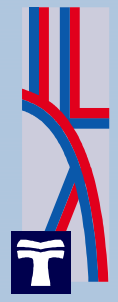
The challenge of calcification in BTK arteries and the relevance for procedural outcome



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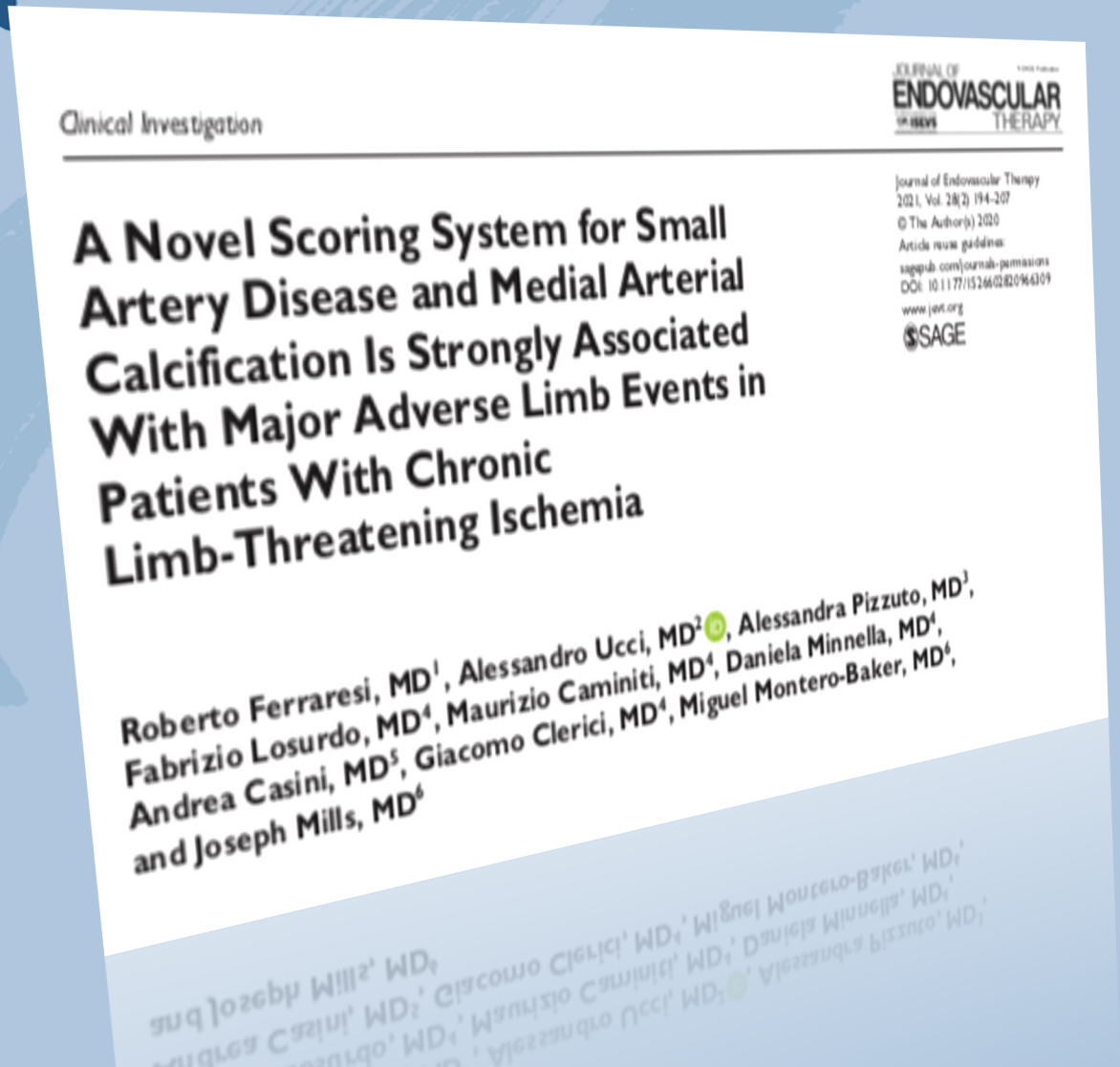
Conflicts of interest:

Honoraria/Consulting/Advisory board/ Proctorship agreement/unrestricted educational grant

- Avinger
- Biotronik
- Cordis
- Medtronic
- Terumo
- Symedrix
- Vivasure

Grade of calcification and clinical outcome -What do we know?



Clinical Investigation

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A Novel Scoring System for Small Artery Disease and Medial Arterial Calcification Is Strongly Associated With Major Adverse Limb Events in Patients With Chronic Limb-Threatening Ischemia

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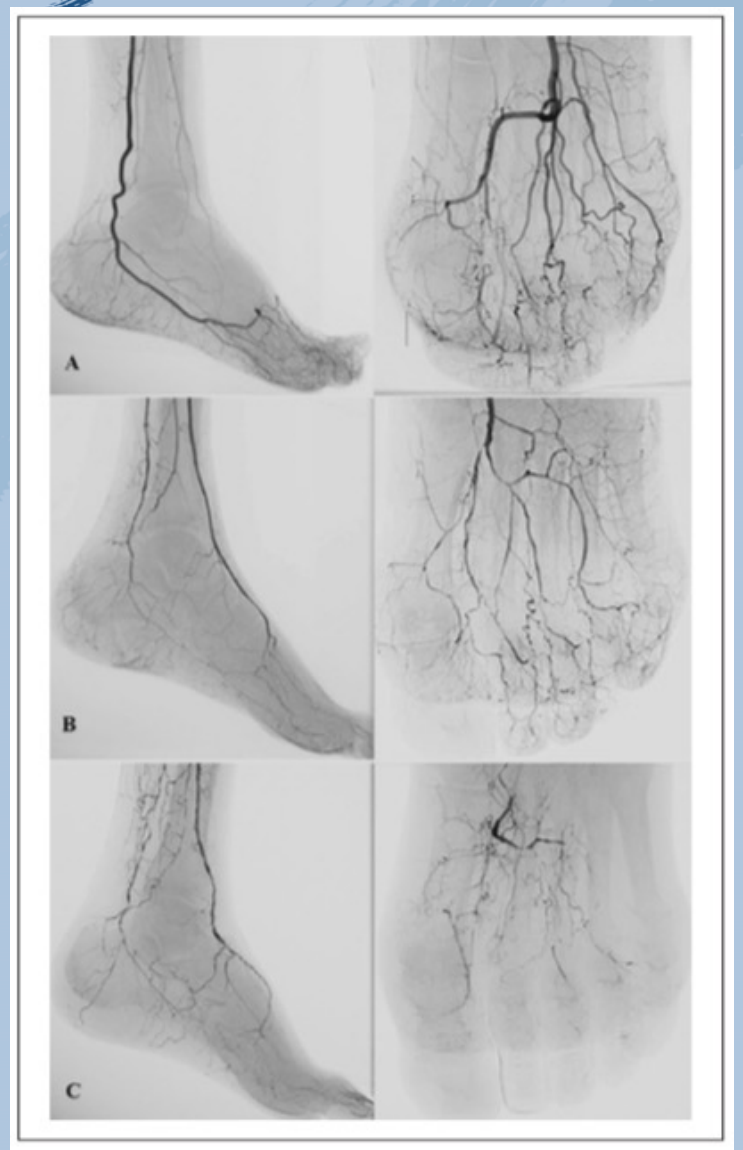
MAC (Medium artery cacification)
& SAD (small artery disease)
Classification

145 patients fu up to 30month

(Ferraresi et al. JEVT2021)

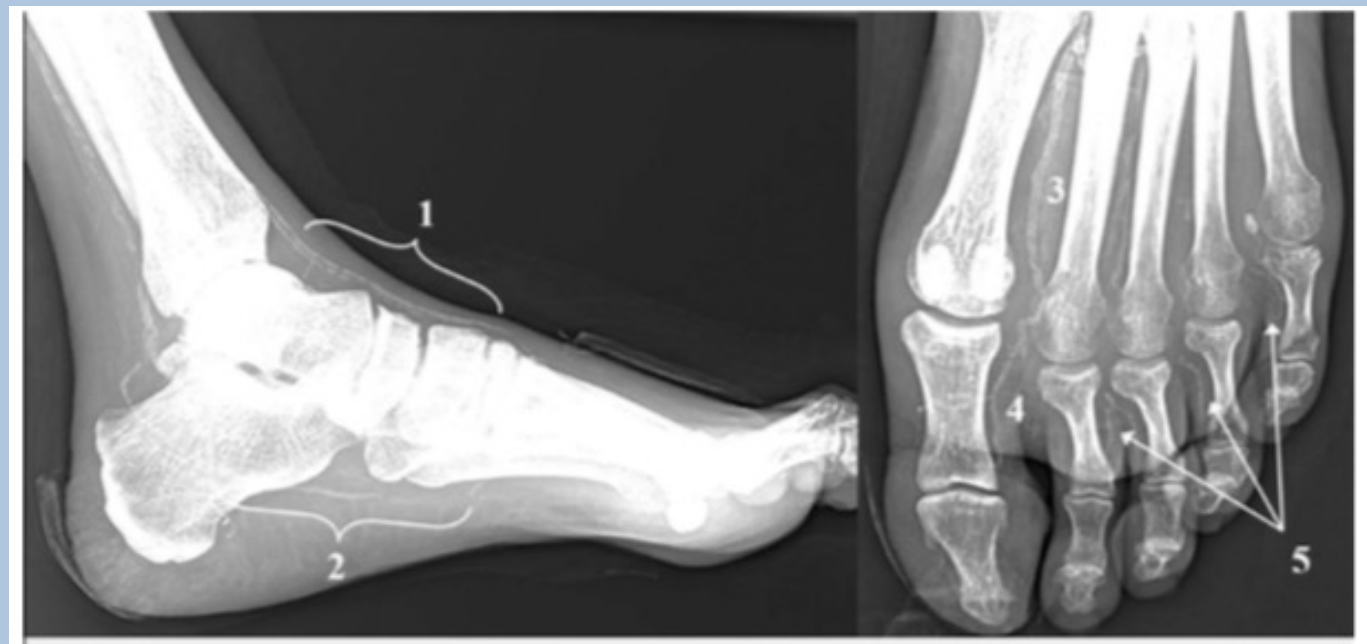
MAC & SAD classification



SAD 0

SAD 1

SAD 2



1	≥ 2 cm?	yes = 1 or no = 0
2		yes = 1 or no = 0
3		yes = 1 or no = 0
4	≥ 1 cm?	yes = 1 or no = 0
5		yes = 1 or no = 0

Sum all points →

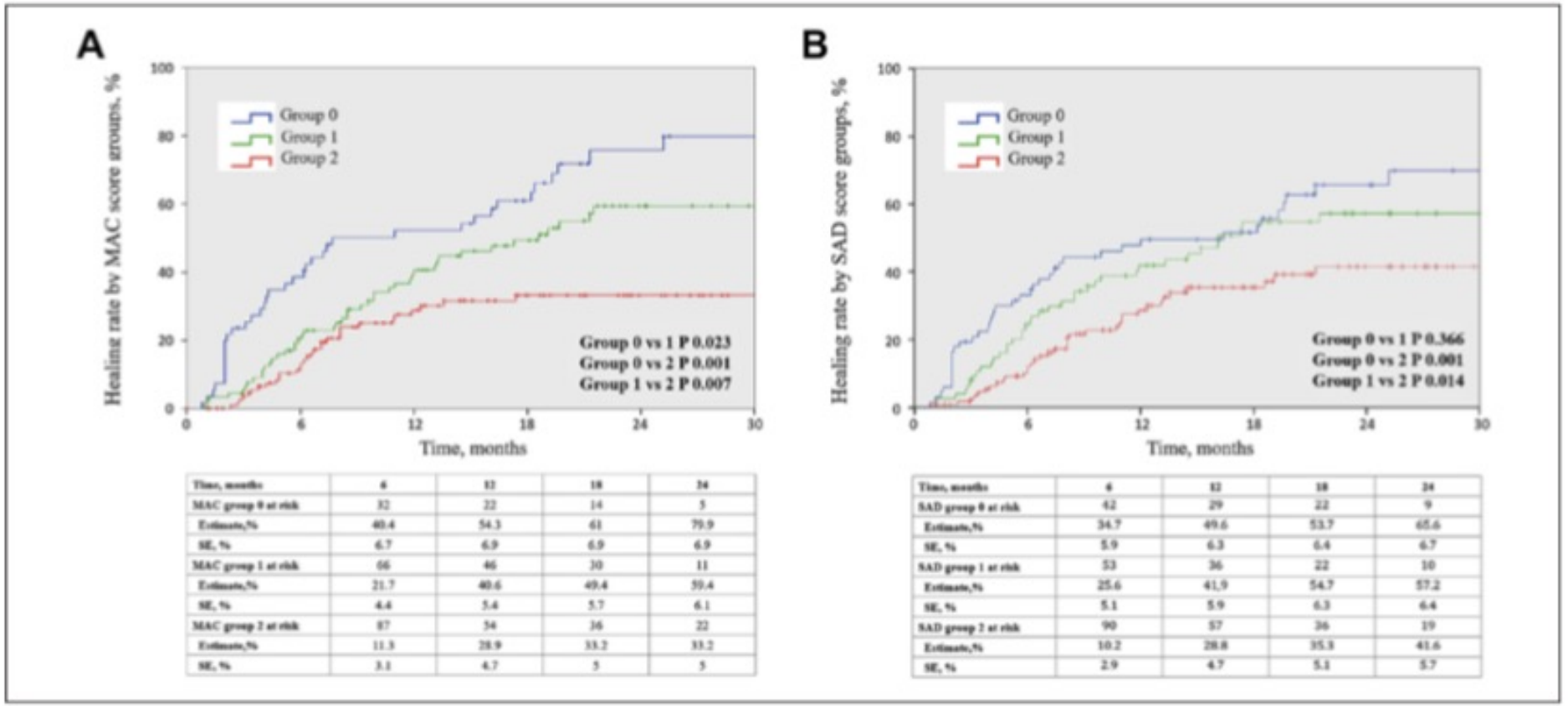
0-1 = no MAC

2-3 = moderate MAC

4-5 = severe MAC

(Ferraresi et al. JEVT2021)

MAC & SAD relevance on clinical outcome – Wound Healing



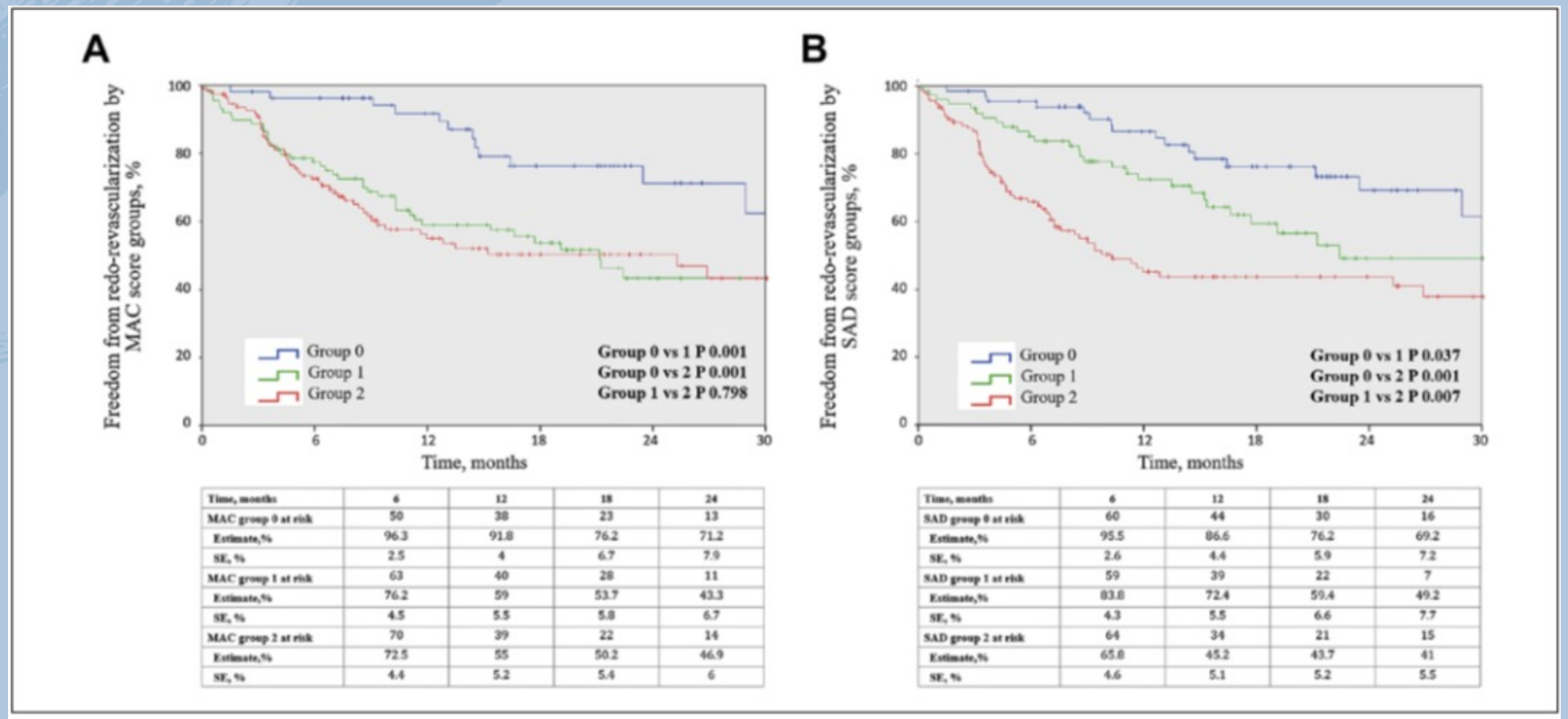
Time, months	6	12	18	24
MAC group 0 at risk	32	22	14	5
Estimate,%	40.4	54.3	61	79.9
SE, %	6.7	6.9	6.9	6.9
MAC group 1 at risk	66	46	30	11
Estimate,%	21.7	40.6	49.4	59.4
SE, %	4.4	5.4	5.7	6.1
MAC group 2 at risk	87	54	36	22
Estimate,%	11.3	28.9	33.2	33.2
SE, %	3.1	4.7	5	5

Time, months	6	12	18	24
SAD group 0 at risk	62	29	22	9
Estimate,%	34.7	49.6	53.7	65.6
SE, %	5.9	6.3	6.4	6.7
SAD group 1 at risk	53	36	22	10
Estimate,%	25.6	41.9	54.7	57.2
SE, %	5.1	5.9	6.3	6.4
SAD group 2 at risk	90	57	36	19
Estimate,%	10.2	28.8	35.3	41.6
SE, %	2.9	4.7	5.1	5.7

Figure 4. Healing estimates for the (A) medial arterial calcification (MAC) groups and the (B) small artery disease (SAD) groups. SE, standard error.

(Ferraresi et al. JEVT2021)

MAC & SAD relevance on clinical outcome – Freedom from Reintervention



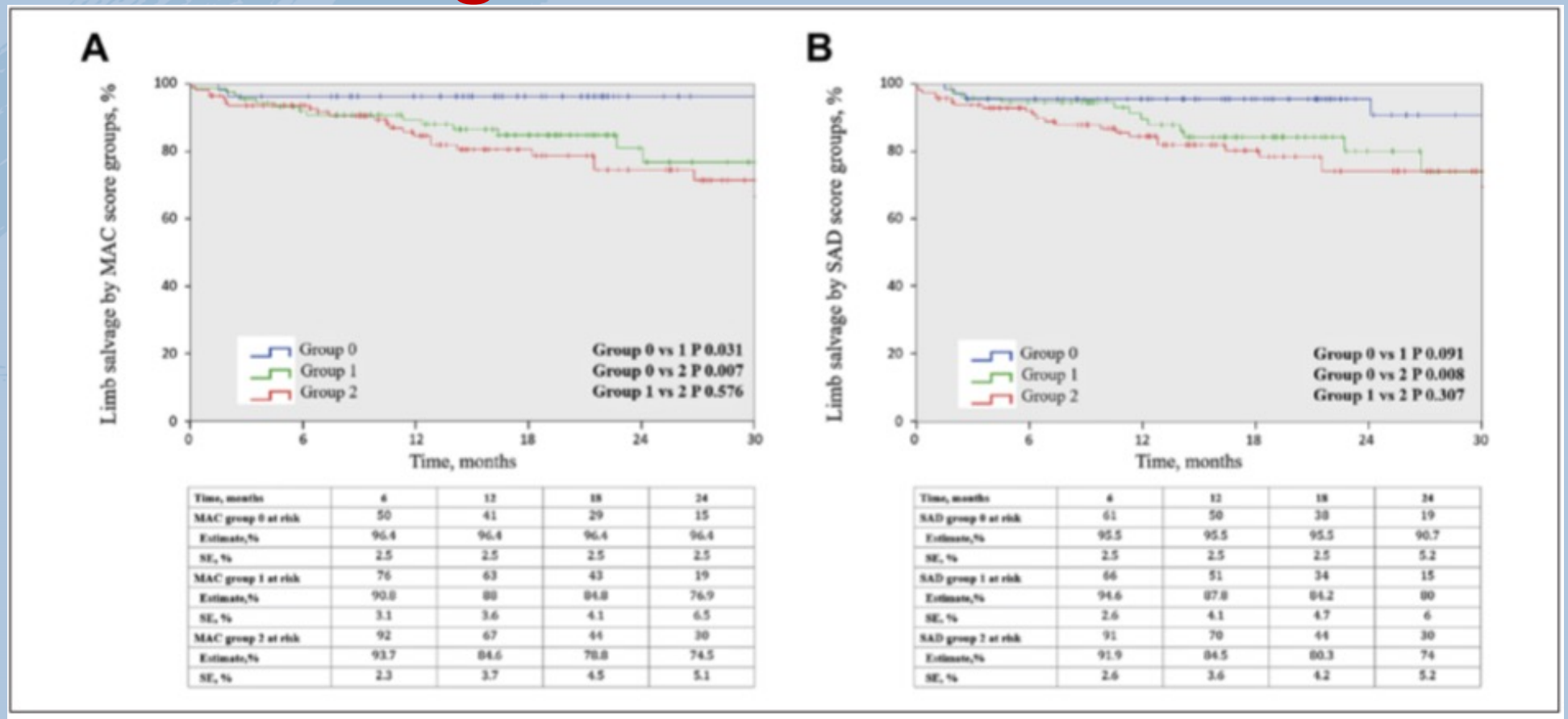
Time, months	6	12	18	24
MAC group 0 at risk	50	38	23	13
Estimate,%	96.3	91.8	76.2	71.2
SE, %	2.5	4	6.7	7.9
MAC group 1 at risk	63	40	28	11
Estimate,%	76.2	59	53.7	43.3
SE, %	4.5	5.5	5.8	6.7
MAC group 2 at risk	70	39	22	14
Estimate,%	72.5	55	50.2	46.9
SE, %	4.4	5.2	5.4	6

Time, months	6	12	18	24
SAD group 0 at risk	60	44	30	16
Estimate,%	95.5	86.6	76.2	69.2
SE, %	2.6	4.4	5.9	7.2
SAD group 1 at risk	59	39	22	7
Estimate,%	83.8	72.4	59.4	49.2
SE, %	4.3	5.5	6.6	7.7
SAD group 2 at risk	64	34	21	15
Estimate,%	65.8	45.2	43.7	41
SE, %	4.6	5.1	5.2	5.5

Figure 6. Freedom from redo revascularization estimates for the (A) medial arterial calcification (MAC) groups and the (B) small artery disease (SAD) groups. SE, standard error.

(Ferraresi et al. JEVT2021)

MAC & SAD relevance on clinical outcome – Limb salvage



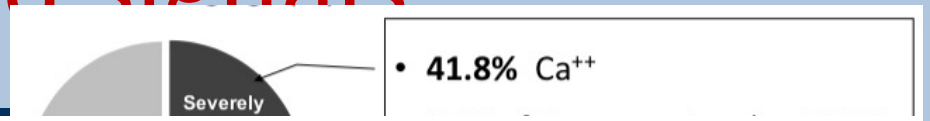
Time, months	6	12	18	24
MAC group 0 at risk	50	41	29	15
Estimate,%	96.4	96.4	96.4	96.4
SE, %	2.5	2.5	2.5	2.5
MAC group 1 at risk	76	63	43	19
Estimate,%	90.0	88	84.8	76.9
SE, %	3.1	3.6	4.1	6.5
MAC group 2 at risk	92	67	44	30
Estimate,%	93.7	84.6	78.8	74.5
SE, %	2.3	3.7	4.5	5.1

Time, months	6	12	18	24
SAD group 0 at risk	61	50	38	19
Estimate,%	95.5	95.5	95.5	90.7
SE, %	2.5	2.5	2.5	5.2
SAD group 1 at risk	66	51	34	15
Estimate,%	94.6	87.8	84.2	80
SE, %	2.6	4.1	4.7	6
SAD group 2 at risk	91	70	44	30
Estimate,%	91.9	84.5	80.3	74
SE, %	2.6	3.6	4.2	5.2

Figure 7. Limb salvage estimates for the (A) medial arterial calcification (MAC) groups and the (B) small artery disease (SAD) groups. SE, standard error.

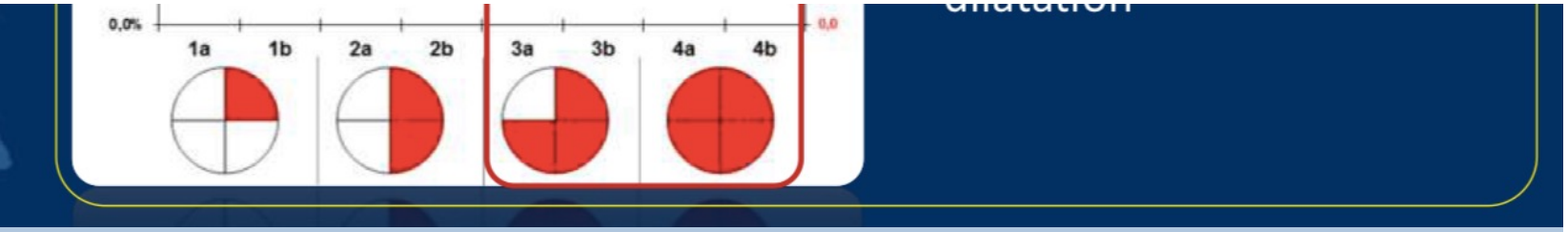
(Ferraresi et al. JEVT2021)

Does Calcium affect the efficacy of Drug eluting technology? Mixed signals

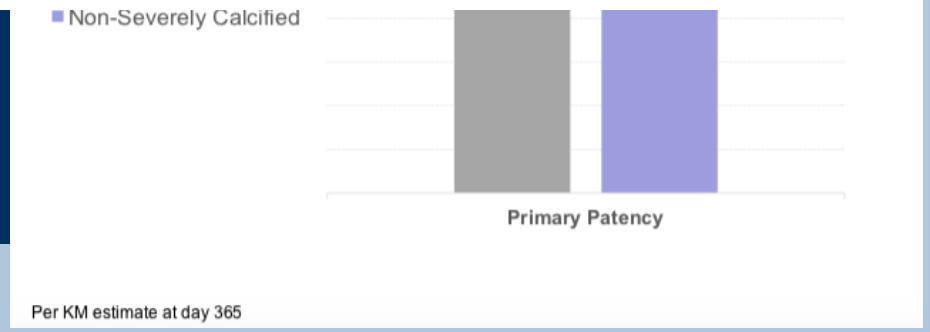


However:

The idea of removing the calcium barrier and improving drug-uptake and vessel wall compliance is appealing



Fanelli @ LINC 2015



Fanelli et al.
Subanalisis on Calcium Illuminate I & II 671 patients

Mode of action: orbital atherectomy

Mechanism of action: orbital atherectomy

Peripheral Orbital Atherectomy System

Dual Mechanism of Action

Atherectomy:

Bi-directional Differential Sanding

Reduces superficial calcium

- Superficial calcium is sanded by diamond surface.[1]
- Differential Sanding reduces plaque while potentially minimizing damage to the medial layer of the vessel.[1,2]
- The OAS generates particulate matter with an average size of ~2 microns, smaller than circulating red blood cells[1]

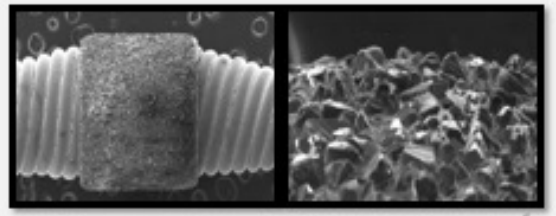
Calcium Modification:

Pulsatile Forces

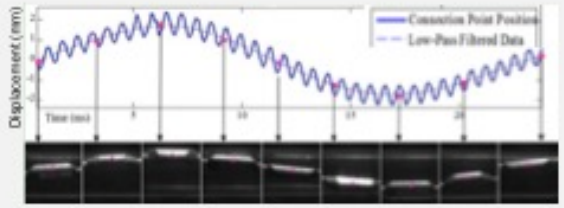
from eccentric-mounted mass may contribute to compliance change:

- Low frequency (18-40 Hz) represents crown orbit inside vessel[3]
- High frequency (1000-1900 Hz) represents rotation of eccentric crown over the wire, producing pulsatile mechanical forces[3]
- These pulsatile forces may affect deeper plaque and contribute to compliance change[4*]

*Results vary based upon plaque morphology, calcification, and anatomy.



Crown surface: 30 micron diamonds, 10 micron exposed.[5]

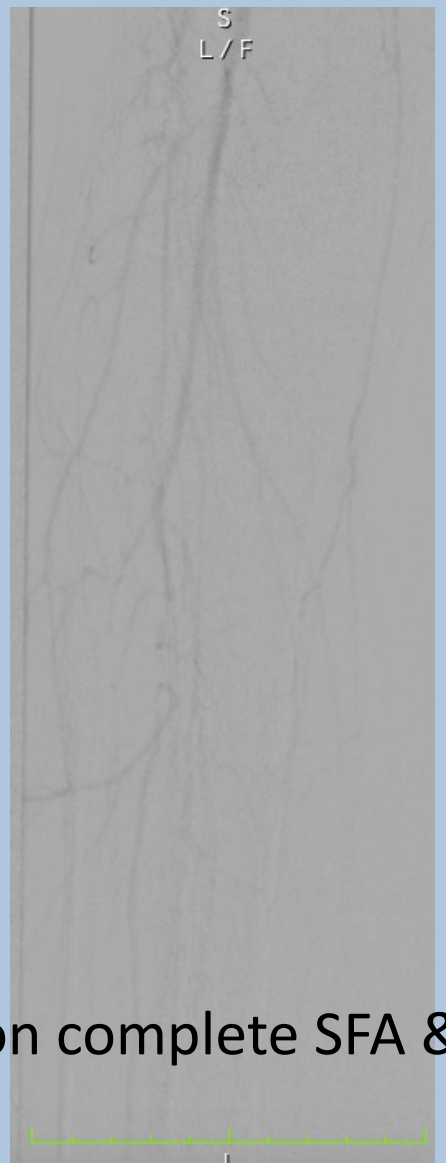


Adapted from Zheng Y, et al. Med Eng Phys. 2016;38(7):639-647.

1. Adams G, et al. J Cardiovasc Transl Res. 2011;4(2):220-229.
2. Krishnan P, et al. J Endovasc Ther. 2017;24(1):167-168.
3. Zheng Y, et al. Med Eng Phys. 2016;38(7):639-647.
4. Saab F, et al. J Cardiovasc Surg (Torino). 2019;60(2):212-220.
5. CSI Data on File.

Case example OA +DCB

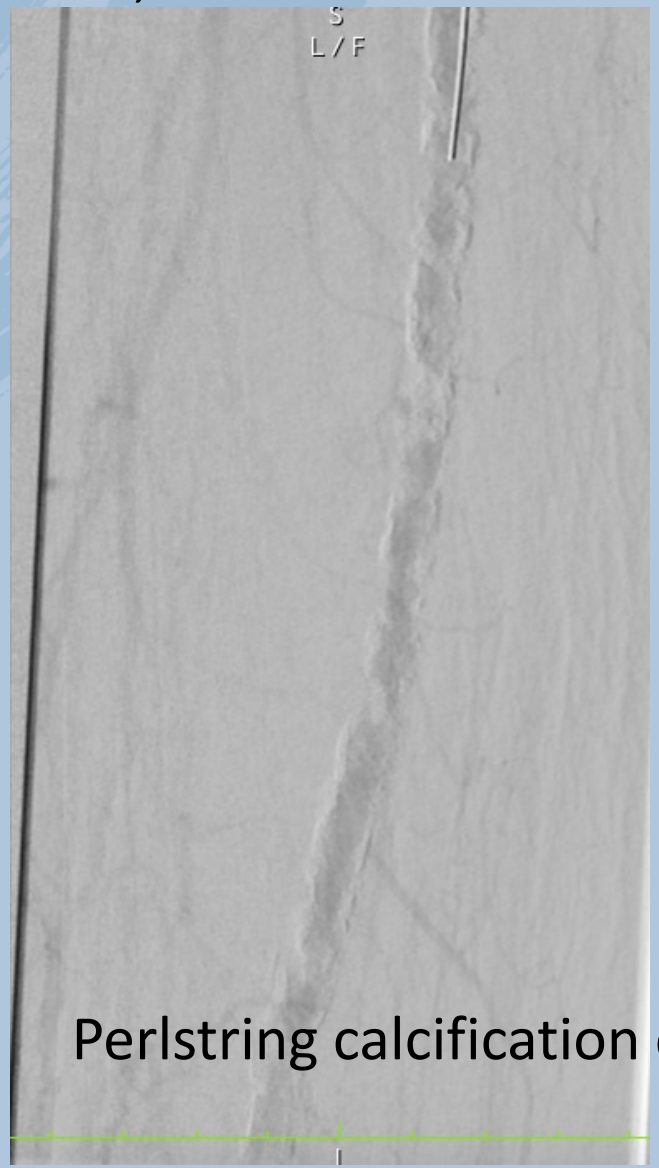
70yo male progressing Rutherford VI, recent surgical TEA of CFA, renal insifficiency hypertension, diabetes



Perlstring calcification complete SFA & pop, TP-trunc CTO

Case example OA +DCB

70yo male progressing Rutherford VI, recent surgical TEA of CFA, renal insifficiency hypertension, diabetes



Perlstring calcification complete SFA & pop, TP-trunc CTO

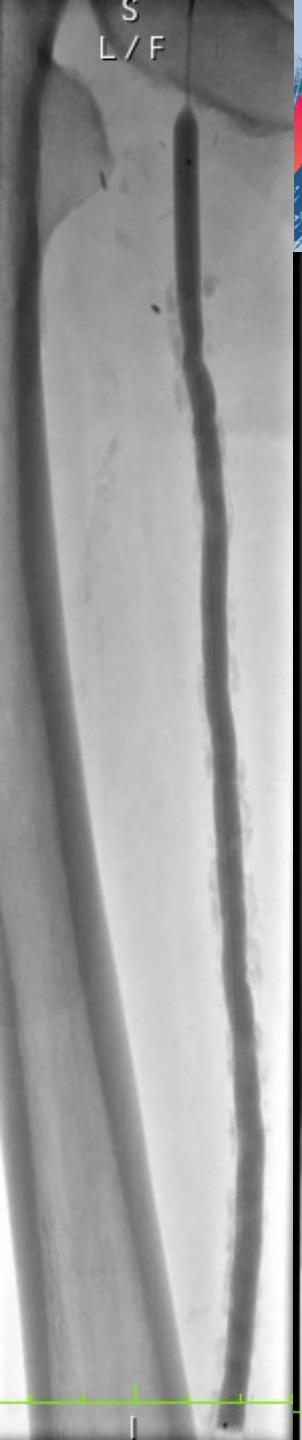
Case example OA +DCB

70yo male progressing Rutherford VI, recent surgical TEA of CFA, renal insifficiency hypertension, diabetes

OA od complete SFA, POP and TP trunc with 2.0 solid

Case example OA +DCB

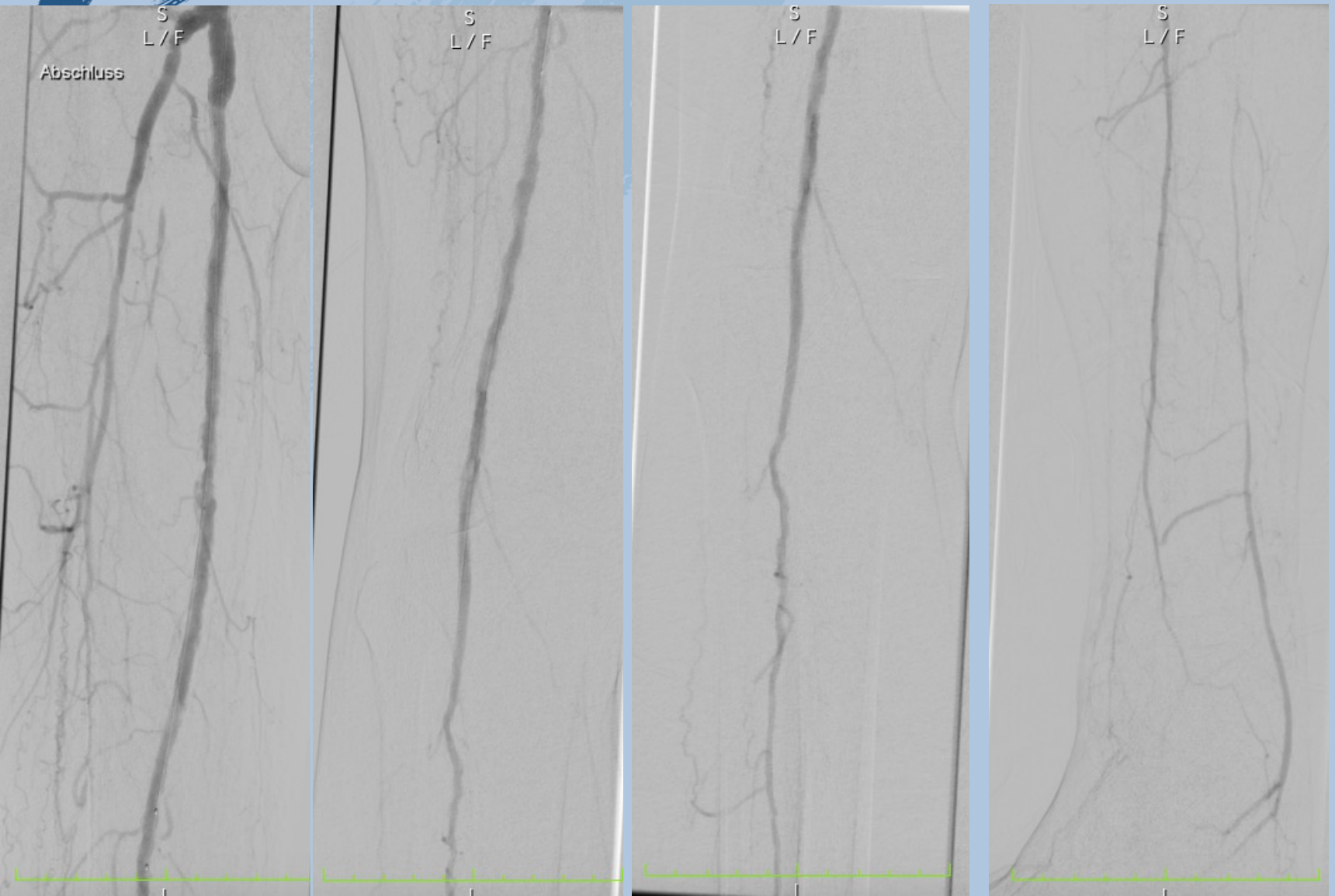
70yo male progressing Rutherford VI, recent surgical TEA of CFA, renal insifficiency hypertension, diabetes



OA followed by 6x200,
5x200 ,4x120 DCBs
Peroneal calcium cracked
with ultra low profile 2,8F Balloon

Case example OA +DCB

70yo male progressing Rutherford V, recent surgical TEA of CFA, renal insifficiency, hypertension, diabetes



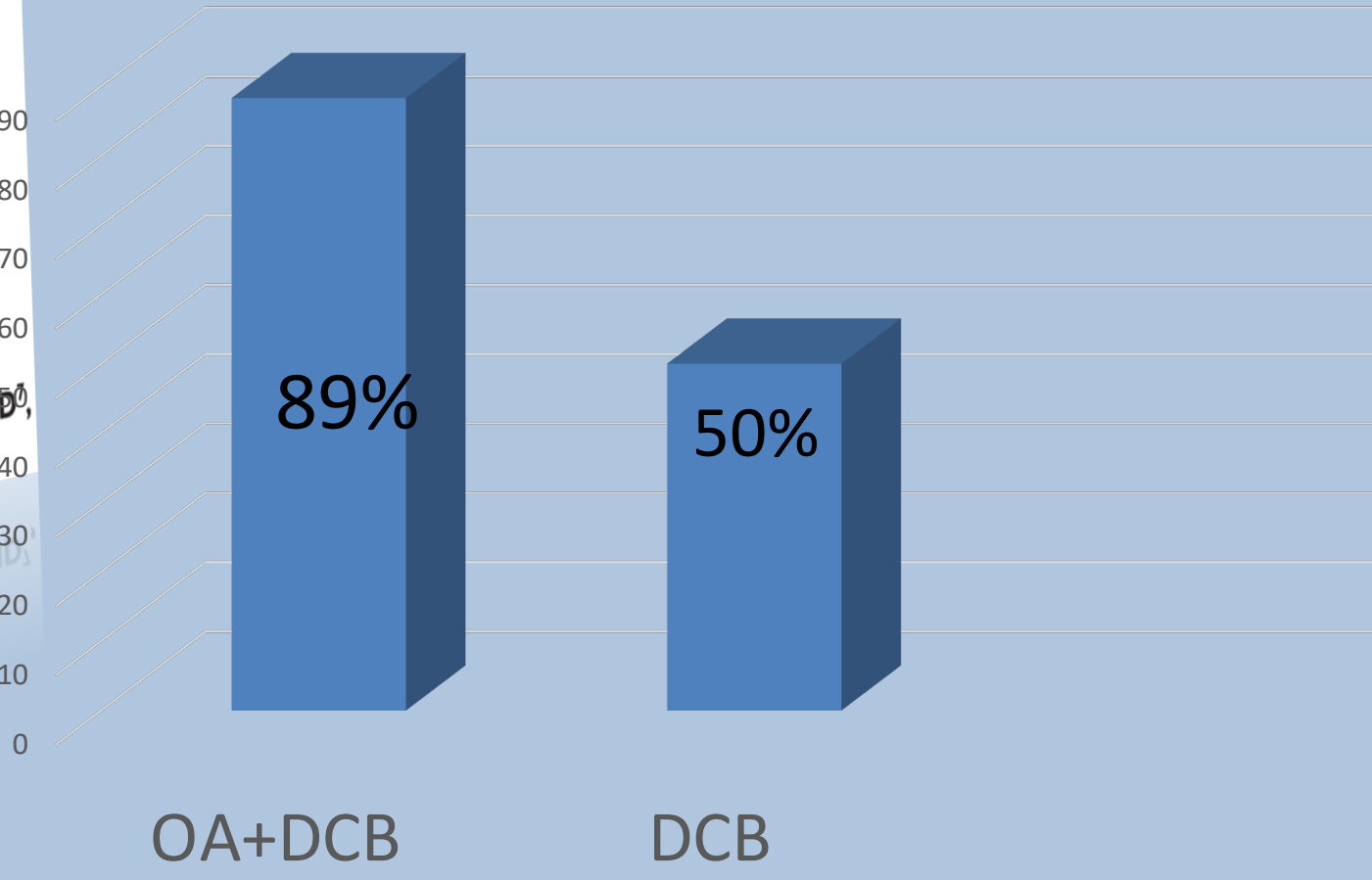
Final result

Optimize BTK

60 patients randomized 1:1
OA+DCB vs. DCB

Orbital Atherectomy Prior to Drug-Coated Balloon Angioplasty in Calcified Infrapopliteal Lesions: A Randomized, Multicenter Pilot Study

Thomas Zeller, MD[1*], Stefanos Giannopoulos, MD[2*], Marianne Brodmann, MD[3], Martin Werner, MD[4], Martin Andrassy, MD[5], Andrej Schmidt, MD[6], Erwin Blessing, MD[7], Gunnar Tepe, MD[8], and Ehrin J. Armstrong, MD[2]



Optimize BTK

66 patients randomized 1:1
OA+DCB vs. DCB

Strong trend favouring OA+DCB in primary patency
88% (OA+DCB) vs. 50% (DCB) and trend concerning technical success (93,3 vs 83,3)

However – limb salvage, survival and freedom from redo-interventions showed no statistical relevant differences after 1 yrs between both groups

More research with bigger cohorts is needed for robust decision making in the BTK vascular bed

Danke für Ihre Aufmerksamkeit

Klinik für Gefäßchirurgie St. Franziskus Hospital Münster
http://www.gefaesschirurgie-muenster.de/