

A new suture for distal coronary artery anastomosis

Minoru ONO, Yoshifumi ITODA, Panthee NIRMAL,
Takehiro ANDO, Ichiro SAKUMA

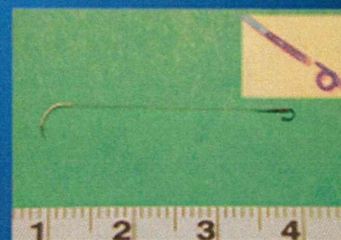
Department of Cardiac Surgery
& Scholl of Engineering
The University of Tokyo, Tokyo, Japan



1

Background

Several distal anastomotic devices have been introduced to facilitate endoscopic/robotic coronary artery anastomosis. U-Clip had been widely applied for this purpose, but withdrawn from the market. C-Port connector is an only device used clinically. We developed a suture for distal coronary anastomosis, which eliminates knot tying after continuous anastomosis.



Characteristics of this suture device

- Easy to manufacture
- Low cost
- No complicated or bulky mechanism
- Simple use (no specific instruction-for –use)
- Enables hand-sewing
- Continuous, interrupted suture, or whatever
- Eliminates knot tying
- Enables distal coronary anastomosis in a limited space

5

Chronic animal model

- ✓ Miniature swine (BW 25-30 kg)
- ✓ Off-pump CABG (LITA-LAD & RIMA-RCA)
- ✓ New suture device (n = 11) vs. Regular 8-0 (n = 3)
- ✓ Timing of evaluation: 1, 3, and 6 months
 1. Survival and adverse events
 2. Graft patency by angiogram
 3. Device failure
 4. Histopathology: inflammatory reaction & invasiveness of anchor mechanism

6

Graft patency by FitzGibbon criteria

	1 mo model		3 mo model		6 mo model		% of A
	LITA-LAD	RITA-RCA	LITA-LAD	RITA-RCA	LITA-LAD	RITA-RCA	
Device (A/B)	5/0	5/0	4/0	4/0	2/0	2/0	22/22 (100%)
Control (A/B)	1/0	1/0	1/0	1/0	1/0	1/0	6/6 (100%)
% of A	6/6 (100%)	6/6 (100%)	5/5 (100%)	5/5 (100%)	3/3 (100%)	3/3 (100%)	28/28 (100%)

Summary of results

- No operative death or late death
- No adverse events
- 100% patency in all anastomoses
- No device fracture or vessel wall invasion
- Similar common inflammatory change
- No thrombus formation at an anastomosis

Conclusion

Safety, feasibility and durability of this new suture device were shown in chronic miniature swine OPCAB model. This may be a promising distal suture device for CABG in a limited space, such as endoscopic or robotic CABG.

9

Novel suturing device for distal coronary artery anastomosis: Preclinical results from swine off-pump coronary bypass model

Yoshifumi Itoda¹, Nirmal Panthee¹, Tsuruhito Tanaka¹, Takehiro Ando²,
Ichiro Sakuma², and Minoru Ono¹

¹ Department of Cardiac Surgery, The University of Tokyo, Tokyo, Japan

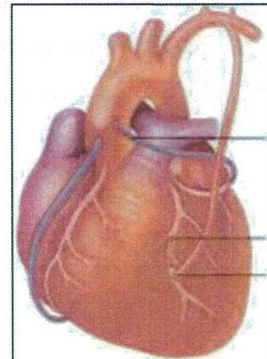
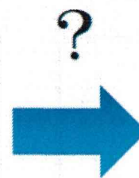
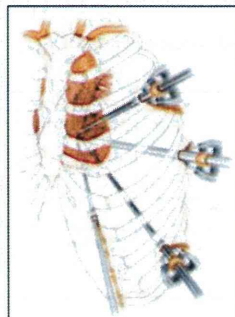
² Faculty of Engineering, The University of Tokyo, Tokyo, Japan



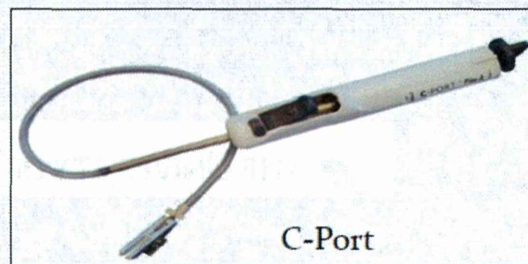
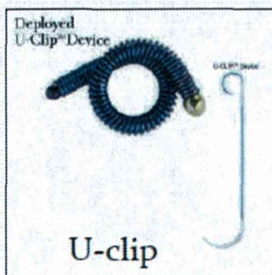
2014 10/13 28th EACTS @ Milan, Italy

Background

- Minimally invasive surgery for CABG...

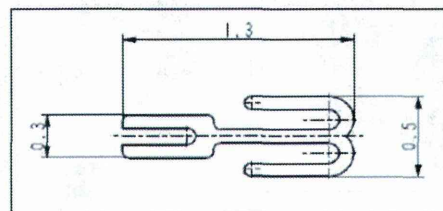
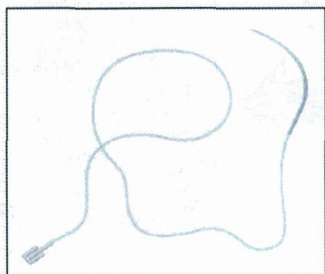


Background



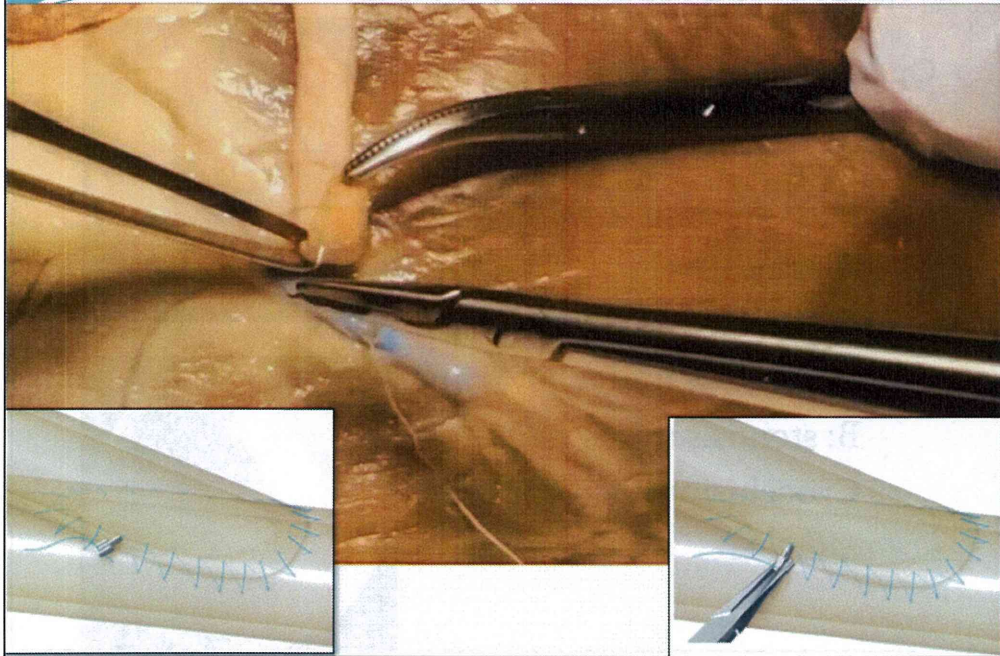
Device design and concept

- ✓ Easily manufactured by laser molding according to CAD
- ✓ This suturing device facilitates running suture which is the most familiar to surgeons.
- ✓ Allow omitting knot tying
- ✓ Allow Various suturing techniques (running, interrupted)
- ✓ Enable running suture in a limited space



- SUS316L stain-less steel
- Anchor shaped mechanism

Anastomotic method



Experimental protocol

- To evaluate safety and feasibility of the device
- Clawn miniature pig, 25-30kg, male
- Harvesting bilateral ITAs
- Off-pump CABG, LITA-LAD and RITA-RCA
- Device group n=11
- Control group (7-0 Prolene®) n=3
- Number of animals

	1 month	3 months	6 months
Device	5	4	2
Control	1	1	1

Experimental protocol

- Operative evaluation
 - suturing time
 - graft flow
- Chronic evaluation (1, 3, 6 mos)

angiography

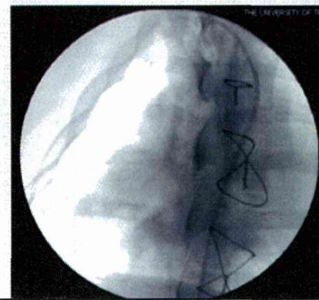
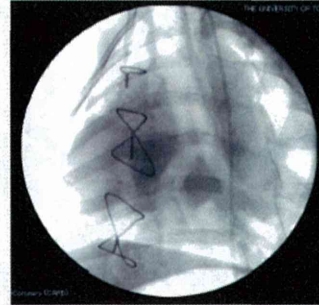
FitzGibbon criteria

A: stenosis under 50%

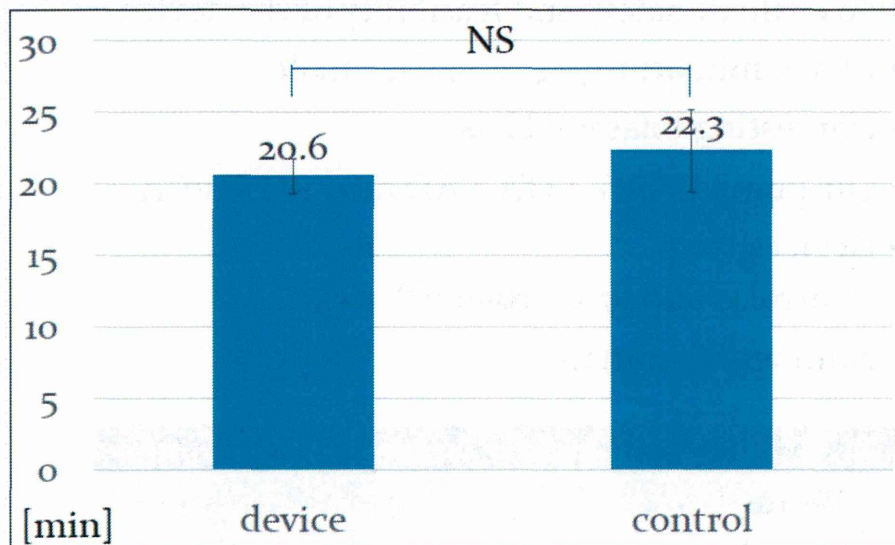
B: stenosis upper 50%

C: occlusion

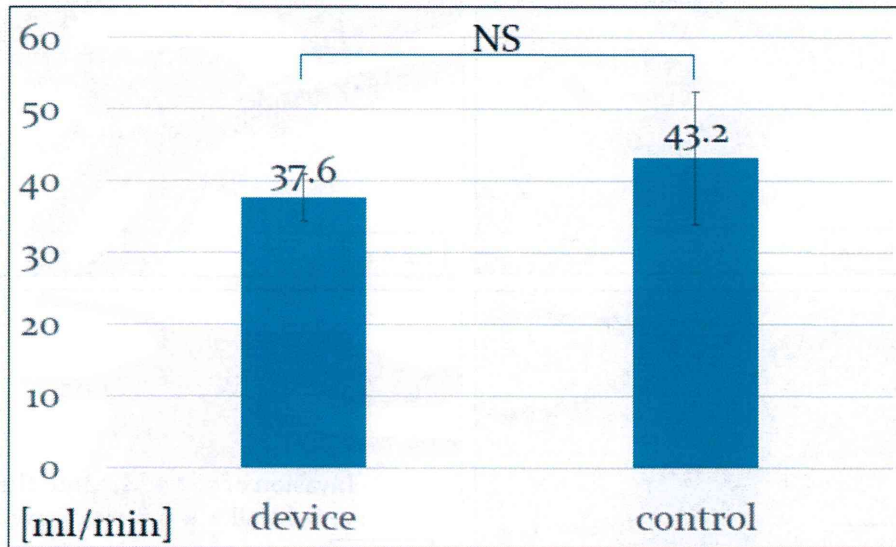
histopathology



Results - suturing time -



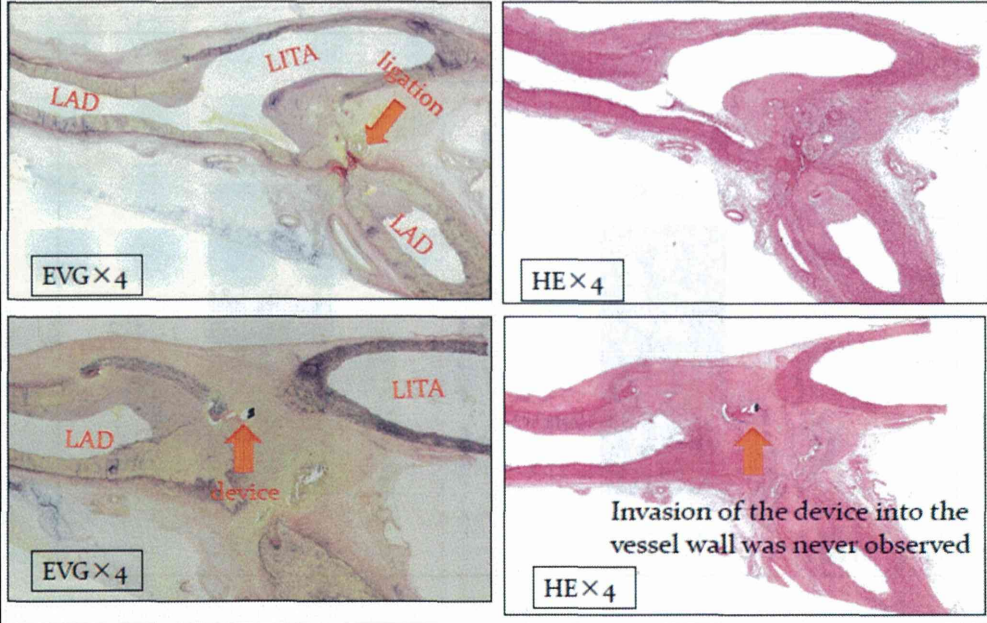
Results - graft flow -



Results - Angiography -

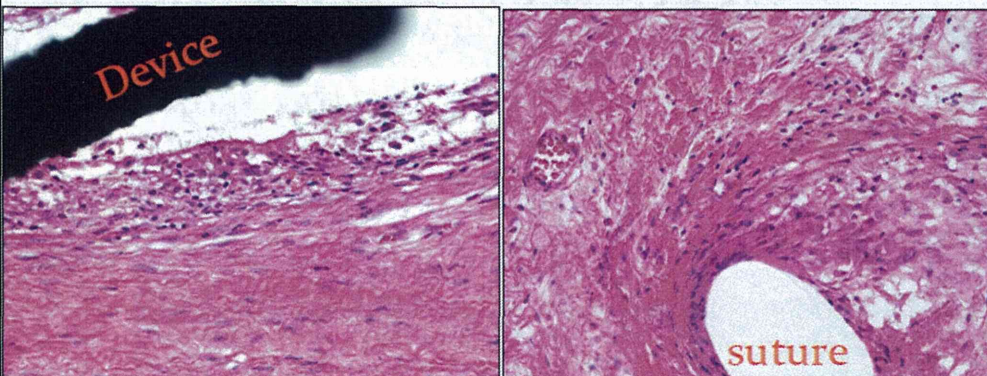
	1 mo		3 mo		6 mo		% of A
	LITA-LAD	RITA-RCA	LITA-LAD	RITA-RCA	LITA-LAD	RITA-RCA	
Device	5	5	4	4	2	2	22 / 22 (100%)
Control	1	1	1	1	1	1	6 / 6 (100%)

Results -histopathology-

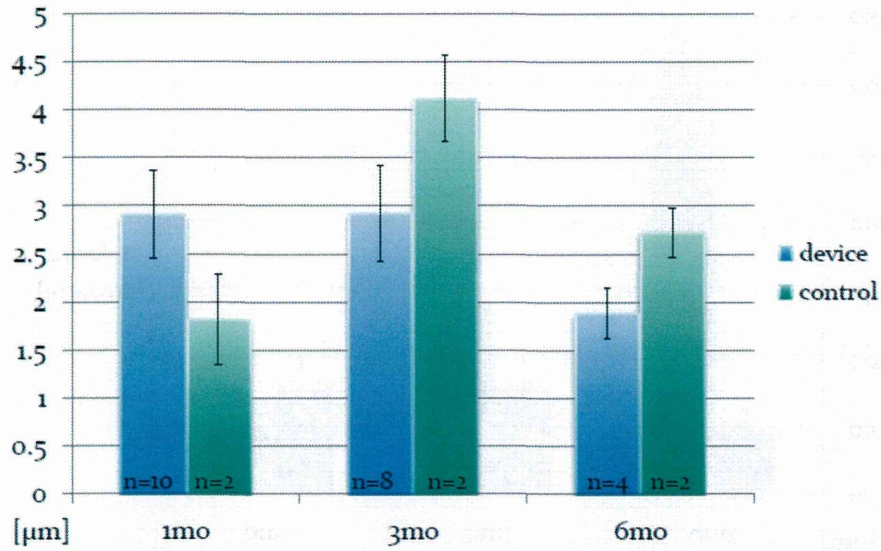


Results -histopathology-

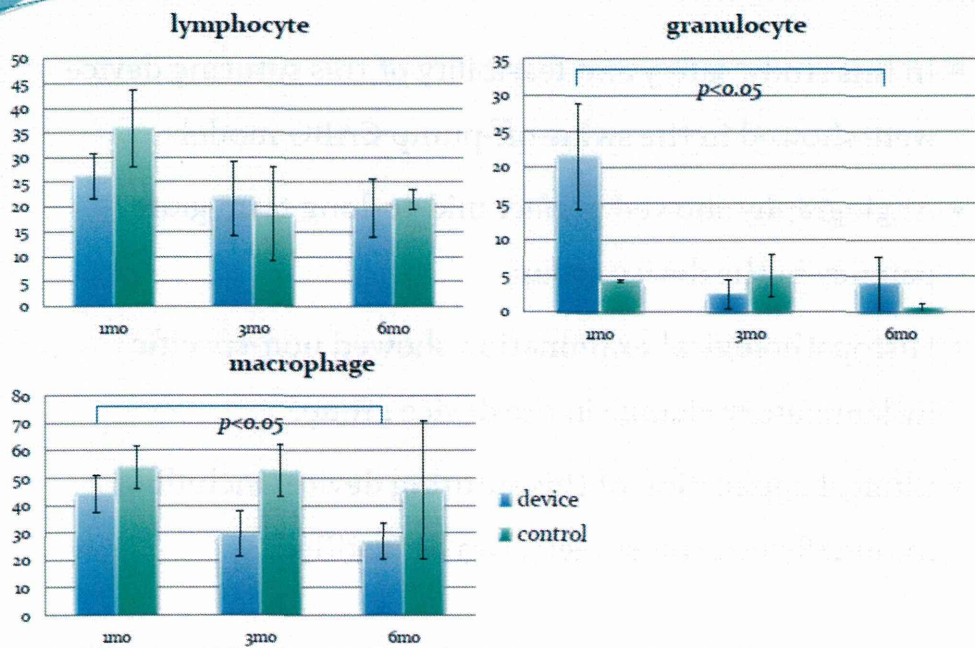
Device group HE ($\times 40$) Control group HE ($\times 40$)



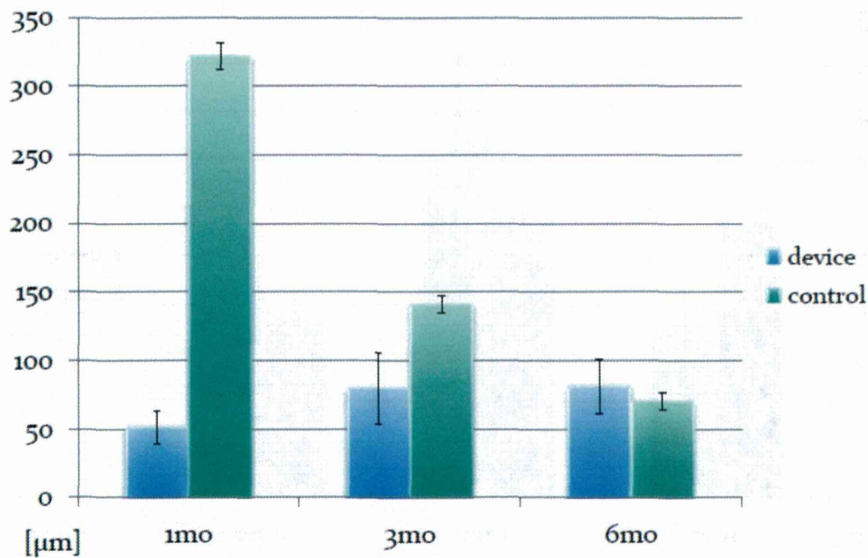
Results -intimal hyperplasia-



Results -inflammatory cell infiltration-



Results –fibrosis-



Conclusion

- In this study, safety and feasibility of this suturing device were showed in the swine off-pump CABG model.
- Angiography showed perfect mid-to-long term graft patency in the device group.
- Histopathological examination showed non-specific inflammatory change in the device group.
- Clinical application of this suturing device, including minimally invasive surgery, can be justified.



THE UNIVERSITY OF TOKYO

新しい冠動脈半自動吻合デバイスの研究 内視鏡下ウサギ頸動脈モデルにおける 前臨床試験中間報告

○近藤 良一¹、井戸田 佳史²、田中 鶴人³、Nirmal Panthee⁴、月原 弘之⁵、縄田 寛⁶、
芦葉 裕⁷、安藤 岳洋⁸、小林 英津子⁹、佐久間 一郎¹⁰、小野 稔¹¹
¹東京大学医学部附属病院 心臓外科
²東京大学工学部 精密工学科

2015 Feb. 18 45th The annual meeting of JSCVS in Kyoto

【背景】

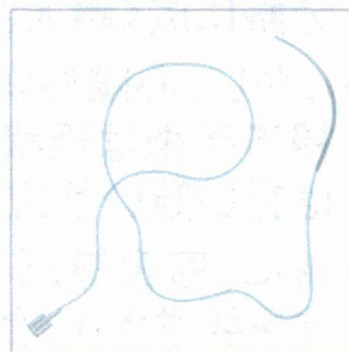
- 低侵襲手術として、鏡視下手術は外科分野に広く導入されている。
- しかし、心臓外科領域においては、鏡視下手術は現状さほど普及しているとは言い難い状況である。
- 特に、冠動脈バイパス手術は繊細な操作を要求され、鏡視下手術は非常に困難である。

【目的】

- 鏡視下吻合の簡易化を目指し、東京大学工学部との連携により、冠動脈半自動吻合デバイスを開発した。
- 本研究では、内視鏡下ウサギ頸動脈モデルを用いて、冠動脈半自動吻合デバイスの有効性を評価した。

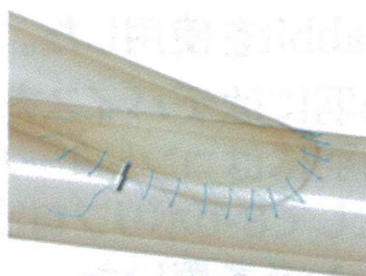
〔デバイス概要〕

- 針付ポリプロピレン縫合糸の針の対側に、ステンレス製の錨状の器具を装着した構造。



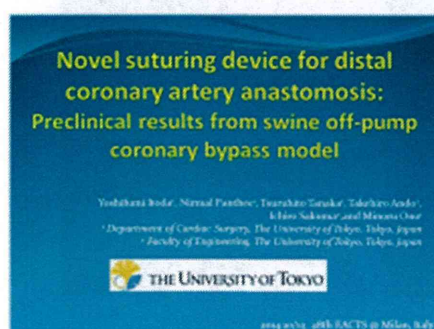
〔デバイス吻合方法〕

- パラシュート法で吻合を開始し、連続縫合を行う。
- 結紮の代わりに錨状部分の溝に糸を挟み、持針器でつまむことで糸と錨状部分を固定する。



〔直視下デバイス吻合実験〕

<28th EACTS>



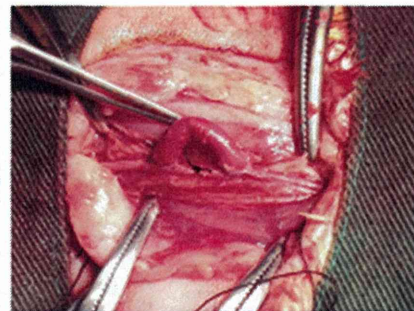
- Clawn Mini-pigに対して直視下で、デバイス、7-0ポリプロピレン糸を用いてCABGを施行。
- 吻合時間、血液流量、血管造影にて非劣性が示された。
- 病理評価にてデバイスに特異的な内膜変化はなく、安全性が示された。

〔鏡視下デバイス吻合実験〕

- New Zealand white rabbitを使用した。
- 9羽にはデバイスを、9羽にはコントロールとして8-0ポリプロピレン糸を用いた。



- 右側頸動脈に右側頸静脈をブリッジ状に吻合した後、頸動脈は離断した。
- 中枢側及び末梢側吻合時間、手術時間、血液流量を比較した。

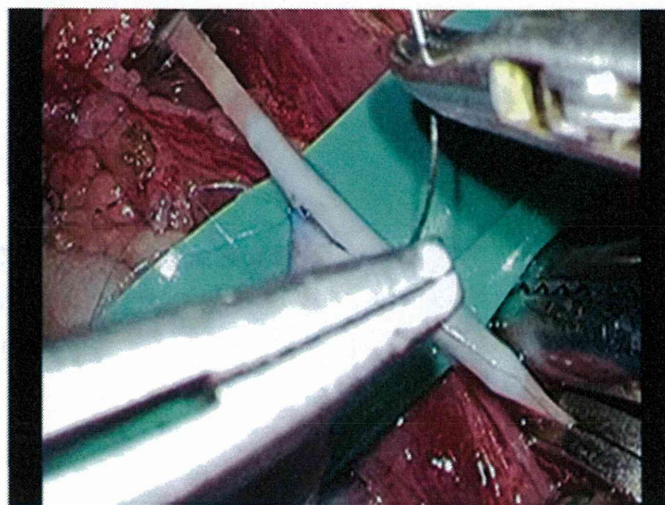


【手術】

- 静脈採取、動脈露出は直視下で行い、吻合の段階で内視鏡ボックスで覆い、鏡視下手術環境を再現した。

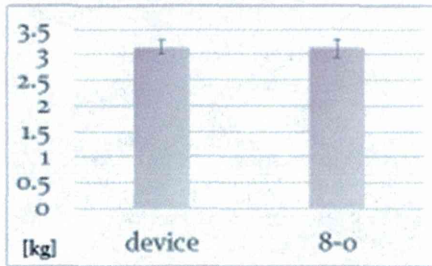


〔手術動画〕



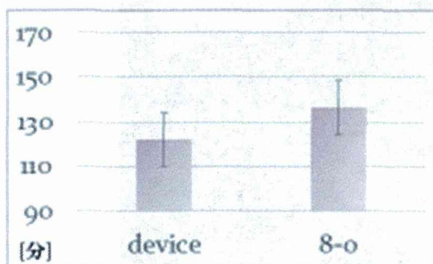
【結果】

〔体重〕



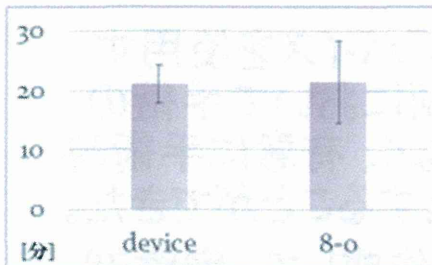
device: $3.14 \pm 0.13\text{kg}$
8-0 : $3.13 \pm 0.18\text{kg}$
($p=0.89$)

〔手術時間〕



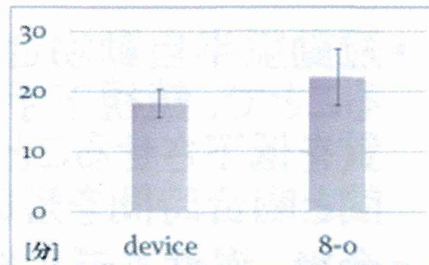
device: $121.89 \pm 11.90\text{分}$
8-0 : $136.56 \pm 11.80\text{分}$
($p=0.025$)

〔中枢側吻合時間〕



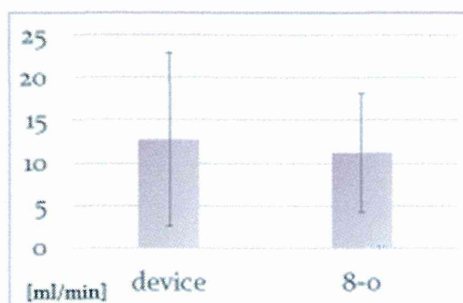
device: 21.11 ± 3.28 分
8-0 : 21.33 ± 6.99 分
($p=0.94$)

〔末梢側吻合時間〕



device: 18.00 ± 2.40 分
8-0 : 22.33 ± 4.78 分
($p=0.036$)

〔血液流量〕



device:
 12.78 ± 10.20 ml/min
8-0:
 11.22 ± 6.92 ml/min
($p=0.73$)

※Veri-Q*を用いて測定