IVL: a reliable and efficacious vessel preparation srtategy

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Disclosure

Speaker name: Francesco Liistro

I have the following potential conflicts of interest to report:

- x Consulting: Medtronic, ACOTEC Ltd, Boston Scientific, Biotronic
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)I do not have any potential conflict of interest

Mecchanism of Target Vessel Failure in peripheral intervention

- Residual s (plaque burden/recoil)
- F.L. Dis
- Thr

Early

- Negative ling
- Intim rplasia

Late

Vessel Preparation

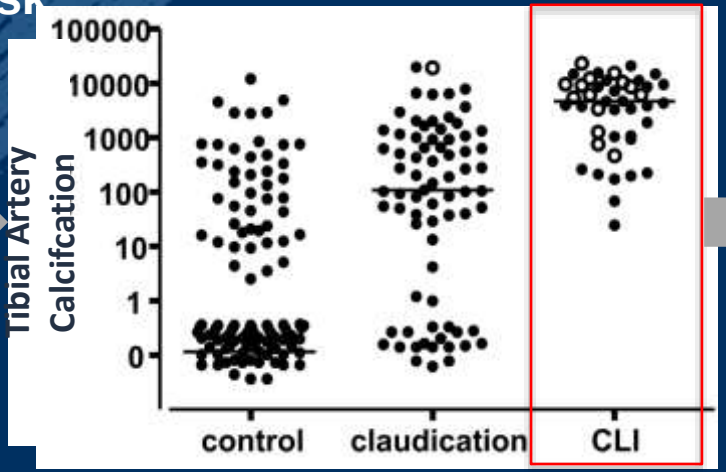
Limit the mechanisms of early angioplasty failure and allow a maximal lumen diameter without flow-limiting dissection to prepare the vessel for a Drug-Elution Strategy

Optimal Balloon Angioplasty

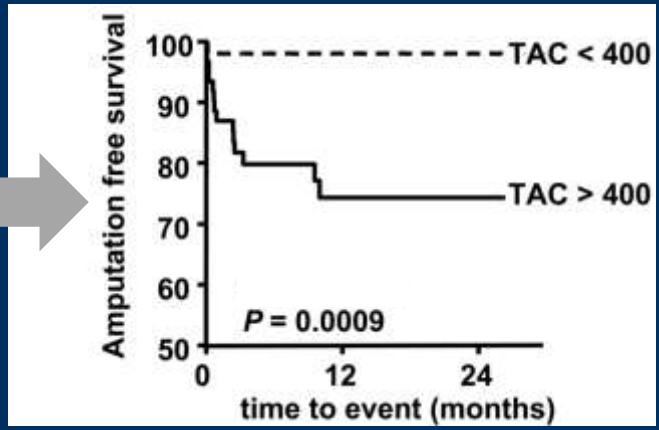
Calcification of peripheral vessels significantly worsens prognosis

Is the presence of calcium related to or predictive of poor outcomes?

Tibial artery calcification is predictive of ischemia severity, wound healing rate[1] & amputation risk[2]



Calcium is a predictor of CLI

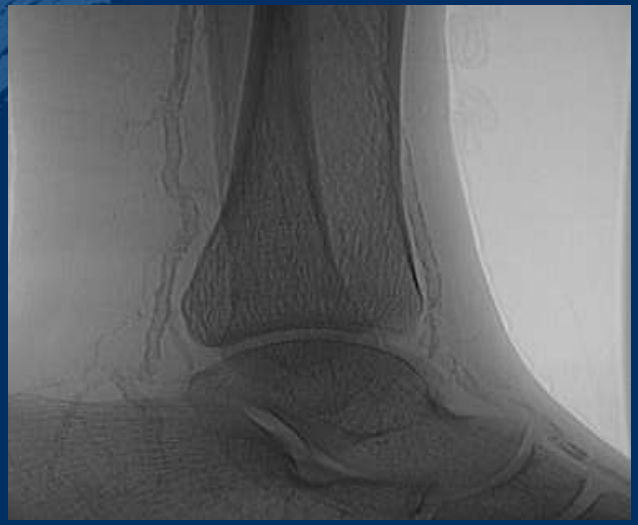


Degree of calcification is a predictor of amputation[2] and wound healing[1]

1) Mori et al, Relationship between tibial artery calcification and wound healing in patients with foot tissue loss, LINC 2017
2 Guzman et al, Tibial artery calcification as a marker of amputation risk in patients with PAD, JACC 2008

Calcification and desert foot

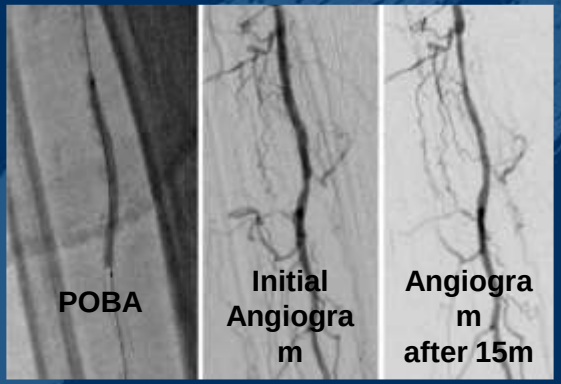
Massive calcification

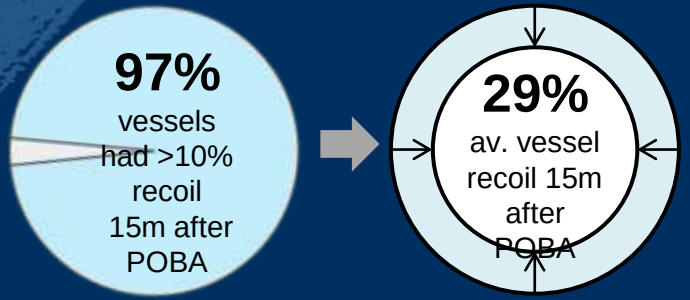


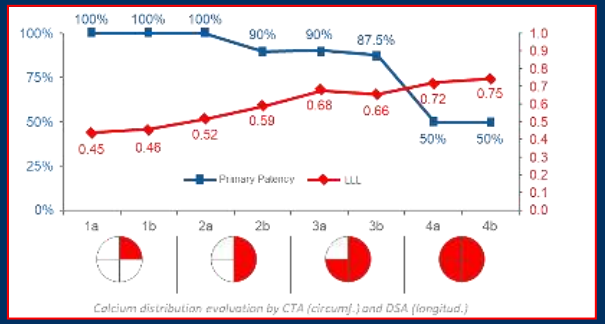
Desert Foot: no distal target

Significant Calcium Burden

- **Calcium increases recoil and severe dissection for the need of high pressure/size balloon inflation**





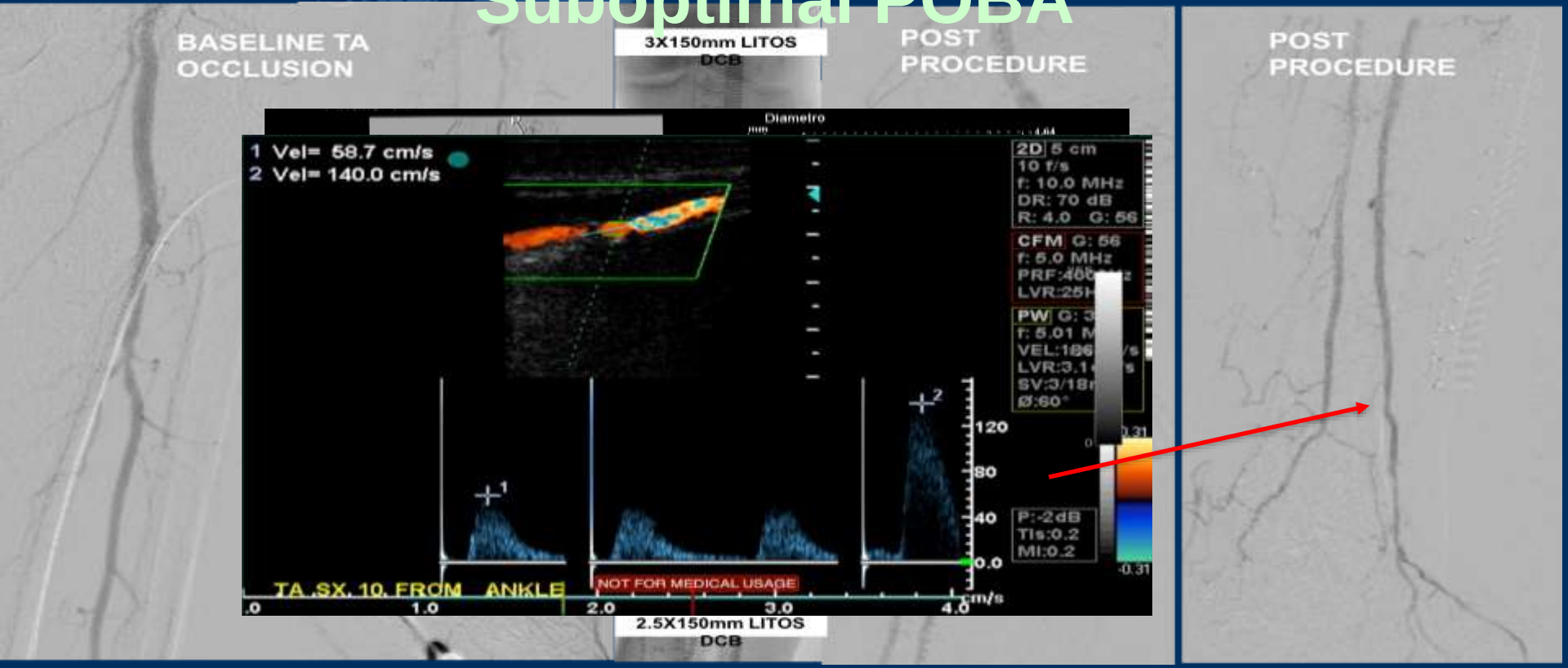


Medial calcification produces vessel recoil, dissection, reduces drug uptake increasing restenosis[2,3,4,5]

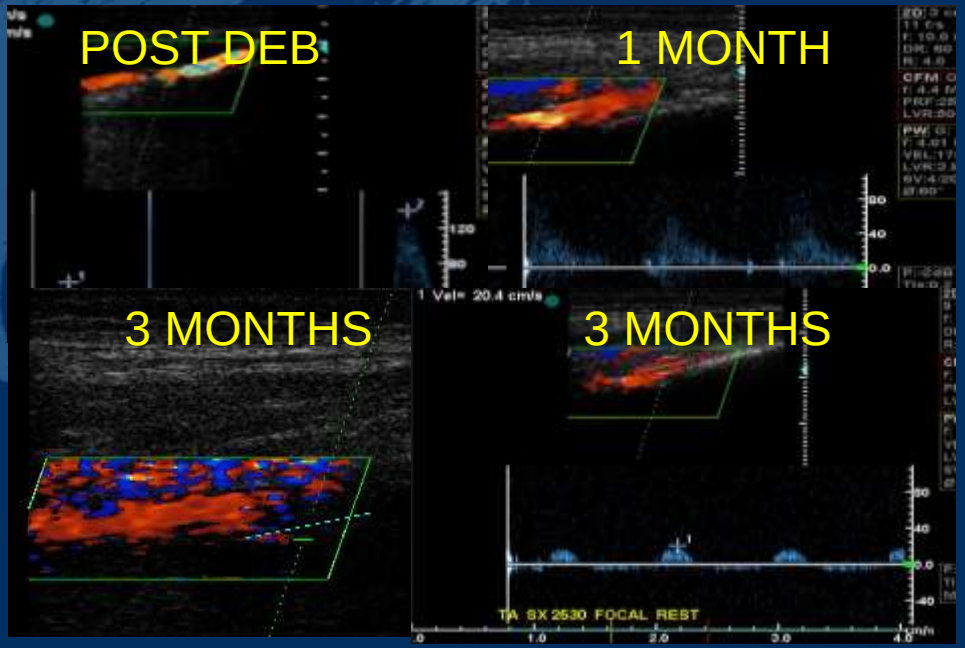
Medial calcification → **Arterial Stiffness** → **Suboptimal PTA result** → **Less drug up-take** → **Early reocclusion**

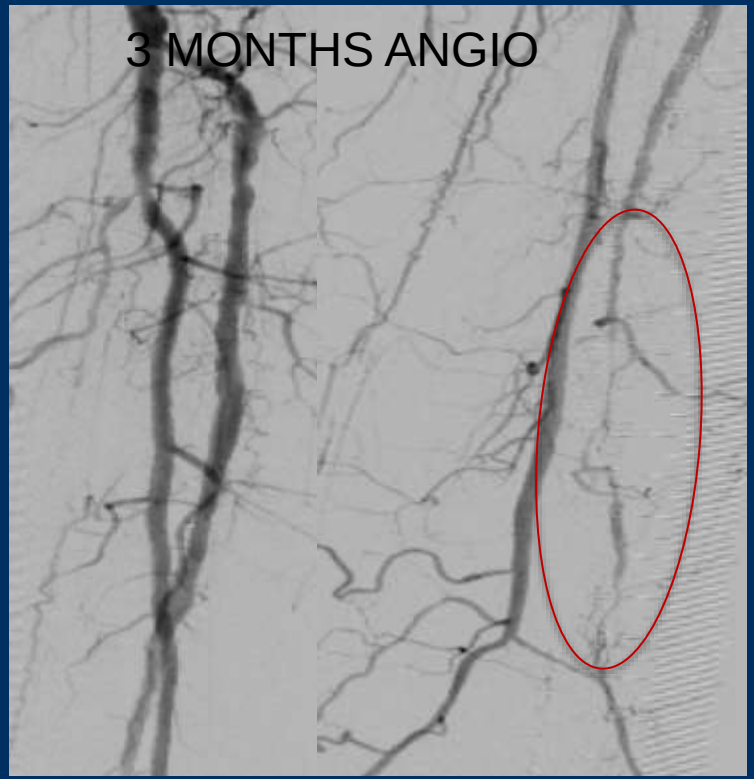
1) Baumann et al, Early recoil after balloon angioplasty of tibial artery obstructions in patients with critical limb ischemia, J Endovasc Ther 2014
2) Guzman et al, Tibial artery calcification as a marker of amputation risk in patients with PAD, JACC 2008
3) Zettervall et al, Association of arterial calcification with CLI in patients with PAD, J Vasc Surg 2017
4) Mustapha et al, One-Month Duplex Ultrasound Evaluation of Vessel Recoil After Tibial Peripheral Vascular Intervention for Critical Limb Ischemia Predicts 12m TLR, AMP 2017

Residual significant narrowing due to Suboptimal POBA



Suboptimal POBA
Early reocclusion also with DCB





Why IVL for peripheral interventions?

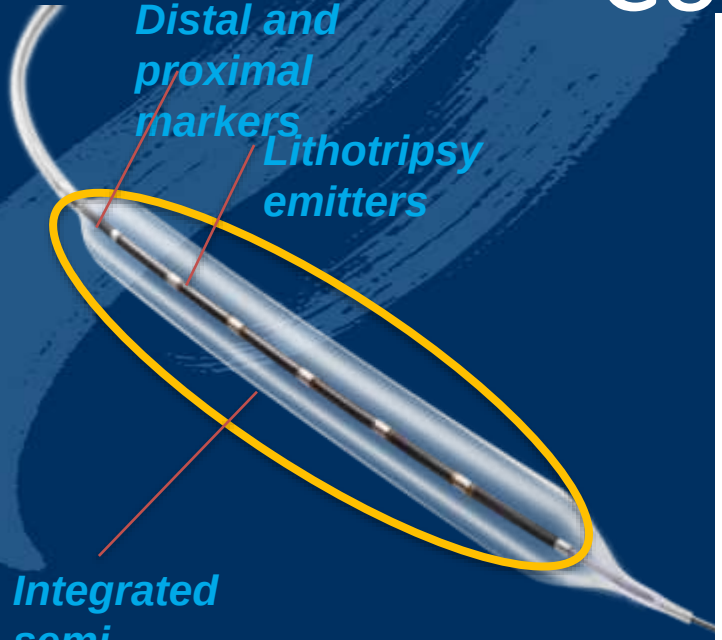
Optimal Balloon Angioplasty

- ✓ Reduce immediate recoil
- ✓ Allows complete vessel dilatation
- ✓ No tissue demage
- ✓ No distal particles embolization
- ✓ Applicable in subintimal

Drug elution strategy

- ✓ Increase drug penetration into the vessel wall
- ✓ Increased drug storage and effect

Shockwave Peripheral IVL System Components



Calcium Barrier reduces optimal PTA and limits penetration of the drug into the media/adventitia

Devices for calcium barrier management before DCB use

- ✓ **High pressure NC ball.**
- ✓ **Scoring balloons**
- ✓ **Debulking devices**
  - **Atherectomy**
    - **Directional**
    - **Orbital**
    - **Laser**
- ✓ **IVL**

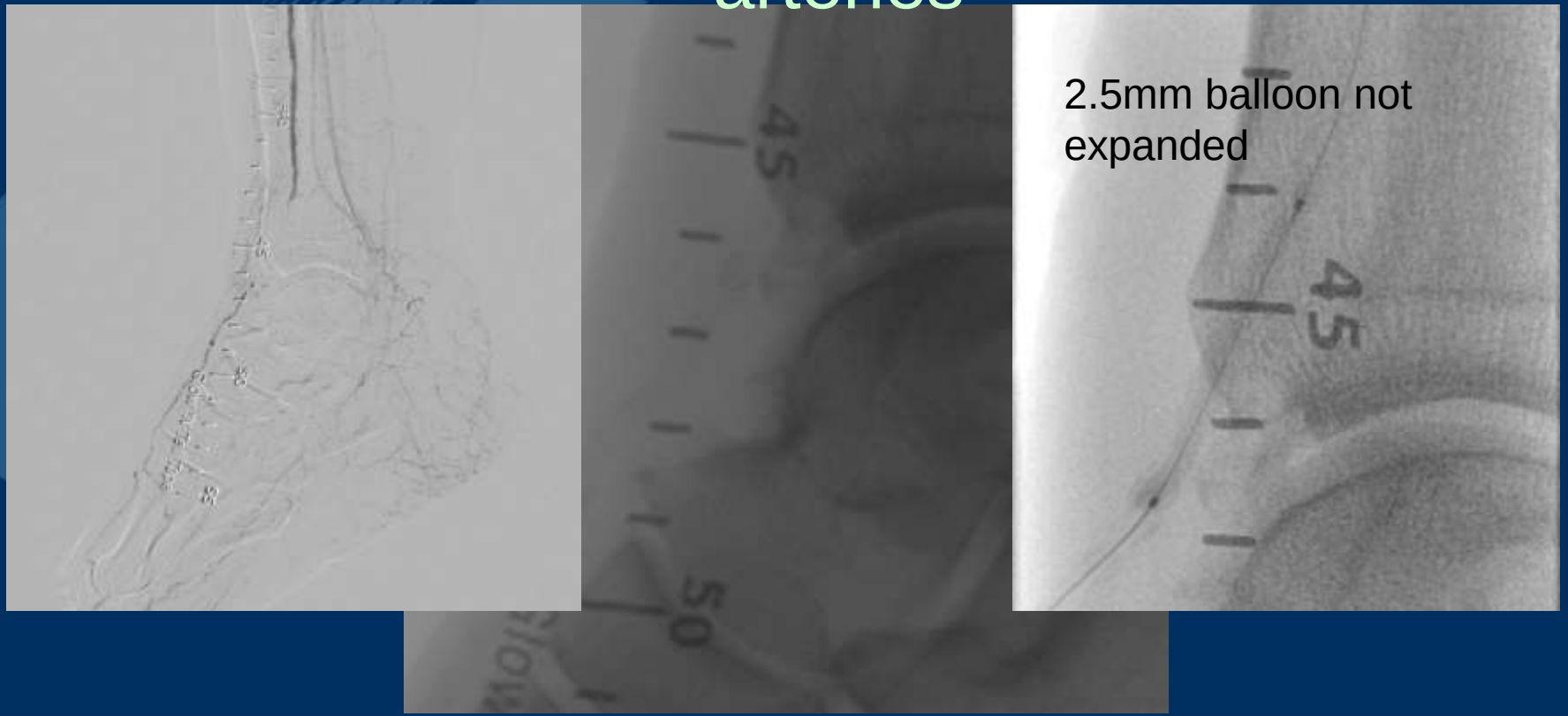
- ✓ Applicable with any 0.014 wire
- ✓ No need of filter to prevent embolization
- ✓ No demage to soft tissues
- ✓ Suitable for BTK and BTA vessels
- ✓ No risk of vessel perforation
- ✓ Low risk of dissection

IVL produces high gain with low complications

		DISRUPT PAD 95 subjects, 8 sites	DISRUPT BTK 20 subjects, 21 lesions, 3 sites
Patients Included	Vessels	Femoral/Popliteal Arteries	Tibial/Peroneal Arteries
	Intermittent Claudication	98.9% (94)	20.0% (4)
	Critical Limb Ischemia	1.1% (1)	80.0% (16)
Safety	Dissections	**1%** (1) Grade D or greater	**0** Grade D or greater
	Embolization	**0** Embolic Events	**0** Embolic Events
	Perforations, abrupt closure, slow/no reflow or thrombosis	**0** Complications	**0** Complications
Effectiveness	Residual Stenosis	**23.8%**	**26.2%**
	Acute Gain	**2.9**mm	**1.5**mm
Follow-Up	30 days	**100%** Freedom from TLR **100%** Patency	**100%** Freedom from TLR **0%** MAE (death, amp. or MI)

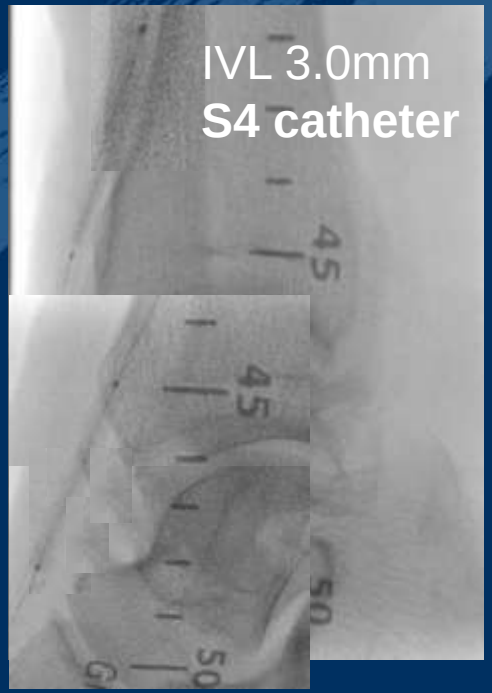
DISRUPT BTK Data are from European studies

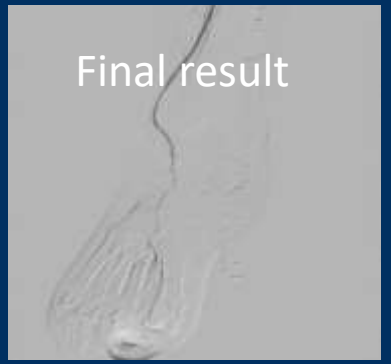
IVL suitable for distal Tibial and prox BTA arteries

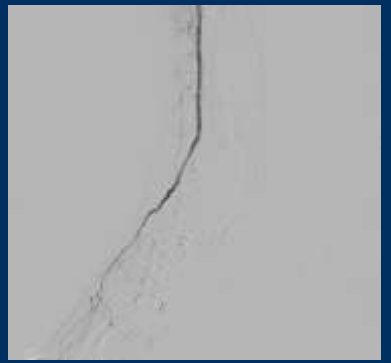


2.5mm balloon not expanded

IVL in prox Dorsalis Pedis Artery

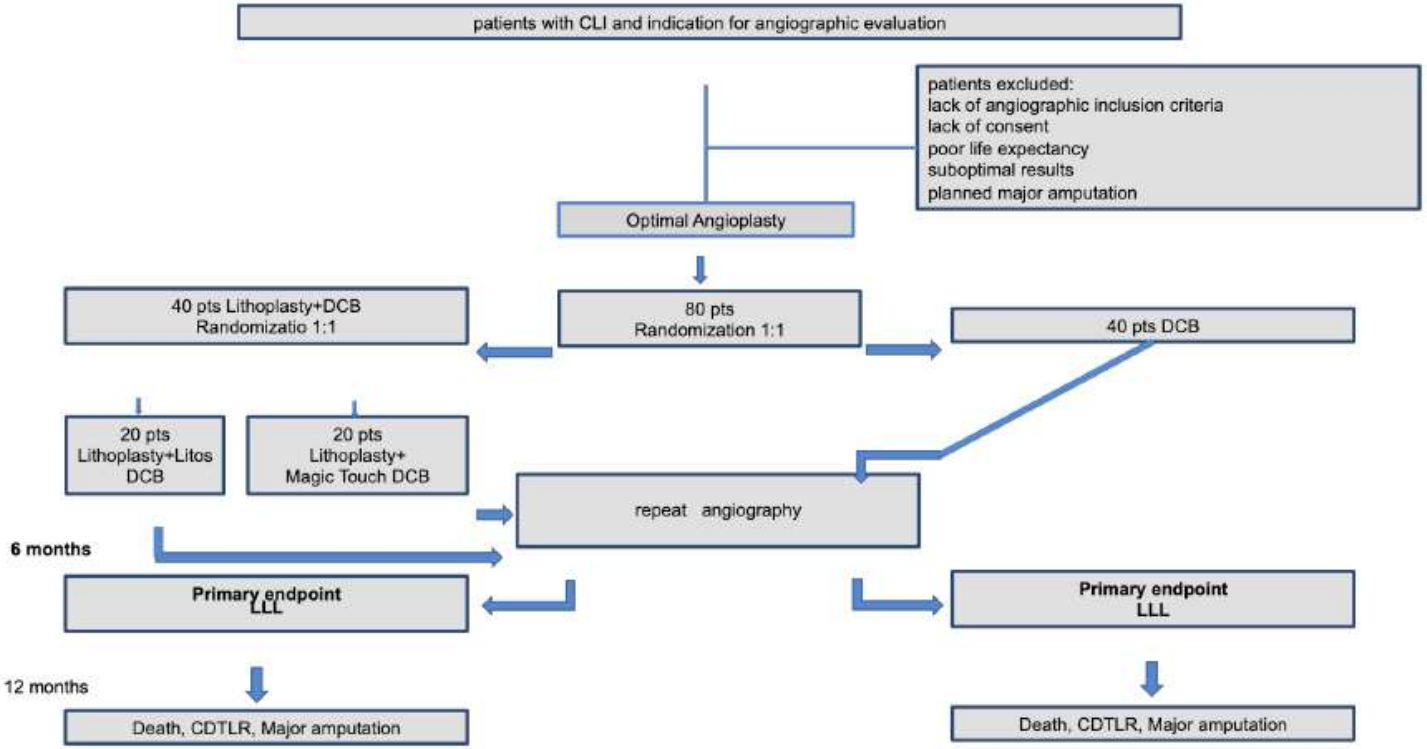






Combination Therapy: DCB+IVL

Debate-BTK Shock

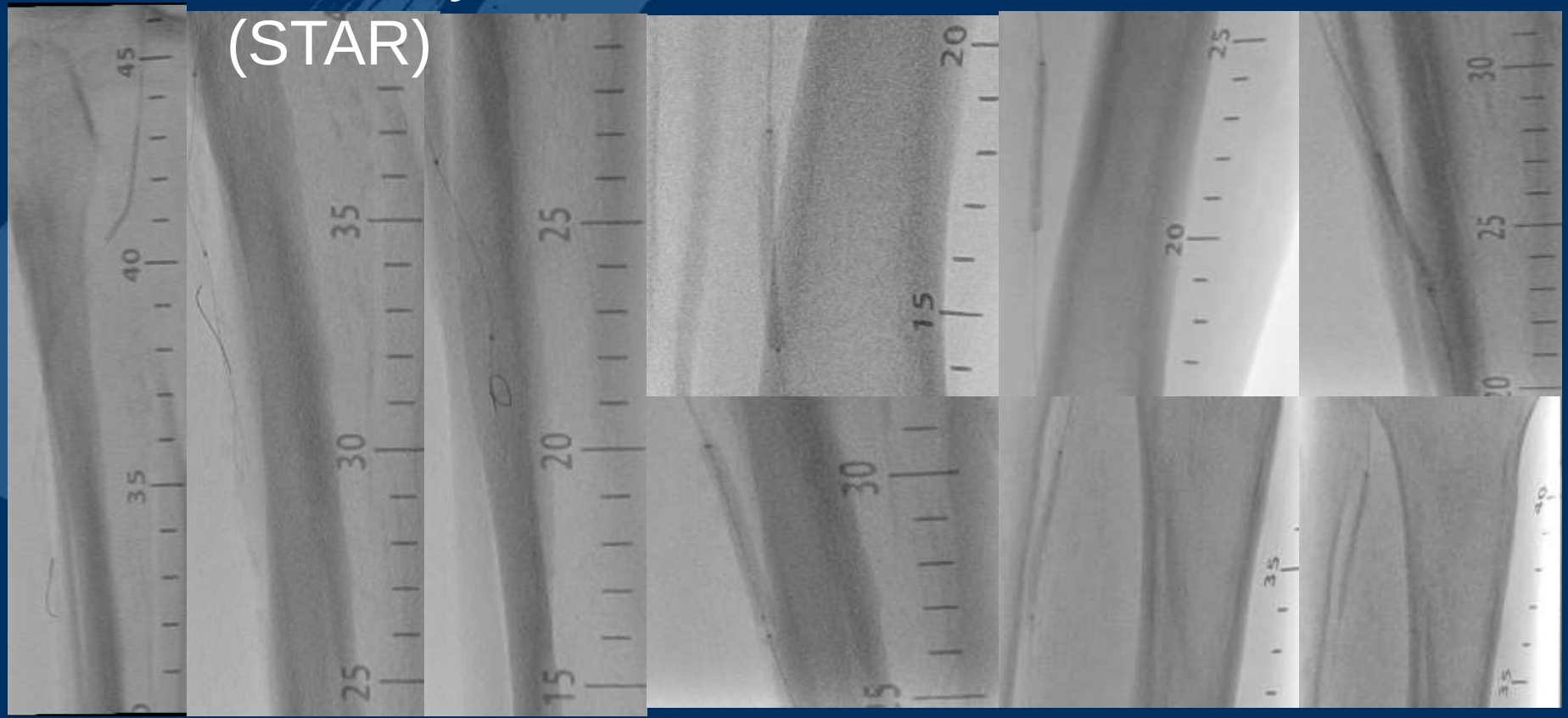


IVL+DCB for subintimal tibial complex recanalization




Subintimal tracking and reentry (STAR)

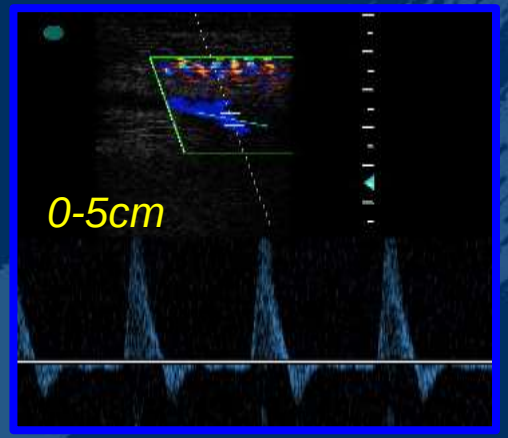
IVL (0.014 S4 catheter 3.5mm)

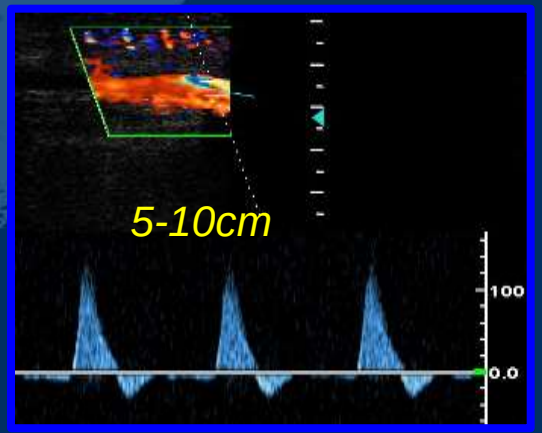


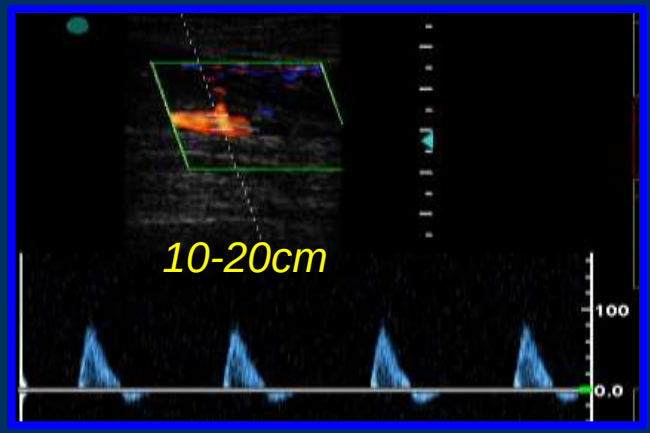
DCB Litos 3.5
300mm

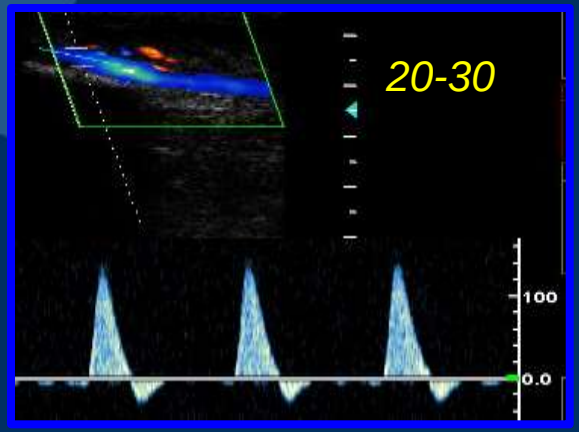
Final result

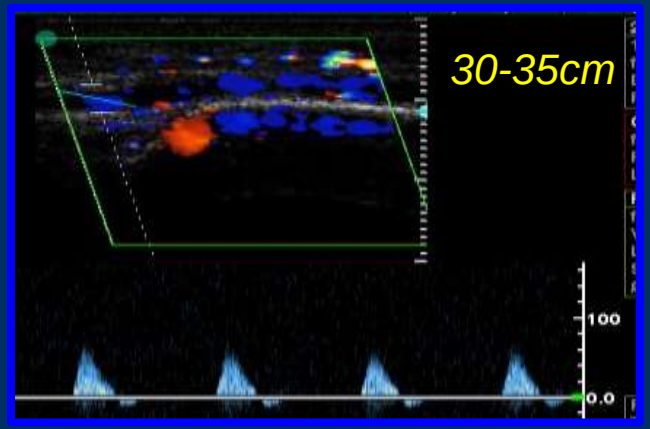
Three-month Duplex US follow-up



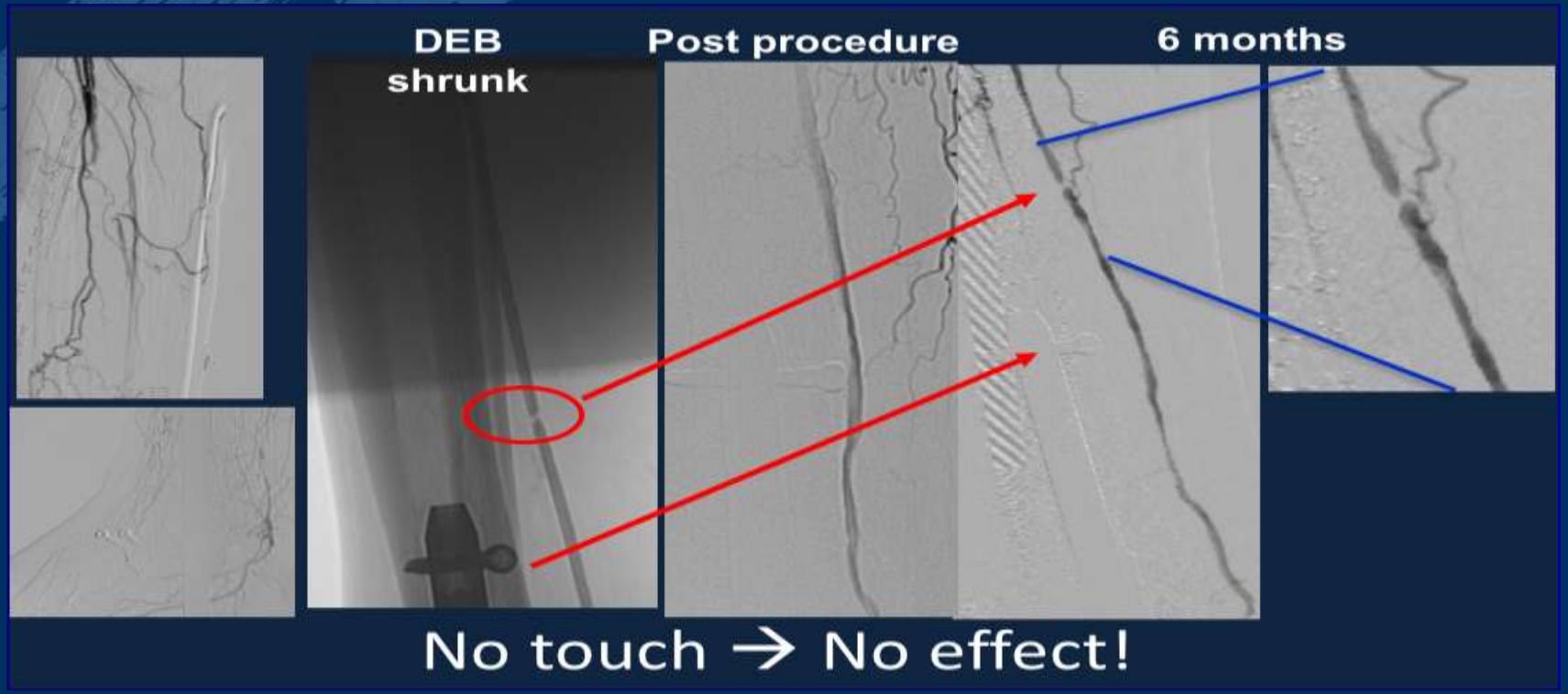




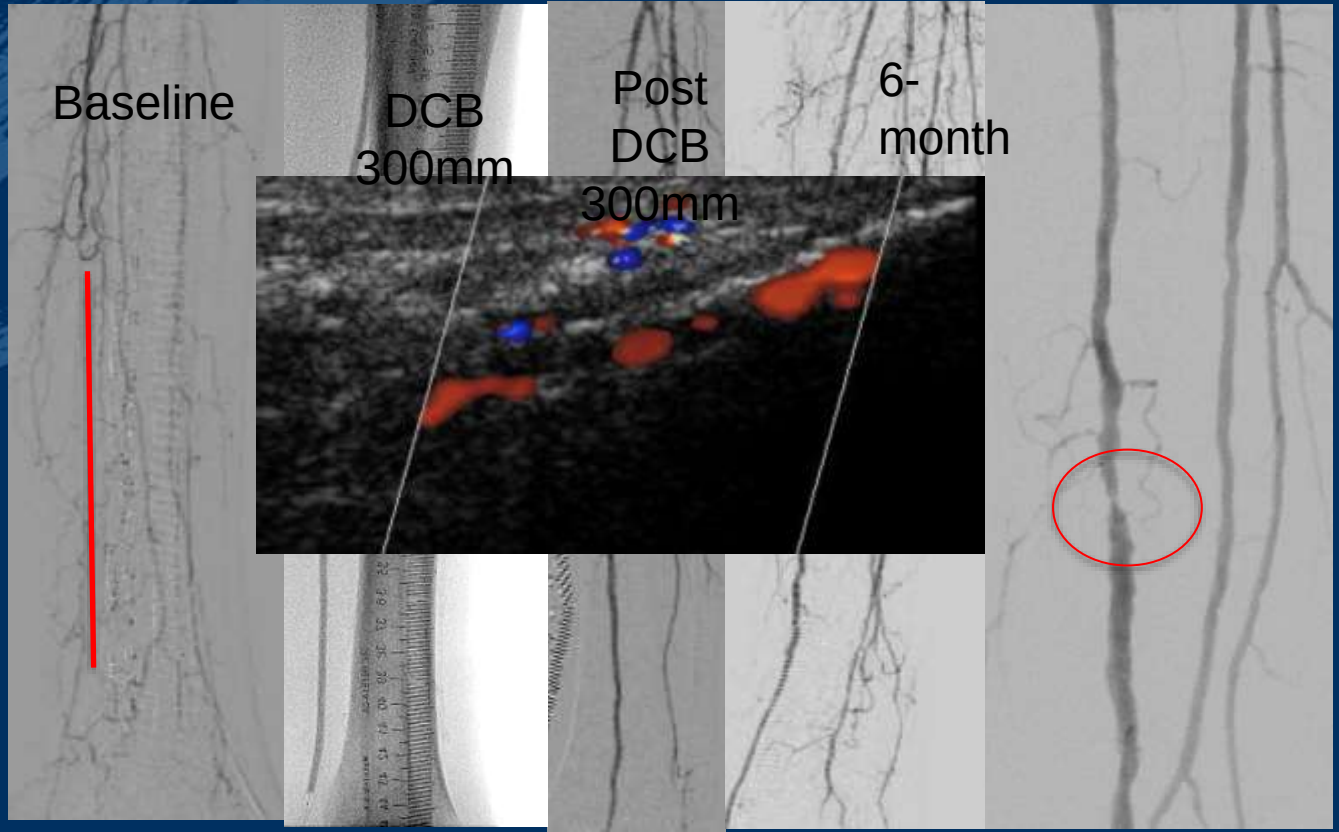




Focal Missing of Drug effect
DCB shrinking and spot restenosis



Spot restenosis due to reduced drug penetration. Is IVL the right tool?



Conclusion

- ✓ Calcium is a real enemy for the Interventionalist
- ✓ Significant calcificationin BTK vessel increases the rare of procedural failure, reocclusion and major amputation.
- ✓ IVL is a safety and efficacious tool for manage calcium barrier reducing residual stenosis
- ✓ IVL may increase the drug vessel penetration and may provide more drug storage and antiproliferative effect
- ✓ Compare to atherectomy, IVL is more safe and can be applied in BTA vessels and in subintimal recanalization.
- ✓ Combination Therapy with DCB may fulfill our expectations for sustained patency

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