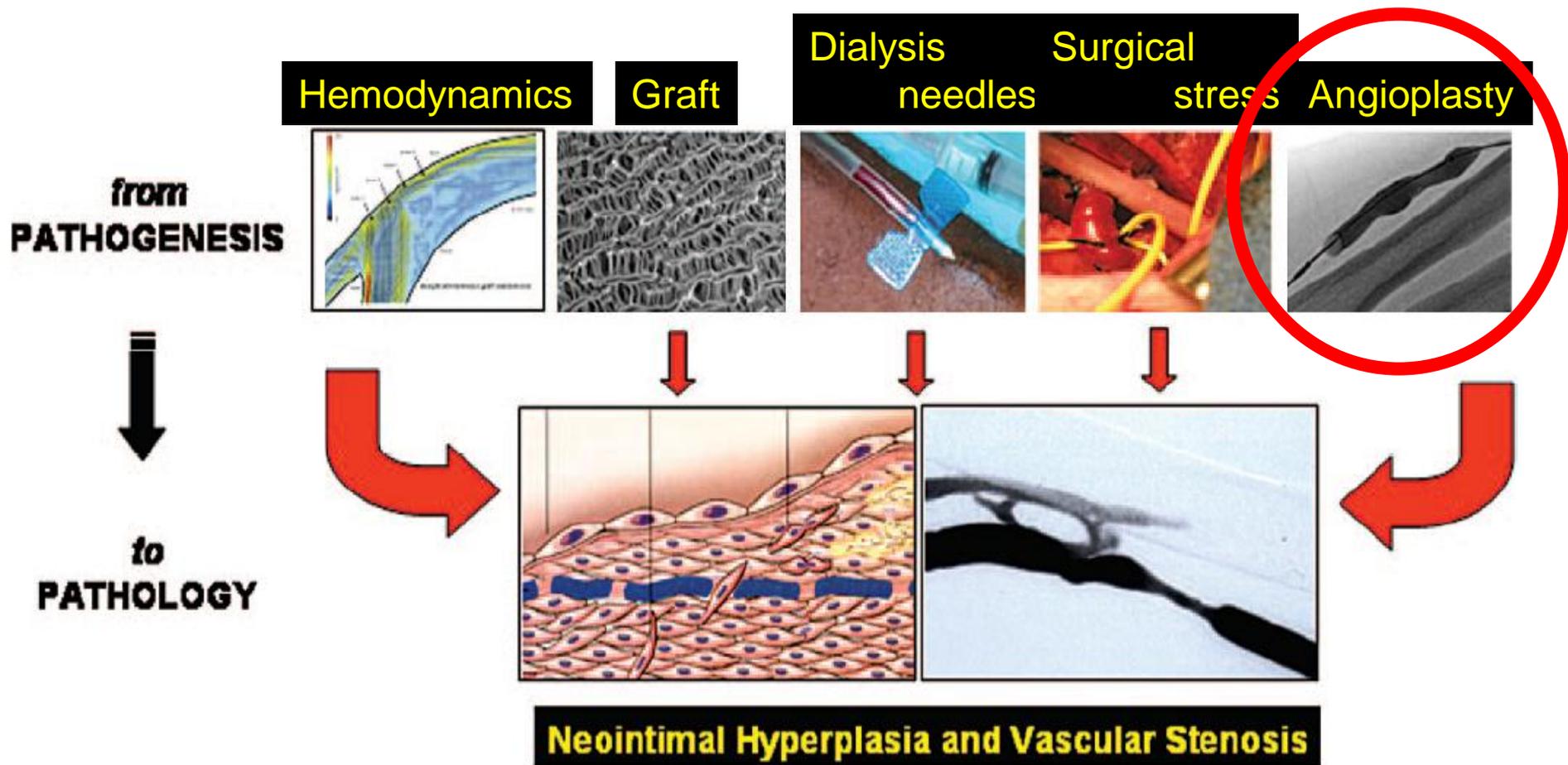


**JSDT Luncheon Seminar
GAMBRO
June 23 /2012**

**New observations and surgical repair in the
PTA repair technique for
VA narrowing**

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clinic
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Re-narrowing due to neointimal hyperplasia



Assumptions

#1 VAIVT is a factor in re-narrowing. Endothelial thickening occurs due to repeated endothelial damage and healing.

PTA → dilation → tissue damage leads to healing → endothelial thickening → re-narrowing

#2 If complete dilation of blood vessels is emphasized to the endpoint of PTA, it leads to severe damage of the vascular endothelium, therefore healing = possible exacerbation of re-narrowing.

Background and Purpose

- 1) Recognizing the fact that VAIVT is a therapy which is performed repeatedly, we reviewed VAIVT overall, such as selection of equipment and dilation methods to obtain better patency periods.
- 2) With full dilation and incomplete dilation in 2004, since there was no significant difference in patency periods, we performed VAIVT to ensure dialysis blood flow volume from 2005 as the endpoints of the therapeutic technique.
- 3) When VAIVT was started, we determined the absolute narrowing by stenosis or scoring .
- 4) We analyzed the significant difference in patency periods depending on the difference in dilation technique.
- 5) Blood flow rate before and after using a balloon was measured and improvement of R.I., and patency periods were observed.

Methods and analysis

- 1) The AVF group was analyzed in 979 cases from 2004 to 2010. The endpoint of VAIVT was when the VA pulse changed to thrill, and full balloon dilation was not an objective. Those who achieved poor blood removal during dialysis after VAIVT were considered unsuccessful.
- 2) We examined patency time as a function of balloon pressurization method.
- 3) The analysis method was the logrank test using the Kaplan-Meier method.

Objective

Cases) 979 , PTA from January 2004 to March 2010

M:F	595:384
Average age	63.1 ± 12.3 ys. (mean ± SE)
Original disease	DM 228 non-DM 750
Average pressurization	8.9 ± 2.99 atm (mean ± SE)

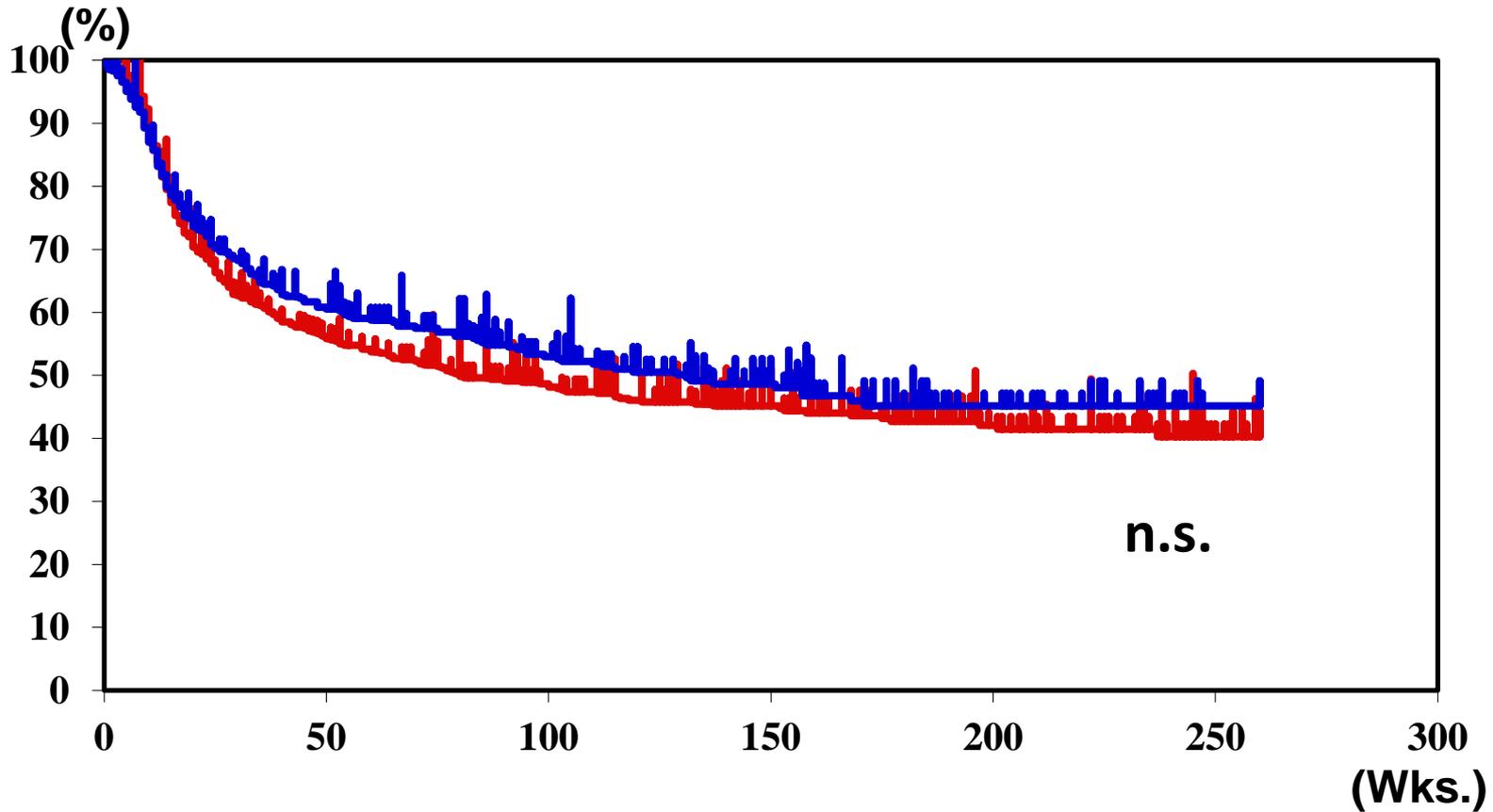
* Cases of narrowing of veins were assessed by converting to a Vascular Access Trouble Score (hereafter, V.A.T.S.)(Table 1), and for patients who obtained a score of 3 or more, PTA was performed only when it was deemed necessary by DSA test and ultrasound.

(Table 1.) Vascular Access Trouble Score

	Score
1) nothing	0
2) hearing high tone sounds at the stenosis area	1
3) a palpable stenosis area	2
4) increased venous pressure	(AVF: 1, AVG: 3)
5) extension of hemostatic time	2
6) blood flow failure after vein puncture toward the direction of the anastomotic site	5
7) vascular failure one hour later	1
8) decreased in the sound of vascular access	(AVF: 2, AVG: 3)
9) decreased pillow pressure	2
10) arrhythmia	1

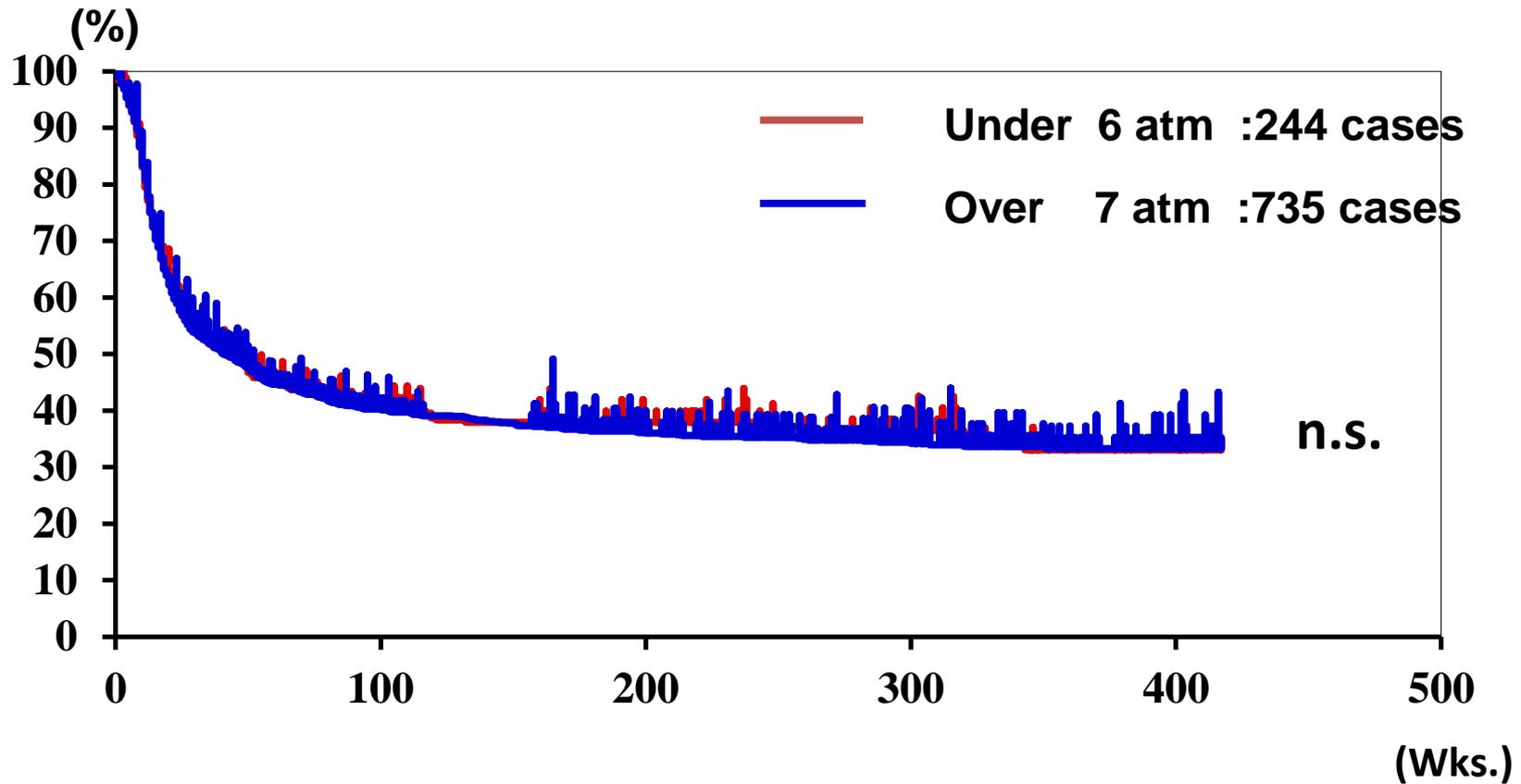
【 DSA : over 3 points, PTA: over 6 points 】

(Fig.1) Primary patency from 2004 to 2010 Cases :AVF 979



— Full dilation : 567 cases
— Incomplete dilation : 412 cases

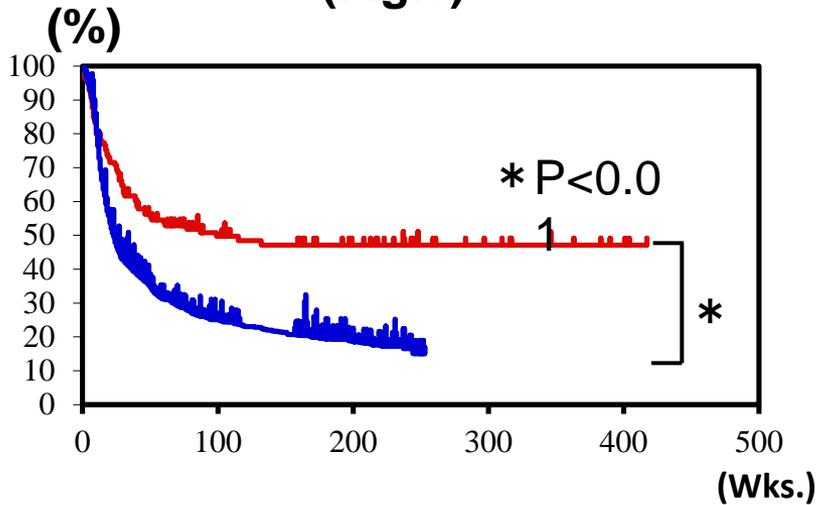
(Fig.2) FIG.2: Comparison of patency time. 244 cases below 6 atmospheres compared to 735 cases below 7 atmospheres. From 2004 to 2010



Primary patency

From 2004 to 2010

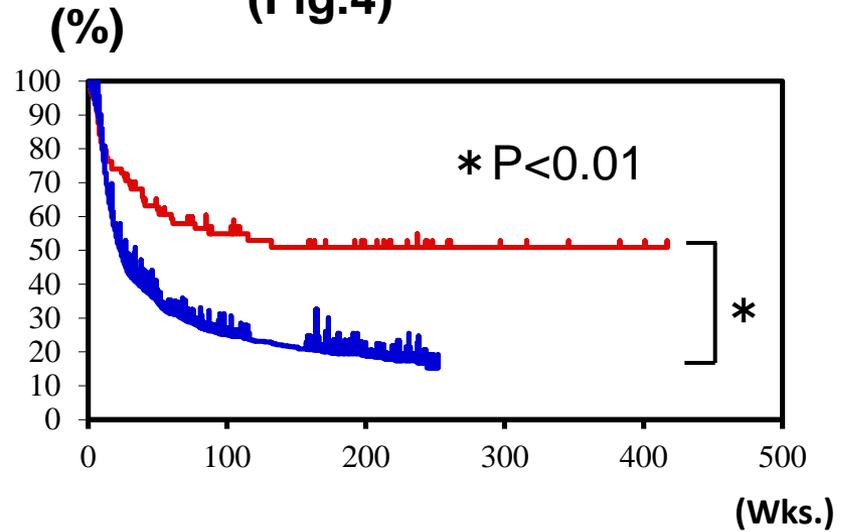
(Fig.3)



— Under 5 atm : 140 cases

— Over 6 atm : 839 cases

(Fig.4)



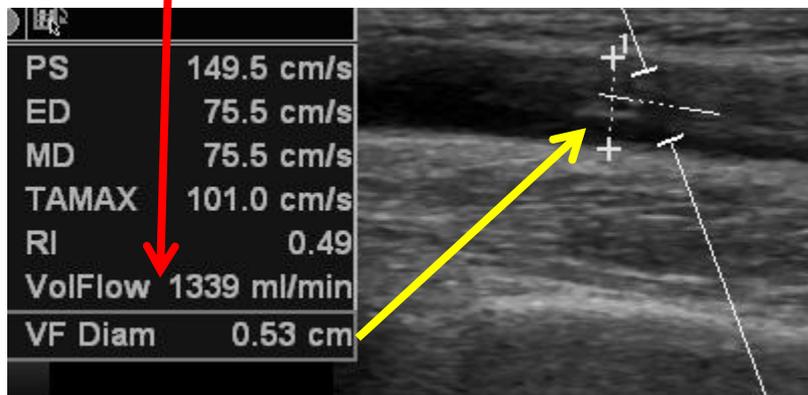
— Under 4 atm : 54 cases

— Over 5 atm : 925 cases

(Fig.5)

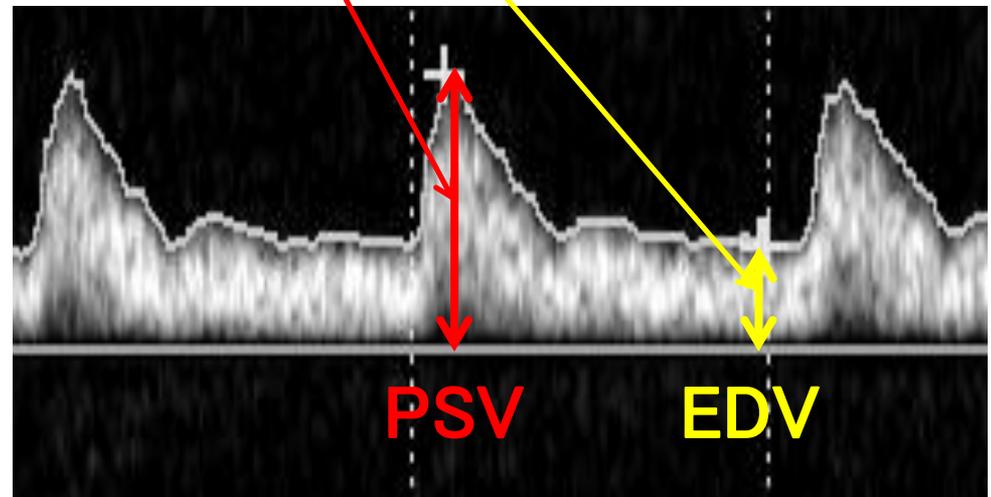
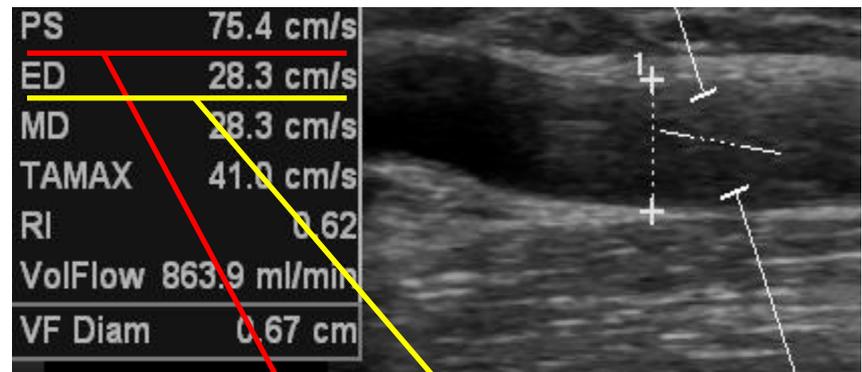
Flow volume ; F.V.

$$F.V(\text{ml}/\text{min}) = V_{m\text{-mean}}(\text{cm}/\text{s}) \times \text{area}(\text{cm}^2) \times 60(\text{s}) \div 100$$



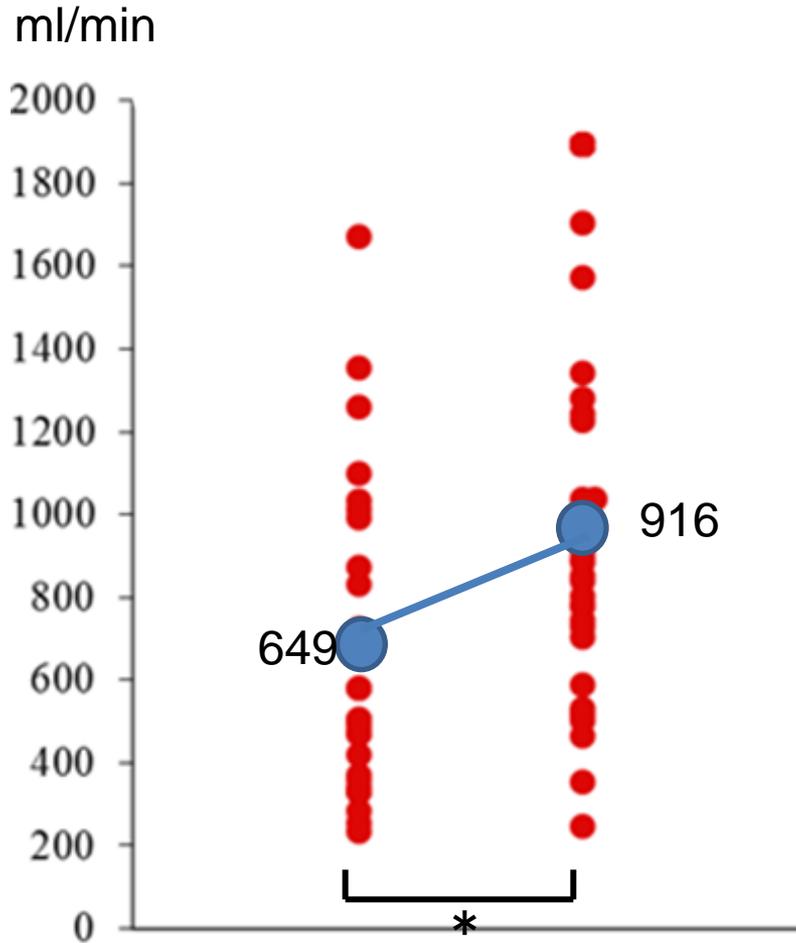
Resistance index; R . I .

$$R.I. = \frac{PSV - EDV}{EDV}$$



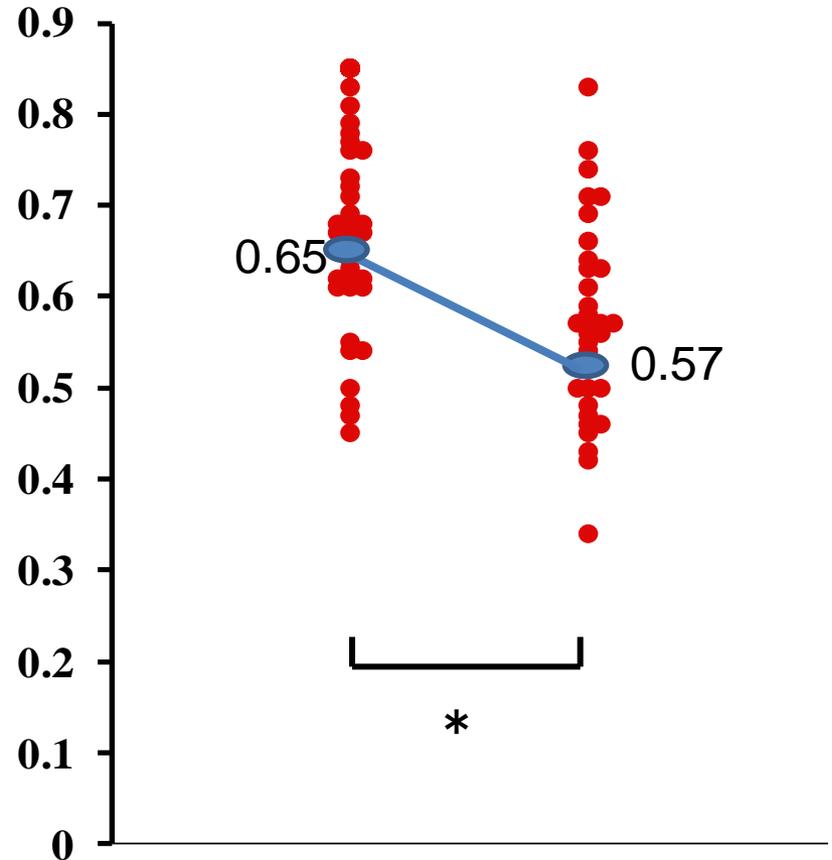
(Fig.6)

Flow volume



(Fig.7)

Resistance Index(R.I.)



Results

- 1) There was no significant difference of patency times between the full dilation group and the incomplete dilation group.
- 2) In these 2 groups, there was no significant difference in balloon pressure at the end of VAIVT.
- 3) FIG. 2: Above a balloon pressure of 7 atmospheres and below a balloon pressure of 6 atmospheres, there was no statistically significant difference in patency times.
- 4) FIG. 3: Below a balloon pressure of 5 atmospheres and above a balloon pressure of 6 atmospheres, there was statistically significant difference in patency times.

Summary

- 1) In dilation up to 5 atmospheres with VAIVT in AVF, the patency period was significantly longer compared to 6 atmospheres or more.
- 2) At narrowed sites in AVF when VAIVT was performed, there was no significant difference in patency periods between cases where full dilation was performed, and cases where it was not.

OCT(Optical Coherence Tomography) imaging system

- ① The OCT (Optical Coherence Tomography) imaging system, among existing imaging modalities, can obtain a high resolution cross-sectional image of blood vessels (approx. $15\ \mu\text{m}$ = 10 times resolution of an intravascular ultrasound device (IVUS) by irradiating near infrared rays from an optical fiber.
- ② The parts which look bright are tissue with endothelial thickening.
- ③ The parts which look dark are fat or a thrombus.

Methods

- #1. The limiting of PTA with regard to vascular access, reduces the amount of repeated narrowing, and ensures blood flow volume required for dialysis.
- #2. OCT was used to make a comparative assessment of the change in blood vessel diameter before and after dilation, and the damage to the vascular endothelium.
- #3. The effect on the endothelium between full dilation and incomplete dilation was examined by OCT.

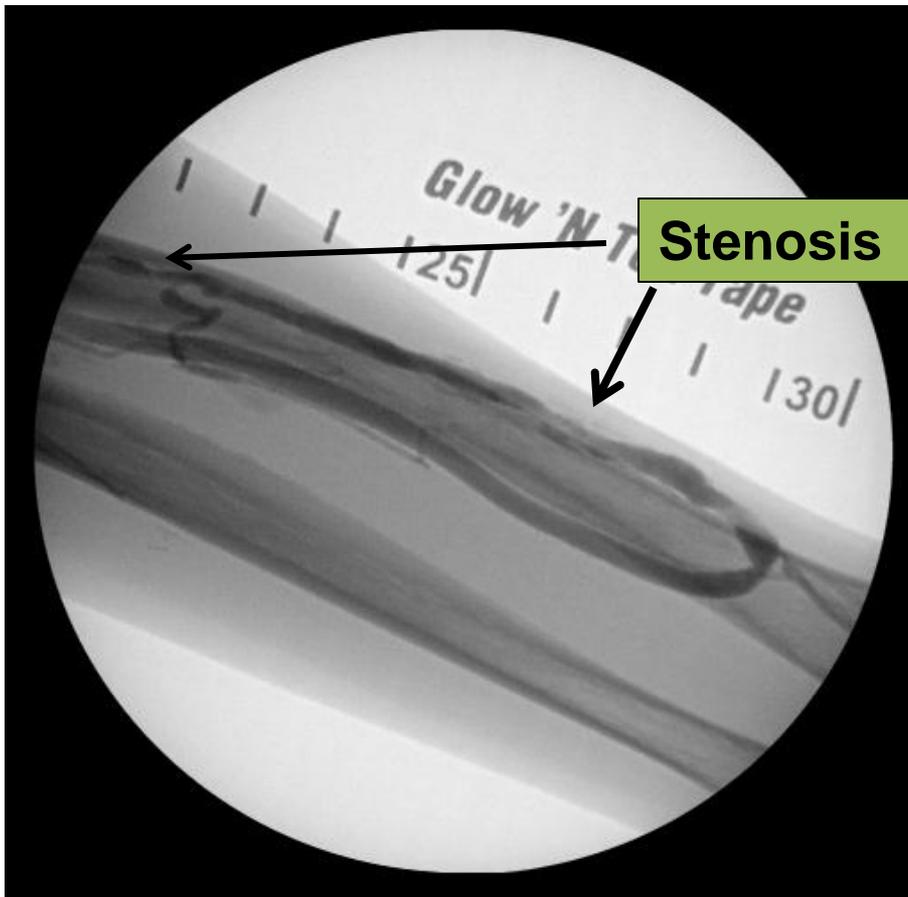
Observations

#1. During observation, the endothelium was examined over the whole length of the narrow part before surgery, and the inner diameter was measured at the narrowest part.

#2. After dilation, the endothelium was observed and the inner diameter measured at the same point as before dilation.

CASE① C.C.: poor blood removal

PRE PTA



June 2011

AVF

Stenosis: two points

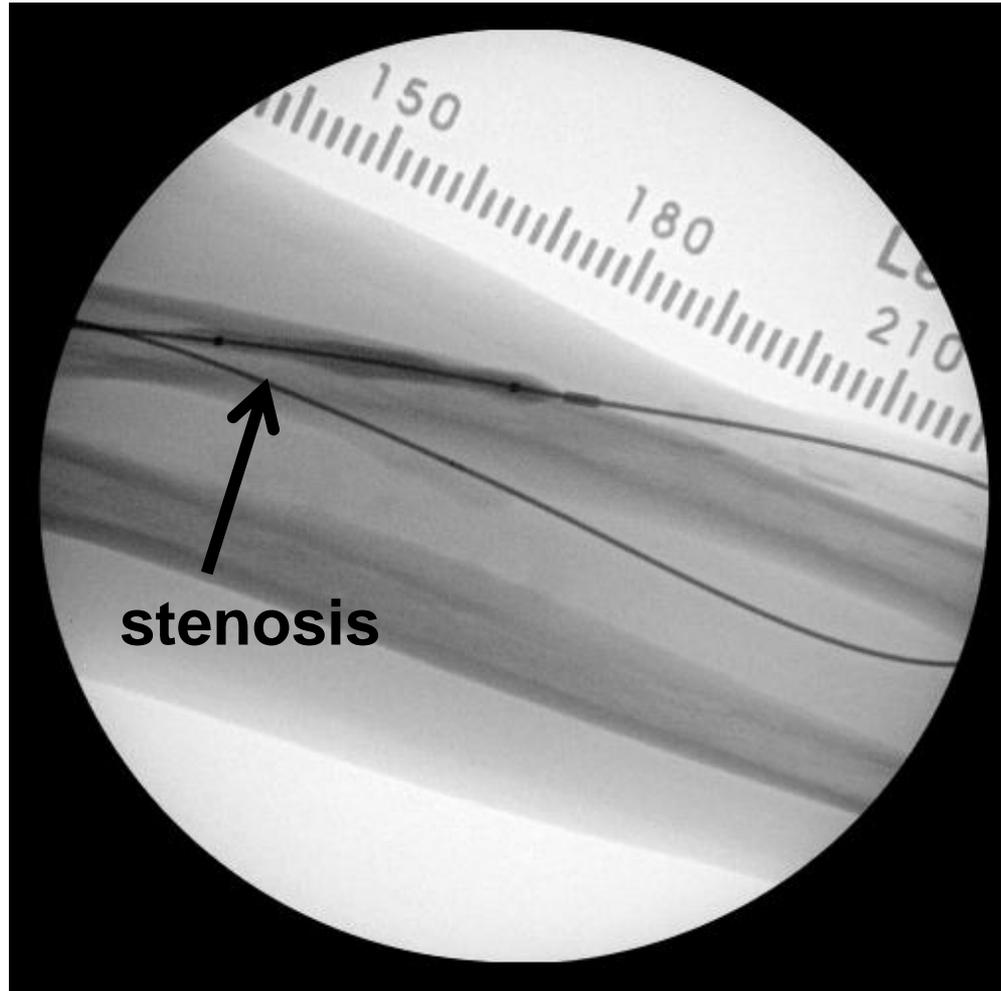
Pre PTA: 3 mnths ago



Pre OCT : Narrowing point

Maximum: 3.23mm
Minimumu: 2.69mm
Mean: 2.91mm

① Dilation



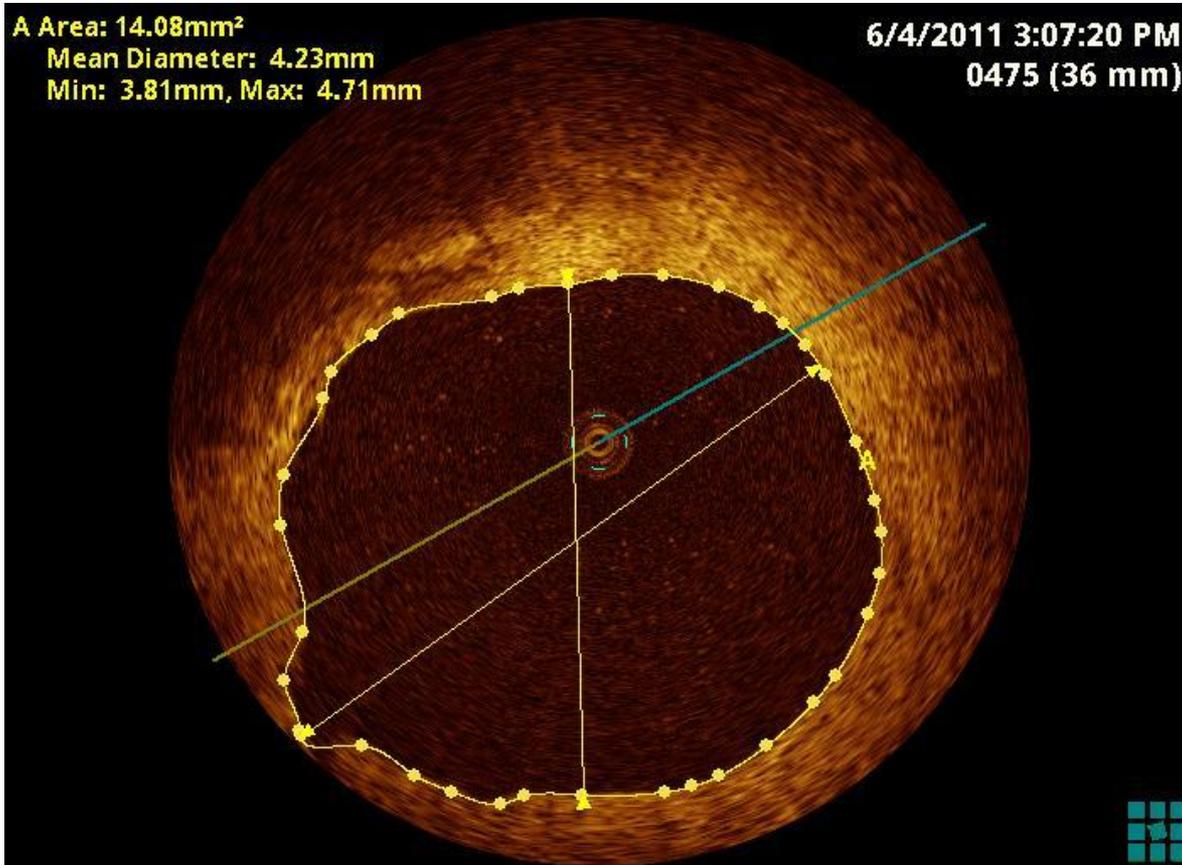
June 2011

conquest

5x40mm

4atm

OCT: first dilation



CONQUEST

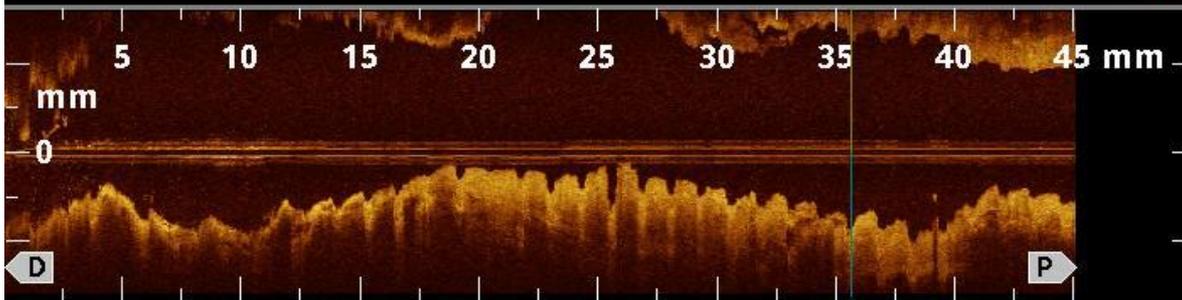
5mm × 4cm

4atm × 60sec.

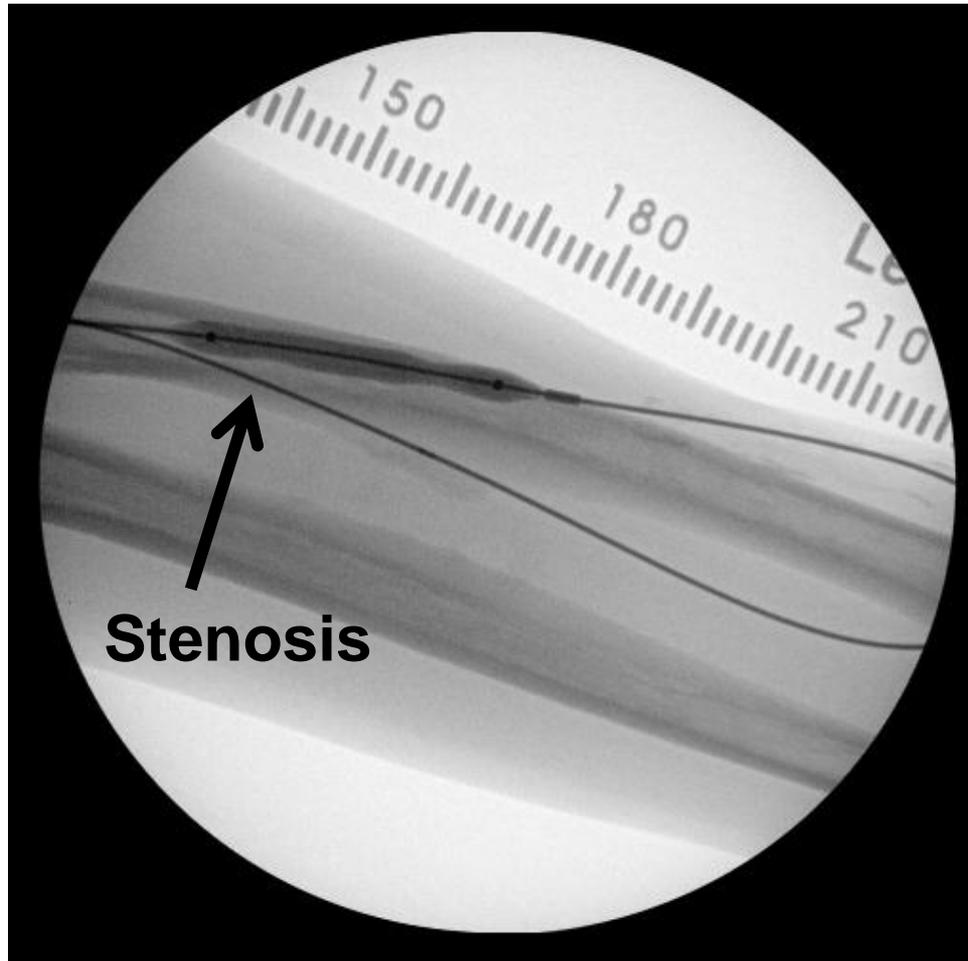
Maximum: 4.71mm

Minimum :3.81mm

Mean : 4.23mm



②Dilation



June 2011

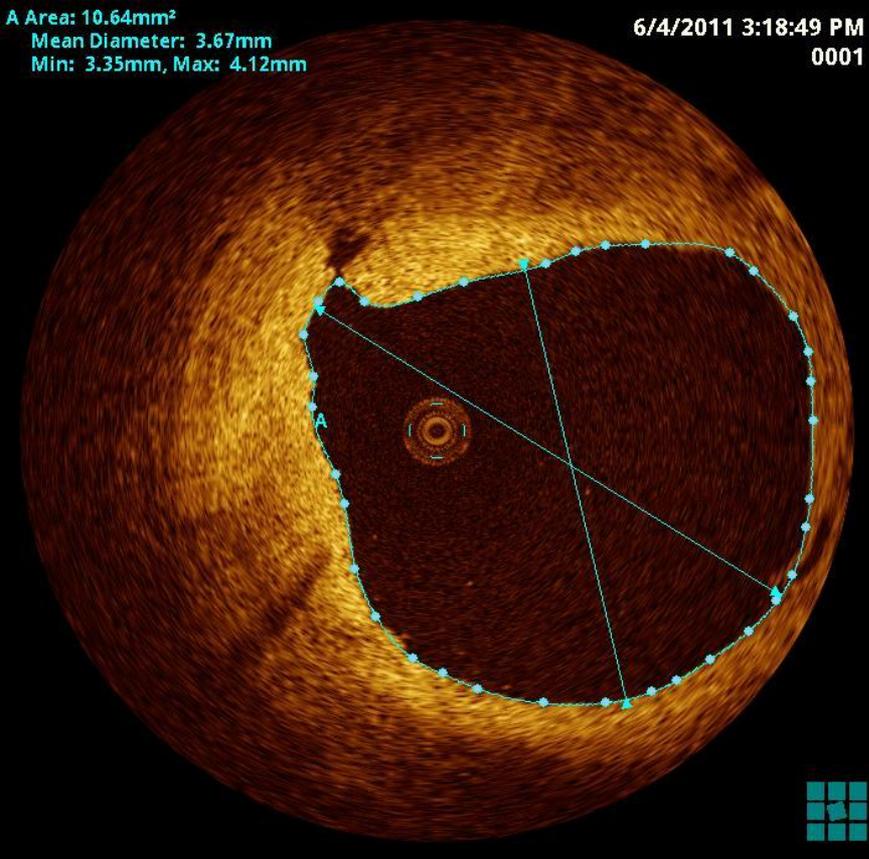
conquest

5x40mm

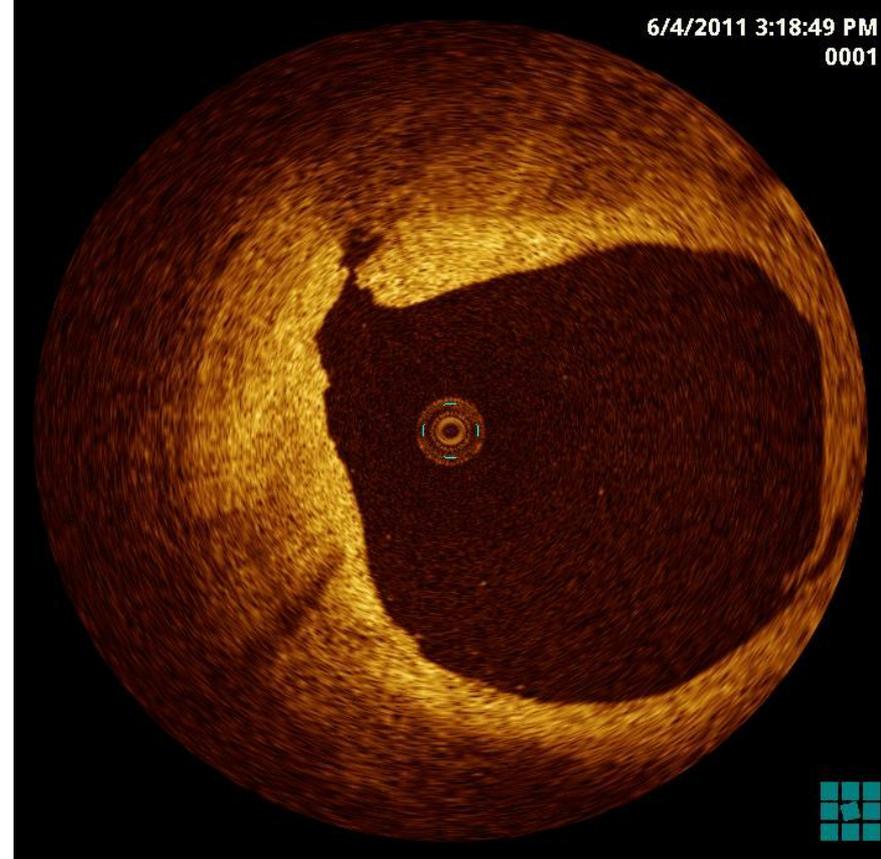
6atm

A Area: 10.64mm²
Mean Diameter: 3.67mm
Min: 3.35mm, Max: 4.12mm

6/4/2011 3:18:49 PM
0001



6/4/2011 3:18:49 PM
0001



OCT(second dilation)
Conquest 5mm × 4cm

6atm × 60sec.

Maximum: 4.12mm

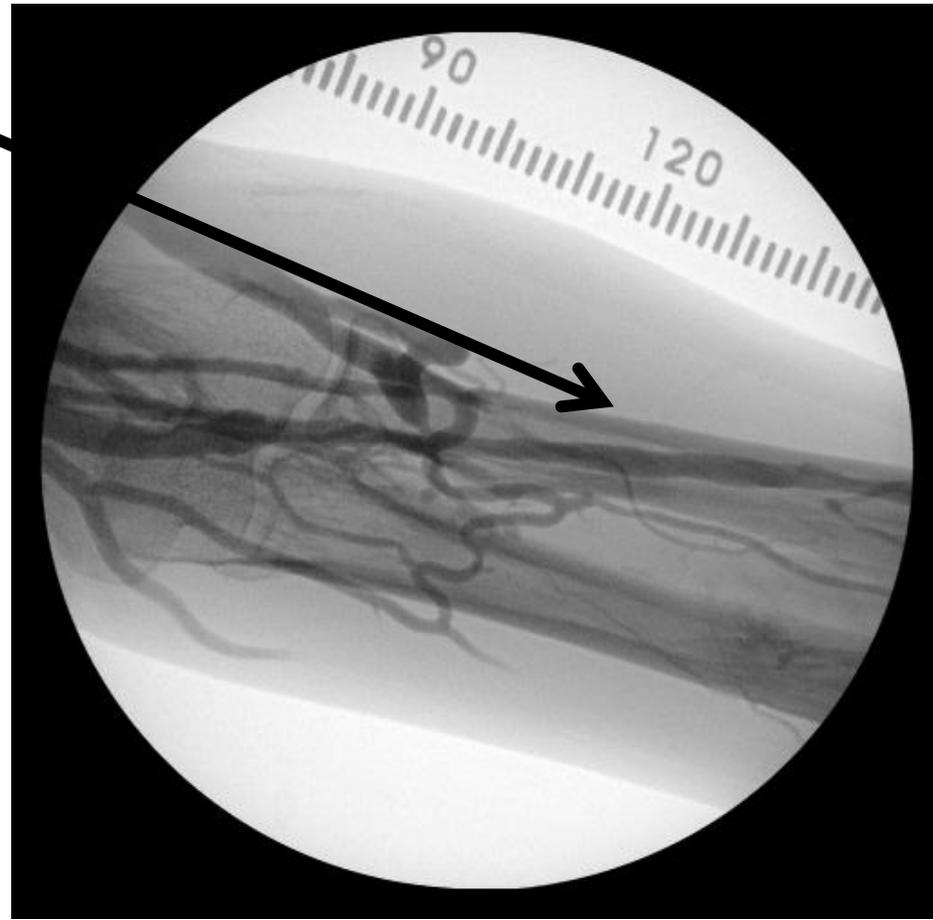
Minimum : 3.35mm

Mean : 3.67mm



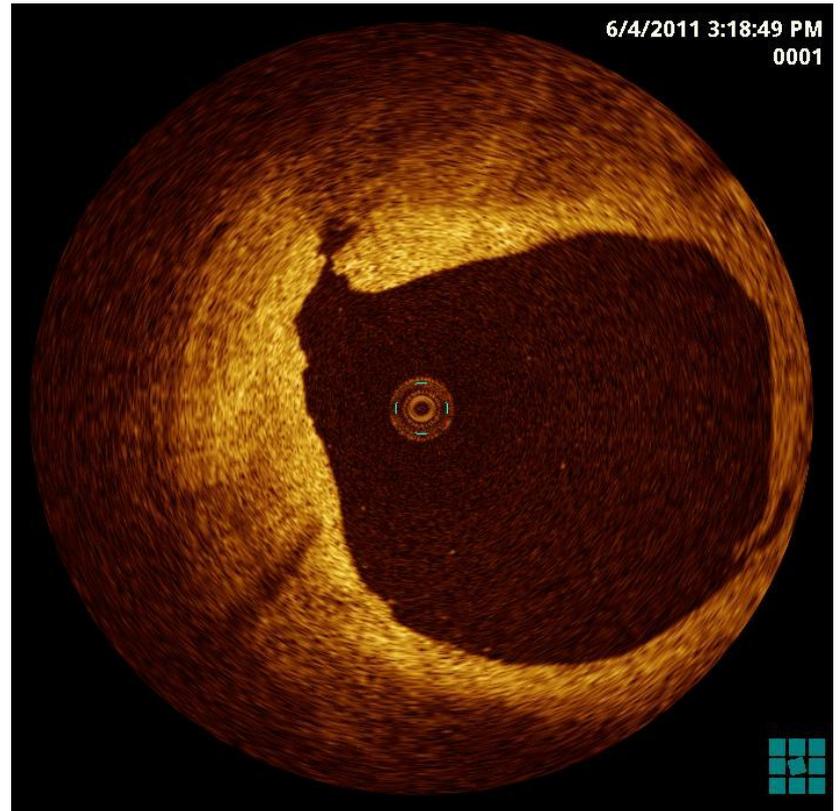
Pre PTA

Post PTA

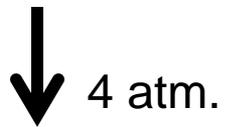




6atm.

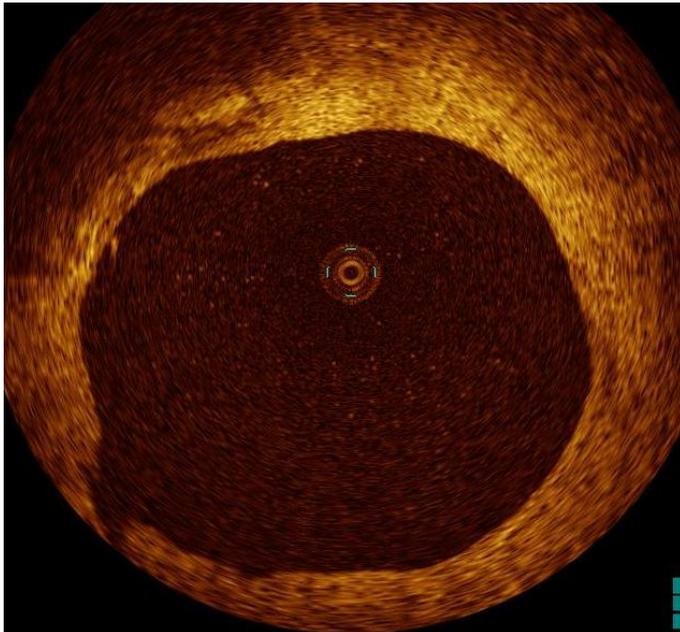


Mean =3.67mm



Mean =2.91mm

4 atm.



Mean =4.23mm

CASE② 64 years male C.C.: poor blood removal

VA: Left arm AVF

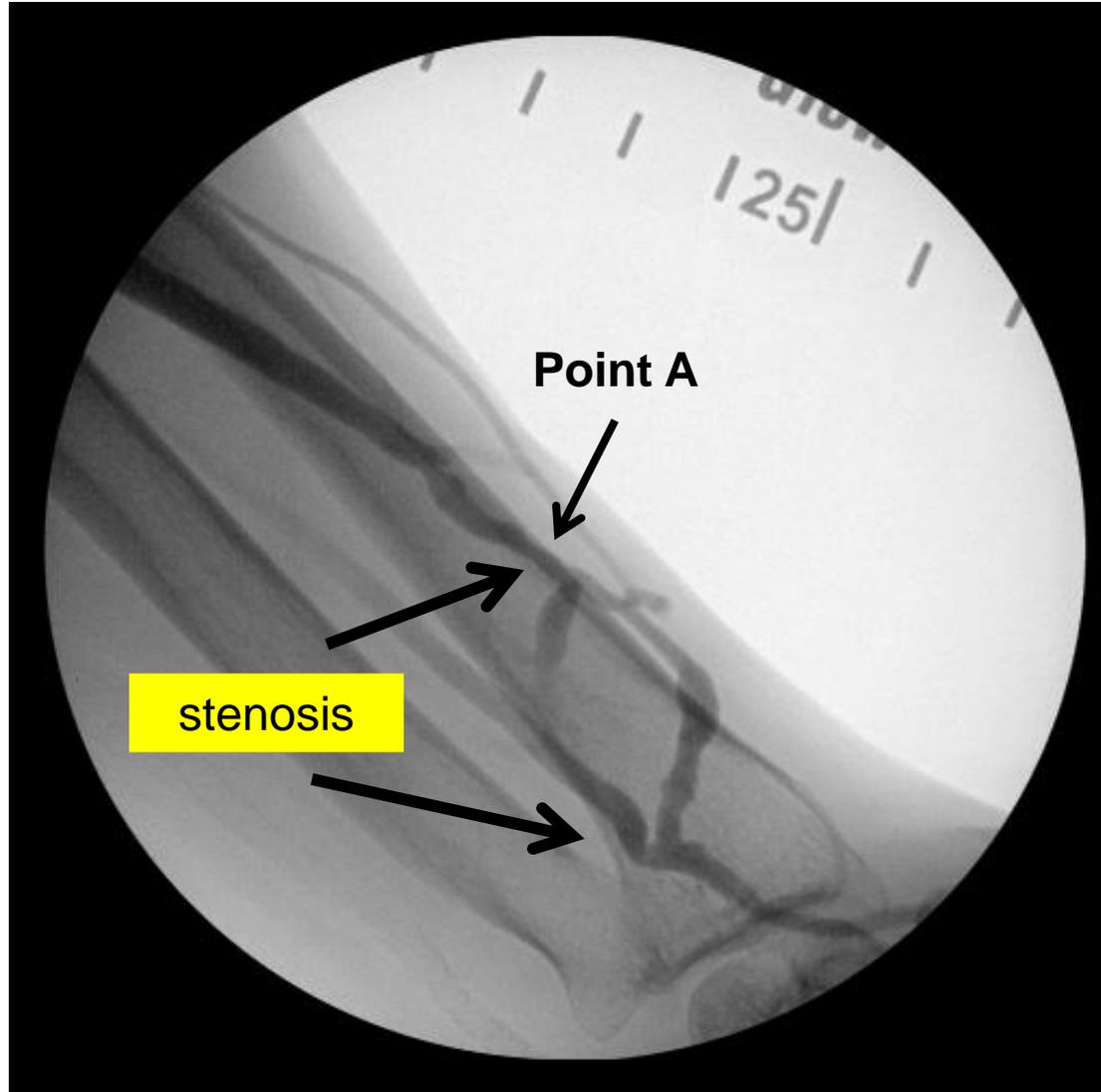
Stenotic points: anastomosis、

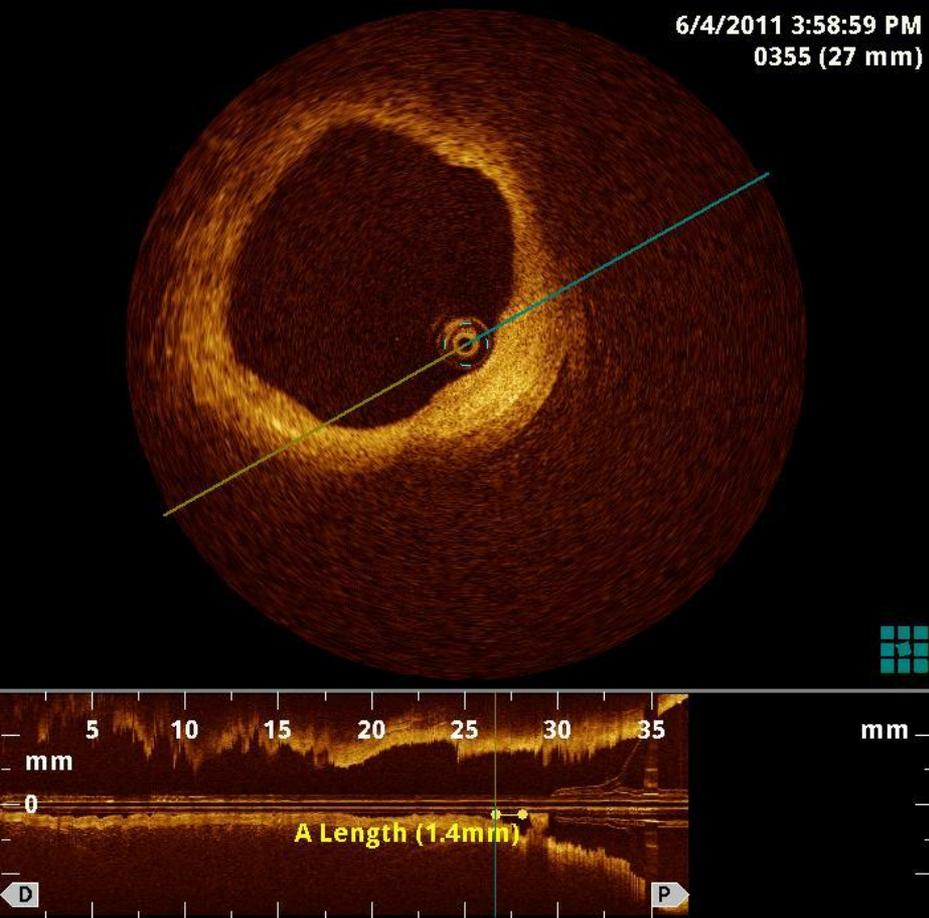
near site of anastomosis

Devise: Ultra high pressure balloon 4mmX4cm

Pre PTA: two months ago

DSA





Case 2 Pre PTA:OCT

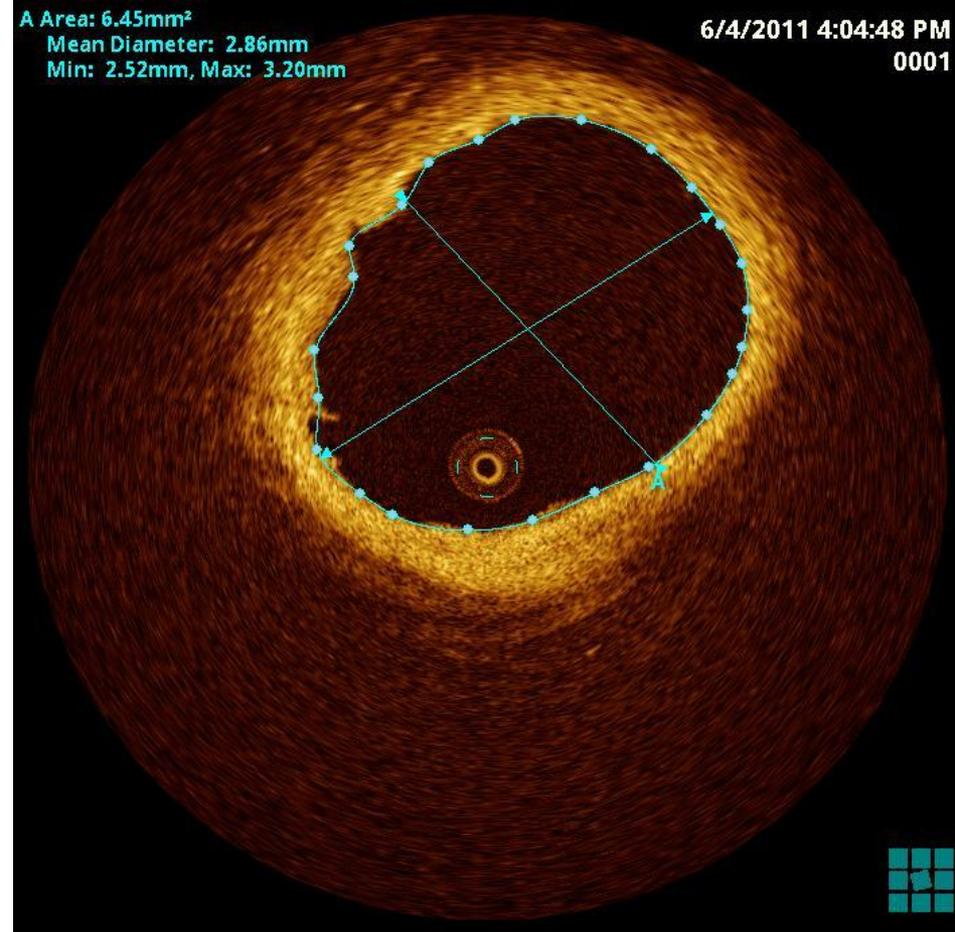
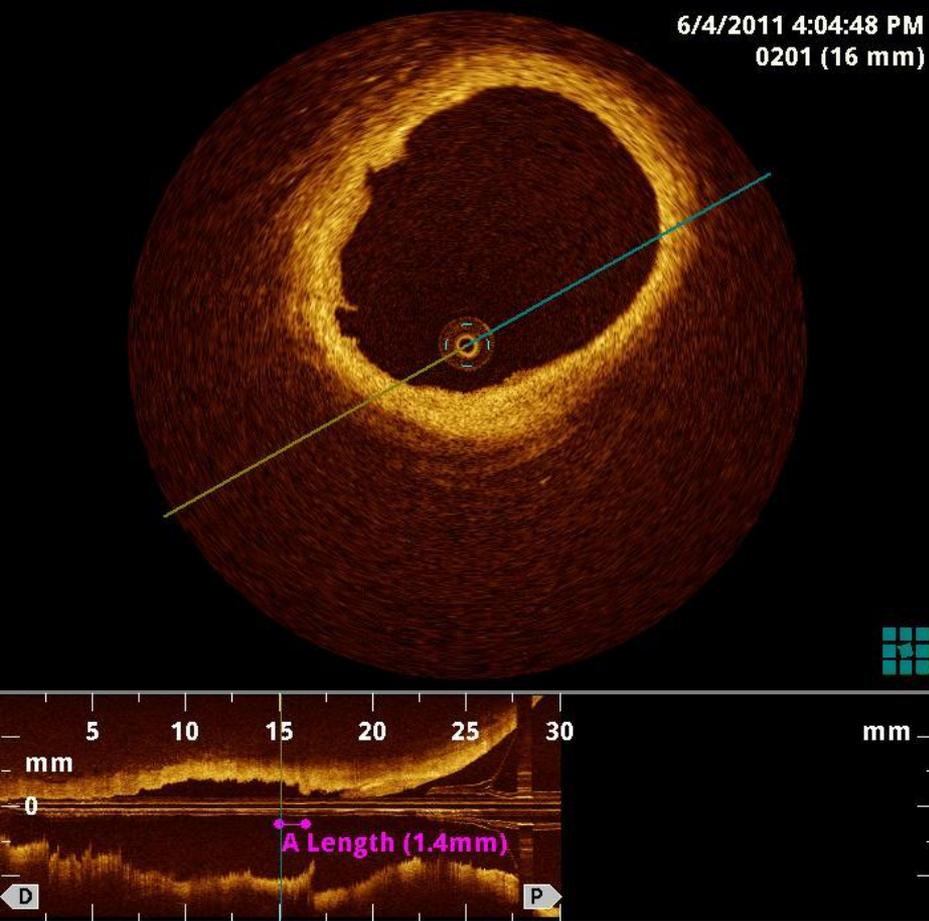
Maximum :2.94mm

Minimum :2.50mm

Mean : 2.73mm

Dilation: 3atm X 30sec.





Case 2 – Post PTA: OCT

First dilation super non-compliant balloon

4mm × 4cm 3atm

Maximum : 3.20mm

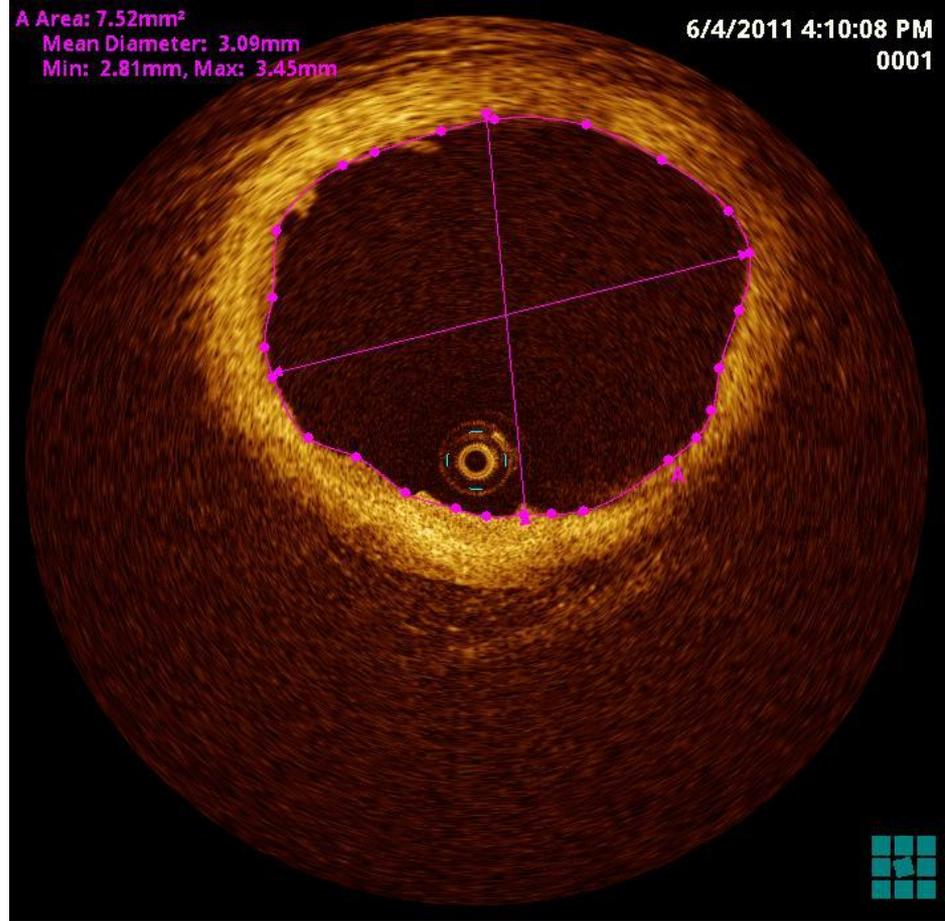
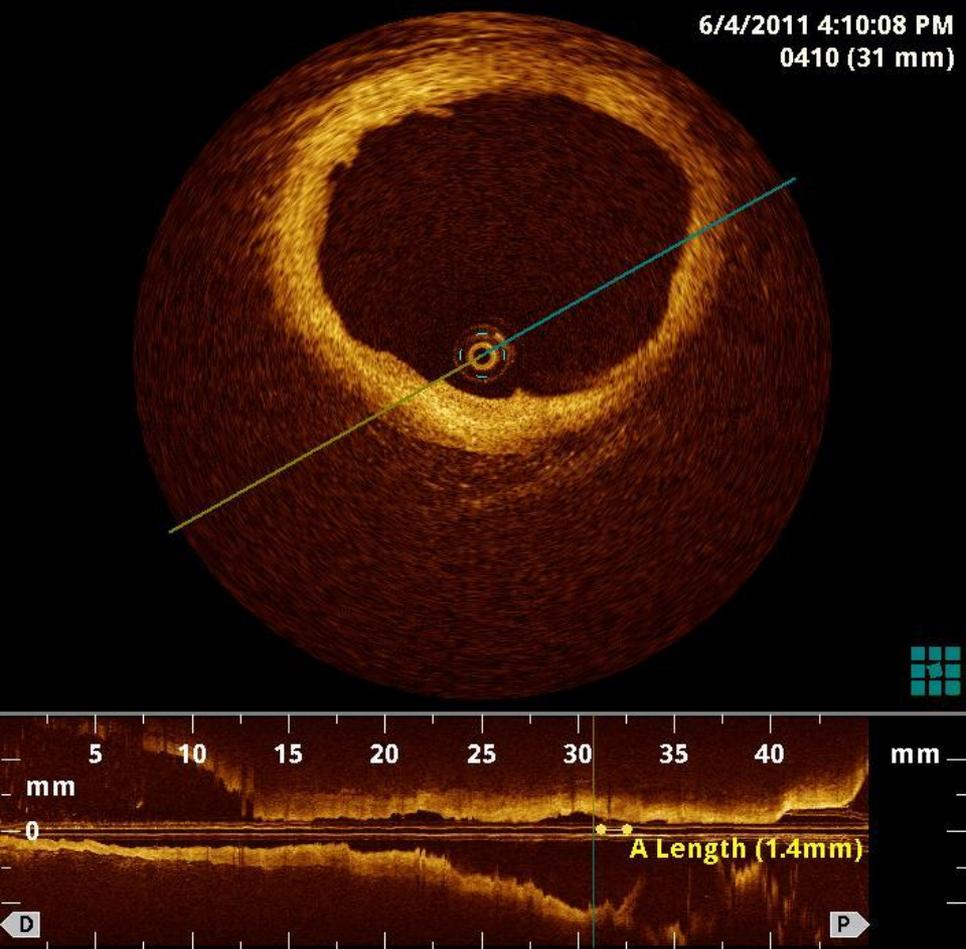
Minimum : 2.52mm

Mean : 2.86mm

Dilation:

8atm X 30sec.





Case 2 – Post PTA: OCT

super non-compliant balloon 4mm × 4cm **8atm**

Maximum : 3.45mm

Minimum : 2.81mm:

Mean : 3.09mm。

Results

- #1. In low-pressure dilation, using an ultra-high pressure balloon, the luminal diameter required for dialysis was obtained by dilation at 3 to 4 atm.
- #2. By repeating dilation at low-pressure several times for 1 min each time, repeat narrowing was almost completely avoided.
- #3. After thrill was obtained, pressurization was performed with the objective of full dilation, but there was no difference in the enlargement of the lumen. Due to additional dilation at higher pressure, the damage to and divergence of the vascular endothelium extended over the whole circumference.

Conclusions

- #1. To observe the endothelium after pressurization in PTA, the degree of endothelial damage was observed by OCT.
- #2. It was confirmed that from when narrowing remains despite sufficient blood flow for dialysis, to when the constriction in the balloon disappears, endothelial damage increases and re-narrowing due to endothelial repair tends to occur easily.
- #3. It is suggested from the image that endothelial damage due to complete dilation leads to re-narrowing at an early stage.

Conclusion Continued

#4. When dilating a narrowed site with VAIVT in order to ensure sufficient dialysis volume during blood extraction in AVF, full dilation is not required.

The important thing is to operate to ensure optimal dialytic blood flow volume at a lower pressure.

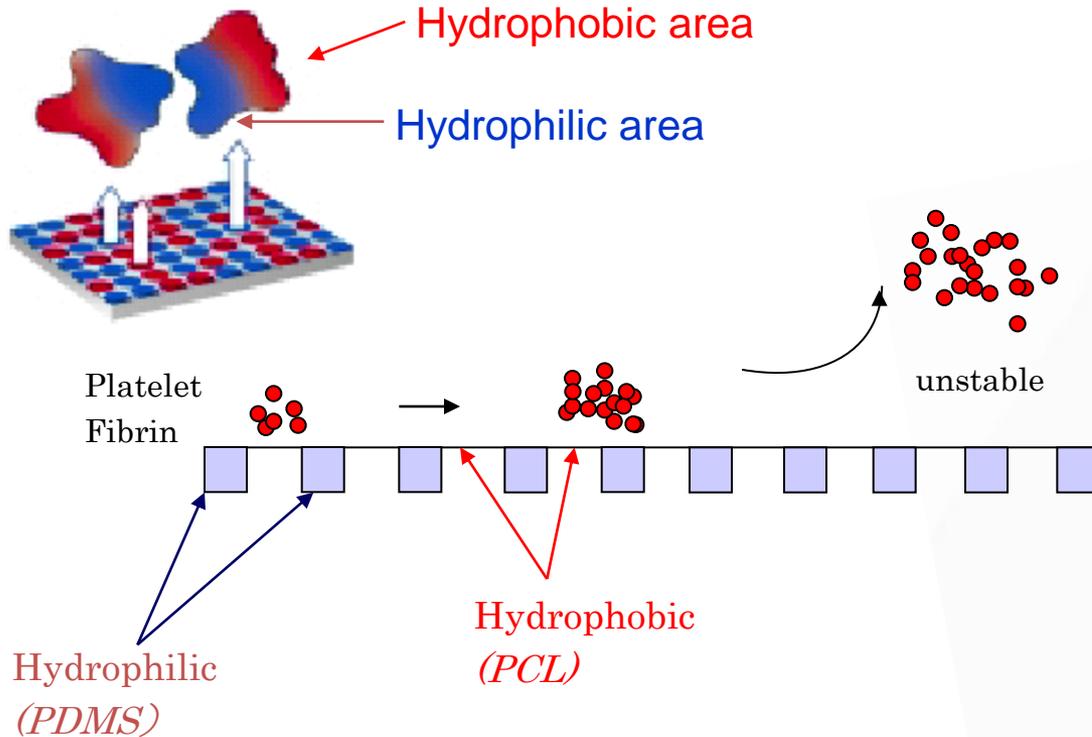
Micro domain structure for Dolphin[®] coating

Description and mechanism



Microdomain surface structure

-reduces protein adsorption and cell activation



When there is the necessity of using a central venous catheter for a treatment, the catheter with the microdomain surface which reduces thrombogenic events and subsequently leads to prolonged catheter survival is better for use.

GamCath Dolphin® Catheter Mechanism of dolphin coating

PDMS-PCL creates hydrophobic/hydrophilic microdomains with about 5-10 nm

If the size of a hydrophobic and hydrophilic domain is below a critical threshold, the probability for stable interaction between the synthetic material and the macromolecules and cell membranes is sharply decreased, since the critical threshold value of free energy for stable interaction is not reached.

*Deppisch et al
Microdomain structure of polymeric surfaces
NDT (1998) 13: 1354-1359*

