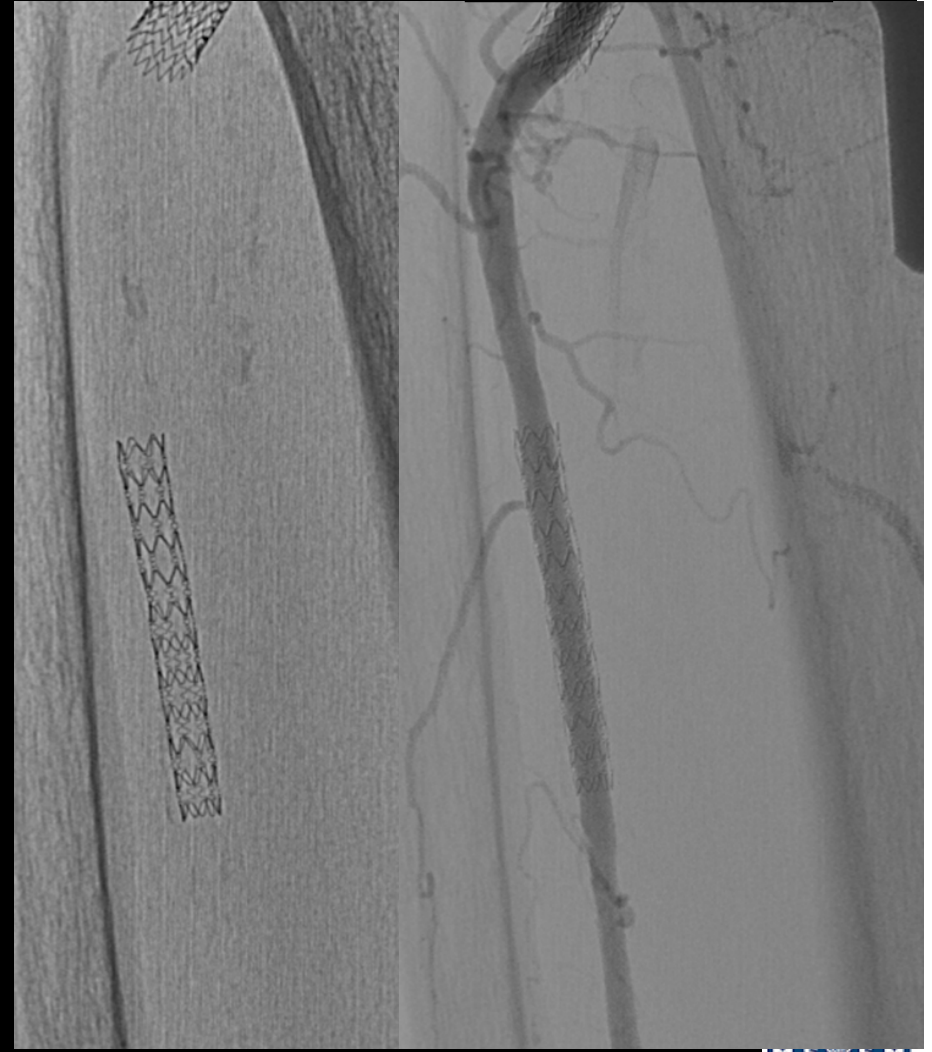


Angiographic Follow Up

18 months

60 months



Conclusions

- Placement of infrapopliteal drug eluting stents is a safe and effective therapy following suboptimal angioplasty in patients with critical limb ischemia
- This procedure has excellent technical success and demonstrates:
 - procedural safety
 - high primary patency
 - Excellent limb salvage rates



Infrapopliteal Drug Eluting Stent Data

<u>Author</u>	<u>Pts</u>	<u>Lesion Length</u>	<u>Primary Patency</u>	<u>Technique</u>	<u>TLR</u>	<u>Amp free survival</u>
BALZER (sirolimus)	114	46mm	86% at 12 months	Primary		96% 12 month
FEIRING (sirolimus)	106	60mm	88% at 36 months	Primary	24% at 3 yr	94% 36 month
COMMEAU (sirolimus)	30	27.6mm	97% at 7 months	Primary	3% at 7 mo	100% 6 month
GRANT (sirolimus)	10	25mm	90% at 12 months	Primary	10% at 1 yr	87 % 12month
ROSALES (sirolimus)	24	51 mm	76% at 12 months	Primary		83% 12month
SIABLIS (sirolimus)	62	55 mm	86% at 12 32% at 36	Secondary	12% at 1 yr 23% at 3 yr	80% 36 month
LOOKSTEIN (sirolimus)	69	50 mm	84% at 12 months	Secondary	9.1% at 1 yr	90 % 12month

Implications

- This data supports the use of Drug Eluting Stents following suboptimal infrapopliteal angioplasty in patients with critical limb ischemia
- Drug Eluting Stents can decrease reintervention rates, peri-procedural morbidity and amputation rates in this high risk patient population
- Numerous unresolved issues remain including:
 - the issue of primary stent placement vs bailout
 - the cost of the device(s) especially for long lesions



Leipzig BTK Registry

Leipzig Experience with Drug-Coated Balloons BTK

- Prospective registry of patients with BTK-lesions
- Without industry-support
- In.Pact Amphirion Deep Paclitaxel-eluting balloon
(Medtronic Invatec)
- Planned FU:
 - Angiography after 3 months
 - Clinical FU 3, 6 and 12 months

Leipzig BTK Registry

BTK-Lesions Treated with the PTX-Coated In.Pact Amphirion Deep

- 104 patients included (Jan 2009 – Feb 2010)

- 109 limbs treated with In.Pact Amphirion

- Clinical limb status

- Ruth 3 19 (17.4 %)

- Ruth 4 19 (17.4 %)

- Ruth 5 70 (64.2 %)

- Ruth 6 1 (0.9 %)



CLI 82.6 %



Leipzig BTK Registry

Subgroup with 3-Mo Angio

- De-novo	55 (65.5 %)
- Restenosis	19 (22.6 %)
- In-stent restenosis	10 (11.9 %)
- Mean lesion-length	173 ± 87 mm
- Stenosis	32 (38.1 %)
- Occlusion	52 (61.9 %)

Leipzig BTK Registry



DEB Below-The-Knee

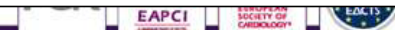
	POB BTK	DEB BTK
Lesion-Length	183 mm	173 mm
Restenosis >50 % @ 3 Mo	69 %	27 %

61% Restenosis Reduction

Length of the Restenoses	155 mm	64 mm
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Schmidt et al. *Catheter Cardiovasc Interv* 2010

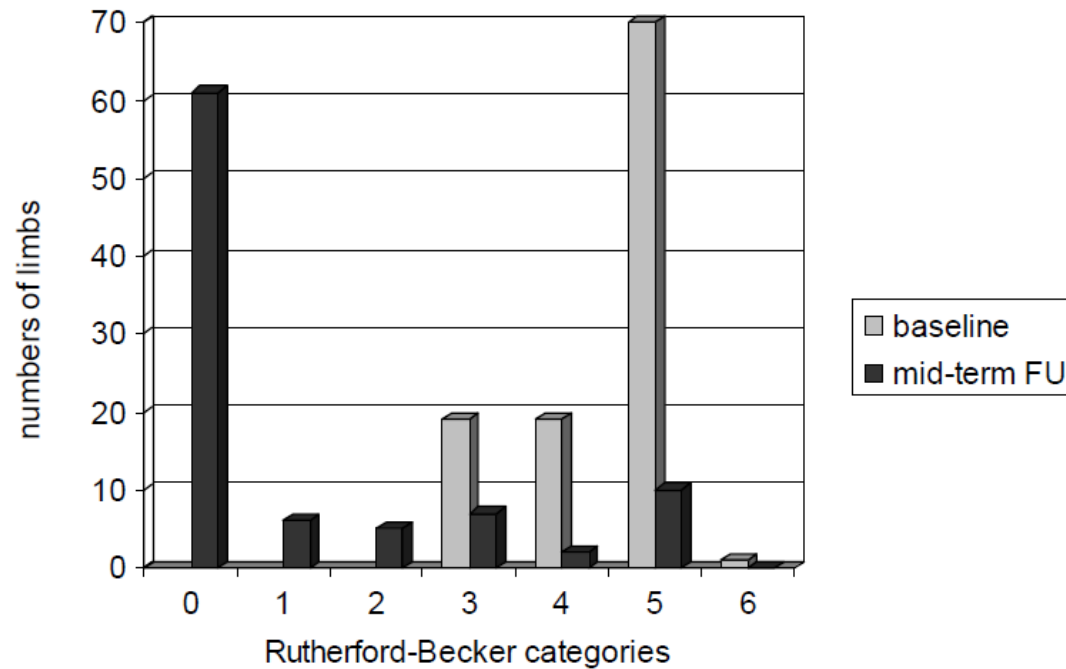
Schmidt et al. submitted



Leipzig BTK Registry



Clinical Follow-Up at 378 Days



3 Below-knee amputations, 1 forefoot-amputation



Leipzig BTK Registry

Riskfactors for Restenosis after DEB

		Tibial			
	Apop (P3)	Prox.	Mid.	Distal	Foot
n treated segments	11	54	45	37	13
Restenosis-rate	9.1%	9.3%	20.0%	18.9%	38.5%

No involvement of foot-arteries in the POBA-series

Leipzig BTK Registry

12.5 Months Follow-Up (Whole Cohort)

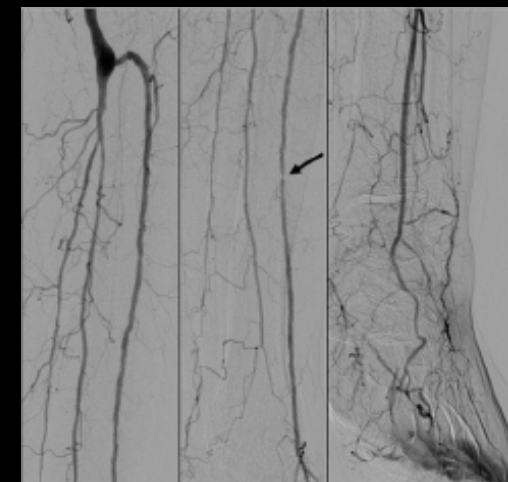
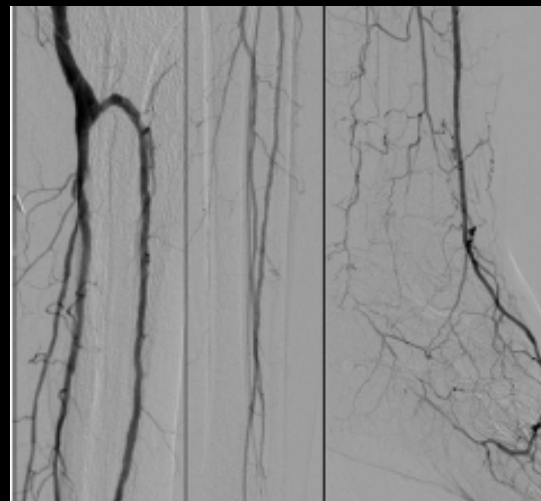
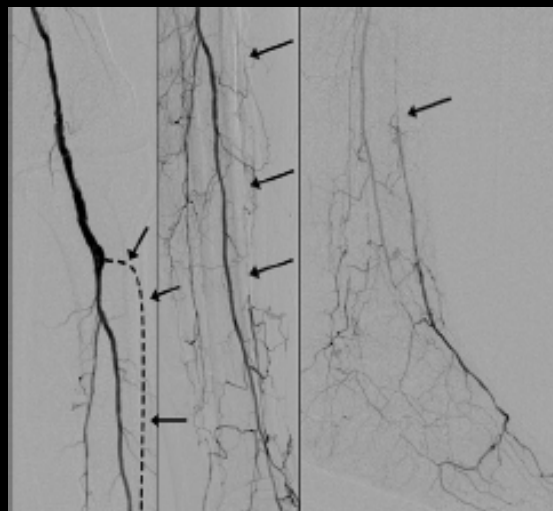
- Mortality 16.3 %
- Amputation 4 (3 BTK, 1 forefoot)
- Angiography available in 3/4 patients 7-21 days prior to amputation showing a patent treated artery !
- Clinical improvement 91.2 %
- Complete woundhealing 74 %
- Re-intervention-rate 17.3 %



First Experience With Drug-Eluting Balloons in Infrapopliteal Arteries

Restenosis Rate and Clinical Outcome

Andrej Schmidt, MD,* Michael Piorkowski, MD,* Martin Werner, MD,* Matthias Ulrich, MD,*
Yvonne Bausback, MD,* Sven Bräunlich, MD,* Henrik Ick, MD,* Johannes Schuster, MD,*
Spiridon Botsios, MD,* Hans-Joachim Kruse, MD,† Ramon L. Varcoe, MD,‡ Dierk Scheinert, MD*
Leipzig and Zschopau, Germany; and Sydney, Australia



Three month angiographic follow up

Artery or Site Involved in PTA	n (%)	Restenosis (%)
Distal popliteal artery	11 (13.1)	1 (9.1)
Anterior tibial artery	48 (57.1)	15 (31.3)
Tibioperoneal trunk	18 (21.4)	3 (16.7)
Posterior tibial artery	16 (19.0)	5 (31.3)
Peroneal artery	18 (21.4)	3 (16.7)
Proximal segment of tibial arteries	54 (64.3)	5 (9.3)
Mid segment of tibial arteries	45 (53.6)	9 (20.0)
Distal segment of tibial arteries	37 (44.0)	7 (18.9)
Arteries distal to the malleolus	13 (15.5)	5 (38.5)



Novel Clinical Study Plan: *In.Pact DEEP*



- RCT of DEB vs PTA (PI: I. Baumgartner, T. Zeller)
- Compliance with “DEFINE” reporting standards
- Complete level of assessment via a combined set of “hard” + “soft” clinical endpoints + lesion specific endpoints
 - Amputation Free Survival
 - Amputation Free Survival + Wound Healing
 - Amputation Free Survival + Wound Healing + TLR free
 - ↓ in % DS by Angio FU
- Independent angio and wound healing corelab

Treatment goals in CLI and BTK disease

Benefits and risks of maximal revascularization



- Optimization of flow to the foot by revascularization of at least one straight line.
- Patients may benefit from 2 or even 3 patent crural vessels.

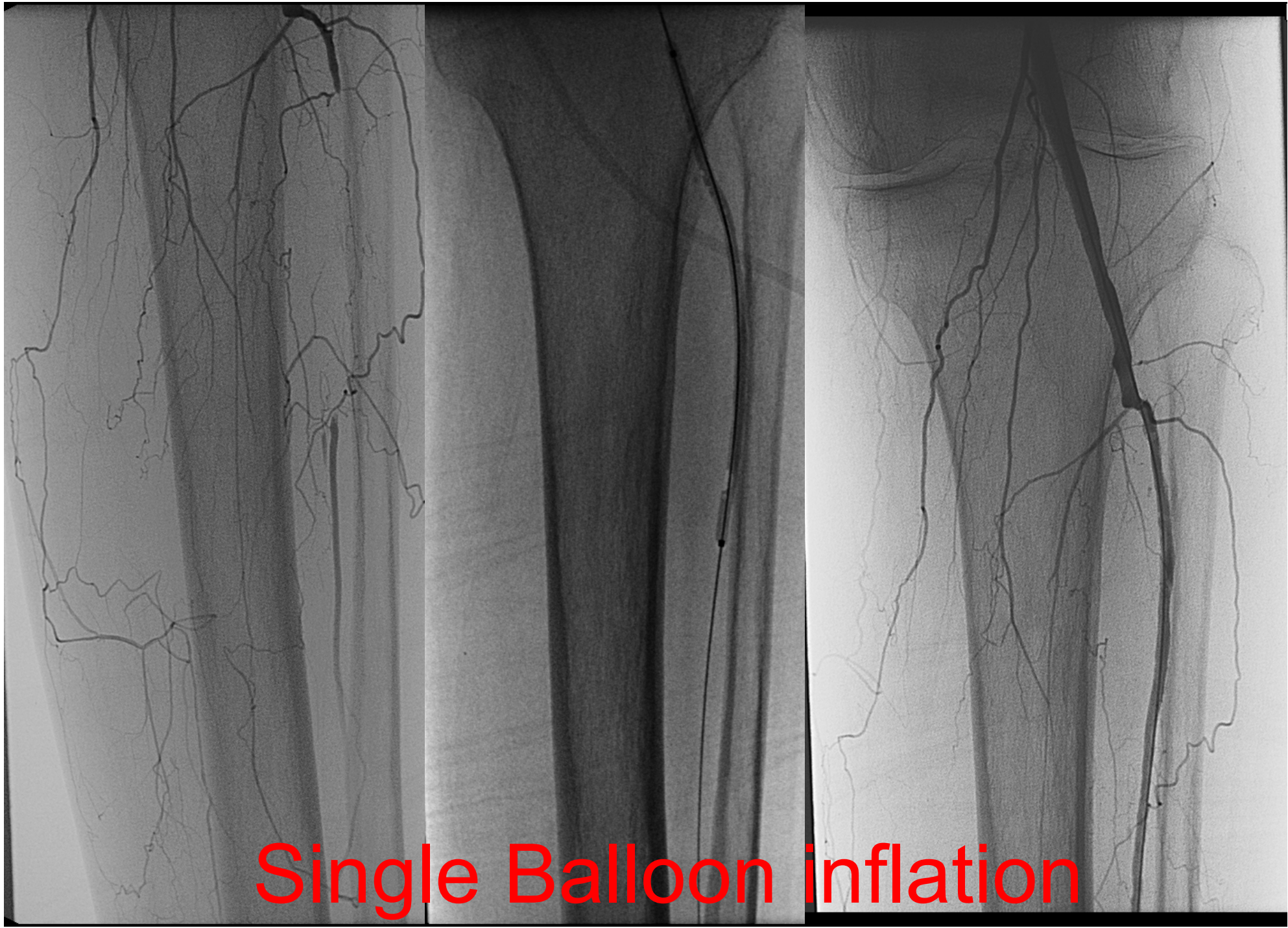
- Contrast amount (renal failure).
- Fluid amount (heart failure).
- Risk of complications.
- Age - general condition.



Most Important Technology for BTK CTOs

- Long low profile balloons
 - Savvy, Sleek (Cordis)
 - Sterling, Sterling ES (Boston)
 - Amphirion Deep (Invatec)





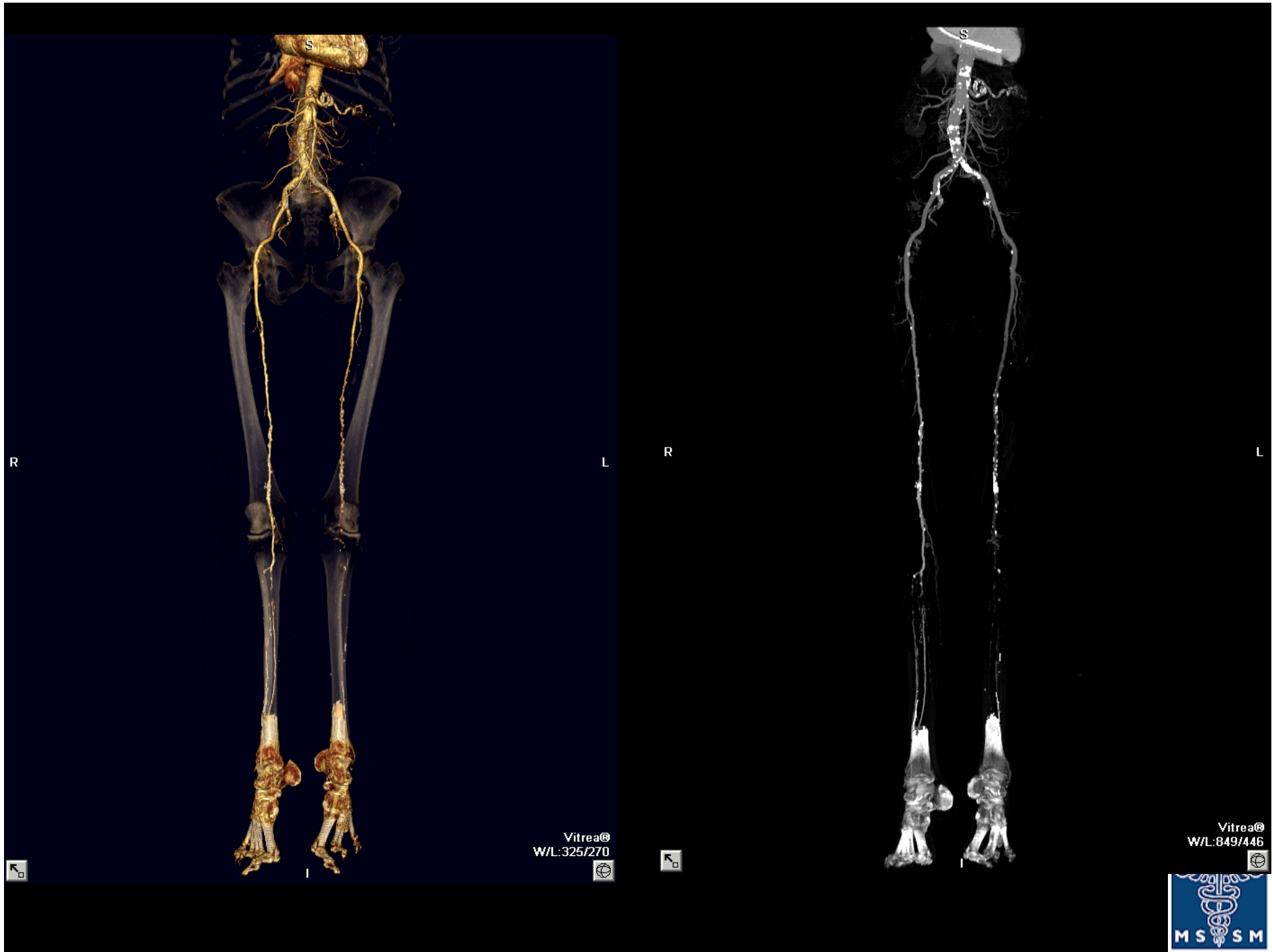
Single Balloon Inflation



Two Balloon inflations







Vitrea®
W/L:325/270

Vitrea®
W/L:849/446



