

2D Perfusion Guided BK-EVT for CLI patient

~ Data release of multicenter study and Case review ~

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Background

Novel Methods for assessing endpoint in BK EVT

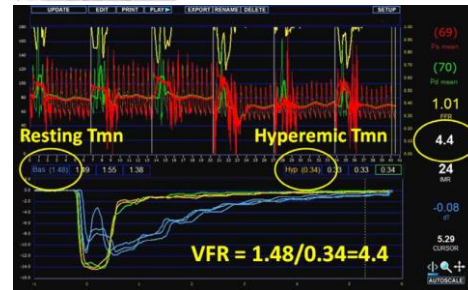
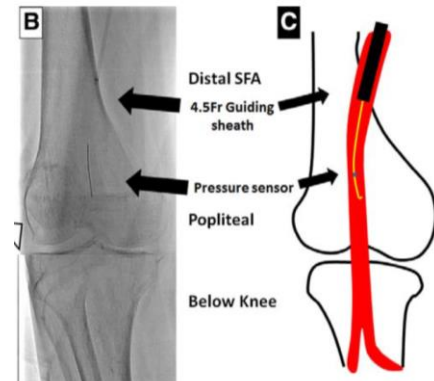
Wound Blush



Utsunomiya et al. JVS 2012; 55; 113-21
Utsunomiya et al. JACC Cardiovasc Interv.
2017 Jan 23;10(2):188-194

Visual assessment only

VFR



Fukunaga et al.
Circ Cardiovasc Interv. 2015;8:e002412.

Additional device

Indigo carmine



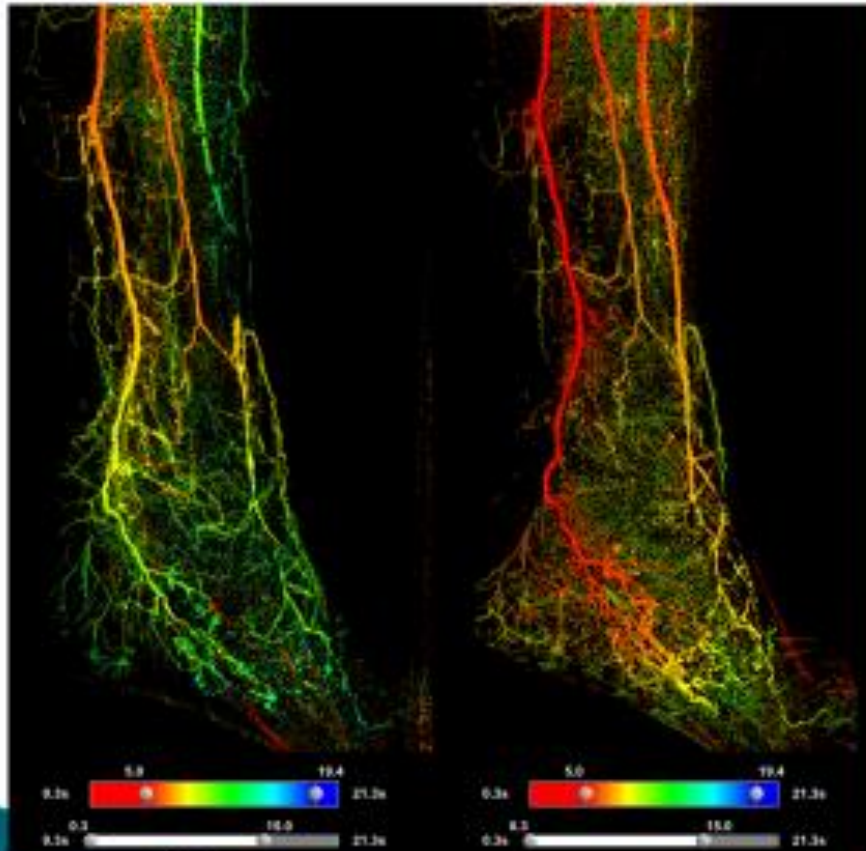
Higashimori et al. J Endovasc Ther. 2015
Jun;22(3):352-5.

Visual assessment only

New imaging modality

2D Perfusion

Philips Volcano is tackling the PAD challenge head on



2D Perfusion imaging technology

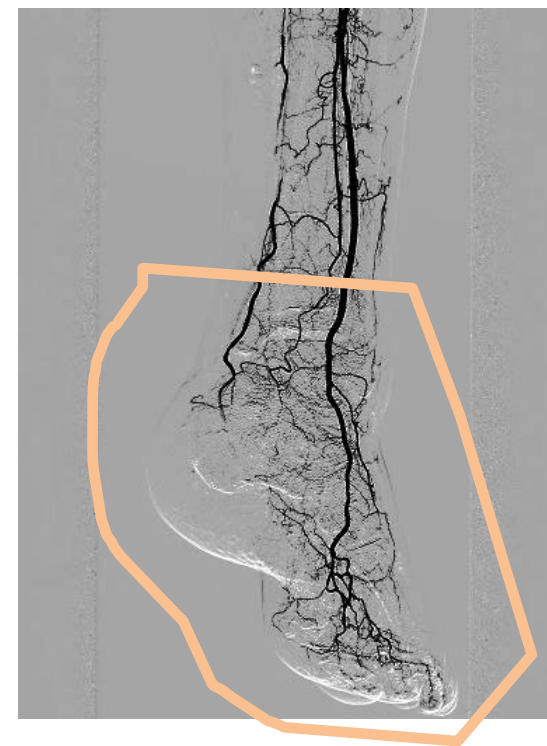
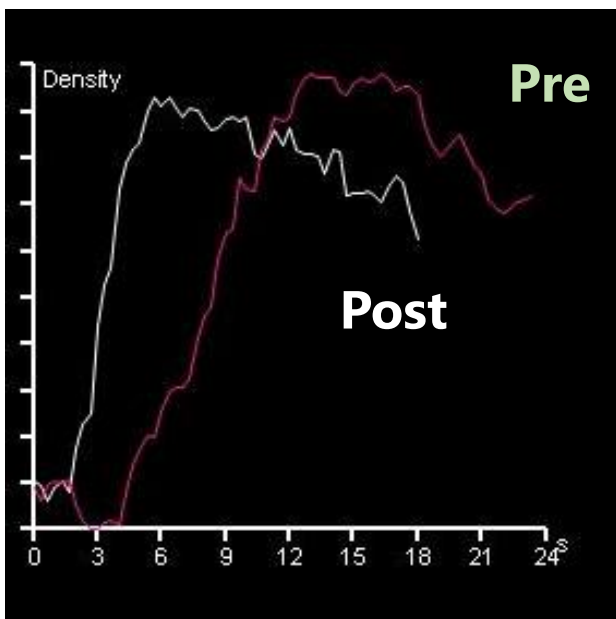
Perfusion Imaging is a software product that provides functional information about tissues perfusion based on a digital subtraction angiography (DSA).

Provides interventionalists an objective understanding of the impact of their treatment to help determine the outcome of perfusion procedures.

Only Take Angio@Pre & Post EVT

Post

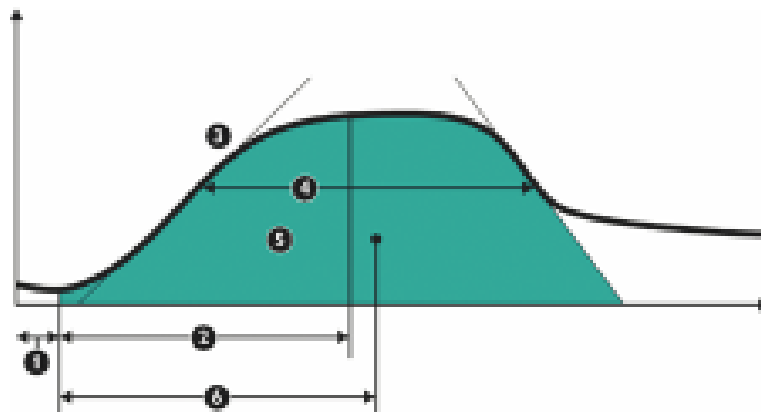
Pre



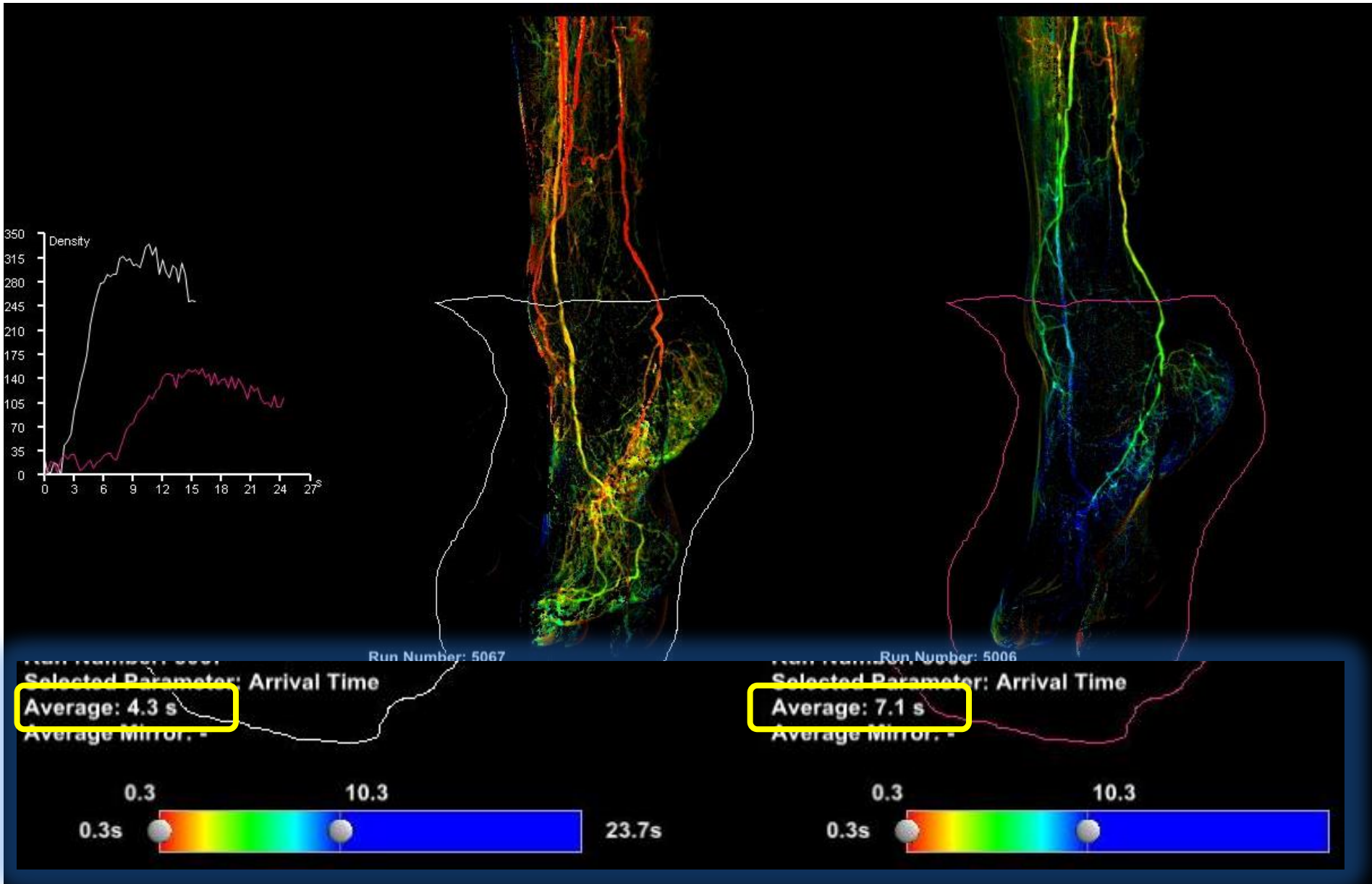
Workflow and parameters

The time-density parameters are defined as follows:

1. **Arrival time:** Time from start of the measurement till the start of the contrast uptake. Provides a ratio of pre and post treatment velocity changes and a gross upper estimate of blood velocity from point of contrast injection to ROI if approximate distance between points are measured (e.g. external lead tape)
2. **Time to peak:** Reflects the flow rate of the bulk of the contrast (compared to fastest contrast in arrival time measure); shorter TTPs suggest higher flow rates
3. **Wash in rate:** Represents the steepness of the slope of the wash in curve
4. **Width:** Metric of duration of average contrast passage time. Larger widths (longer mean transit times) suggest slower passage of flow in and out of a region of interest
5. **Area under curve:** When the total amount of contrast is constant in a region of interest, it can be used to estimate volumetric blood flow
6. **Mean transit time:** Similar to width parameter, but taking asymmetry into account



Quantitative Evaluation



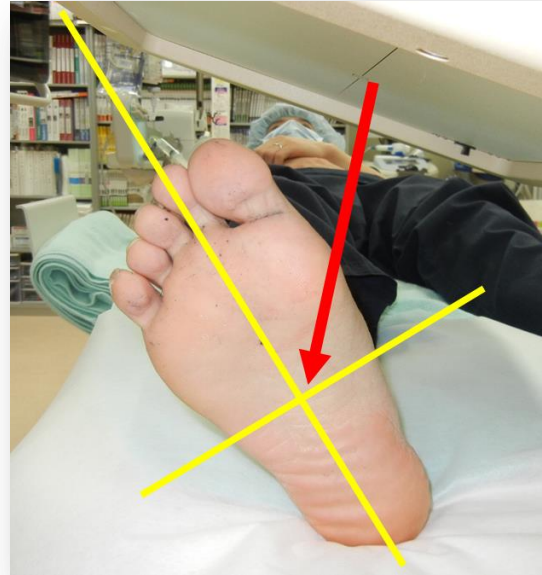
Original Protocol of 2D perfusion

1. Catheter position



3-4.5Fr catheter placed in the P2.

2. Projection



45 degree inner anterior oblique from long axis

3. Acquisition protocol



- ✓ Iodixanol (VISIPAQUE®)
- ✓ Injection of 3ml/sec over 2sec.
- ✓ ROI of hole foot area

Definition in order to evaluate results

What "Successful Wound Heal" after BK EVT?

Success

- ✓ Complete heal without any additional intervention or unplanned surgery.



Unsuccess

- ✓ **Delayed healing** over 6M.
- ✓ **Remained Rest pain** after EVT.
- ✓ **Re-intervention** before wound healing.
- ✓ Wound **dehiscence or infection** after amputation.
- ✓ Need for **adjunctive therapy or major amputation**.



2DP multicenter study

The Relation of 2D Perfusion Angiography and Wound Healing rate in Patients with Critical Limb Ischemia after Endovascular Treatment Therapy -Multicenter Prospective Study-

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Material and Method

Study Design and Patients

- ✓ A prospective, multicenter, single-arm, open label .
- ✓ CLI patients: planned infra-inguinal EVT.

Inclusion and Exclusion Criteria

Inclusion criteria

- Age >20 years old
- Rutherford category class (RCC) 5–6
- Performed 2D perfusion angiography both pre and post procedure.

Exclusion Criteria

- **Intense inflammation** (Wifi fI-3)
- **Major tissue loss** (Wifi W-3)
- Not available contrast media (ex: ESRD)

Study Subjects

2DP angiography during EVT with CLI
94 pts, 121 limbs

Term: Jun. 2017 – Aug, 2018

Exclusion

- AK group: 7 limbs
- Not evaluable (motion): 2 limbs
- Intense inflammation: 1 limbs

2DP success at
pre and post BK EVT for CLI
82 pts, 100 limbs

Clinical
Follow-up
(Over 3 months)

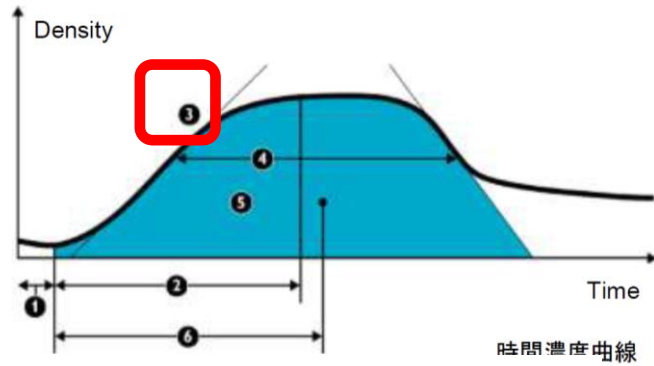
Success group
69 limbs

Unsuccess group
31 limbs

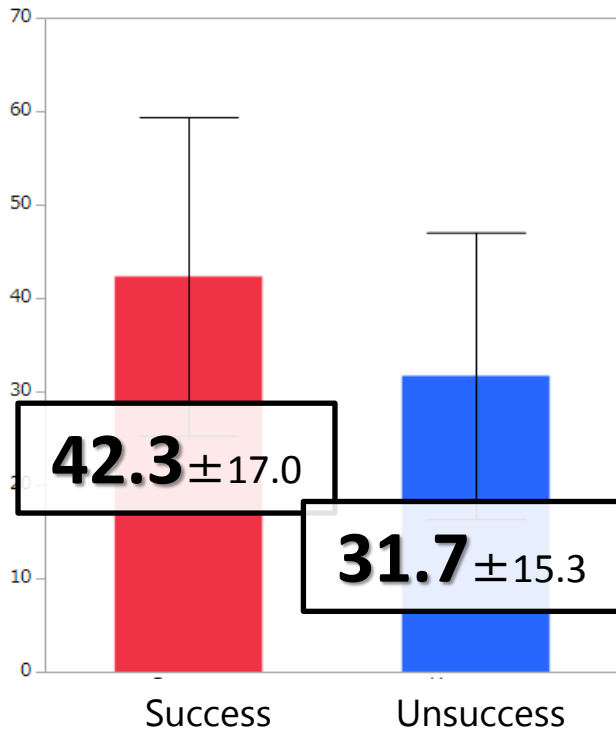
Exclusion

- Lost follow-up within 3 month: 2 limbs

Significant parameter

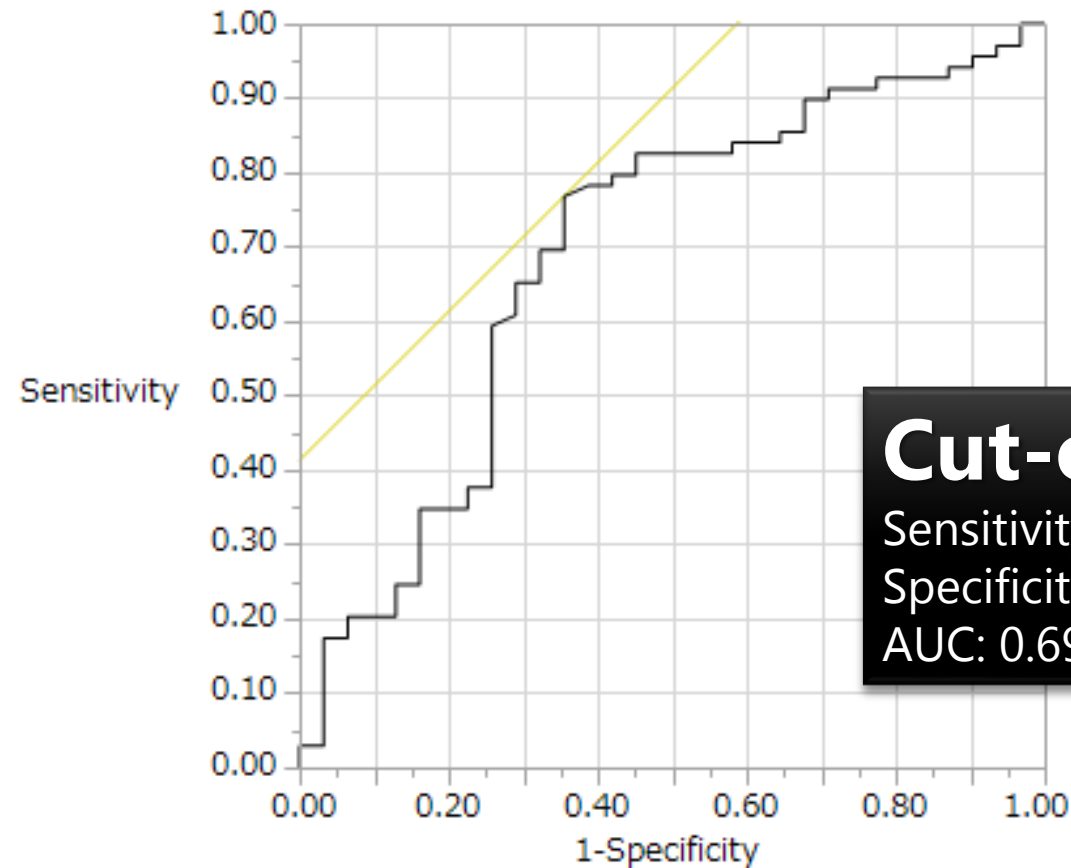


時間濃度曲線



“Wash-in rate”

(WIR, maximum slope of time-density curve)



Predictor of Wound Success

-Angiographic or Procedural Variables-

Uni-variate

Multi-variate

	OR	95%CI	p value	OR	95%CI	p value
WIR > 31.8	6.02	2.39 - 15.17	0.0001	5.33	1.85 - 15.35	0.0019
Wound Blush	6.58	2.55 - 16.95	<0.0001	3.76	1.23 - 11.45	0.0198
Treated Vessel Number (Per 1 vessel)	2.19	1.09 - 4.37	0.0178	1.51	0.61 - 3.72	0.36
Pedal Artery Angioplasty	2.11	0.85 - 5.24	0.11	1.50	0.45 - 4.95	0.51
Angiosome Direct	1.61	0.61 - 4.25	0.34	1.11	0.31 - 4.05	0.87

Logistic regression analysis

Summary of this study

- ✓ **2D perfusion angiography in the BK EVT for CLI.**
New imaging modality based on DSA.
Can get both visual and quantitative information.
- ✓ **Make easier protocol.**
Perform in short time during procedure.
Lower addition of contrast.
- ✓ **Novel outcome “Wound Success”.**
For evaluating the effect of initial EVT in the setting of CLI with “small” ulcer or gangrene.
Defined as complete healing without any additional intervention or surgery.
- ✓ **Predictive parameter “Wash-in rate” and cutoff “31.8”**
Clearly know prognosis of the wound immediately after EVT.

CASE REVIEW 1

Low WIR after initial EVT, wound unsuccessful case

CASE 1: Unsuccess Case

70's y.o. male

HD/DM

ADL: Crutch Walking

Frailty scale 5

Left leg

Wifi 4 (W2, I3, FI0)

ABI: 1.29

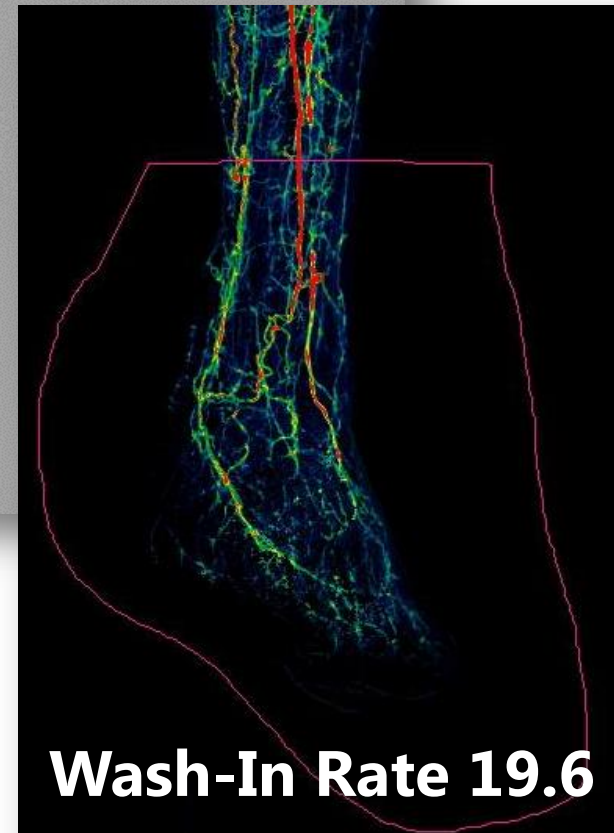
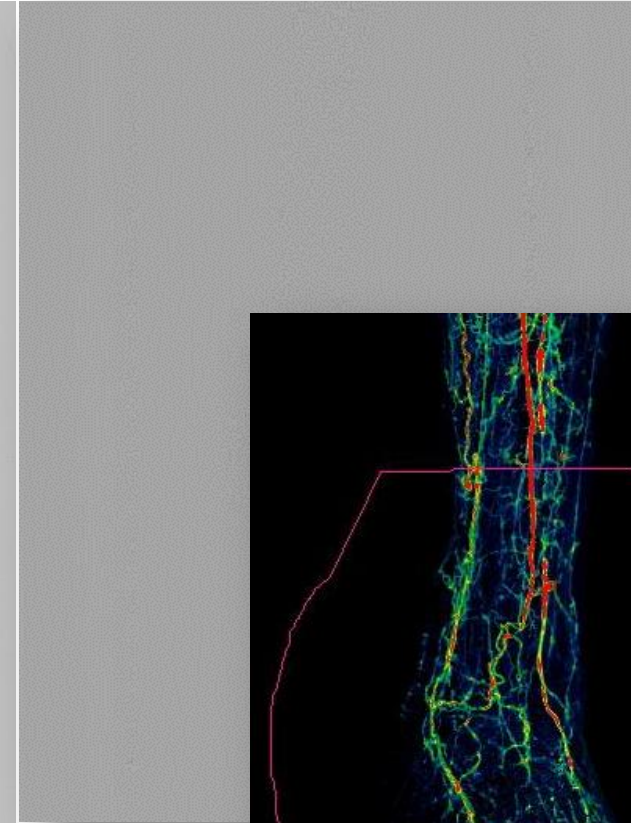
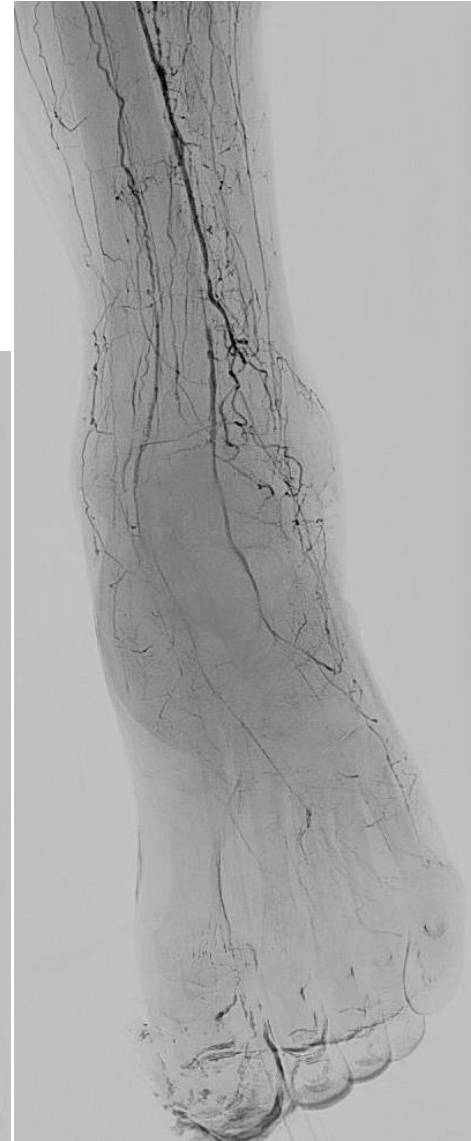
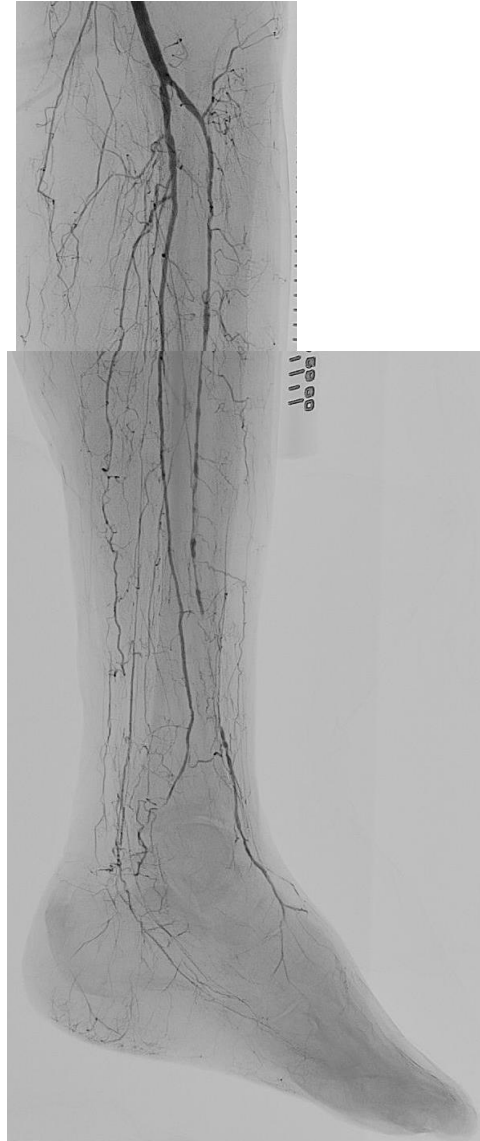
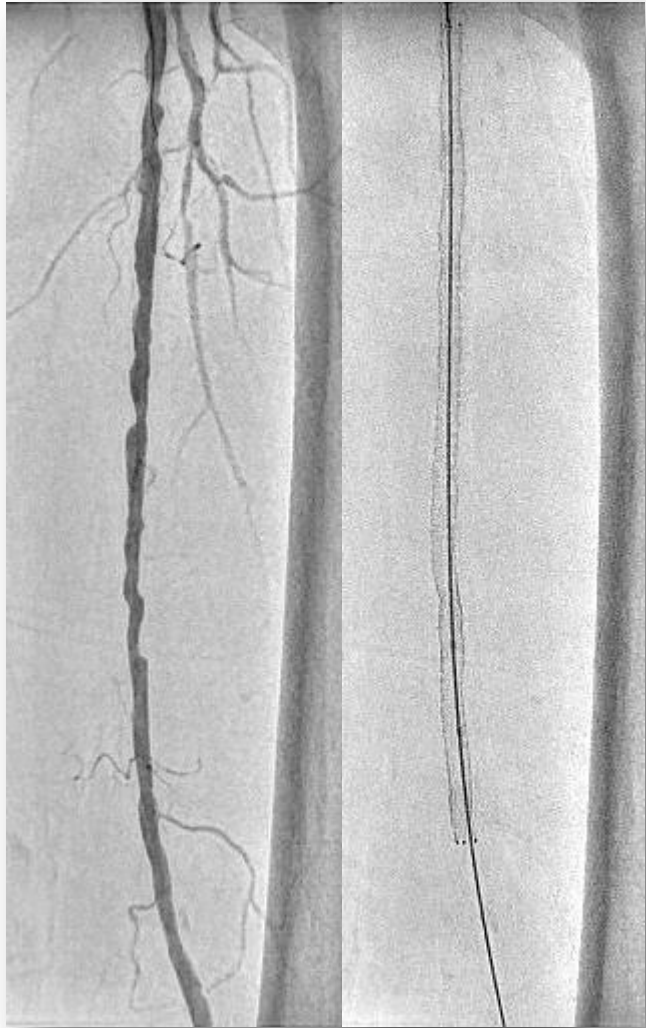
SPP: 28/ 31 mmHg



CASE 1: Unsuccess Case

Day 5 EVT for Lt. SFA and BK

Perfusion Angiography



CASE 1: Unsuccess Case

Day 5 EVT for Lt. SFA and BK



Wound Blush (-)

CASE 1: Unsuccess Case

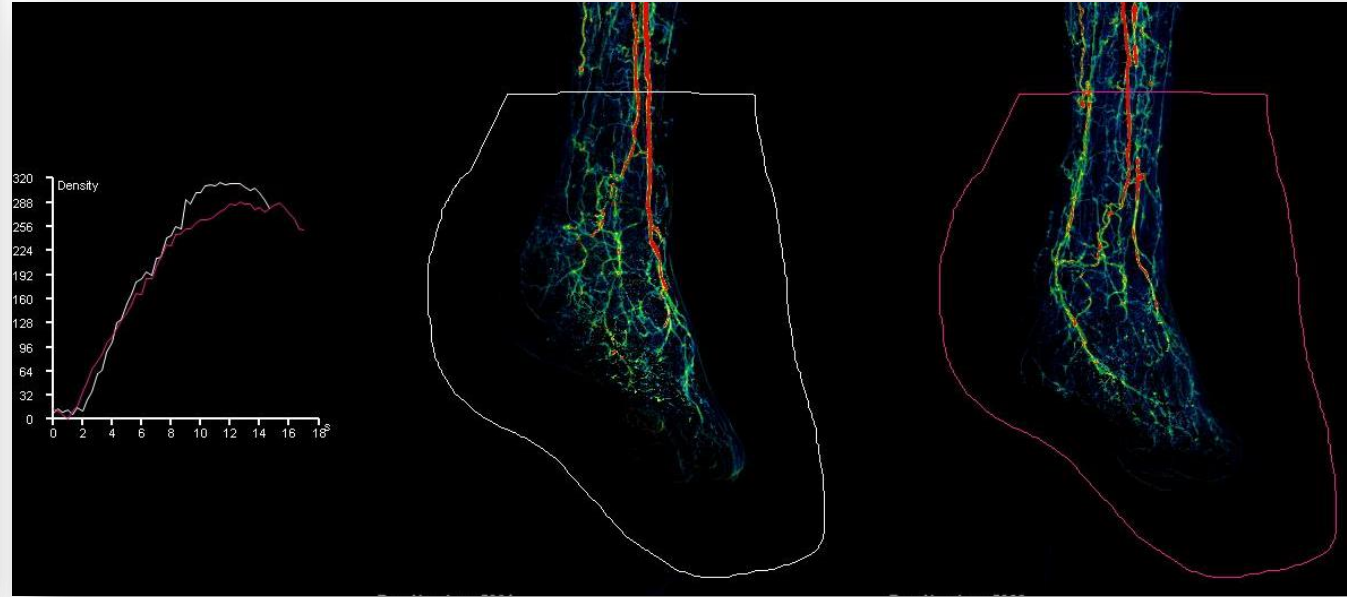
Day 5 EVT for Lt. SFA and BK

Post

Pre

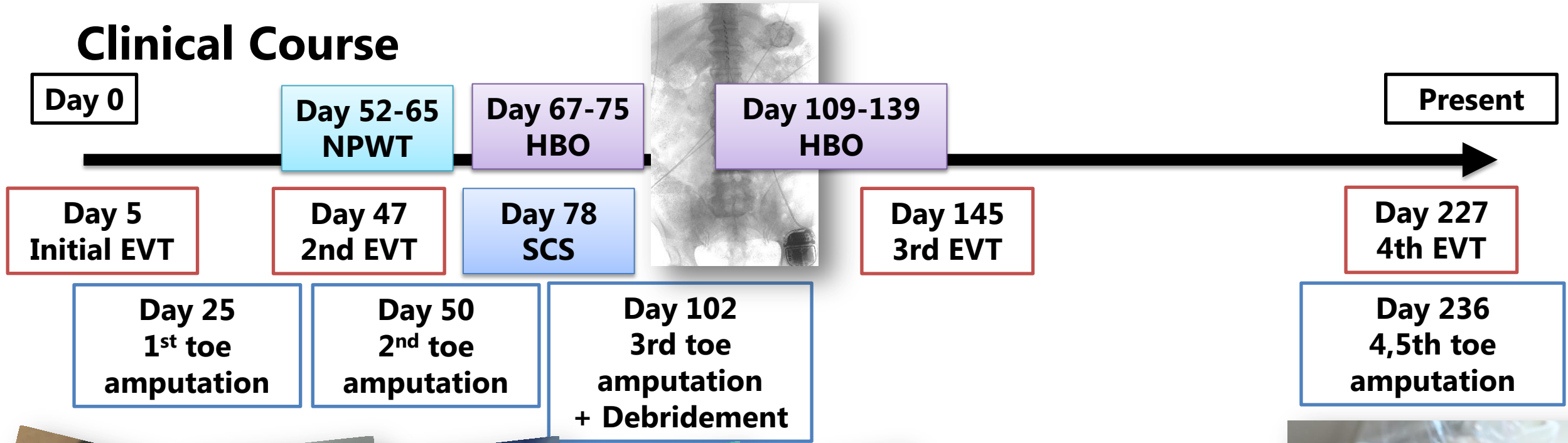
Post WIR: **25.9**
(<31.8)

Pre WIR: **19.6**



CASE 1: Unsuccess Case

Clinical Course



CASE REVIEW 2

2D Perfusion Guided EVT

CASE 2: 2DP Guided EVT Case

80's y.o. male

HD/DM

ADL: Wheel chair

Frailty scale 7

Right leg

Wifi 1 (W1, I1, FI0)

ABI: 0.85

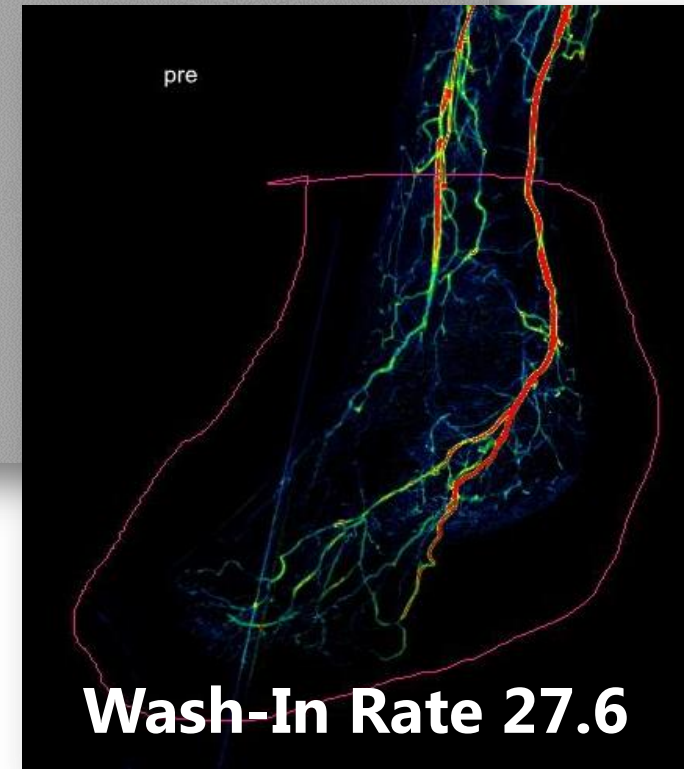
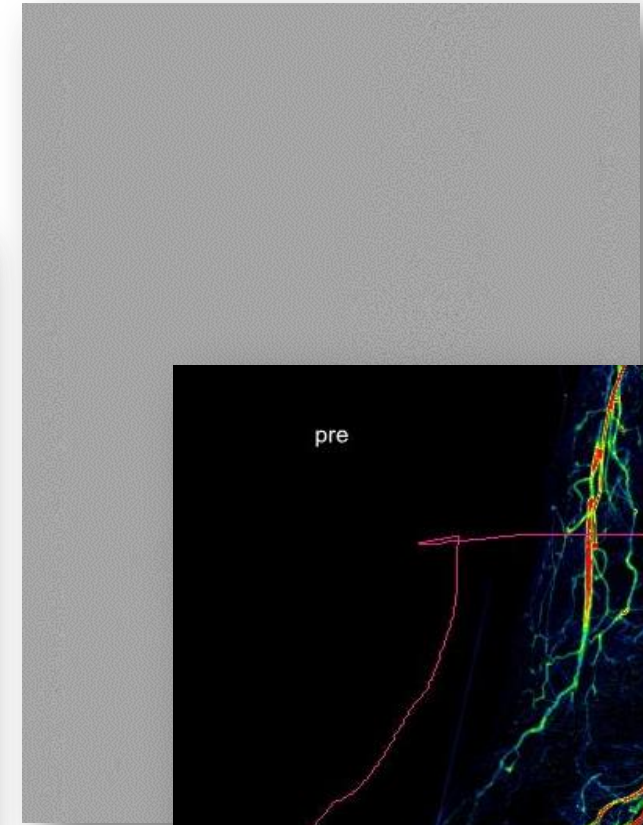
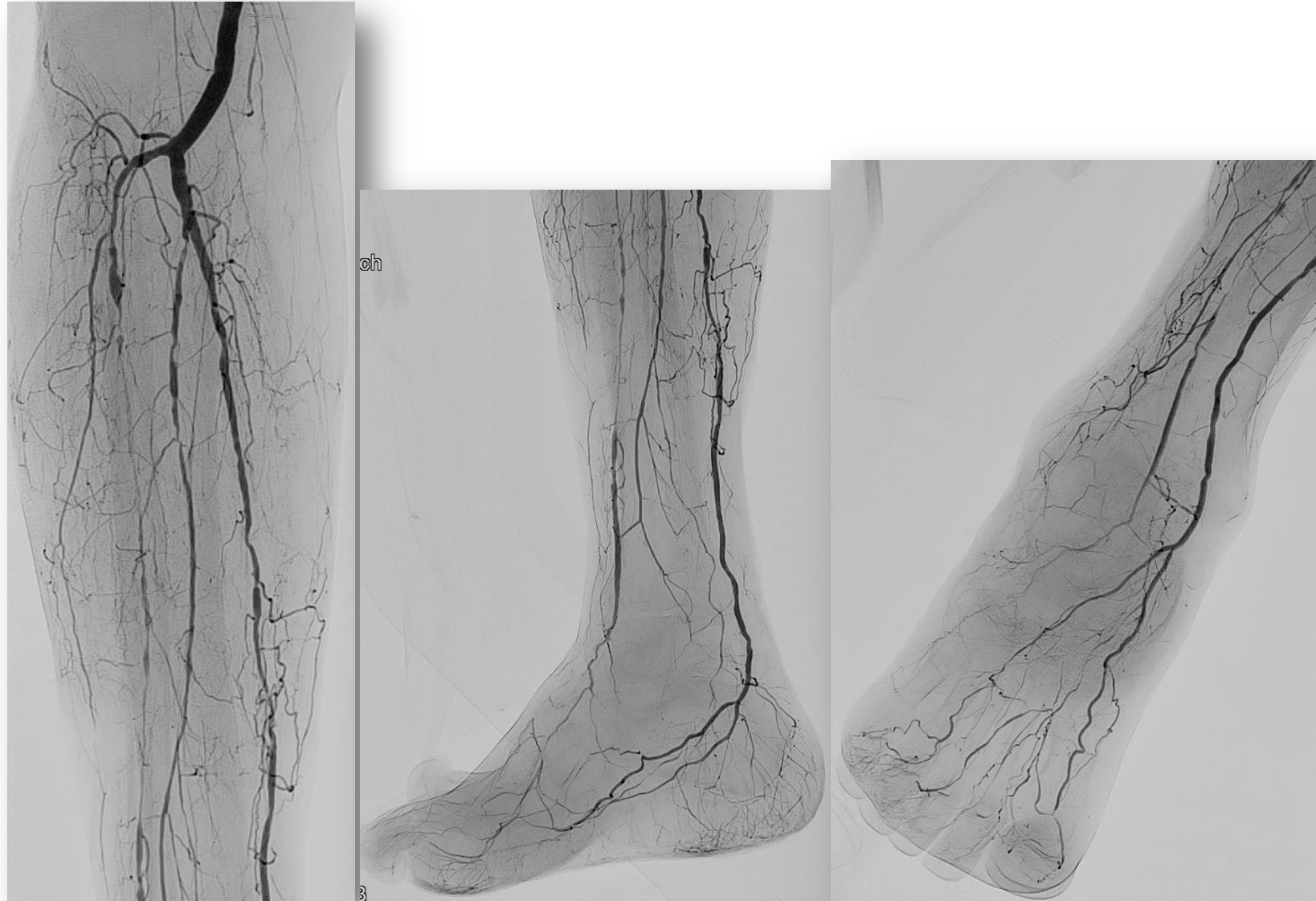
SPP: 51/ 0 mmHg



CASE 2: 2DP Guided EVT Case

EVT for Rt. BK

Perfusion Angiography

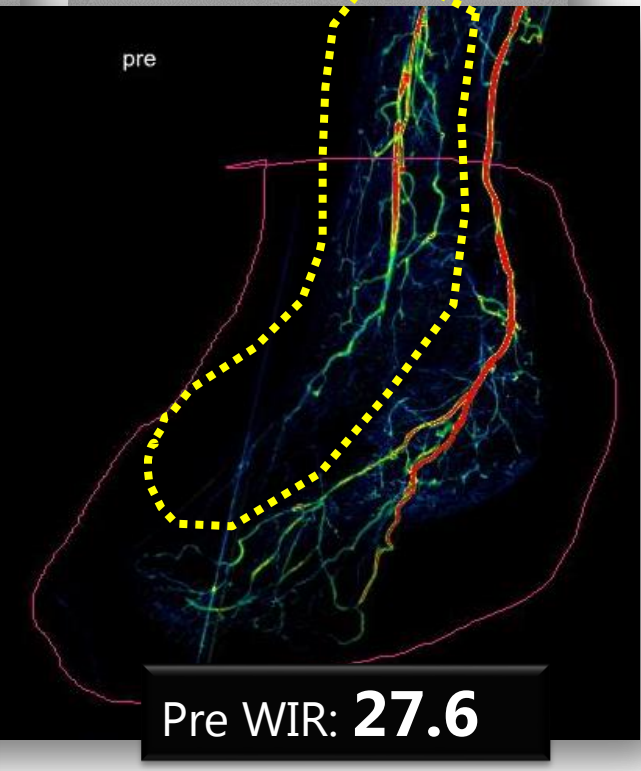
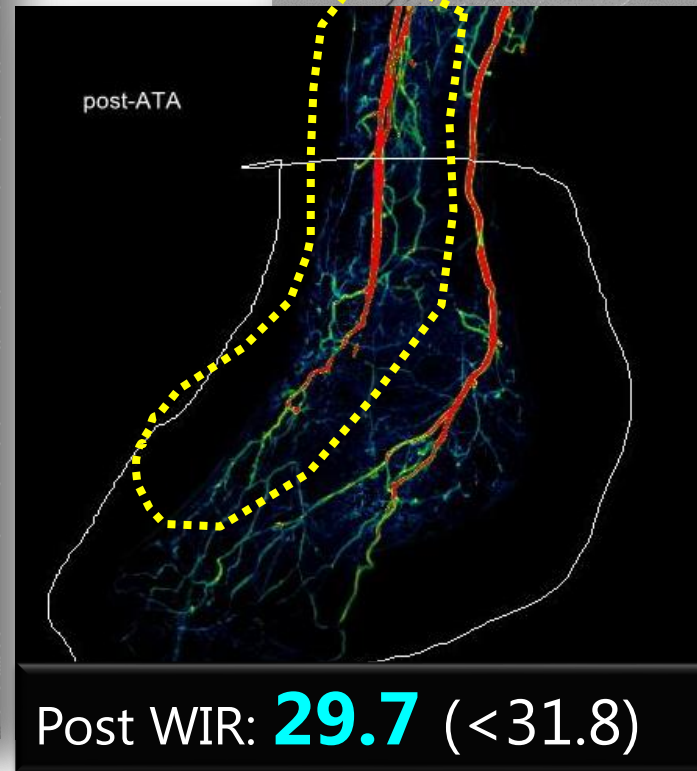
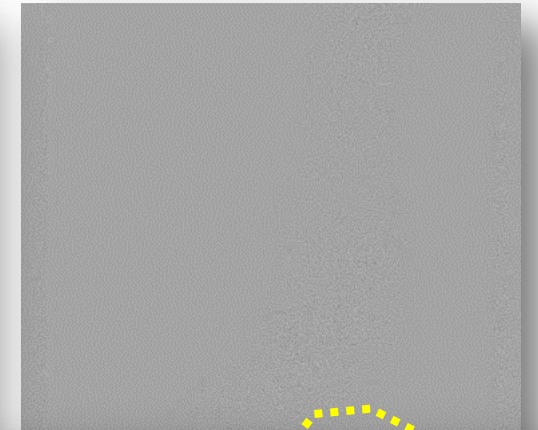


CASE 2: 2DP Guided EVT Case

POBA for ATA (Angiosome guided)

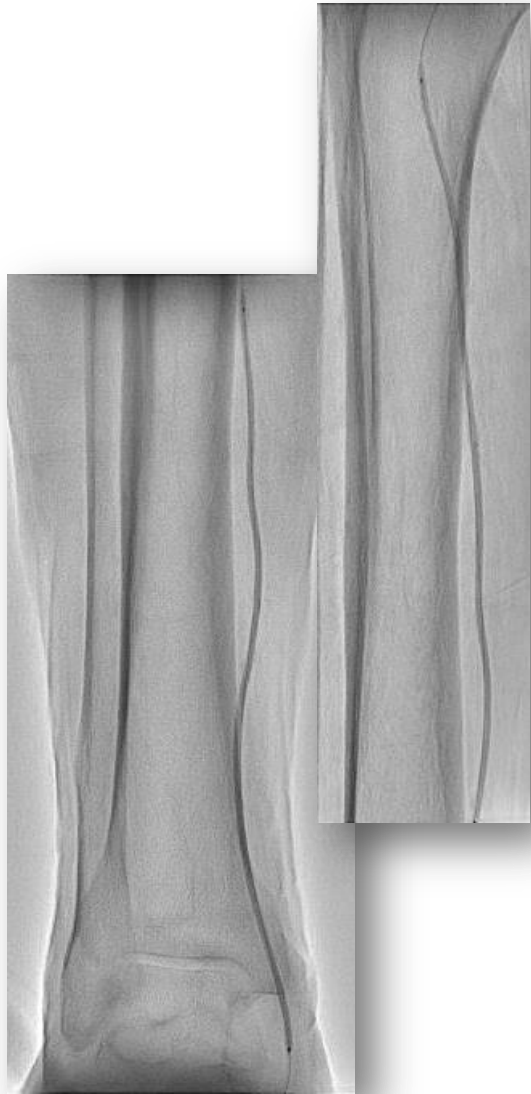
Post

Pre



CASE 2: 2DP Guided EVT Case

Additional POBA for PTA (2DP guided)



2DP Guided EVT Case

POBA for ATA and PTA

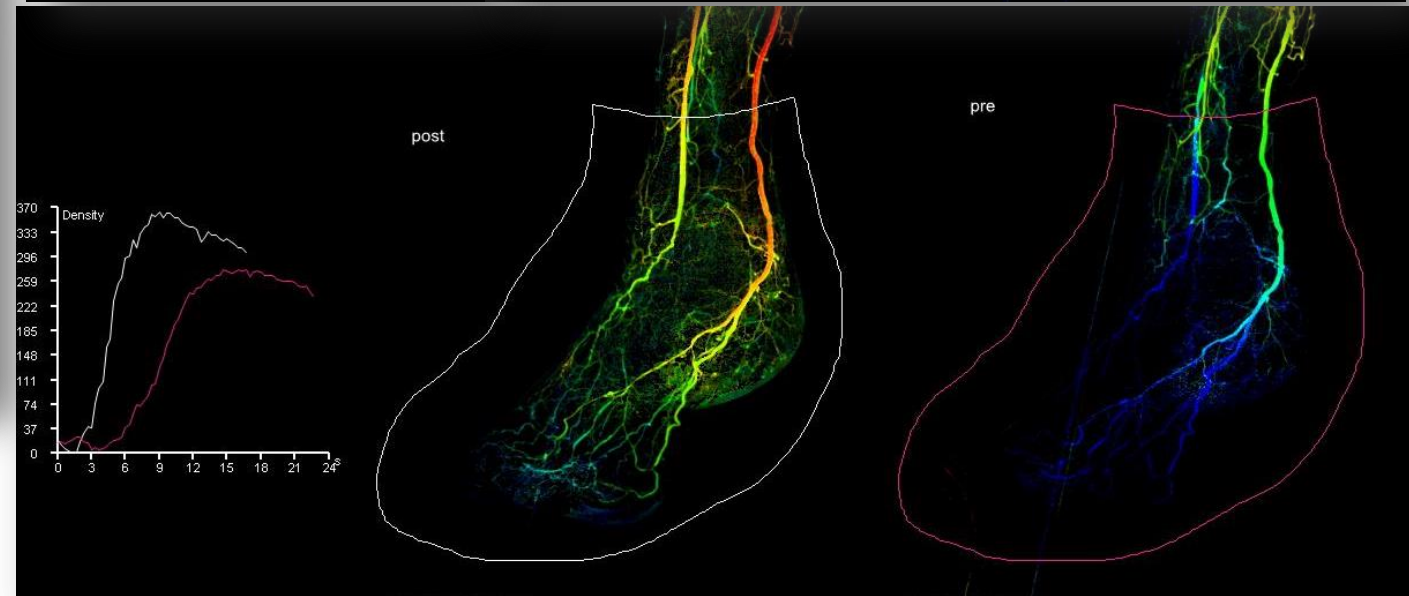
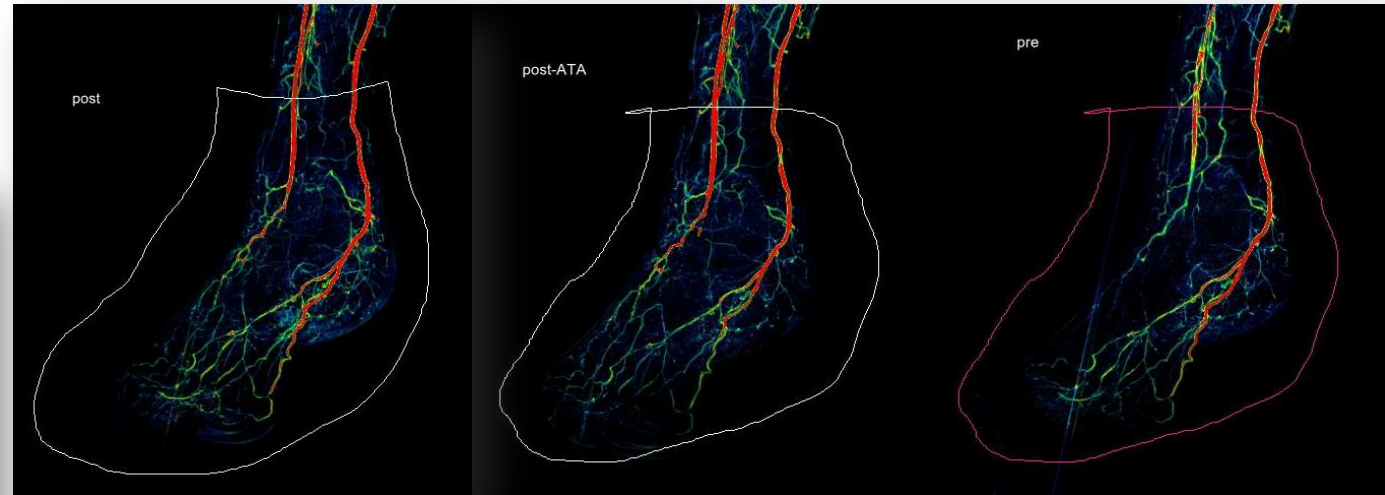
Post PTA
WIR: **41.4** (>31.8)

Post ATA
WIR: **29.7**

Pre
WIR: **27.6**

Post

Pre



Time density curve and
Color mapping at **Arrival Time**

2DP Guided EVT Case

Clinical Course



Pre



3 weeks after

- ✓ Complete epithelialization within 3 months.
- ✓ No need for additional intervention.
- ✓ No rest pain.
- ✓ No additional surgery.

Conclusion

- ✓ 2D perfusion can **easily perform** during BK-EVT .
- ✓ Can get **quantitative information** immediately after EVT.
- ✓ The cutoff "**31.8**" at **Wash-in rate** was useful for judgment of the end point of BK-EVT.