

DAS 2017

October 19th, 2017 14:00~15:00

Room 1

New devices and new technique

**Effectiveness of super-non-compliance balloon
by the Gradual Expansion Technique
(GET : Ikeda method) in animal model**

Ikeda Vascular Access Dialysis and Internal Medicine Clinic

Kiyoshi Ikeda M.D.

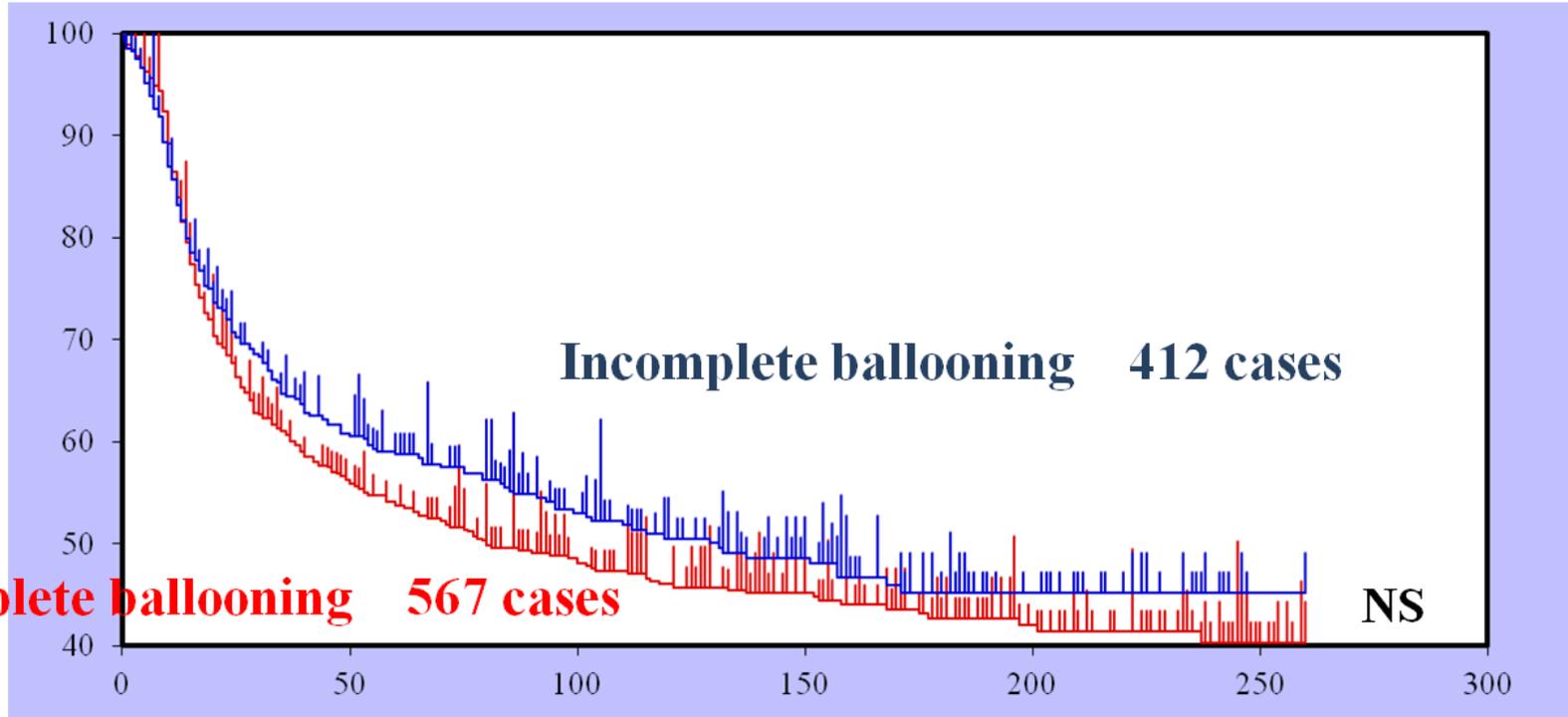
Second Department of Pathology, Akita University School of Medicine

Masato Takahashi M.D. Ph.D. , Yukinobu Ito M.D.



Fig.1:Primary patency from 2003 to 2010 Cases :AVF 979

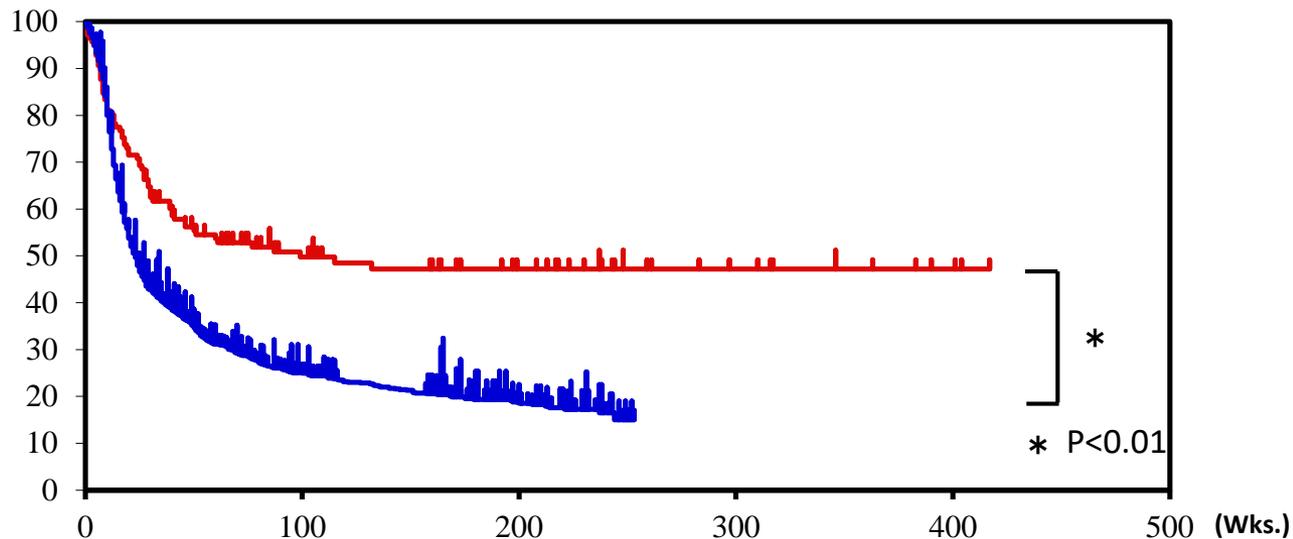
(%)



(days)

In 2012 at EDTA

Fig.2:Primary patency From 2003 to 2010 Cases :AVF 979



— Under 5 atm : 140 cases

— Over 6 atm : 839 cases

Ikeda method (Gradual Expansion Technique : GET)

2014.8.7 PTA

DORADO 5mmX4cm

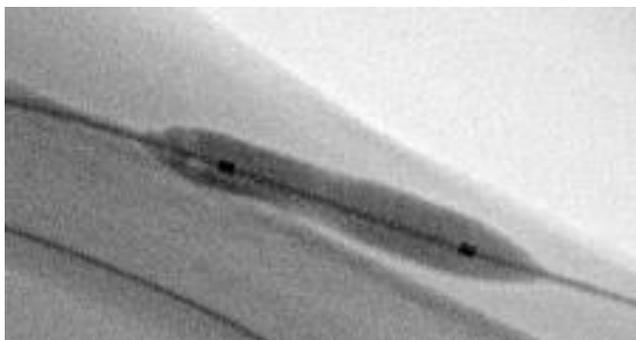


Super-non-compliance balloon vs Others

Dog-bone phenomenon

As shown in the figure, when using a semi-compliance balloon that looks like it is being bitten by a dog, causes intimal injury and the main objective is not achieved due to the fact that the balloon expands beyond the optimal size.

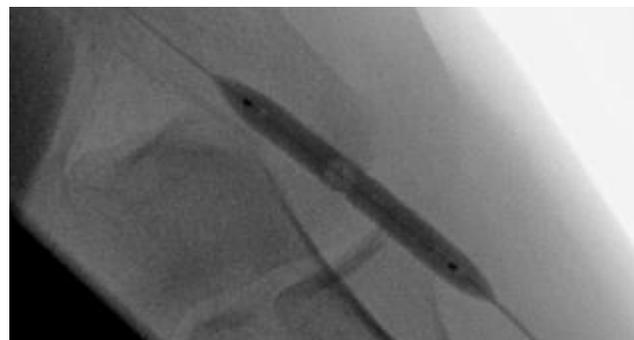
Semi-compliance balloon



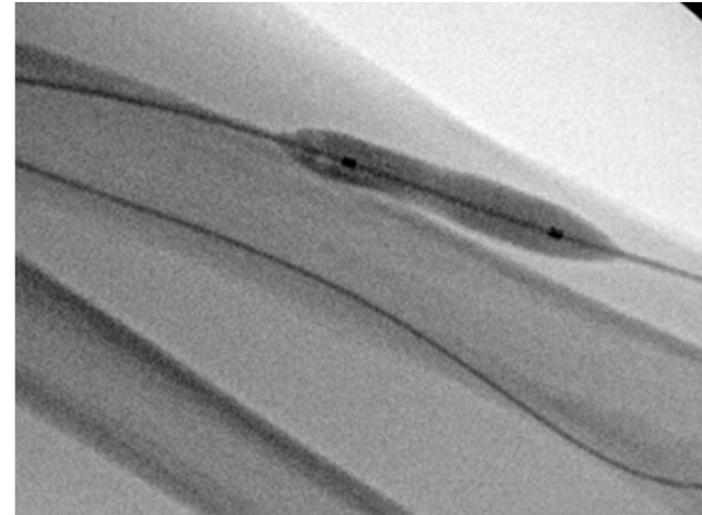
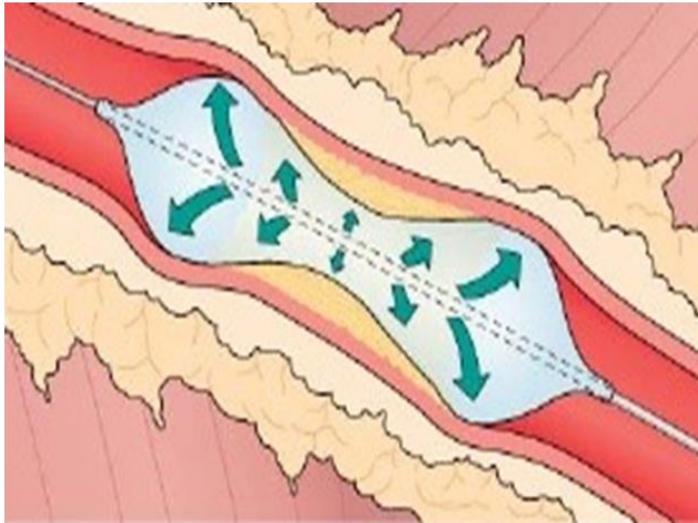
Super-non-compliance Balloon

As shown in the figure, using a super-non-compliance balloon eliminates the occurrence of dog bone phenomenon. Vein damage is also avoided because the balloon is limited in its expansion.

Super-non-compliance balloon



We have to understand the dog-bone phenomenon. As you can see, Semi-compliant balloon can't expand effectively at the stenosis points because of their dog-bone phenomenon. Compliance balloons cause damage around the point of stenosis when they are used under high pressure. We want to expand only stenosis points in order to minimize the damage as much as we can. So, we usually use super-non-compliance balloon (Conquest, Drado, Yoro), because they never expand more than their size.



Semi-compliance-balloon

【Hypothesis】

- #1 Depending on balloon technique intima-media damage can be reduced.
- #2 Device specificity affects intima-media damage.

Based on the hypothesis, I commissioned two experiments that were performed by Dr. Masato Takahashi and Dr. Yukinobu Ito from Second Department of Pathology at Akita University School of Medicine.

For the past 20 years, they have studied about Blood Flow Stimulates and Progressive Intimal Thickening by creating arteriovenous anastomosis in Japanese male rabbits.

In the first experiment

We investigated morphological differences of gradual expansion method (known as ikeda method) vs high pressure single expansion method.



【Method 1】

(First experiment)

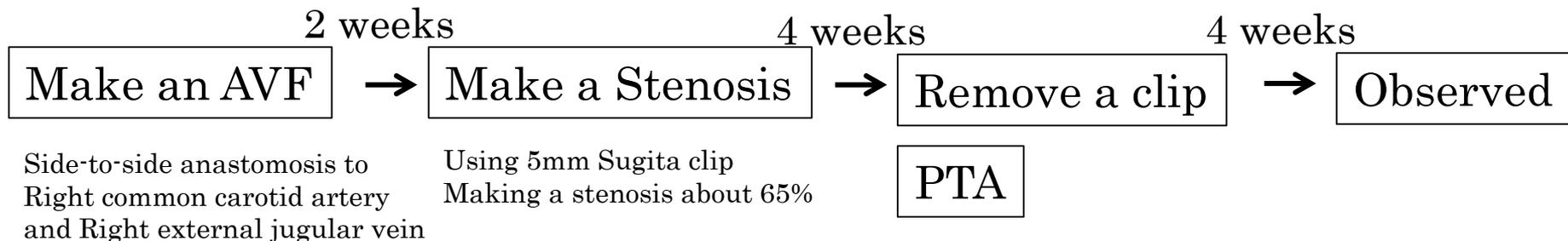
Experimental model:

Japanese white male rabbits (3-4kg) (n=6)

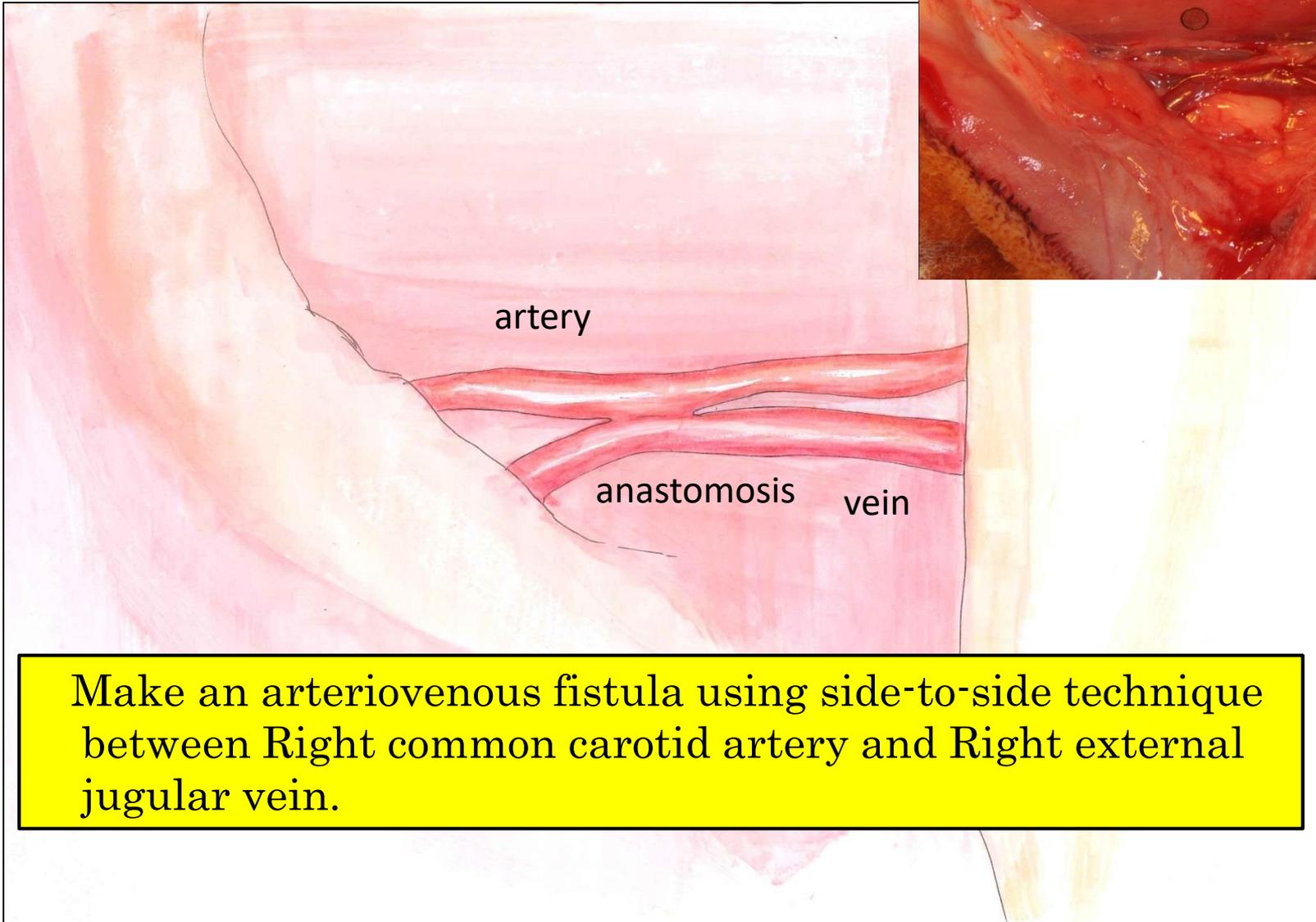
Different expansion technique

High pressure single expansion (n=3)

Ikeda method (n=3)

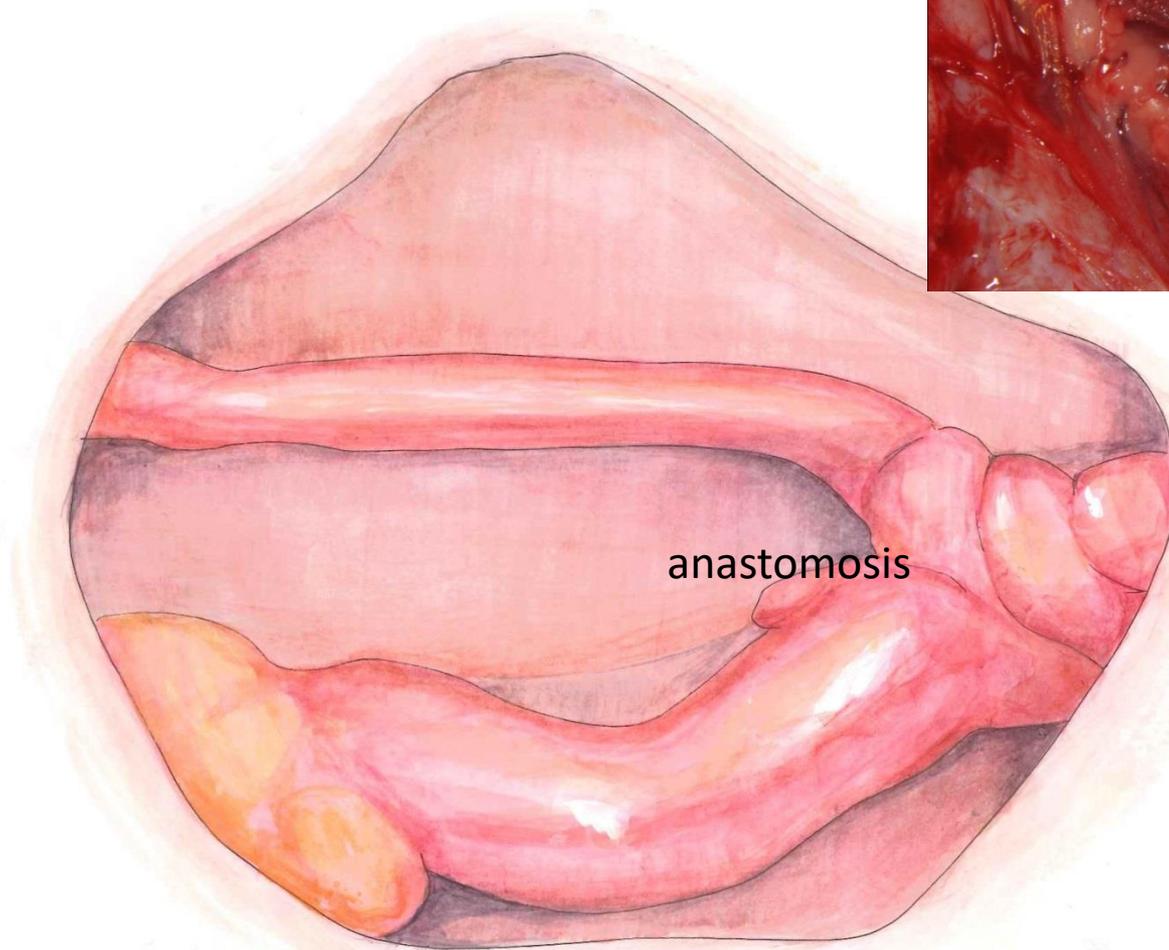
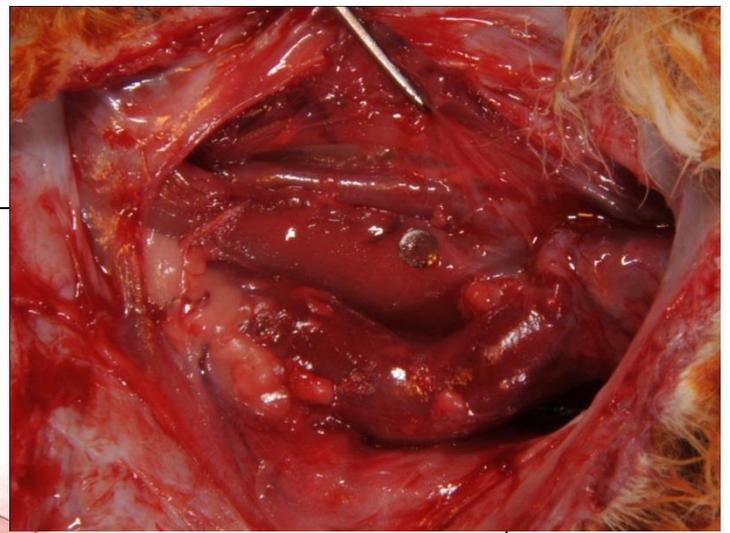


1. Make an AVF



Make an arteriovenous fistula using side-to-side technique between Right common carotid artery and Right external jugular vein.

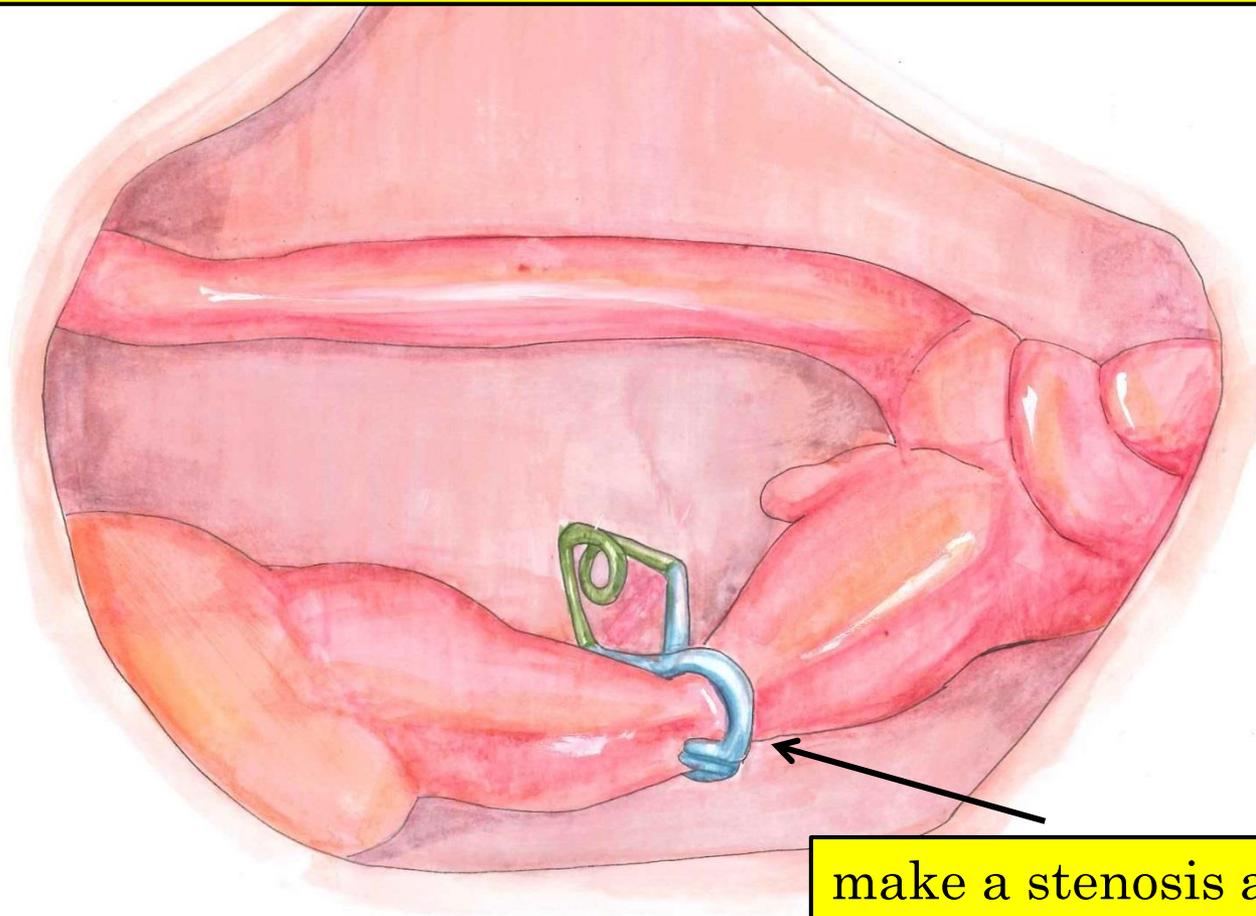
2. After 2 weeks make a AVF



The venous expanded from 2mm to 10mm after 2 weeks.

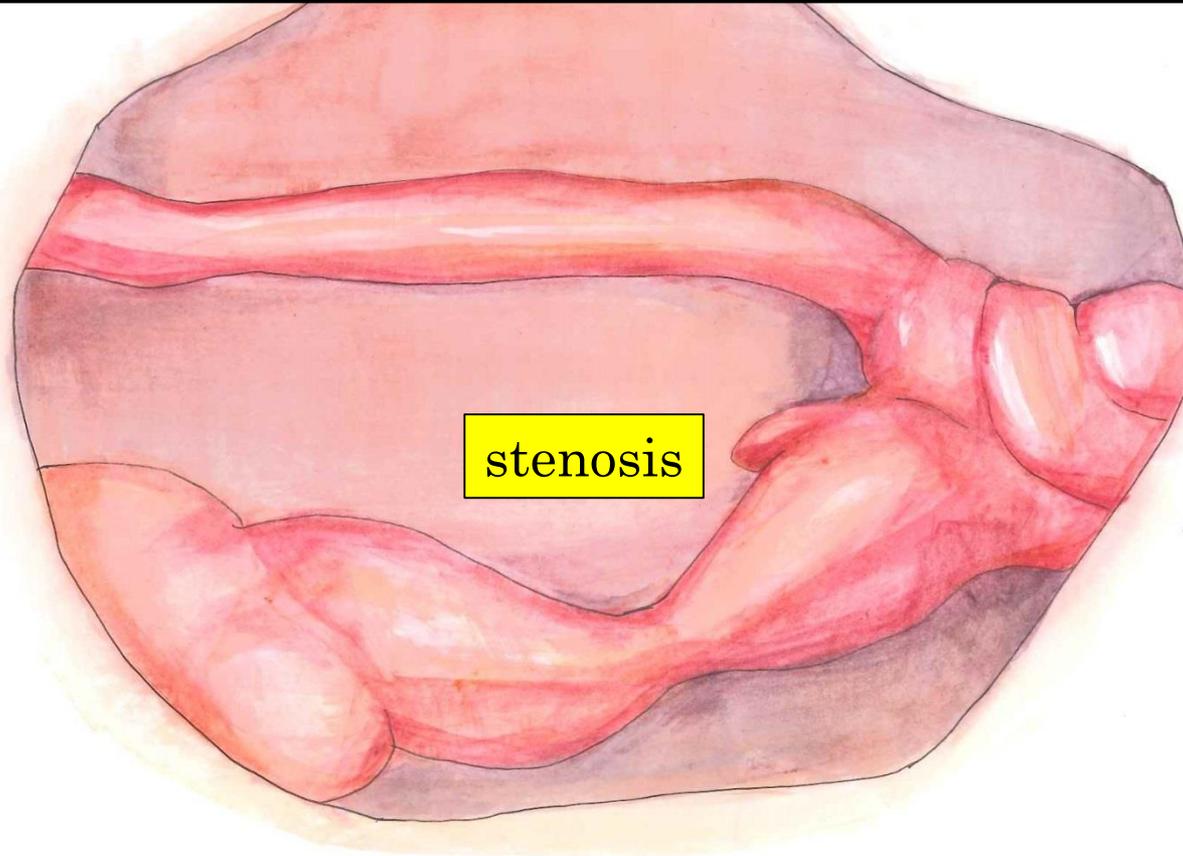
3. Make a stenosis using a Sugita clip

After 2 weeks, make a stenosis to the venous heart side using Sugita clip. Using a diameter 3.5mm Sugita clip and then make a stenosis about 65%.

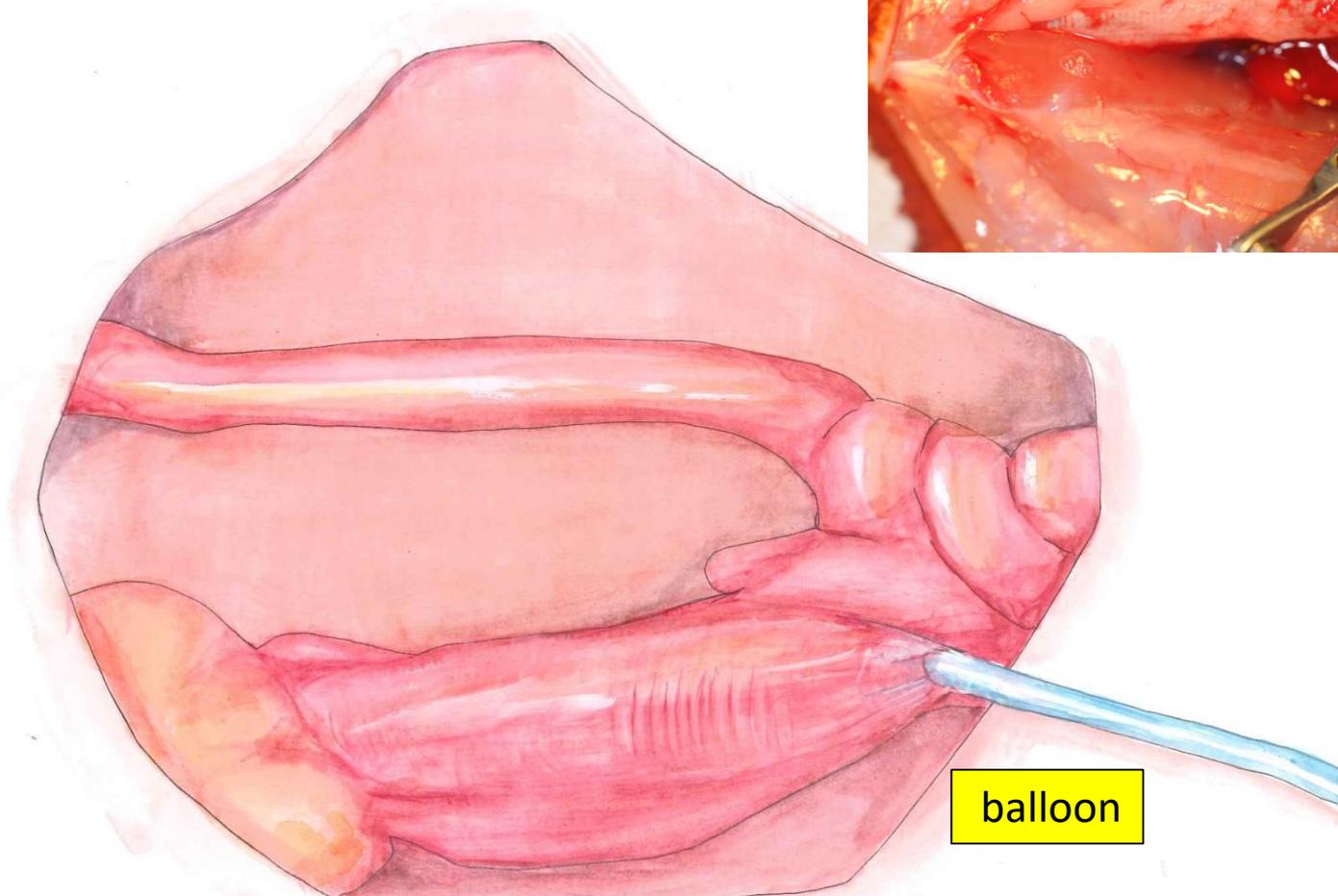
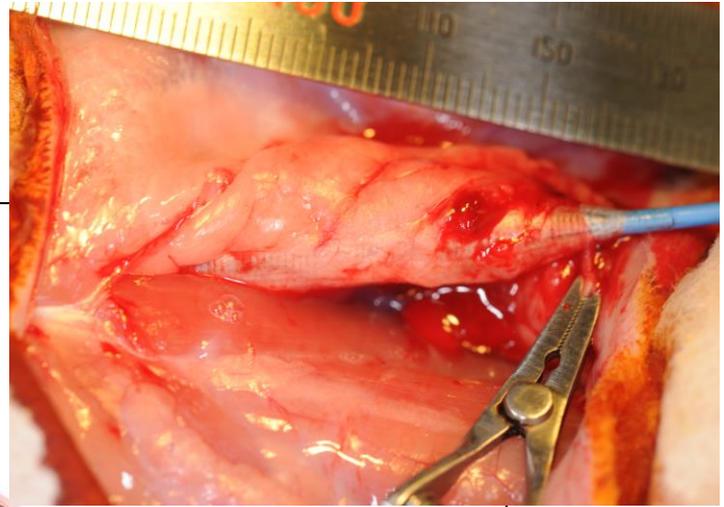


4. Remove Sugita clip after 4 weeks making a stenosis

Using a diameter 3.5mm Sugita clip and then make a stenosis about 65%.
After 4 weeks, remove the Sugita clip.



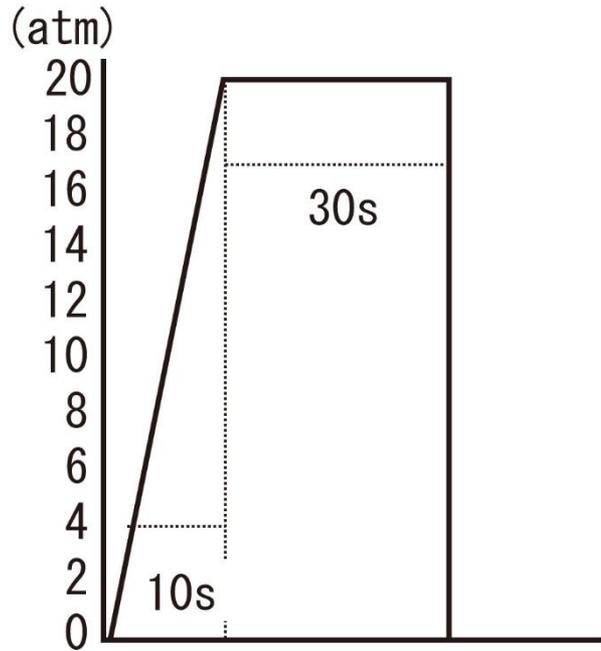
5. Expand by 10mm balloon



- ① High pressure single expansion and Ikeda method
- ② Super-non-compliance balloon and semi-compliance balloon

Fig.3: How to expansion of First Experiment

< High pressure
single expansion >



< Ikeda method >

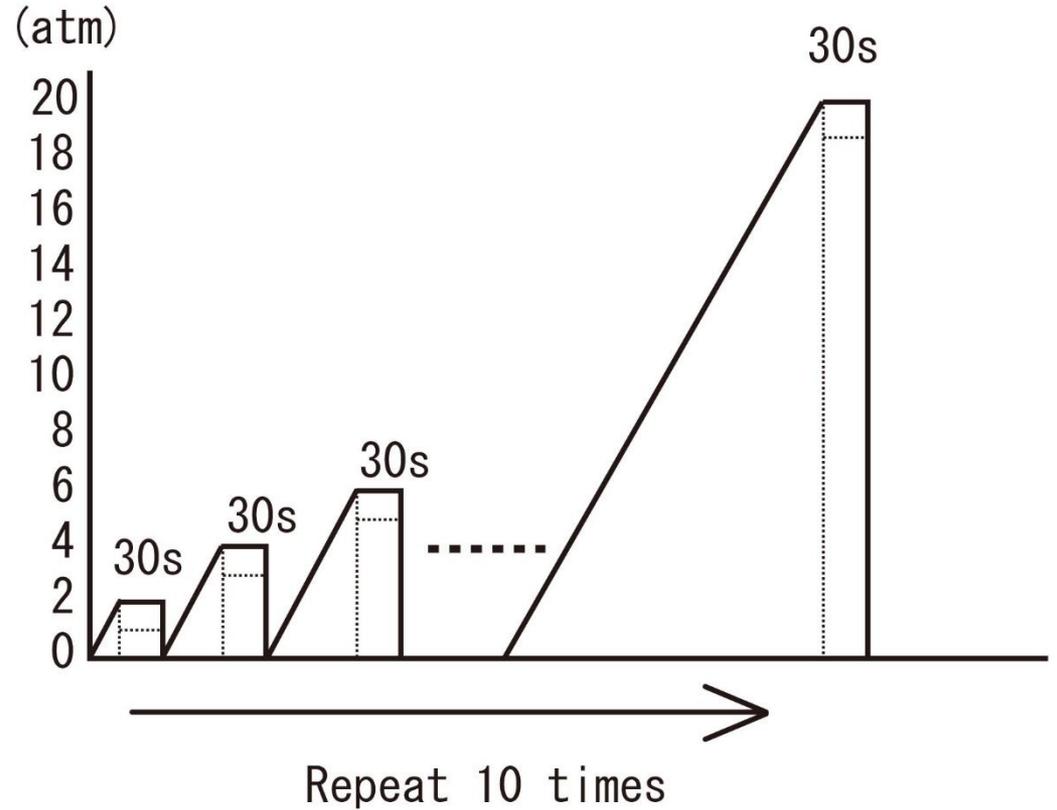
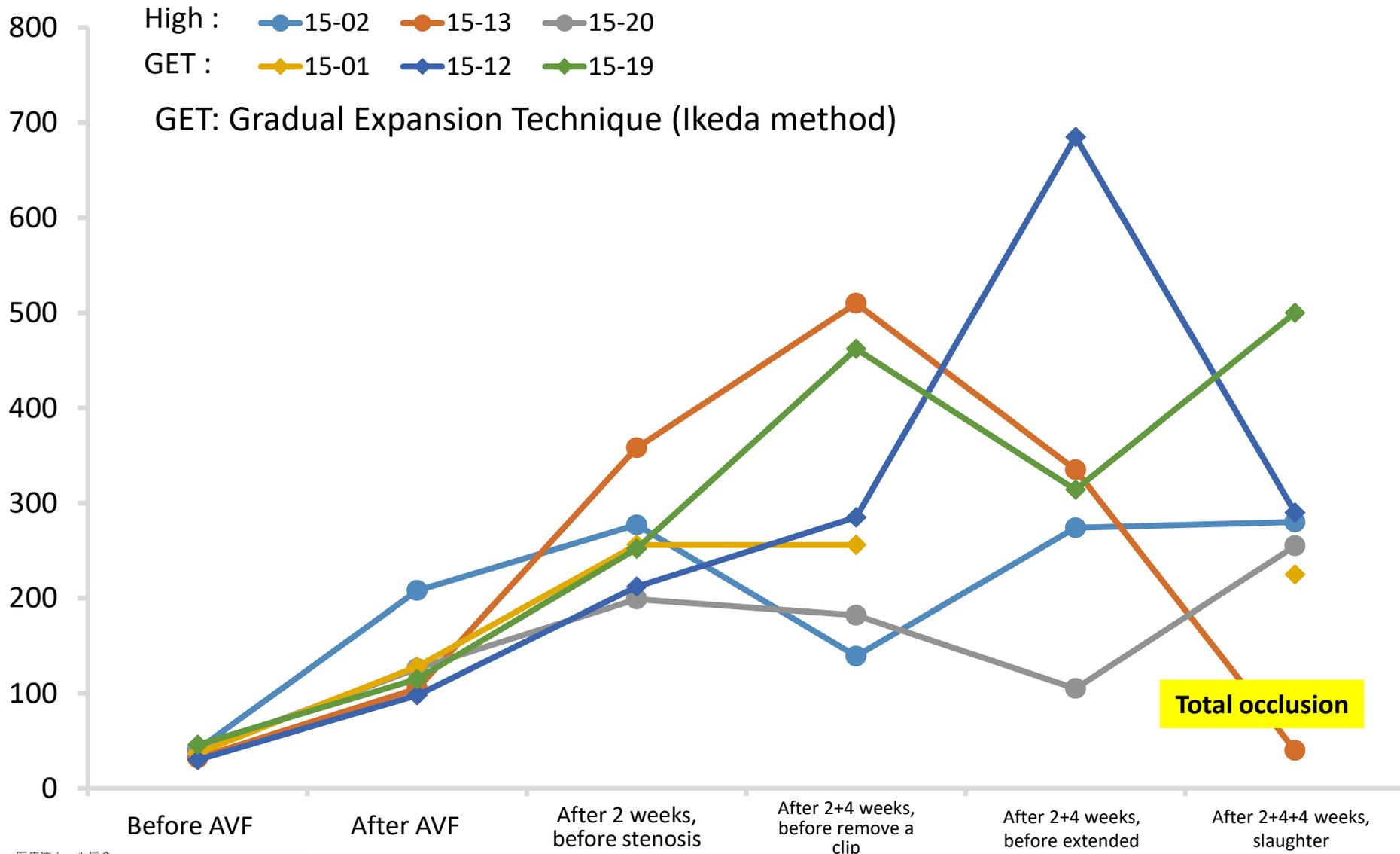


Fig. 4 : Comparison of blood flow among 6 rabbits



【Results 1】

(First experiment)

An occlusion was observed in the rabbit that the high pressure single expansion method was used on.

But the other 5 rabbits showed regular flow volume.

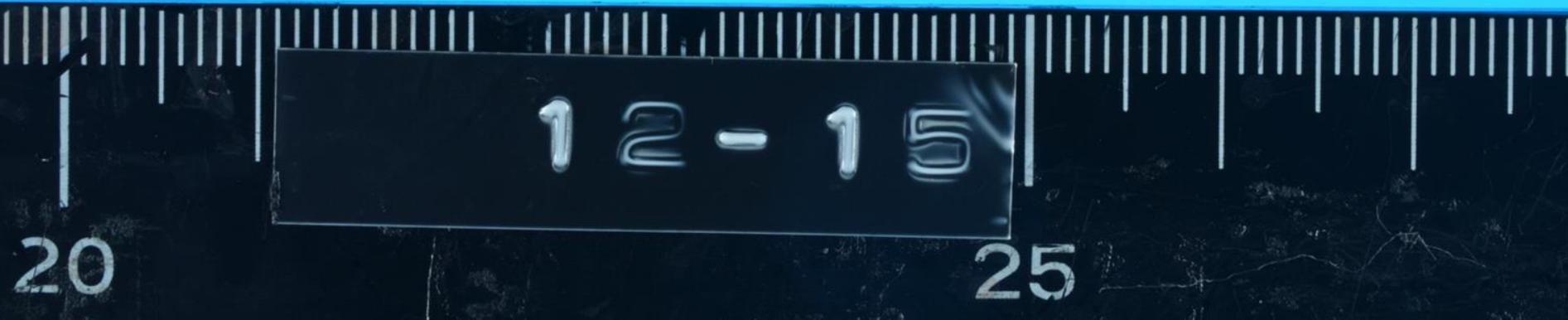
Ikeda method

Common carotid artery

stenosis

AVF

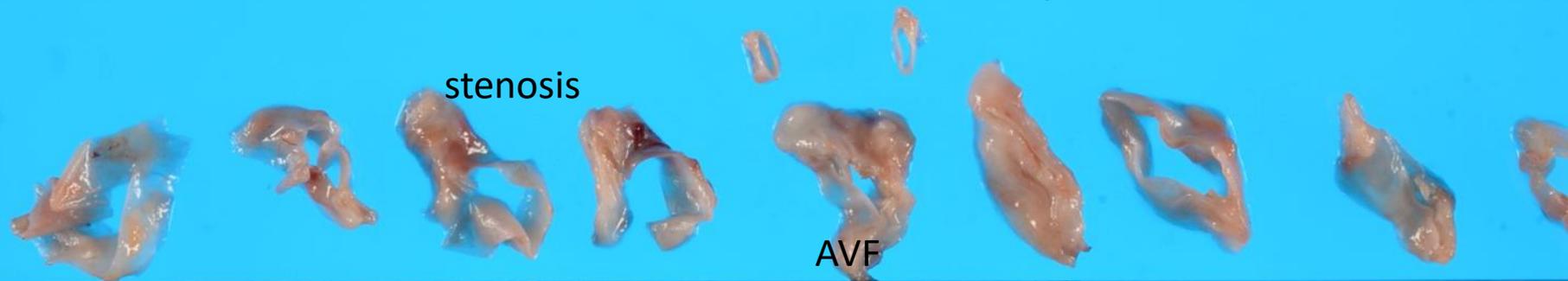
Jugular vein



Common carotid artery

stenosis

AVF

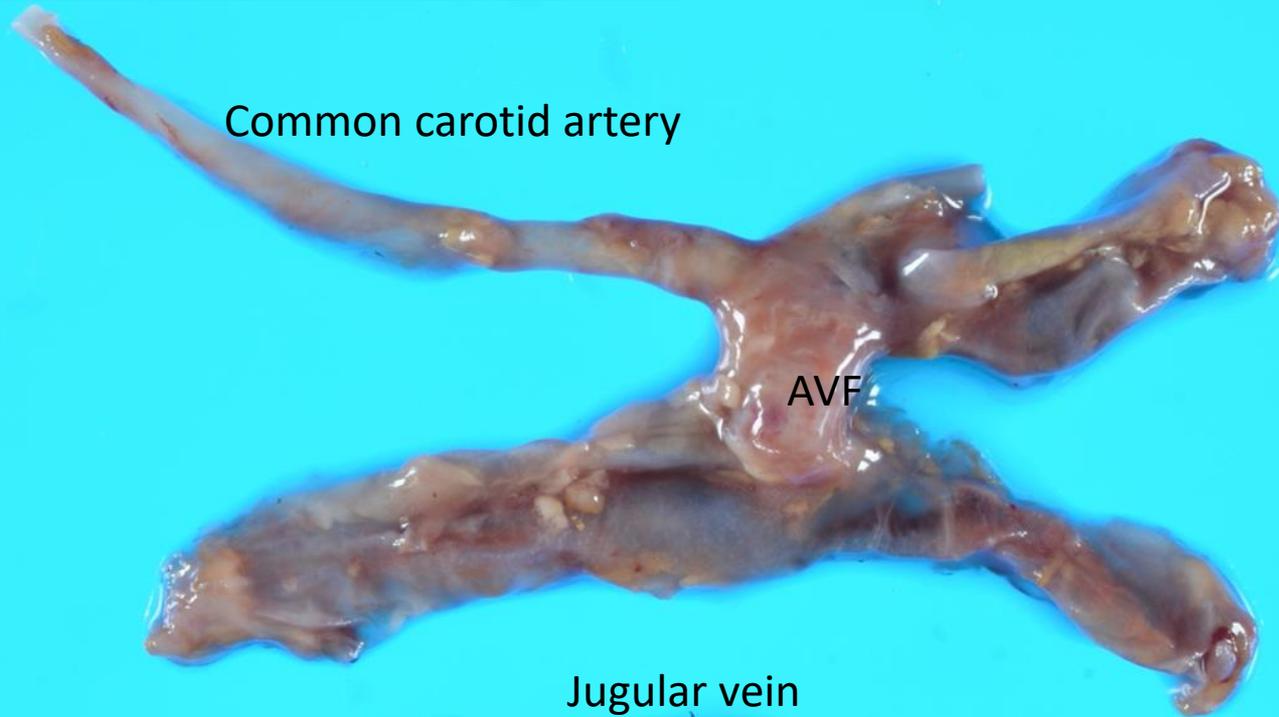


20

12-15

25

High pressure single expansion



High pressure single expansion

Common carotid artery



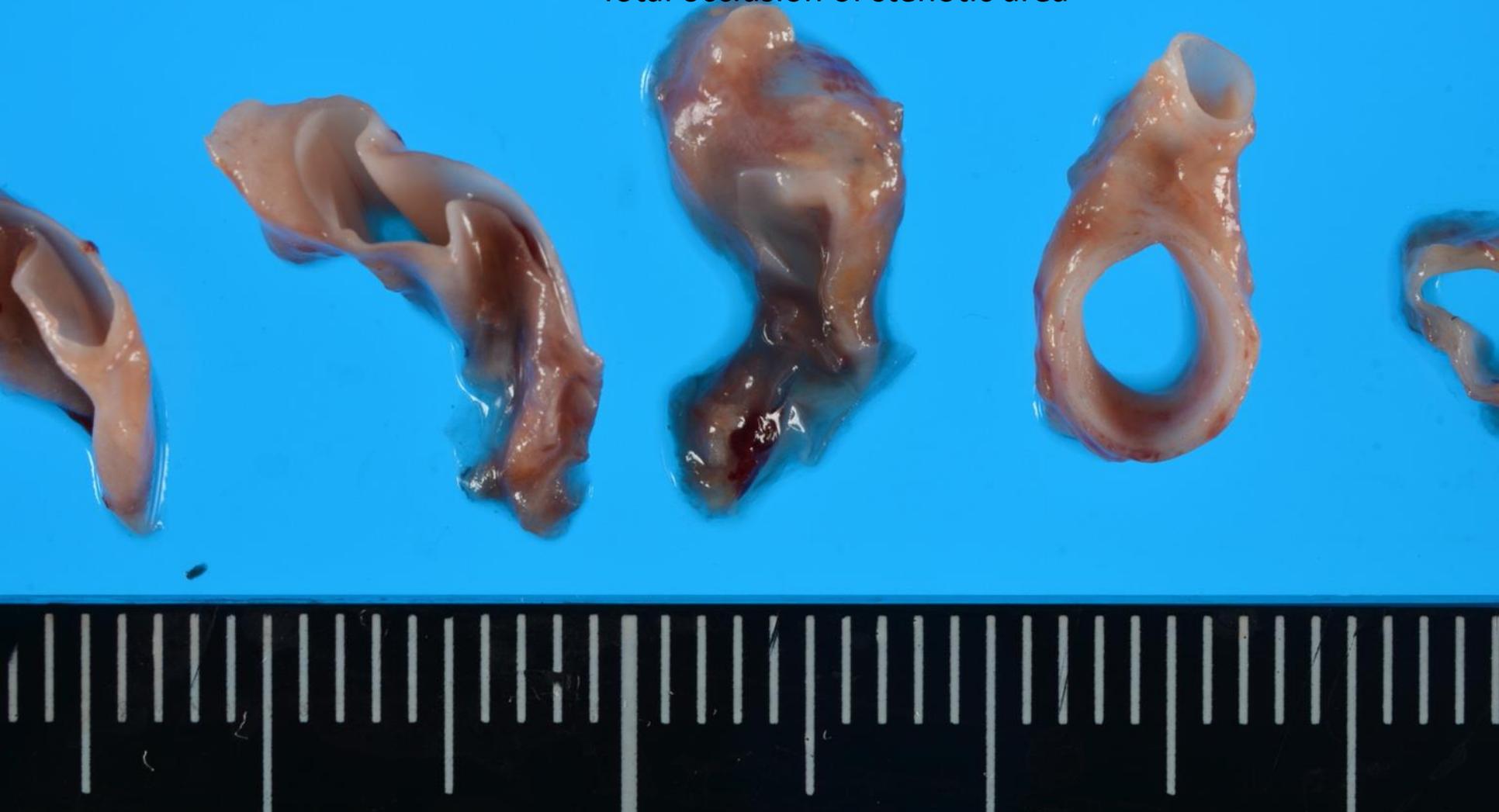
Total occlusion of stenotic area



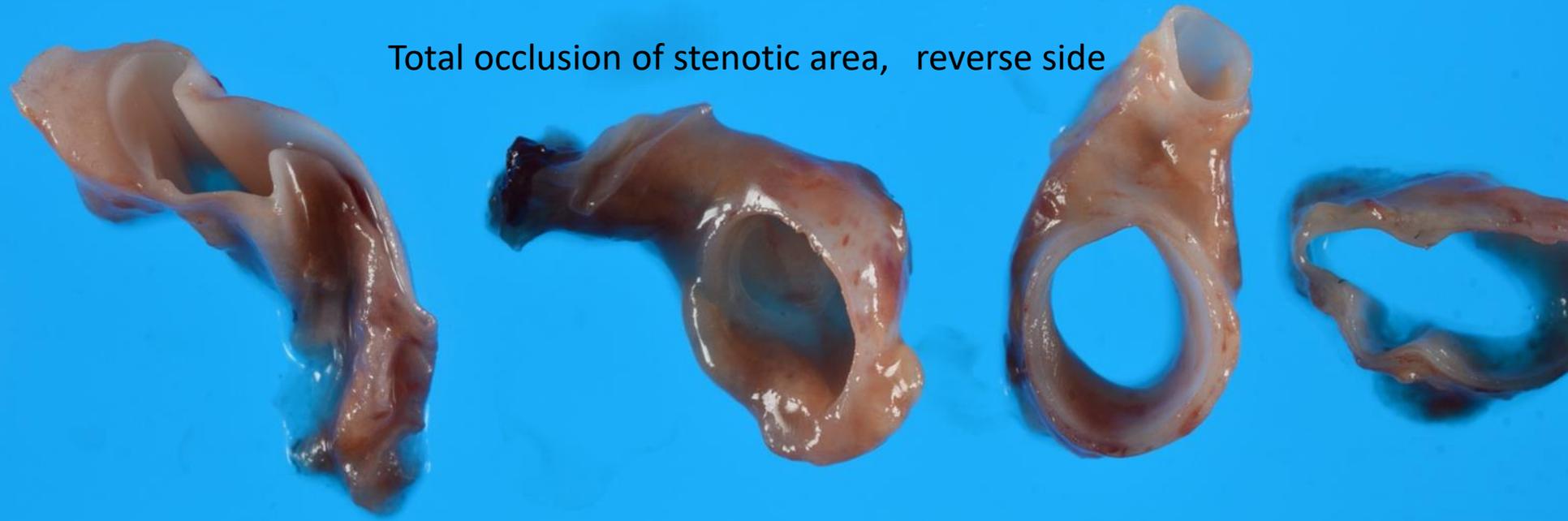
AVF



Total occlusion of stenotic area



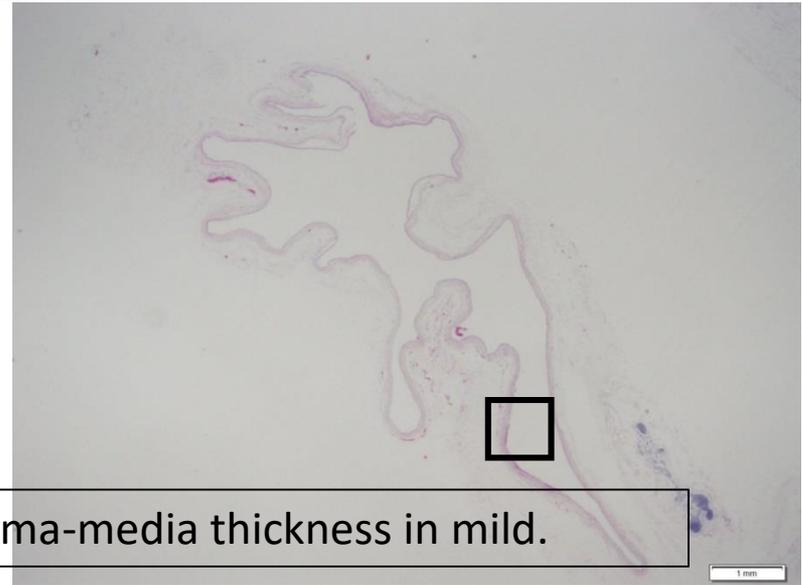
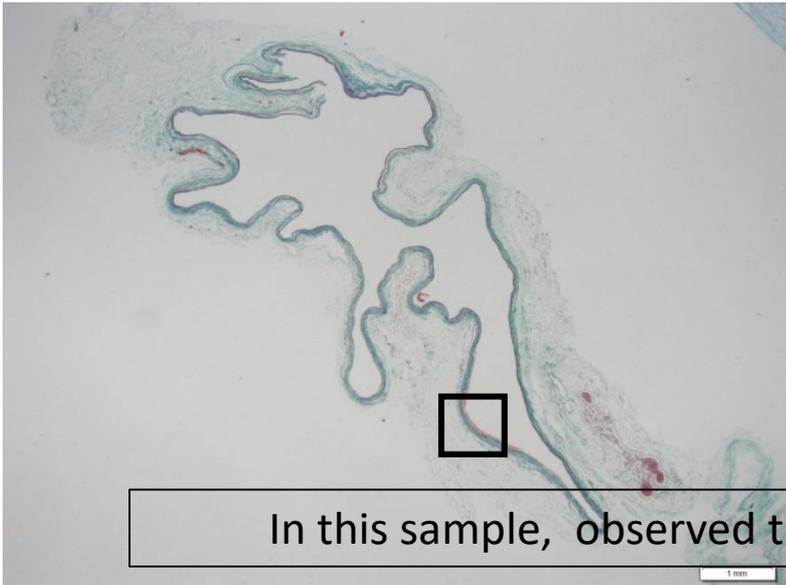
Total occlusion of stenotic area, reverse side



EM,1.25X

Ikeda method

HE,X1.25

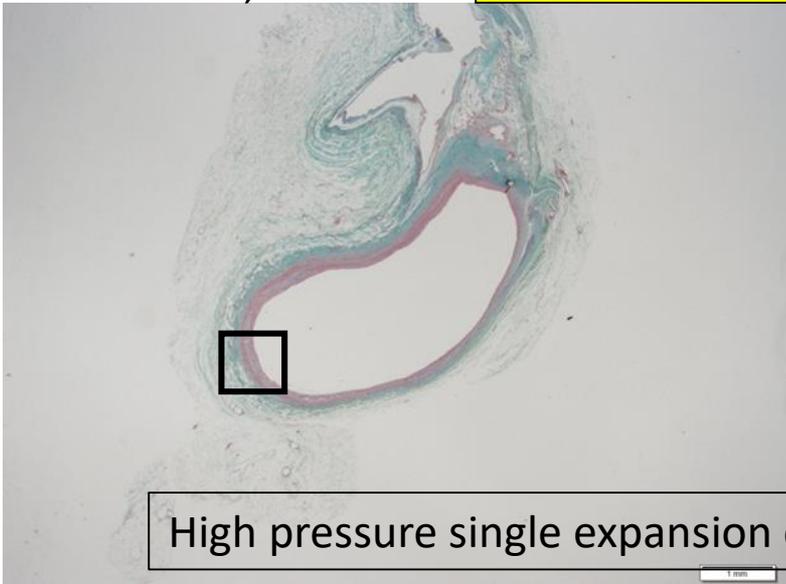


In this sample, observed the intima-media thickness in mild.

EM,X1.25

High pressure single expansion

HE,X1.25

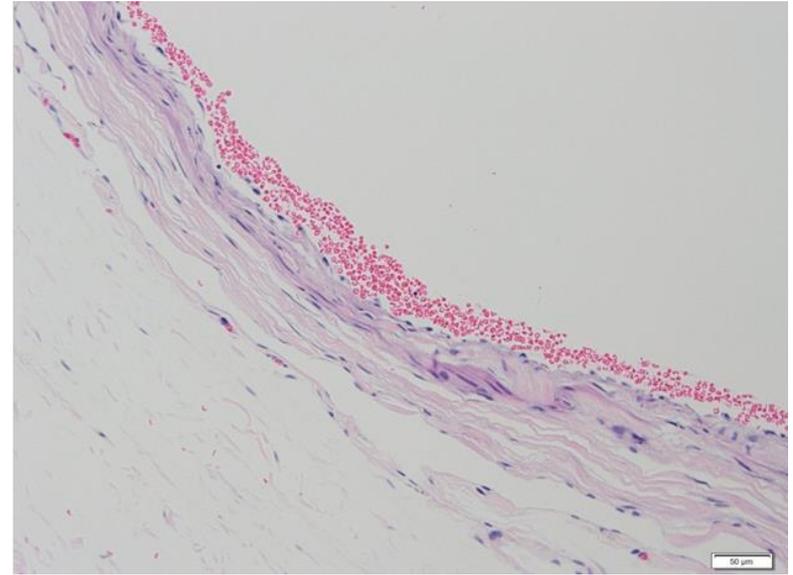
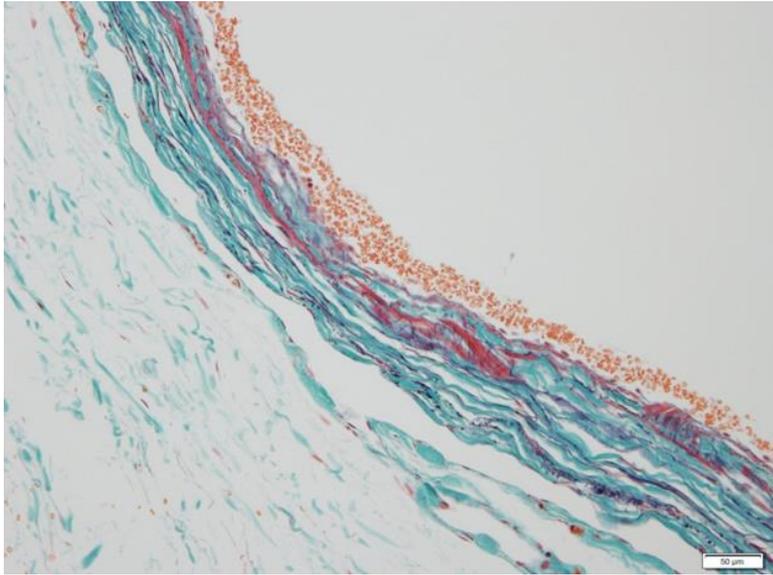


High pressure single expansion caused thickening leaving only a slit.

EM,X20

Ikeda method

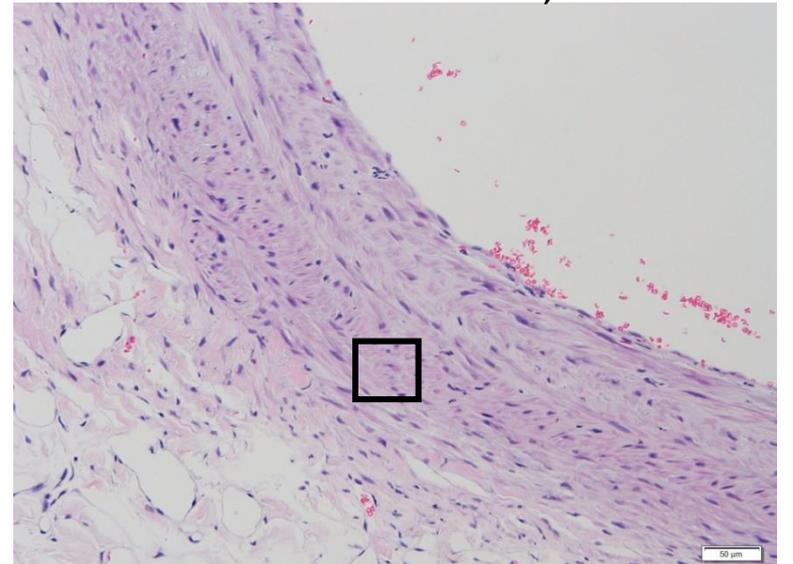
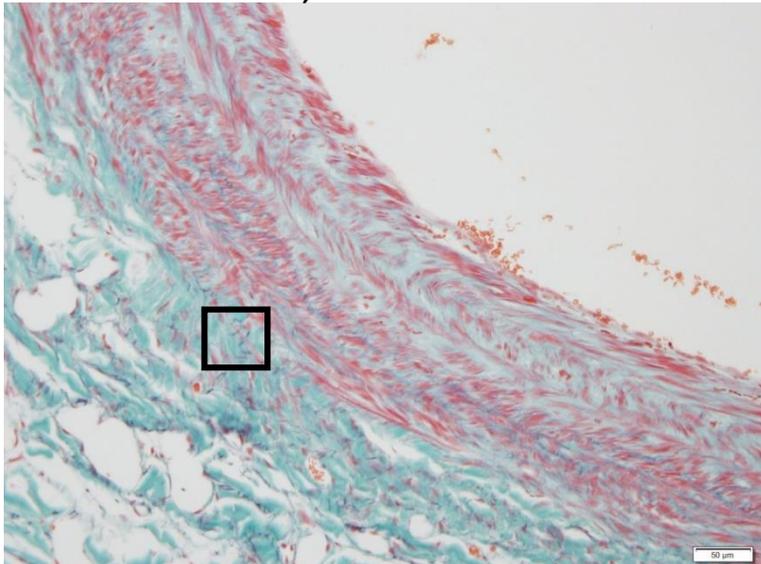
HE,X20



EM,X20

High pressure single expansion

HE,X20

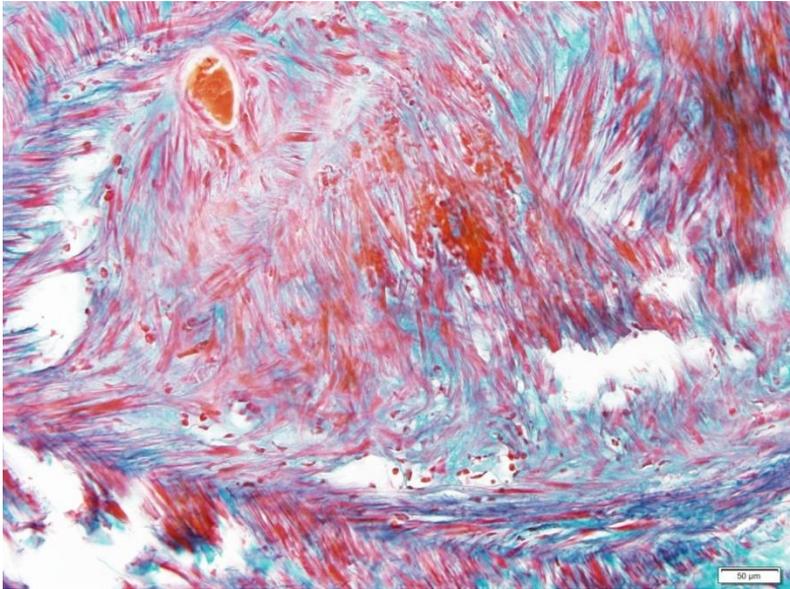


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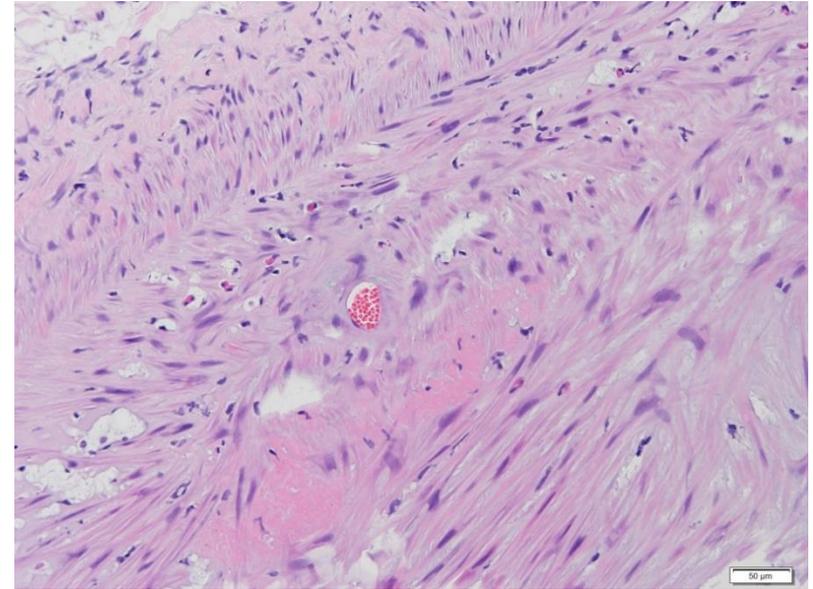
池田バスキュラーアクセス・透析・内科

Access/Nephrology/Dialysis

High pressure single expansion



EM,X20



HE,X20

Fibromuscular intima-media thickening with eosinophils and myxomatous degeneration can be seen.

【Results 2】 (first experiment)

Pathological Examination 1

- 1) In the single pressure group, an obstruction was observed in one of the three rabbits.
- 2) Infiltration of smooth muscle cells and intima-media thickening were also observed.
- 3) Compared to the single pressure group, the Ikeda method rabbits showed markedly milder intima-media thickening and greatly reduced infiltration of smooth muscle cells.
- 4) Even though we increased the pressure to 20 atm. using the Ikeda technique, thickening of the membrane was mild and there was no rupture.

In the second experiment

We examined the differences of the balloon specificity using Ikeda method.



【Method 2】

(Second experiment)

Experimental model:

Japanese white male rabbits (3-4kg) (n=6)

Different balloon devices

Super-non-compliance balloon (n=3)

Semi-compliance-balloon (n=3)

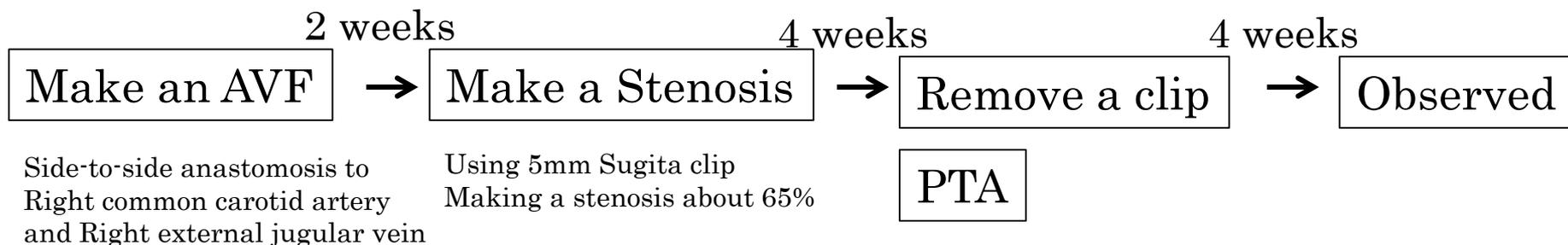


Fig.5: How to expansion of Second Experiment

< Gradual Expansion Technique (Ikeda method) >

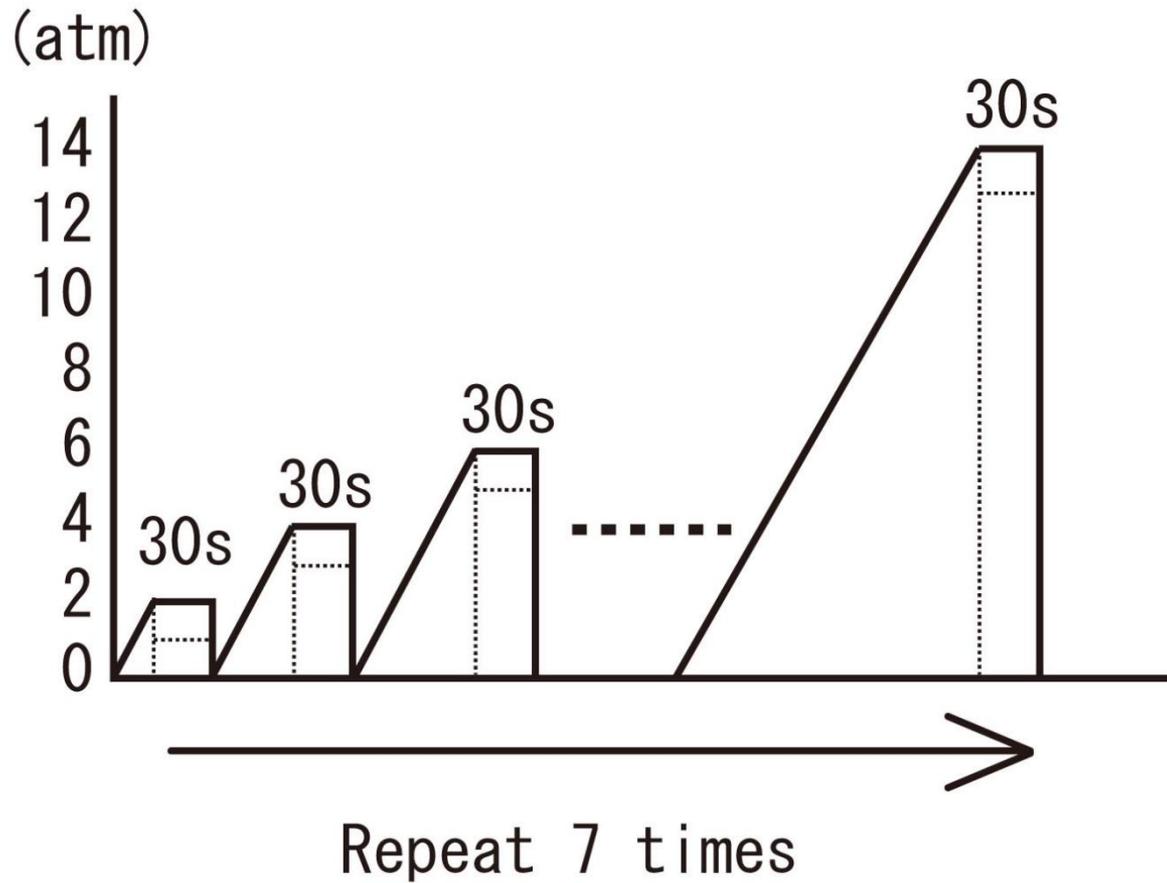
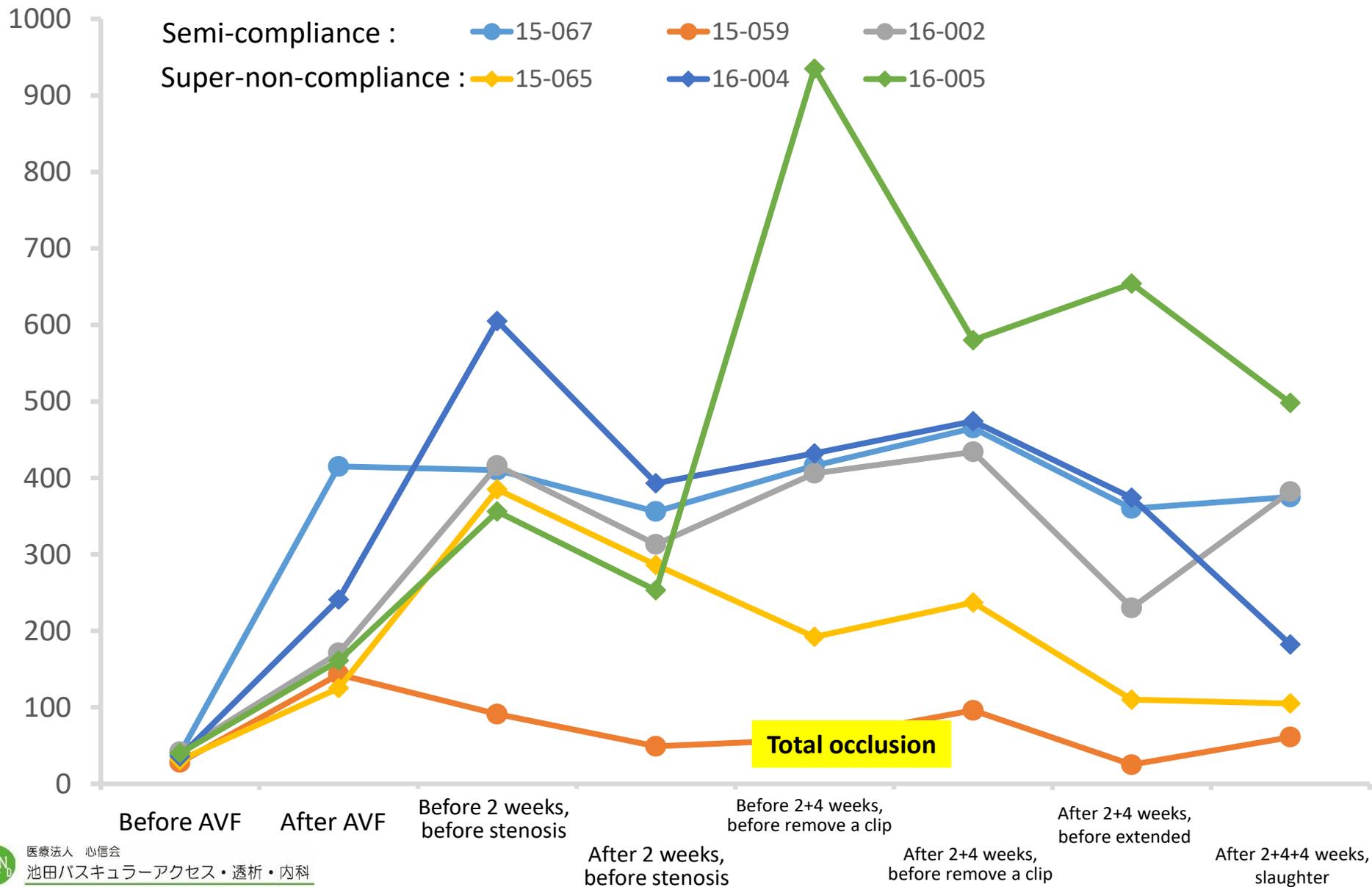
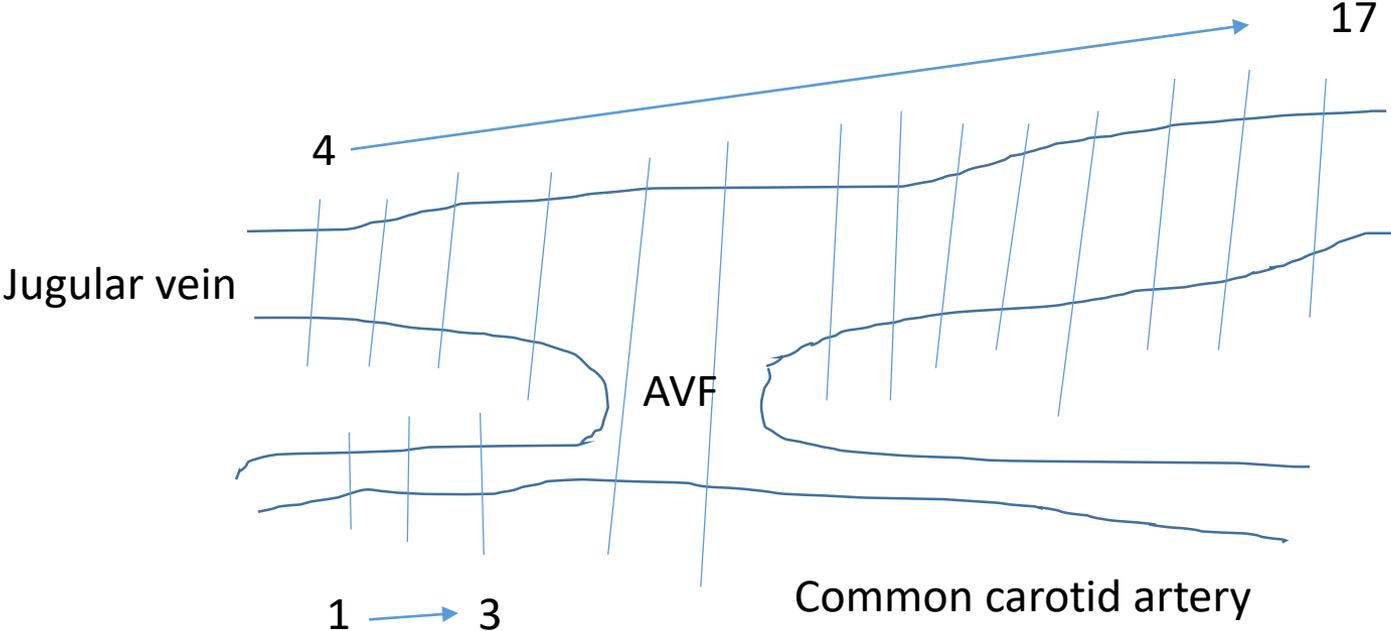
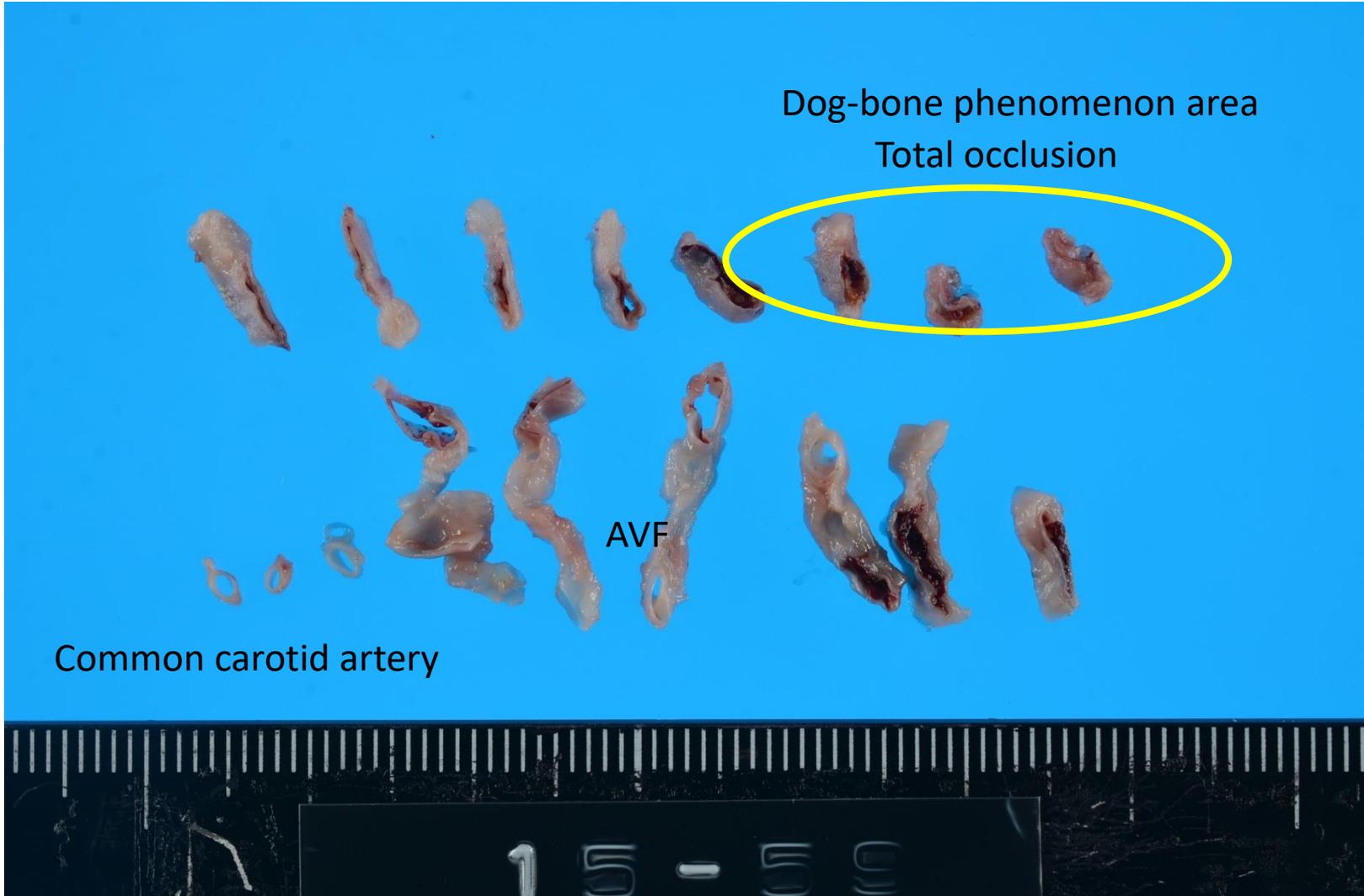


Fig. 6 : Comparison of blood flow among 6 rabbits





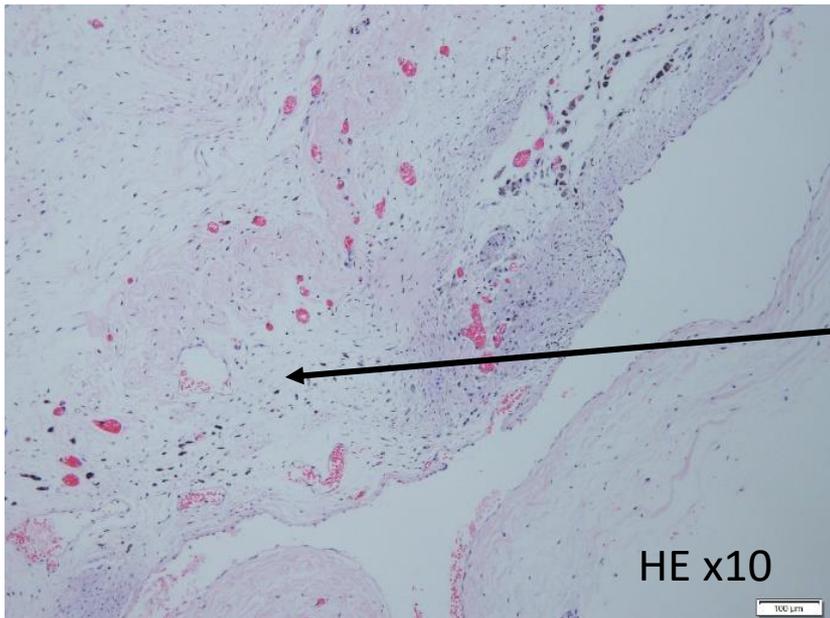
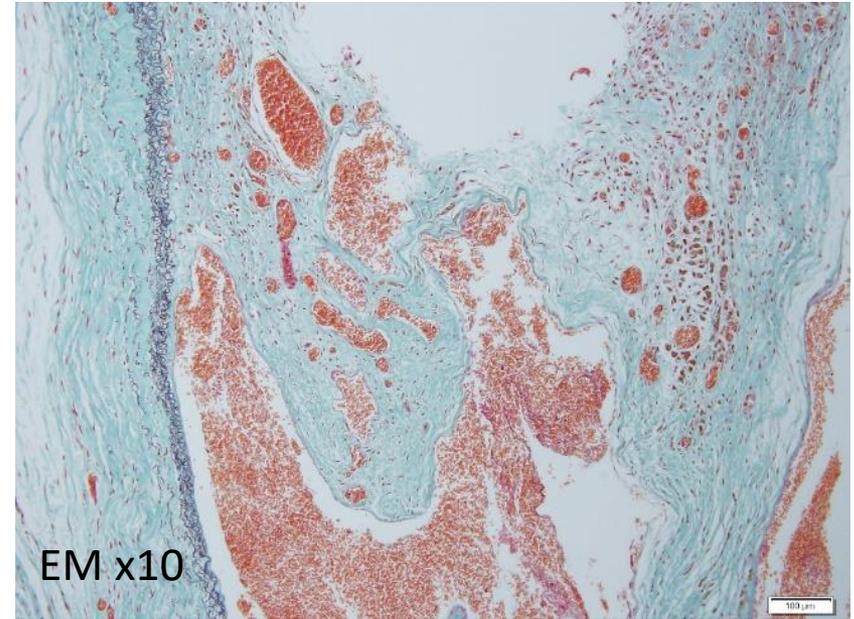
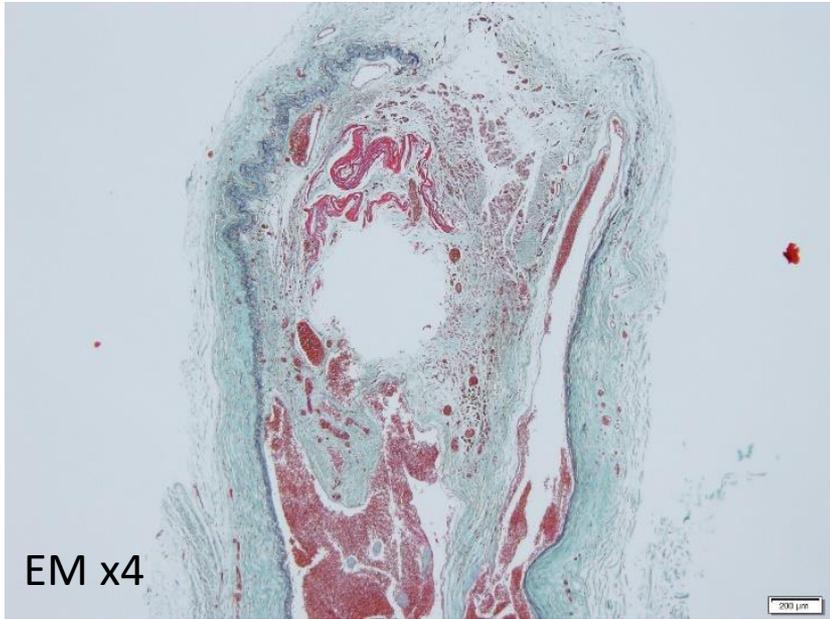


Dog-bone phenomenon area
Total occlusion

AVF

Common carotid artery

Total occlusion occurred at the edge of dog-bone phenomenon area



Medium membrane where rupture was observed.

【Results 3】 (second experiment)

Pathological Examination 2

- 1) Vascular damage including medium membrane rupture was also observed in the dog bone area due to over expansion of the semi-compliance balloon. There was little damage at the stenosis point however.
- 2) In the other 2 rabbits there was minimal dog bone phenomenon but there was significant damage observed at the stenosis point.
- 3) The three rabbits using super-non-compliance balloon showed partial intima-media thickening but in very few locations.
- 4) Using super-non-compliance balloon the intima thickening was minimal, no rupture and migration of smooth muscle cells into the intima was observed.

【Conclusions】

- #1 Using Gradual Expansion Technique (Ikeda method) by super-non-compliance balloon membrane damage can be greatly reduced.
- #2 Dog-bone phenomenon indicated tissue damage.

I regret to announce a leading dialysis doctor and vascular surgeon, Dr. Ohira Seiji, passed away on Sept. 5th. I would like to offer my sincere condolences.

And I wish to thank Dr. Masato Takahashi and Dr. Yukinobu Ito for their contributions.

