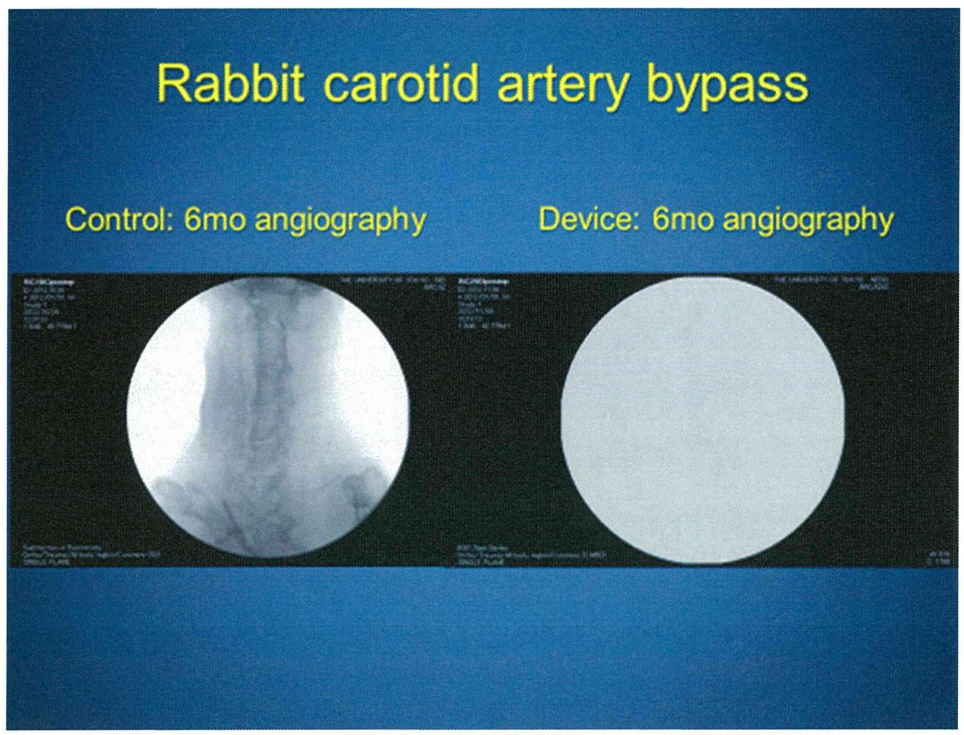
- Simple-shape device
- Easily manufactured by laser cutting
- Allows hand-suturing (most familiar for surgeons)
- Eliminates knot tying
- Allows both continuous and interrupted suturing
- Enables suturing in a limited working space

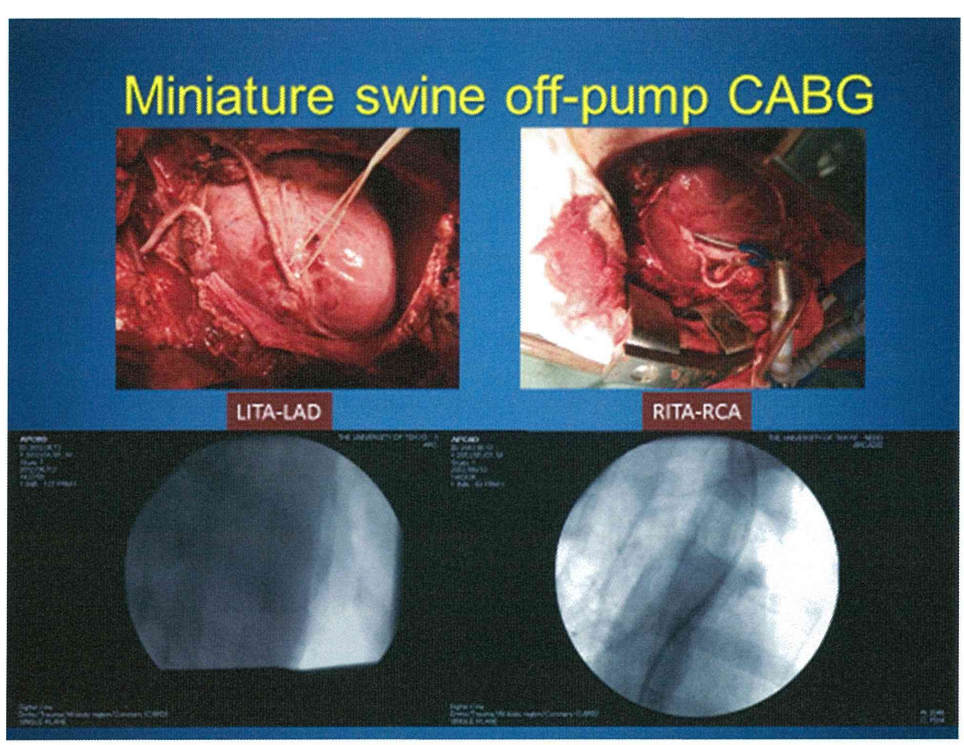
Promising for endoscopic / robotic surgery
in abdomen as well as in chest

Device testing in rabbit carotid artery model

- Design: Comparison with regular suture
- Method: Carotid artery bypass with jugular vein
- Models: Chronic phase evaluation of patency and inflammatory reaction
- Results: Equal patency and inflammatory cell infiltration

	1mo patency	3mo patency	6mo patency	3mo Inflammation	thrombus
device	75% (3/4)	80% (4/5)	100% (2/2)	mild	none
control	75% (3/4)	80% (4/5)	100% (2/2)	mild	none
p value	1.00	1.00	1.00	**	**


Rabbit carotid artery bypass
Control: 6mo angiography
Device: 6mo angiography


Miniature swine off-pump CABG
LITA-LAD
RITA-RCA

Miniature swine off-pump CABG

- Design — Comparison with regular suture
- Models — Chronic phase evaluation of patency and inflammatory reaction
- Results — Equal patency and inflammatory cell infiltration

	1mo patency	3mo patency	6mo patency	3mo Inflammation	thrombus
device	100% (4/4)	100% (5/5)	100% (2/2)	mild	none
control	100% (1/1)	100% (1/1)	100% (1/1)	mild	none
p value	1.00	1.00	1.00	**	**

SaD06.2
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USE OF A NEW DEVICE FOR DISTAL CORONARY ANASTOMOSIS -PIG MODEL-

Yoshifumi Itoda[1], Panthee Nirmal[1], Takehiro Ando[2]
Ichiro Sakuma[2], and Minoru Ono[1]
[1]Department of Cardiac Surgery, The University of Tokyo
[2]Department of Precision Engineering, The University of Tokyo

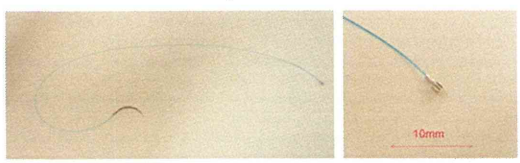
Abstract— OBJECTIVE: Different devices have been developed for distal coronary anastomosis for minimally invasive coronary artery bypass surgery. But none of these devices have been universally adopted. In this study, we describe the safety and efficacy of a new anastomotic device that we developed using swine coronary bypass model. METHODS: The device enables us to skip manual ligation with easy pinching motion after conventional suturing. Five miniature pigs were used for this study. Bilateral internal thoracic arteries were harvested and anastomosed to right coronary artery and left descending artery, respectively using new device (n=4), and conventional poly propylene suture (n=1). After 1 month of operation, pigs were sacrificed and evaluated. RESULTS: Suture time measured during surgery revealed no significant difference between device group and conventional sample. Angiography after 1 month showed good patency (FitzGibbon A). Pathological findings revealed no specific inflammatory change around devices and surrounding tissues. CONCLUSION: The device we developed was feasible for distal coronary anastomosis in present swine model.

HEADINGS

In recent years, robotically assisted surgery has been introduced to cardiovascular surgery as a minimally invasive procedure. But it was pointed out that there were several obstacles to apply robotics to coronary artery bypass. Main points of these problems include difficulty to perform a running suture and tying without tactile feedback in limited space. In previous reports, different devices including various adhesives and one shot type systems for coronary distal anastomosis. But none of them have been universally adopted for some reasons; patency, handling, indication, and costs. We developed the new device which has feasibility for minimally invasive surgery followed by robotic surgery for coronary distal anastomosis. In this report, its effectiveness and safety was evaluated using swine coronary bypass model.

METHODS AND MATERIALS

The device was designed simply with biocompatible stain-less steel mechanism combined to the free end of the ordinary mono-propylene suture (figure 1). The device enables us to skip manual ligation with easy pinching motion after conventional suturing.



Five healthy male pigs (Crown miniature pig, 25-30kg) were used in this study. Under general anesthesia, chest was opened and left internal thoracic artery (LITA) and right internal thoracic artery (RITA) were harvested in skeletonized fashion. Heart was stabilized with heart positioner and left descending coronary artery (LAD) and right coronary artery (RCA) were dissected. Using coronary shunt and retractor tape, coronary anastomoses were done (LITA to LAD, RITA to RCA, respectively). New devices were used in four of five pigs.(Figure 2) Conventional polypropylene suture was used in the remain. After the operation, 100mg of oral aspirin was administered for one month and finally pigs were sacrificed and anastomoses were evaluated by following way. (1) Suture time was measured during operation. (2) Blood flow was also measured at graft side after completion of anastomosis (Figure 3). (3) Angiography was done using C-arm X-ray system after 1 month of operation. (4) Anastomotic sites were resected and histologically examined about inflammatory change.

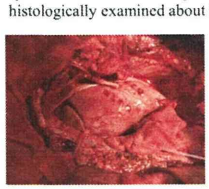


Figure 2
Right is head side of this picture. LITA was anastomosed to mid portion of LAD. RITA was anastomosed to proximal part of RCA which is covered by right atrial appendage.

Figure 3
Coronary blood flow was measured using BeriQ transitional flow meter after anastomosis. Optimal flow pattern appears at a diastolic period.

RESULTS

(1) Average suture time using new device was 16.75 min. in LITA-LAD anastomosis, and 18.25 min. in RITA-RCA. This times were as equal as conventional samples; 18 min. and 24 min.(Table 1).

(2) Blood flows varied depends on the demand of coronary flow. LITA-LAD flow was relatively low compared to control sample, but flow pattern showed good diastolic pulse (Table 2).

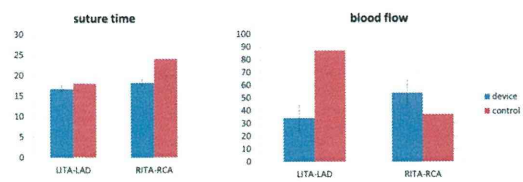
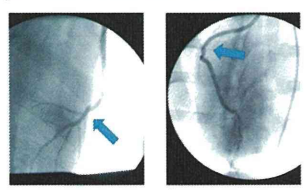


Table 1
Suture time using the device compared with control sample. There no significant difference between these times.

Table 2
Blood flow after anastomosis using the device revealed lower compared to control sample in LITA-LAD, and equal in RITA-RCA.

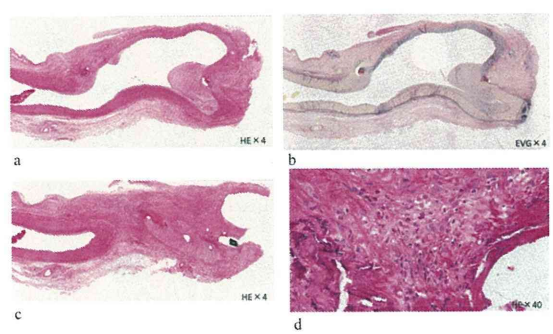
(3) Angiography after 1 month of operation revealed FitzGibbon A (without stenosis up to 50%) in all anastomoses. No evidences of parse-string suture and device specific stenosis were shown (Figure 4).



a b

Figure 4
Angiography was performed through femoral artery canulation and selective insertion to bilateral internal thoracic arteries. Anastomosis cite was evaluated by FitzGibbon criteria. These samples (a; LITA-LAD, b; RITA-RCA) showed FitzGibbon A. Arrows are the suture devices.

(4) Pathological study showed general inflammatory response including cell filtration, fibrosis and neointimal hyperplasia. Foregin bodies such as the suture and the mechanism located at anastomosis cite induced the resposes . There were no specific change by using new devices; invasiveness to vessels and surrounding tissues (figure 5). Inflammatory cells which represented by lymphocyte, gulanurocyte, and macrophages appeared surrounding the device.



a b c d

Figure 4
One month after the operation the anastomosis cite was resected and stained by Hematoxylin-eosin and Elastica-van-Gieson stain. a; LITA-LAD anastomotic lumen was presented. b; Used sutures were detected by fibrosis (red sign). Neointimal hyperplasia was mainly seen at a heel side of the anastomosis. c; The suture device were located nearby vessel's wall. d; In the hyper field, around the mechanism, inflammatory cell infiltration and fibrosis were observed. These responses were equally seen in the control sample.

CONCLUSION

It was confirmed that the device we developed has feasibility to use in coronary artery bypass surgery in this mid-term chronic study. Now we are challenging more long period model. Evaluating efficacy of this devise in closed or limited operative space, further research is necessary.

Department of Cardiac surgery, The University of Tokyo, Hongo 7-3-1, Bunkyo-ku, Tokyo, Japan (corresponding author to provide phone: +81-03-3815-5411, e-mail: inguinail@yahoo.co.jp).

東京大学 THE UNIVERSITY OF TOKYO

Use of a New Suture Device for Distal Coronary Artery Anastomosis -Swine Coronary Bypass Model-

Yoshifumi Itoda[1], Nirmal Panthee[1], Takehiro Ando[2], Ichiro Sakuma[2] and Minoru Ono[1]

[1]Department of Cardiac Surgery, The University of Tokyo
[2]Department of Precision Engineering, The University of Tokyo

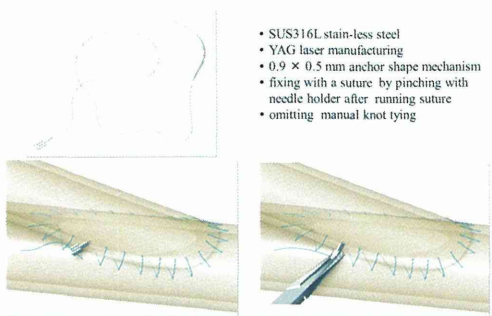
Abstract— BACKGROUND: Minimally invasive and robotic techniques have been spreading in coronary bypass surgery. But introduction of these methods has some obstacles in anastomotic technique. We developed a new suture device that simply consists of an anchor-shaped stainless steel mechanism attached to a free end of the polypropylene suture. This device enables us to skip manual ligation by pinching motion after conventional suturing.
METHODS: Thirteen pigs were used in this study. Bilateral internal thoracic arteries (ITA) were harvested. Left ITA was anastomosed to left anterior descending artery (LITA-LAD). And right ITA was anastomosed to right coronary artery (RITA-RCA). Suture time was measured. Eleven of thirteen pigs were operated upon using the suture device (group D), and the remaining by conventional 7-0 polypropylene suture (group C). Six pigs of group D and one pig of group C underwent angiography just after anastomosis. The remaining underwent angiography at one month after operation. Histopathological examination of anastomosis was performed after pigs were euthanized.
RESOULTS: LITA-LAD anastomosis was done in 18.4±1.2 min in group D, 16±2.0 min in group C (p=0.42). RITA-RCA anastomosis was done in 20.1±1.2 min in group D and 24.5±0.5 min in group C. Angiography demonstrated FitzGibbon B in one anastomosis of each group, the remaining were FitzGibbon A (92.3%). Histopathologic examination showed common inflammatory responses in both groups. Device-specific inflammatory changes were not observed.
CONCLUSIONS: This new suture device showed an excellent safety and quality equal to conventional suturing technique in this swine model.

Introduction

In recent years, robotically assisted surgery has been introduced to cardiovascular surgery as a minimally invasive procedure. But it was pointed out that there were several obstacles to apply robotics to coronary artery bypass. Main points of these problems include difficulty to perform a running suture and tying without tactile feedback in limited space. In previous reports, different devices including various adhesives and one shot type systems for coronary distal anastomosis. But none of them have been universally adopted for some reasons; patency, handling, indication, and costs. We developed the new device which has feasibility for minimally invasive surgery followed by robotic surgery for coronary distal anastomosis. In this report, its effectiveness and safety was evaluated using swine coronary bypass model.

DEVICE DESIGN

The device was designed simply with biocompatible stain-less steel mechanism combined to the free end of the ordinary poly-propylene suture (figure 1). The device enables us to skip manual knot tying with easy pinching motion after conventional suturing.



- SUS316L stain-less steel
- YAG laser manufacturing
- 0.9 × 0.5 mm anchor shape mechanism
- fixing with a suture by pinching with needle holder after running suture
- omitting manual knot tying

METHODS

Thirteen healthy male pigs were used in this study. Under general anesthesia, chest was opened and left internal thoracic artery (LITA) and right internal thoracic artery (RITA) were harvested in skeletonized fashion. Heart was stabilized with heart positioner and left descending coronary artery (LAD) and right coronary artery (RCA) were dissected. Using coronary shunt and retractor tape, side-to-end anastomoses were done (LITA to LAD, RITA to RCA) (Figure 2). New devices were used in eleven of thirteen pigs (Group D). Conventional polypropylene suture was used in the remain (Group C). (1) Suture time was measured during operation. (2) Blood flow was also measured at graft side after completion of anastomosis. As a chronic experimental model, five pigs of Group D and one pig of Group C were administered 100mg of oral aspirin for one month and (3) angiography was done using C-arm X-ray system after 1 month of operation. After the evaluation, finally pigs were sacrificed (4) anastomotic sites were resected and histologically examined about inflammatory change (Figure 3).

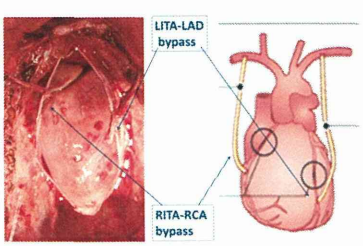
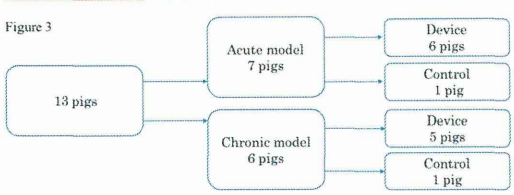


Figure 2
LITA was anastomosed to mid portion of LAD. RITA was anastomosed to proximal part of RCA which is covered by right atrial appendage.

Figure 3



RESULTS

(1) Average suture time using new device was 18.4 ± 1.2 min. in LITA-LAD anastomosis, and 20.1 ± 1.2 min. in RITA-RCA. This times were as equal as conventional samples; 16.0 ± 2.0 min. and 24.5 ± 0.5 min. (Table 1).
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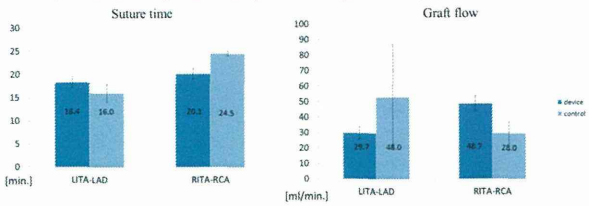

Table 1
Suture time by the device compared with control sample. There no significant difference between these times.

Table 2
Blood flow after anastomosis by the device showed lower compared to control sample in LITA-LAD, and equal in RITA-RCA.

(3) Angiography was performed through femoral artery canulation and selective insertion to bilateral internal thoracic arteries. Anastomosis cite was evaluated by FitzGibbon criteria*. Figure 4 shows samples of angiogram. Table 3 shows all anastomoses evaluated by FitzGibbon criteria.

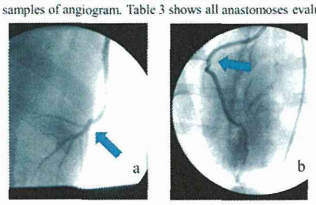

Figure 4
These samples (a; LITA-LAD, b; RITA-RCA) showed FitzGibbon A. Arrows are the suture devices.

*FitzGibbon Criteria
- A: stenosis under 50%
- B: stenosis upper 50%
- C: occlusion

	Acute model		Chronic (1 mo) model		
	LITA-LAD	RITA-RCA	LITA-LAD	RITA-RCA	% of A
Group D (A / B)	6 / 0	5 / 1	5 / 0	5 / 0	21 / 22 (95.5 %)
Group C (A / B)	1 / 0	0 / 1	1 / 0	1 / 0	3 / 4 (75.0 %)
total	7 / 7 (100 %)	5/7 (71.4 %)	6 / 6 (100 %)	6/6 (100 %)	24 / 26 (92.3 %)

[number of anastomosis]

Table 3
FitGibbon B were detected each one RITA-RCA anastomosis in both Group D and Group C acute model. % of criteria A was 95.5% of Group D and 75% of Group C and 92.3% of all anasomotoses.

(4) Pathological study showed common inflammatory response including cell filtration, fibrosis and neointimal hyperplasia. Although foreign bodies such as the suture and the device were likely to lead these responses, there were no specific change by using new devices; invasiveness to vessels and surrounding tissues (figure 5). Inflammatory cells which represented by lymphocyte, gulanurocyte, and macrophages appeared in the hyper field.

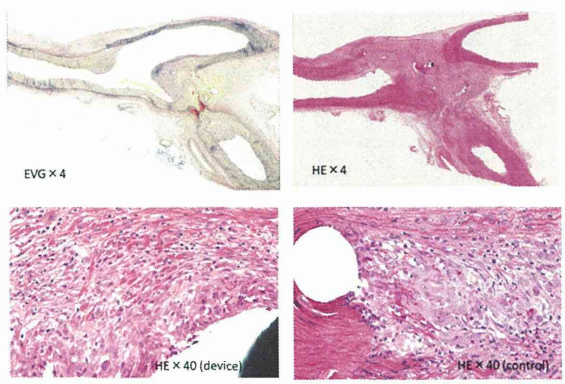

Figure 4
One month after the operation the anastomosis cite was resected and stained by Hematoxylin-eosin and Elastica-van-Gieson stain. a; LITA-LAD anastomotic lumen and intimal hyperplasia were presented. Neointimal hyperplasia was mainly seen at a heel side of the anastomosis. b; Used device were detected nearby anastomosis. c; In the hyper field, around the mechanism, inflammatory cell infiltration and fibrosis were observed. These responses were equally seen in the control sample (d).

Conclusion

It was confirmed that the device we developed has feasibility to use in coronary artery bypass surgery in present acute and mid-term chronic study. Now we are challenging longer period model. Further research is necessary to evaluate efficacy of this device in closed or limited operative space.

日本人工臓器学会
利益相反（COI）開示
筆頭発表者名：井戸田 佳史

演題発表に関連し、開示すべきCOI関係にある企業などはありません。

Department of Cardiac surgery, The University of Tokyo, Hongo 7-3-1, Bunkyo-ku, Tokyo, Japan (corresponding author to provide phone: +81-03-3815-5411, e-mail: inguma@cyahoo.co.jp).

JSAO / IFAO2013


新しい冠動脈吻合用デバイスの研究
~ブタ冠動脈バイパス手術での前臨床試験~
Development of A New Device for Distal Coronary Artery Anastomosis
○井戸田佳史[a], Nirmal Panthee[a], 安藤岳洋[b], 佐久間一郎[b], 小野稔[a]
[a]東京大学 心臓外科
[b]東京大学工学部精密工学科
Yoshifumi Itoda[a], Nirmal Panthee[a], Takehiro Ando[b], Ichiro Sakuma[b], and Minoru Ono[a]
[a] Department of Cardiac Surgery, The University of Tokyo, Tokyo, Japan
[b] Department of Precision Engineering, The University of Tokyo, Tokyo, Japan
東京大学
THE UNIVERSITY OF TOKYO
日本コンピュータ外科学会
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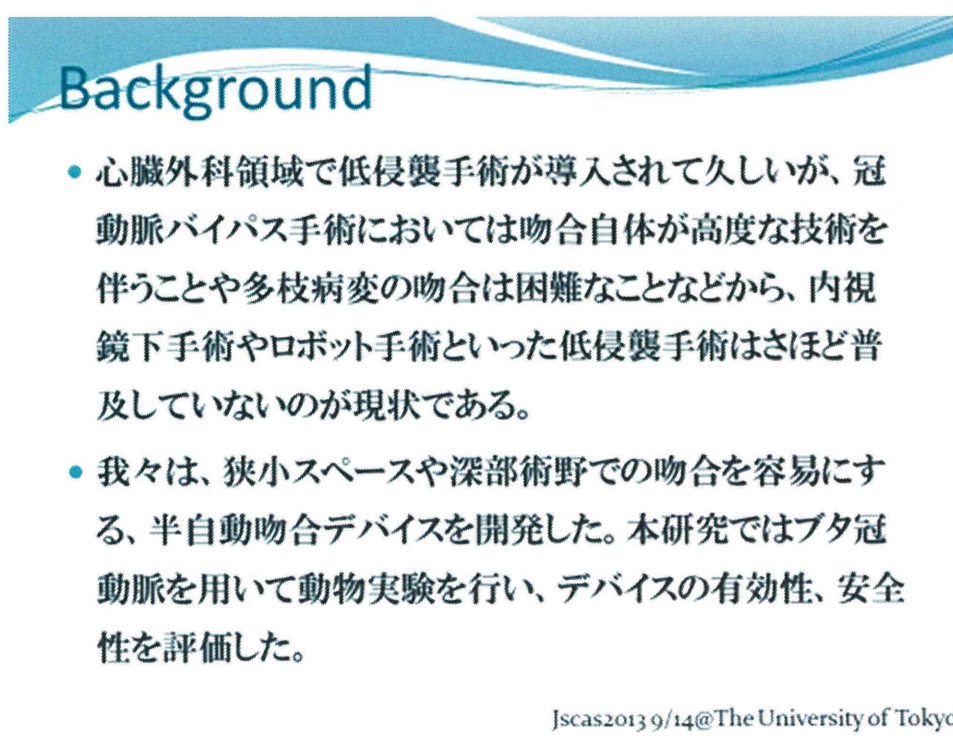
Background
• 心臓外科領域で低侵襲手術が導入されて久しいが、冠動脈バイパス手術においては吻合自体が高度な技術を伴うことや多枝病変の吻合は困難なことなどから、内視鏡下手術やロボット手術といった低侵襲手術はさほど普及していないのが現状である。
• 我々は、狭小スペースや深部術野での吻合を容易にする、半自動吻合デバイスを開発した。本研究ではブタ冠動脈を用いて動物実験を行い、デバイスの有効性、安全性を評価した。
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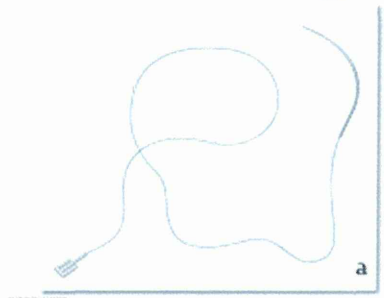
Device Design



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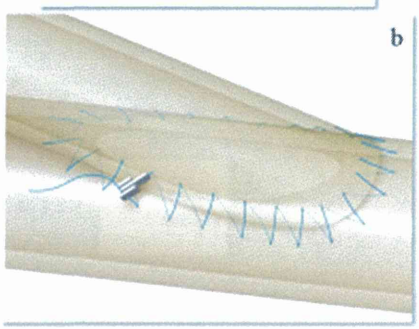
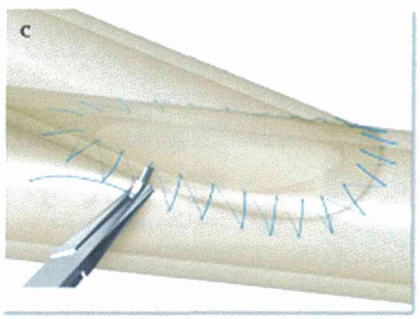
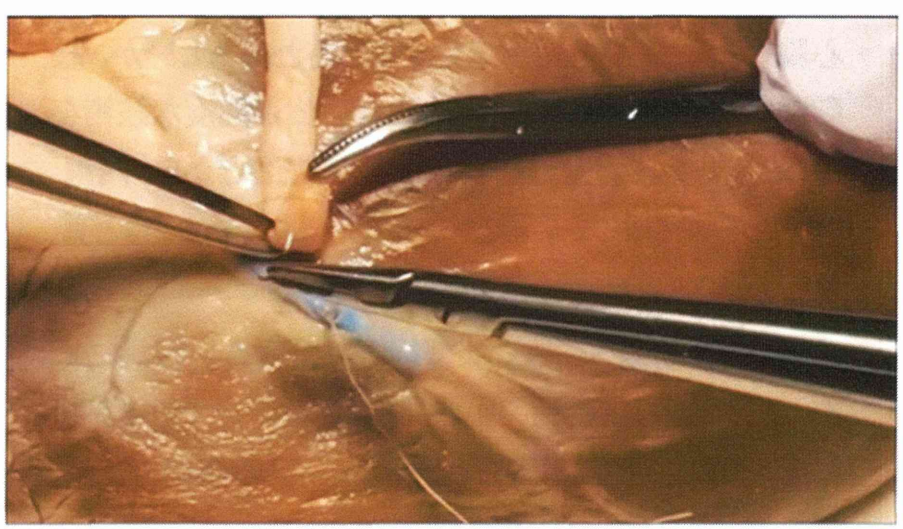




Anastomosis procedure



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Experimental protocol

- 急性期および慢性期におけるブタ冠動脈吻合実験。
- 全身麻酔下に開胸、両側内胸動脈を剥離し LITA-LAD及びRITA-RCA吻合を施行。
- 13頭のブタを用い、11頭はデバイスを用いて吻合(D群) 残りの2頭については従来のpolypropylene糸を用いて吻合(C群)。吻合時間およびgraft flowを計測。
- 急性期実験としてD群のうち6頭とC群のうち1頭は吻合後に血管造影検査を施行。
- 慢性期実験として残りのD群5頭とC群1頭は1ヶ月後に血管造影を行い、安楽死後吻合部を切除し病理評価を行った。

Experimental protocol