Comment traiter les lésions calcifiées des artères fémoro-poplitées

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Disclosures

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I have the following potential conflicts of interest to report:

Personal fees and grants from: BD, Biotronik, Boston Scientific, Medtronic, Terumo Aortic, WL Gore (medical advisory board, educational course, speaking)

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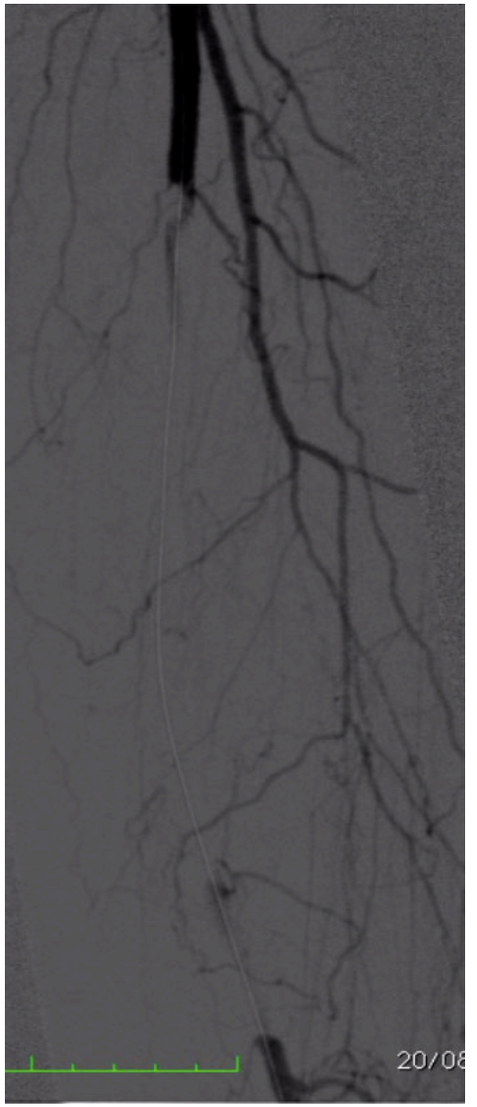
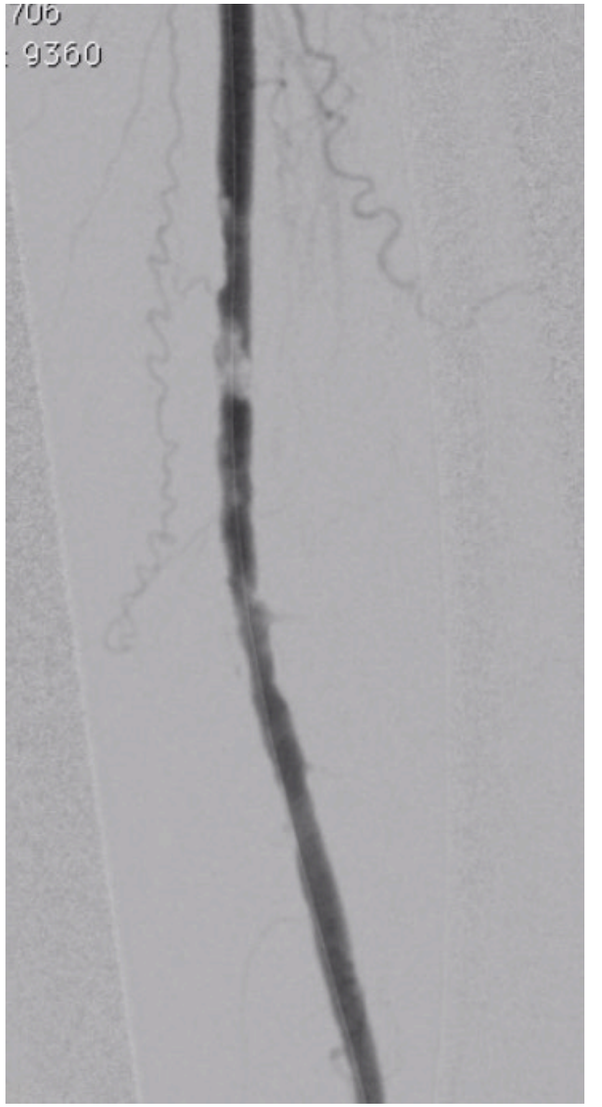
Factors associated with restenosis in peripheral interventions

- Lesion length[1]
- Diabetes[2]
- CTOs[3]
- Calcification[4]





1. Norgren et al. Eur J Vasc Endovasc Surg 33, S1-S75:2007
2. DeRubertis et al. J Vasc Surg 2008;47:101-108
3. Lida et al. CVIR 2011;78:611-7
4. Cioppa et al. CV Revasc Med 2012: 219-23

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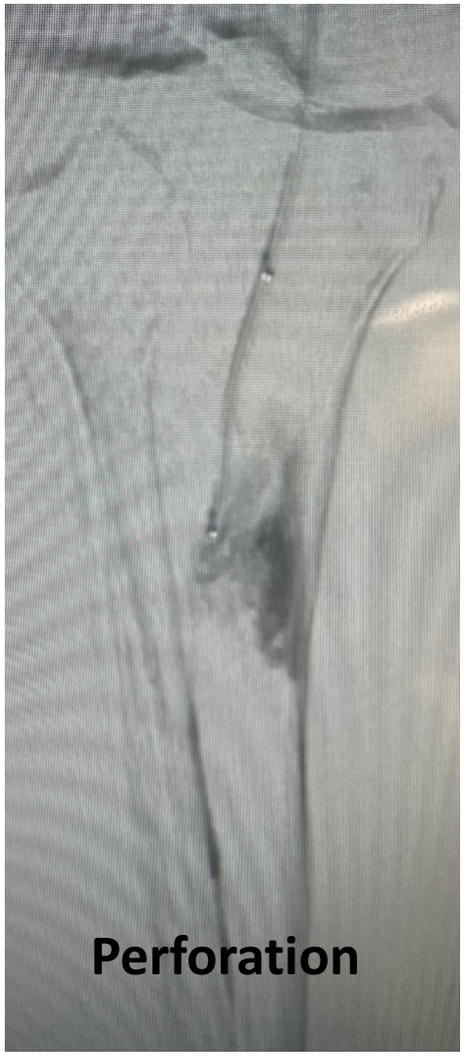
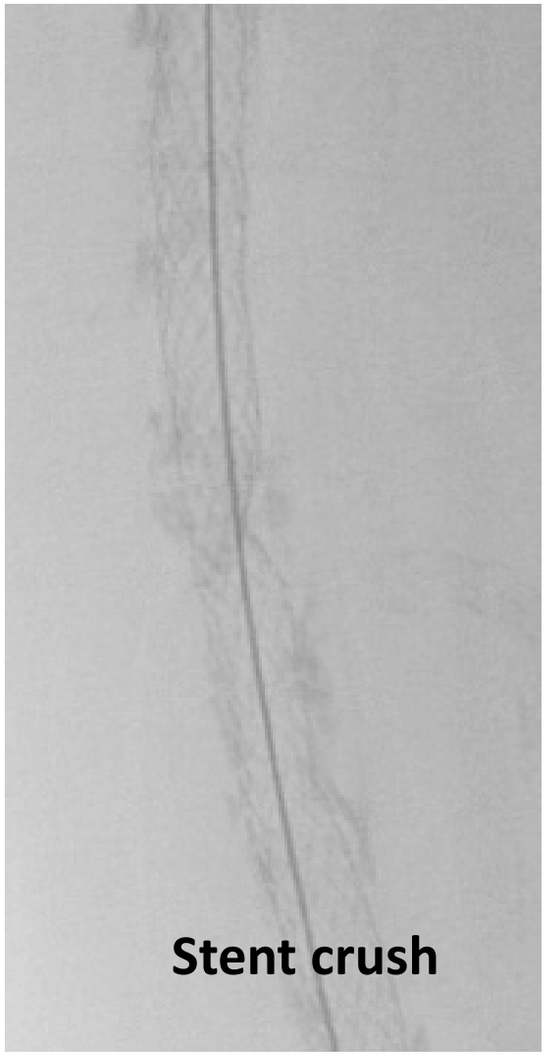
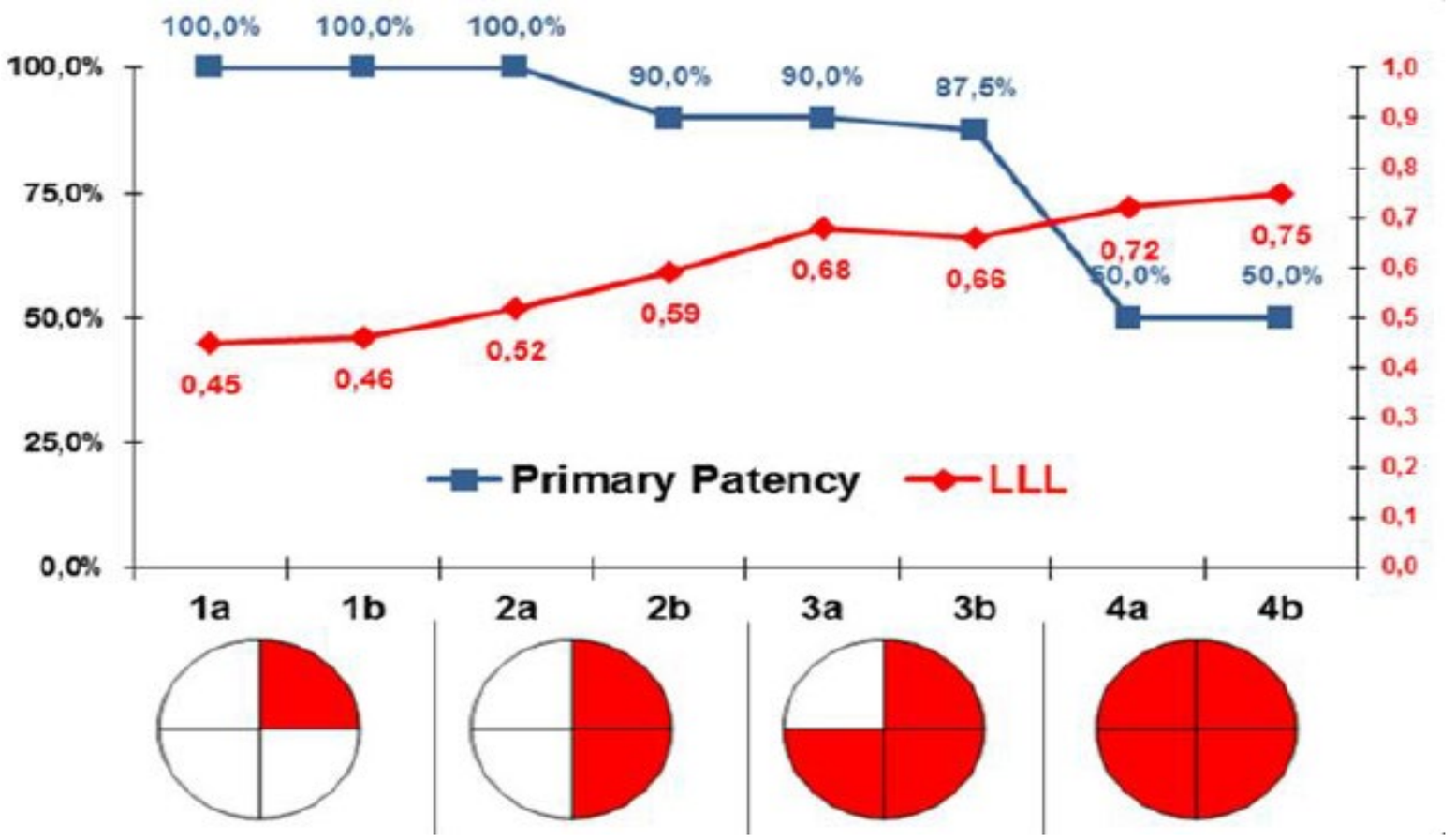
Challenges associated with treating calcified lesions



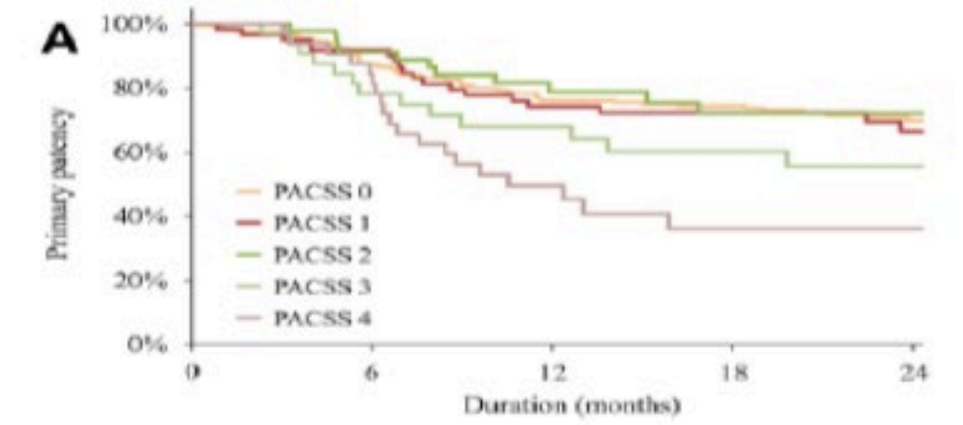


Impact of calcium

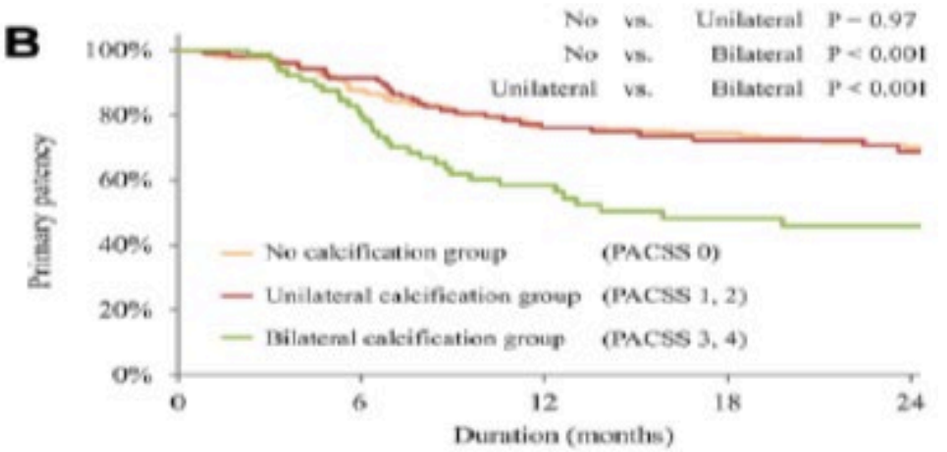


Fanelli F et al. Cardiovasc Intervent Radiol 2014

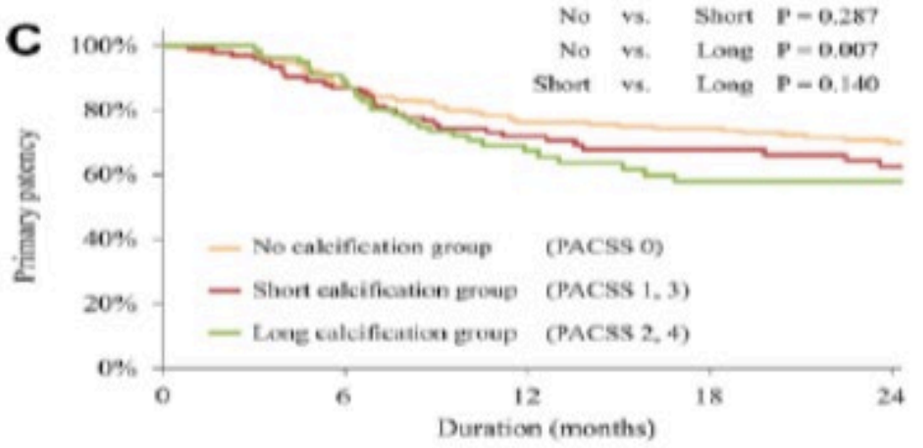
Impact of calcium



PACSS 0	214	175	138	113	85
PACSS 1	63	55	41	32	24
PACSS 2	47	41	28	21	16
PACSS 3	36	25	20	14	11
PACSS 4	34	27	13	8	7



No	214	194	169	118	62
Unilateral	110	102	84	57	28
Bilateral	70	62	51	29	15



No	214	194	169	118	62
Short	99	77	59	45	33
Long	81	67	40	28	22

Okuno et al. JEVT 2016

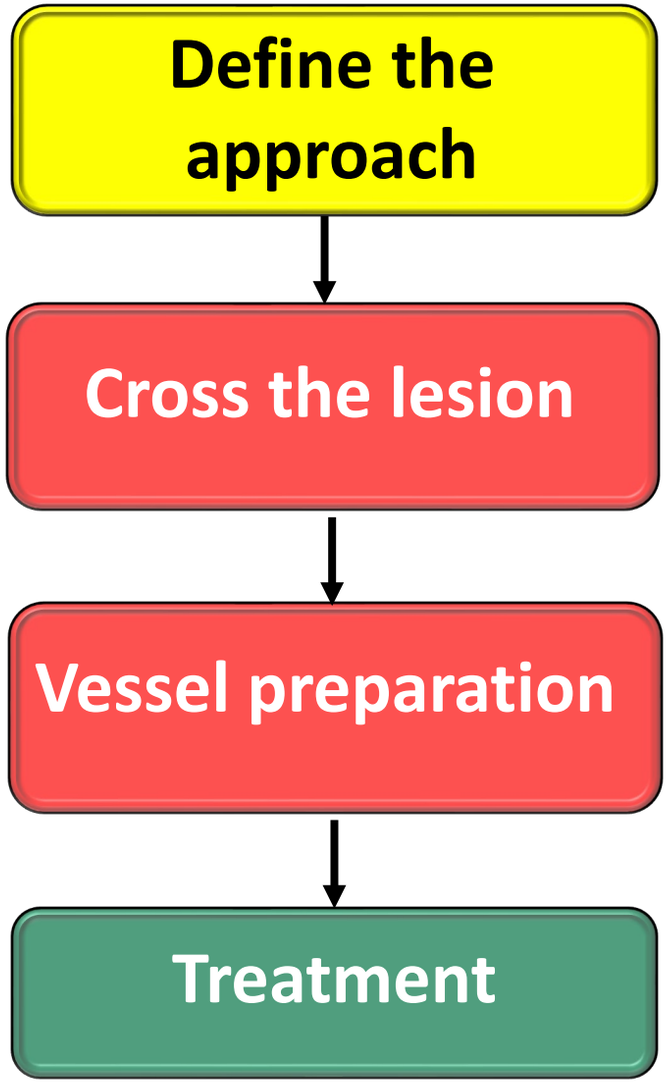
How do treat a calcified lesion ?

Retrograde femoral, antegrade femoral, pedal, axillary, brachial, radial…

Intraluminal, subintimal, re-entry devices, SAFARI…

POBA, Scoring balloonn - Chocolate balloon – Intravascular lithotrypsie - Atherectomy…

Coated and non coated devices (coverd stents)



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Gouëffic Y, EMC, 2022
Dubosq M, Medicina (Kaunas), 2022

1

Subintimal vs Intraluminal crossing

Subintimal Versus Intraluminal Approach for Femoropopliteal Chronic Total Occlusions Treated With Intravascular Ultrasound Guidance

Yusuke Tomoi, MD; Mitsuyoshi Takahara, MD, PhD; Shoichi Kuramitsu, MD, PhD; Yoshimitsu Soga, MD, PhD; Osamu Iida, MD; Masahiko Fujihara, MD; Daizo Kawasaki, MD, PhD; Kenji Ando, MD; on behalf of the IVORY Study Investigators*

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Tomoi Y et al. J Am Heart Assoc 2021

1 Subintimal vs Intraluminal crossing

Variable	Overall population			Matched population		
	SWP (n=186)	IWP (n=314)	SD (%)	SWP (n=170)	IWP (n=293)	SD (%)
Peripheral Arterial Calcium Scoring System classification						
Grade 0	39.2%	33.4%	12.1	38.8%	37.0%	3.7
Grade 1	20.4%	18.2%	5.8	19.4%	20.0%	1.4
Grade 2	14.5%	14.3%	0.5	15.9%	14.1%	5.1
Grade 3	8.6%	10.8%	7.5	7.6%	8.9%	4.7
Grade 4	17.2%	23.2%	15.1	18.2%	20.0%	4.5

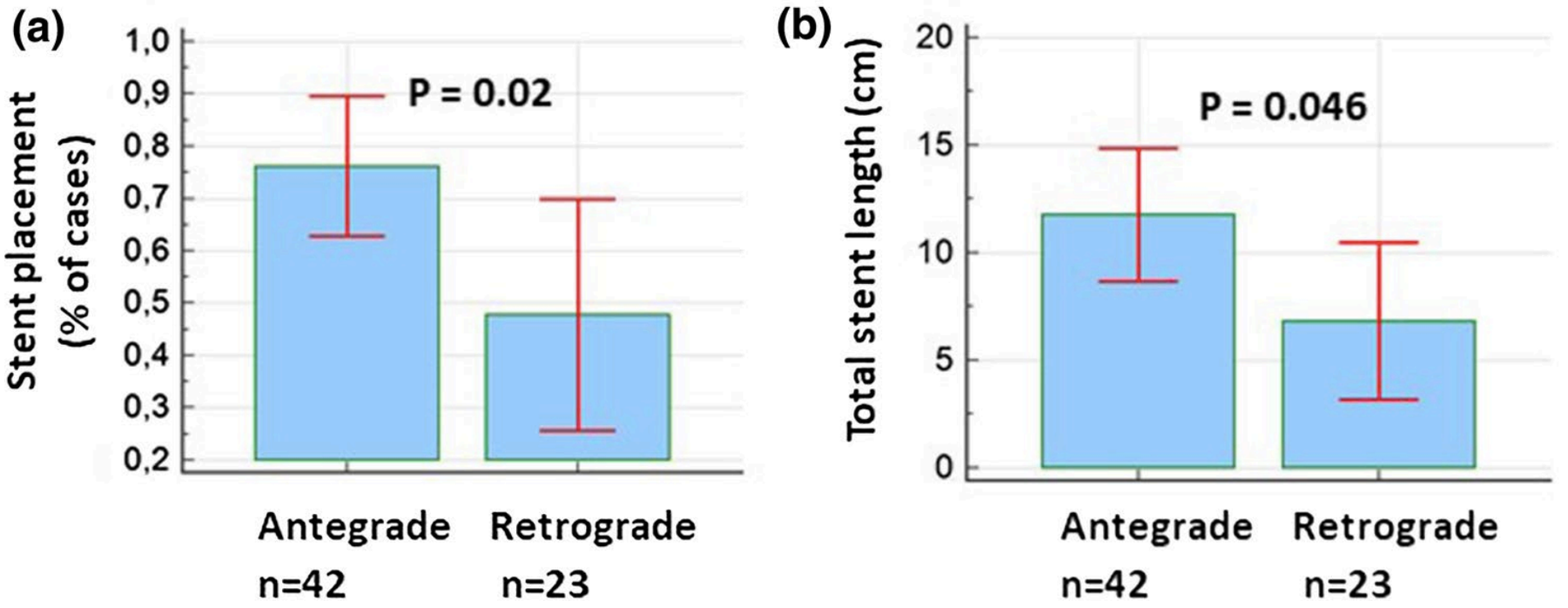
	Subintimal wire passage	Intraluminal wire passage	*P* value
1-year clinical outcomes			
Restenosis	48.2% (33.4–63.1%)	40.8% (18.3–63.4%)	0.40
All-cause mortality	5.5% (1.9–8.9%)	8.6% (3.7–13.4%)	0.70
Major amputation	1.7% (0.0–4.1%)	1.3% (0.0–3.0%)	0.98
Major adverse limb events	18.8% (11.9–25.2%)	17.6% (10.7–23.9%)	0.55

1

Antegrade vs Retrograde access

Comparison of ante-versus retrograde access for the endovascular treatment of long and calcified, de novo femoropopliteal occlusive lesions

Sorin Giusca[1] · Micheal Lichtenberg[2] · Saskia Hagstotz[1] · Christoph Eisenbach[1] · Hugo A. Katus[3] · Christian Erbel[3] · Grigorios Korosoglou[1]



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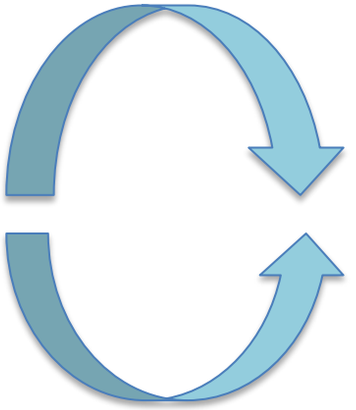
2

Vessel preparation…



3

Treatment

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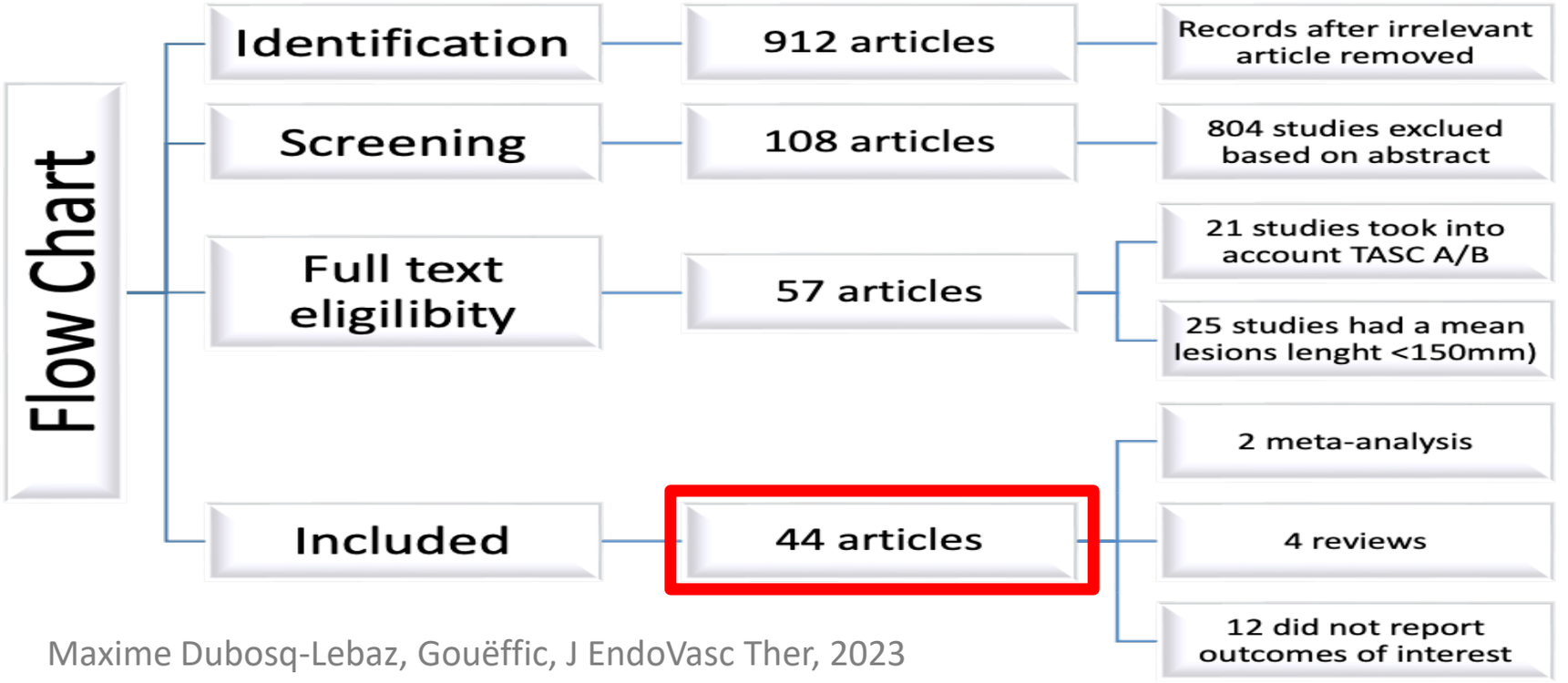
3

Treatment

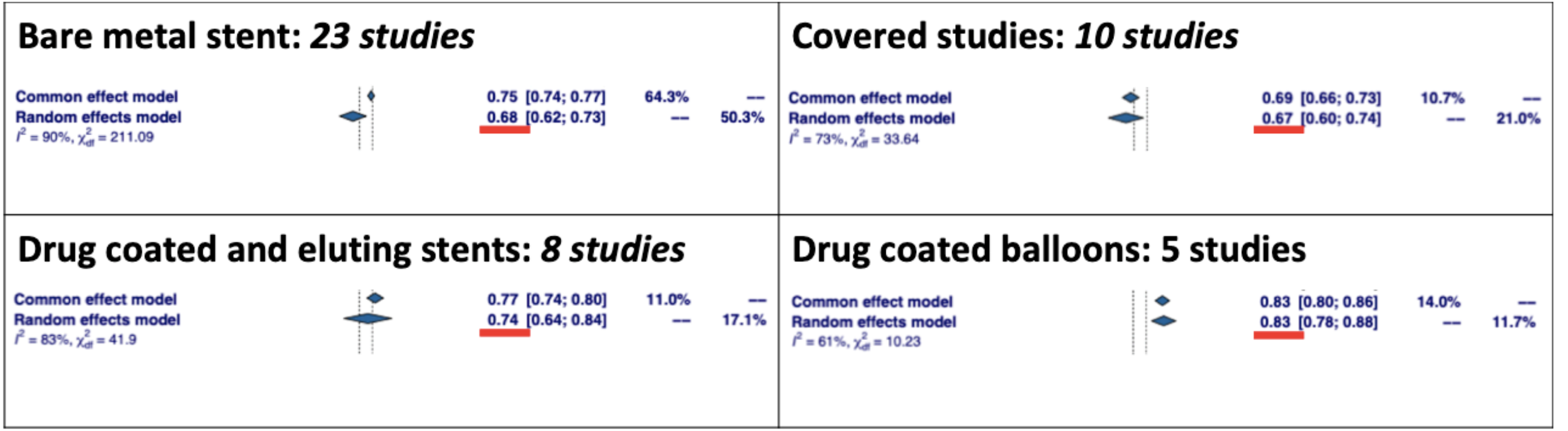
Systematic Review and Meta-analysis of Clinical Outcomes After Endovascular Treatment in Patients With Femoropopliteal Lesions Greater Than 150 mm

Maxime Dubosq-Lebaz [1], Audrey Fels [2], Gilles Chatellier [2], Yann Gouëffic [3]



Maxime Dubosq-Lebaz, Gouëffic, J EndoVasc Ther, 2023

Patency Based on Devices



Drug coated devices seem to have a better patency rate at 1-year

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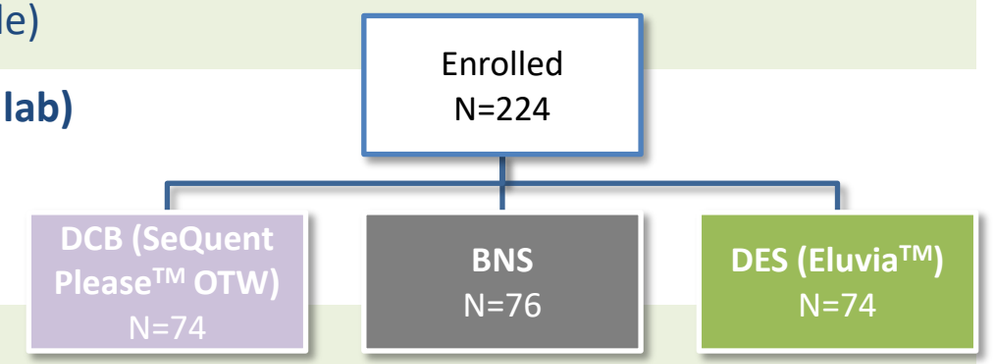
Maxime Dubosq-Lebaz, Gouëffic, J EndoVasc Ther, 2023

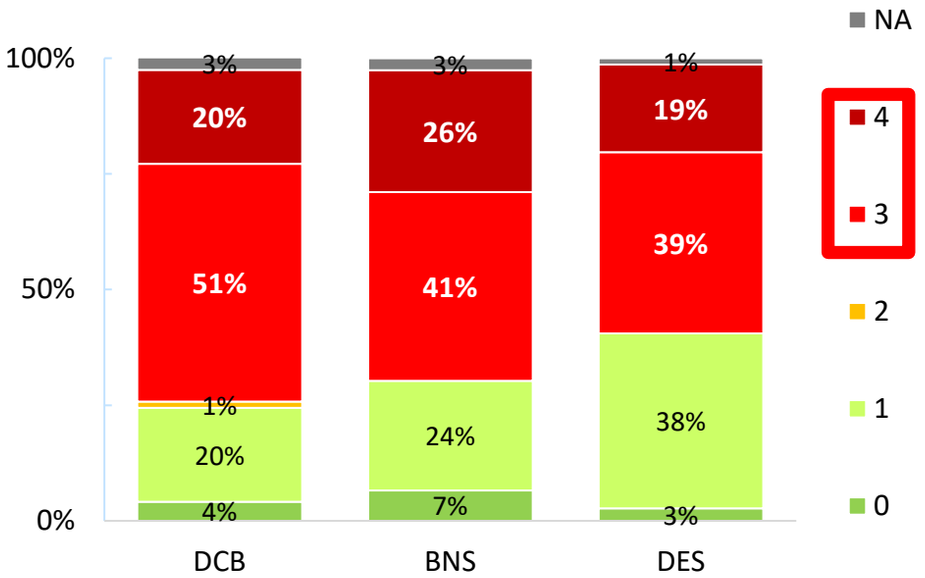
SPORTs

Study Design

Principal Investigator	Gunnar Tepe, MD RoMed Klinikum, Germany
Design	Prospective, randomized (1:1:1), open-label, multicenter
Objective	**Compare angiographic and clinical outcomes of TASC C/D lesions in the SFA** after treatment with DES (**Eluvia™** Drug Eluting Vascular Stent System, Boston Scientific), DCB (**SeQuent Please™ OTW**, BBraun), or BNS (**bare nitinol stent**, any commercially available)
Primary Endpoint	**Angiographic diameter stenosis at 12 months (core lab)** Hypothesis: 1) Superiority of DES over BNS 2) Noninferiority of DCB versus BNS
Patients	N=224 Key inclusion criteria: • Rutherford classes 2-4 • **Lesion length at least 13 cm** (treatment length at least 15 cm) • Lesions in the SFA and/or proximal popliteal artery • Diameter stenosis ≥70%



Calcification (PACSS)



	DCB (N=74)	BNS (N=76)	DES (N=74)	P-value
Lesion length, mm	**221** ± 87	**227** ± 78	**235** ±78	0.57
Occlusion	**70%**	**74%**	**85%**	0.08
Occlusion length, mm	175 ± 91	151 ± 81	179 ±89	0.18
RVD, mm	5.0± 0.6	5.2 ± 0.7	5.3 ± 0.7	0.01
MLD in lesion, mm	0.4 ± 0.7	0.3 ± 0.7	0.2 ± 0.6	0.18
% Diameter Stenosis	92.6 ±13.2	94.2 ±11.7	96.8 ±9.7	0.10
Bail out stent	**58%**	--	--	--

Mean ± SD or %. Core lab.

bare nitinol stent; DCB, drug-coated balloon (SeQuent Please™ OTW); DES, drug-eluting stent (Eluvia™); PACSS, Peripheral Arterial Calcification Severity Score; RVD, ference vessel diameter. This investigator-sponsored study is supported by grant funding from Boston Scientific. Boston Scientific is not responsible for the collection, analysis or reporting of these studies which remain the sole responsibility of the investigators. Sequent Please not available for sale in the United States.

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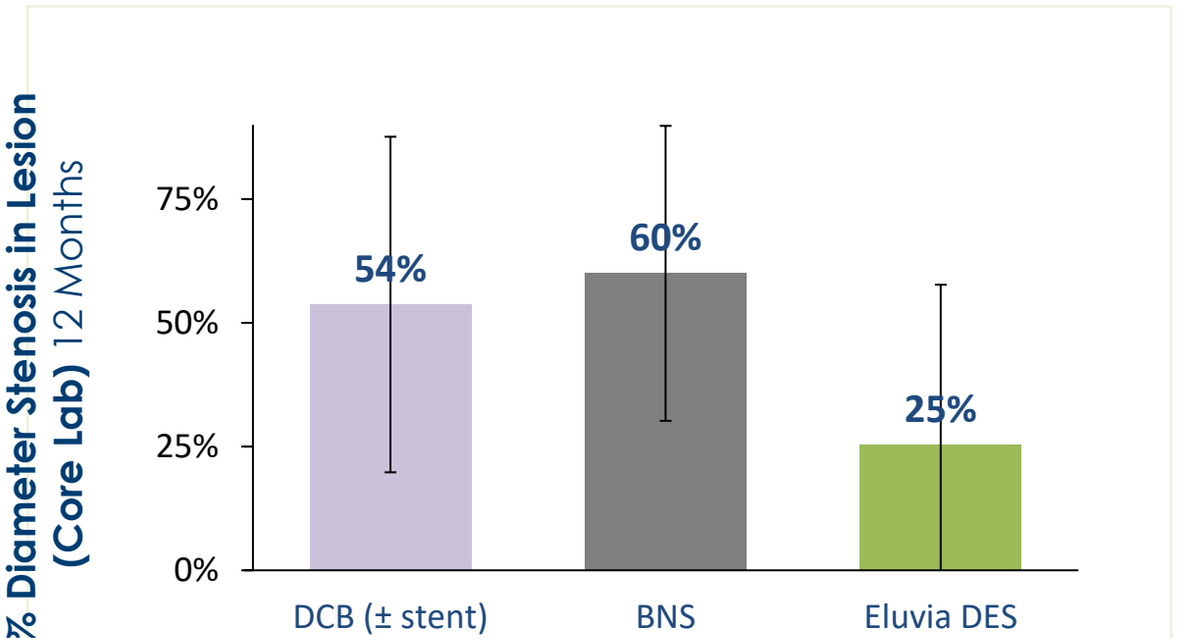
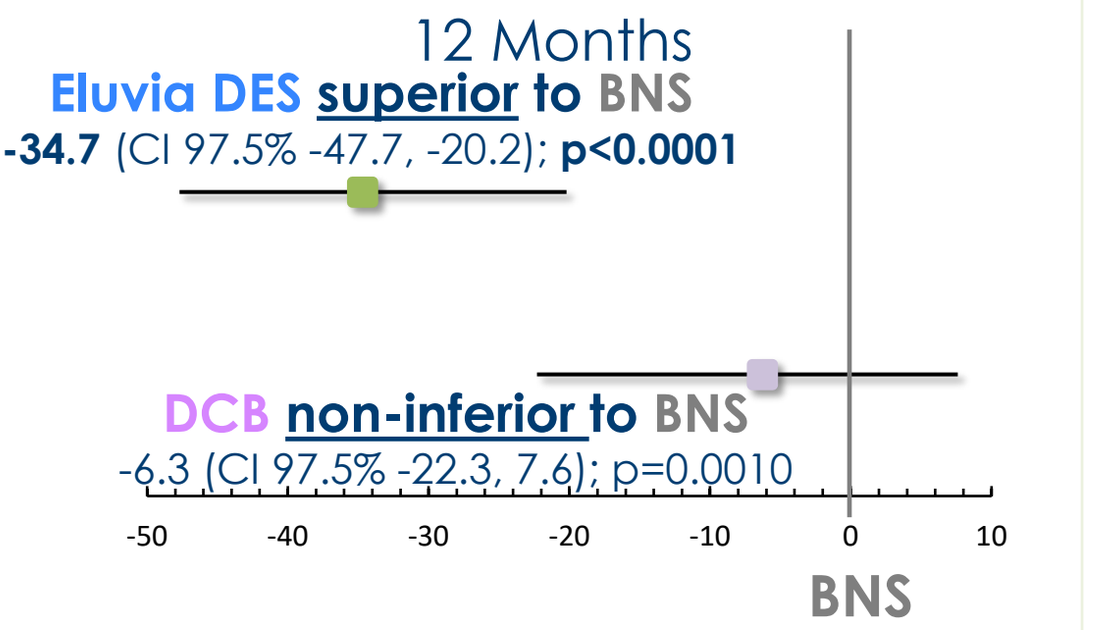
SPORTs

12-month angiographic results superior for Eluvia DES vs BNS

DCB startegy non-inferior vs BNS



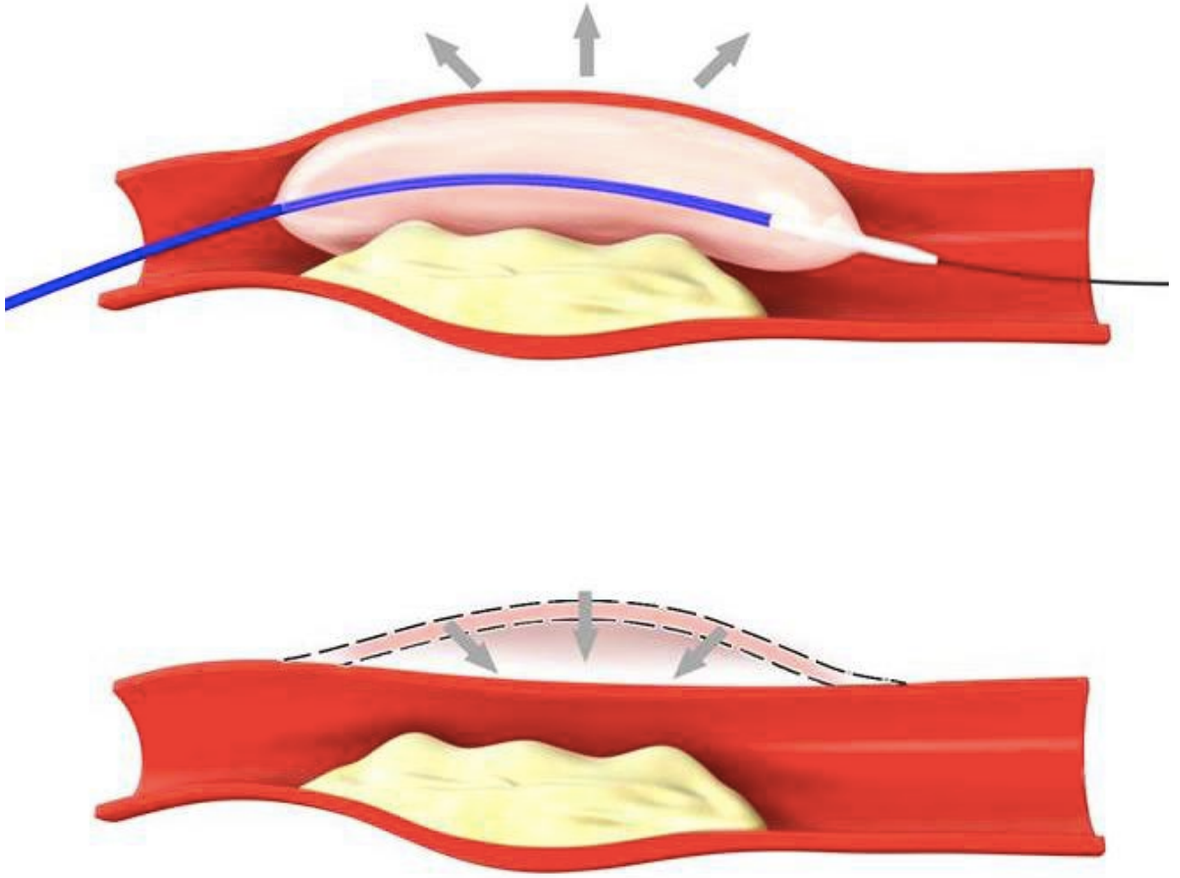
Primary Endpoint: % Diameter Stenosis vs BNS



Drug coated devices seems to provide the best outcomes

2

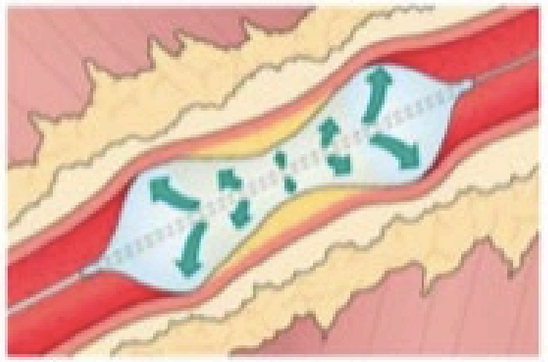
Vessel preparation: POBA problems

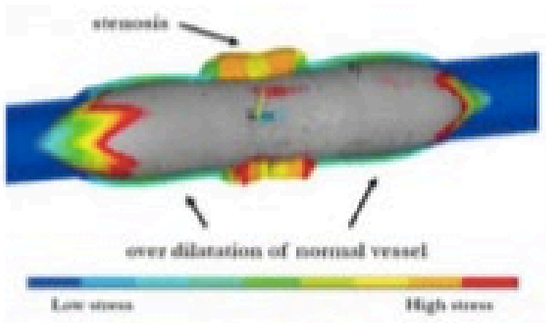


Vessel non-compliance leads to overstretch in non-diseased tissue causing **dissection**, **recoil**, excessive injury and poor outcomes

2

Vessel preparation: POBA problems

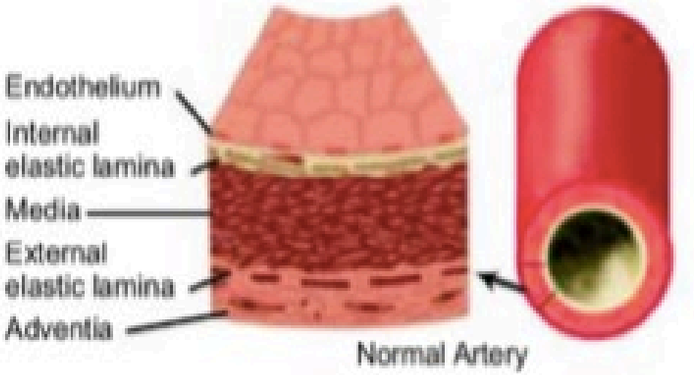


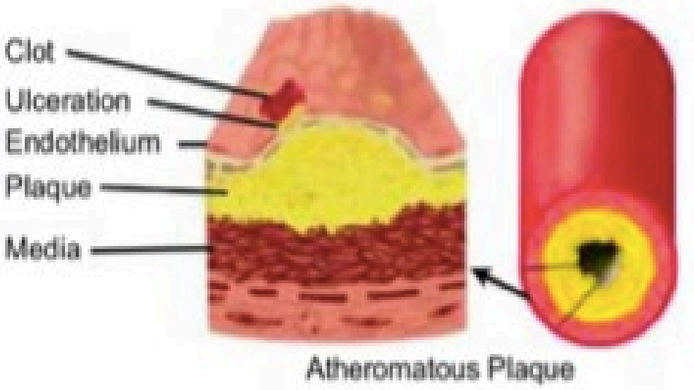


High Pressure Inflation
↑ Wall Stress

Restenosis
Revascularization failure

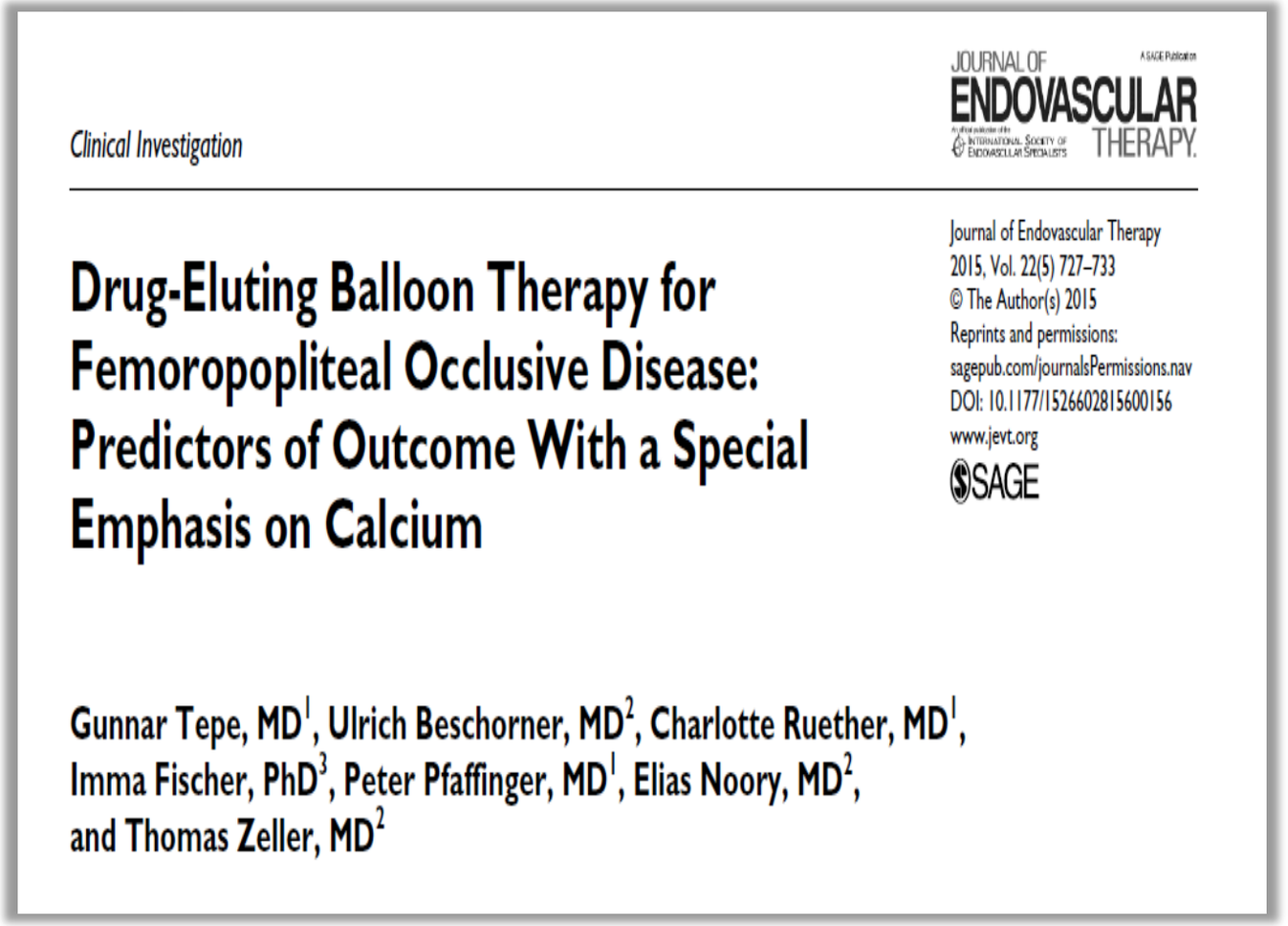
↑ Injury
Disrupts IEL





Courtesy of K. Stavroulakis

2 Vessel preparation and drug coated devices



Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY
An official publication of the International Society of Endovascular Specialists
A SAGE Publication

Drug-Eluting Balloon Therapy for Femoropopliteal Occlusive Disease: Predictors of Outcome With a Special Emphasis on Calcium

Gunnar Tepe, MD[1], Ulrich Beschorner, MD[2], Charlotte Ruether, MD[1], Imma Fischer, PhD[3], Peter Pfaffinger, MD[1], Elias Noory, MD[2], and Thomas Zeller, MD[2]

Journal of Endovascular Therapy
2015, Vol. 22(5) 727–733

DOI: 10.1177/1526602815600156
www.jevt.org
SAGE

- Retrospective analysis of 91 patients
- Analysed at 6M post DCB
- Lesion calcification analysed by core labs (PACSS score + angiographic calcium score)

- **Severity of lesion calcification is associated with LLL after treatment with DCB.**

- Author conclusion: "**One possible approach to overcome this limitation might be plaque modification or removal prior to DEB usage.**"

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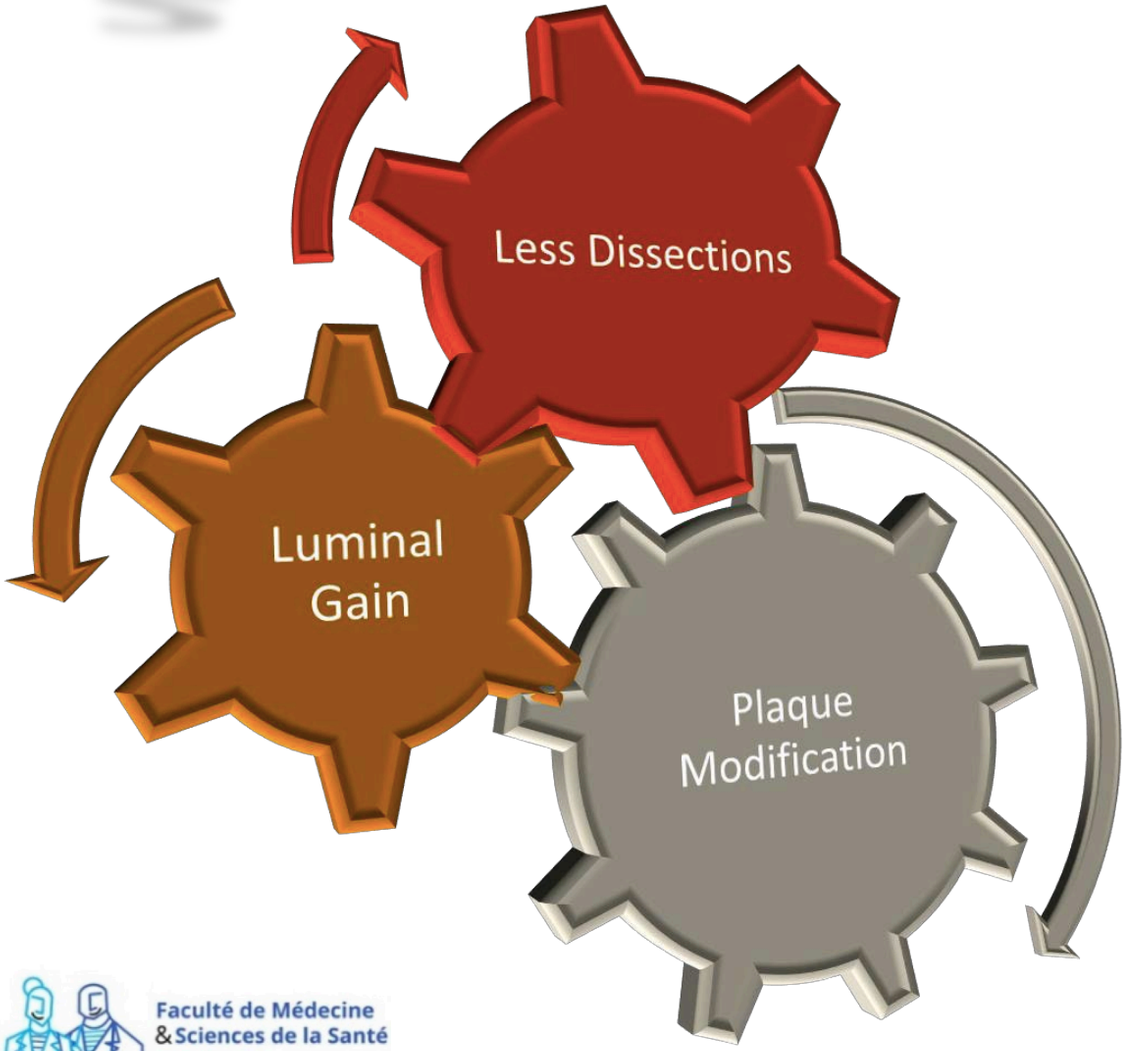
2

Vessel preparation: Why Debulking ?



Increased Drug Uptake

Less or Better Scaffolding

Improved patency ?

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Drug uptake after vessel preparation

Calcified plaque modification alters local drug delivery in the treatment of peripheral atherosclerosis

Abraham R. Tzafriri, PhD[1,2], Fernando Garcia-Polite, PhD[1,2], Brett Zani, PhD[1], James Stanley, DVM, MS, PhD[1], Benny Muraj, MV[1], Jennifer Knutson, BS[1,3], Robert Kohler, MS[3], Peter Markham, MS[1], Alexander Nikanorov, MD, PhD[3], and Elazer R. Edelman, MD, PhD[2,4]

[1]CBSET Inc, 500 Shire Way, Lexington MA, USA

[2]IMES, MIT, 77 Massachusetts Avenue Cambridge, MA, USA

[3]Cardiovascular Systems, Inc, 1225 Old Hwy 8NW, Saint Paul, MN, USA

[4]Cardiovascular Division, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA

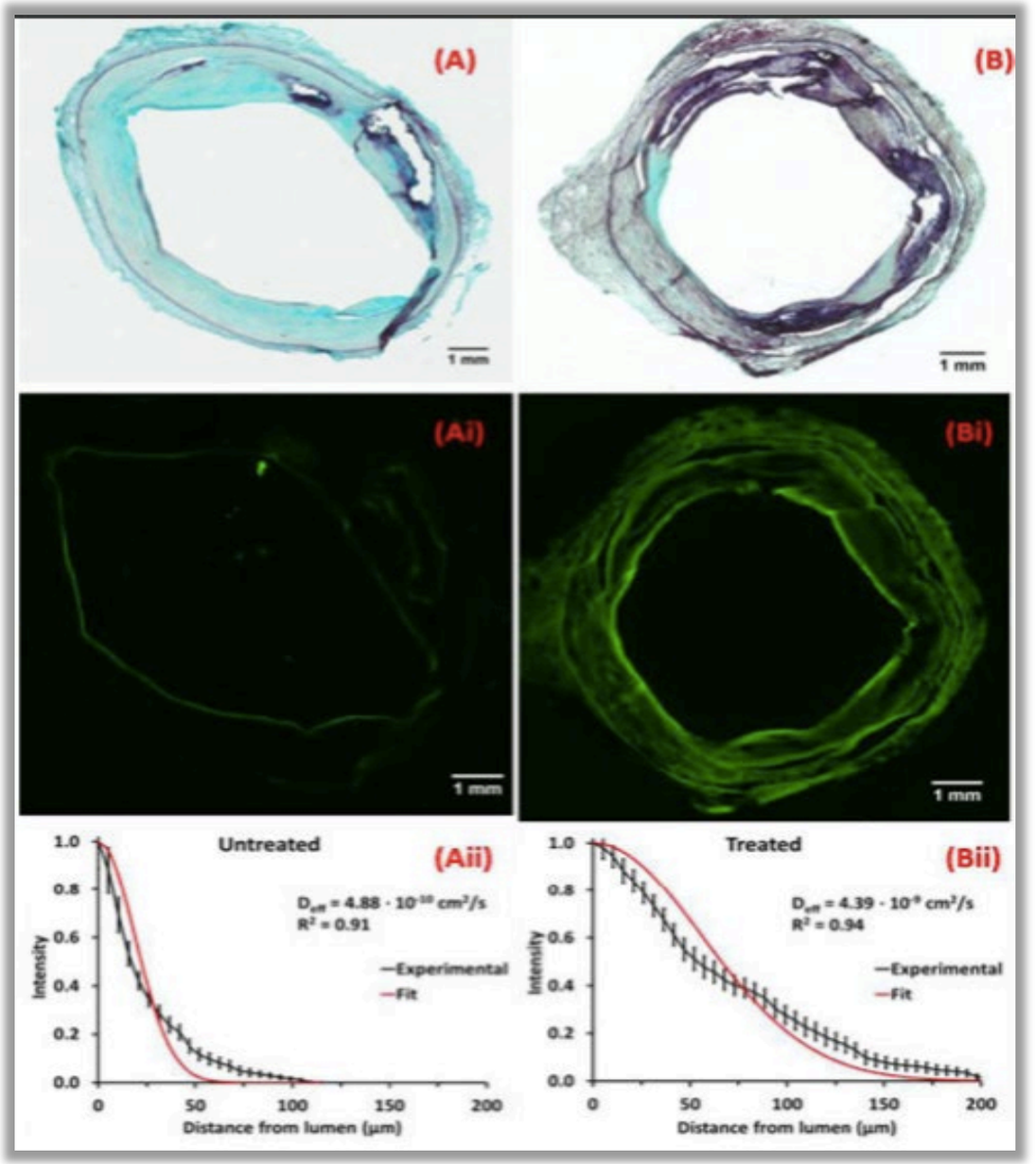
Abstract

Background—Calcific atherosclerosis is a major challenge to intraluminal drug delivery in peripheral artery disease (PAD).

Objectives—We evaluated the effects of orbital atherectomy on intraluminal paclitaxel delivery to human peripheral arteries with substantial calcified plaque.

Methods—Diagnostic angiography and 3-D rotational imaging of five fresh human lower limbs revealed calcification in all main arteries. The proximal or distal segment of each artery was treated using an orbital atherectomy system (OAS) under simulated blood flow and fluoroscopy. Explanted arterial segments underwent either histomorphometric assessment of effect or tracking of ^{14}C-labeled or fluorescent-labeled paclitaxel. Radiolabeled drug quantified bulk delivery and fluorescent label established penetration of drug over finer spatial domain in serial microscopic sections. Results were interpreted using a mathematical model of binding-diffusion mediated arterial drug distribution.

Results—Lesion composition affected paclitaxel absorption and distribution in cadaveric human peripheral arteries. Pretreatment imaging calcium scores in control femoropopliteal arterial segments correlated with a log-linear decline in the bulk absorption rate-constant of ^{14}C-labeled, declining 5.5-fold per calcified quadrant ($p=0.05$, $n=7$). Compared to controls, OAS-treated femoropopliteal segments exhibited 180μm thinner intima ($p<0.001$), 45% less plaque calcification, and 2 log orders higher paclitaxel bulk absorption rate-constants. Correspondingly, fluorescent paclitaxel penetrated deeper in OAS-treated femoropopliteal segments compared to controls, due to a 70% increase in diffusivity ($p<0.001$).



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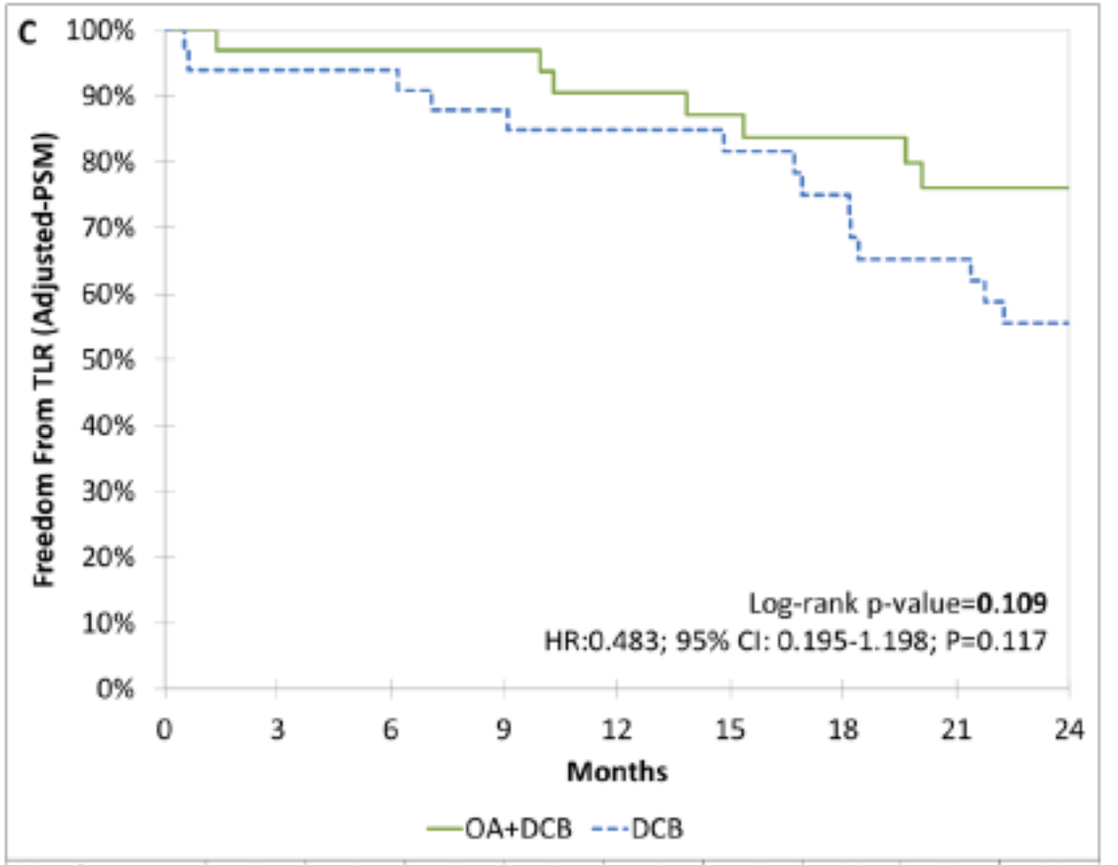
Original Clinical Studies

Two-Year Outcomes of Orbital Atherectomy Combined With Drug-Coated Balloon Angioplasty for Treatment of Heavily Calcified Femoropopliteal Lesions

Damianos G. Kokkinidis, MD, MSc[1], Omar Jawaid, MD[1], David Cantu[1], Brad J. Martinsen, PhD[2], Zsuzsanna Igyarto, PhD[2], Javier A. Valle, MD, MSCS[1], Stephen W. Waldo, MD[1], and Ehrin J. Armstrong, MD, MSc[1]



Months	0	3	6	9	12	15	18	21	24
OA+DCB at risk	33	33	33	32	28	25	24	21	18
Events	0	1	1	1	3	5	5	7	7
FF TLR ± SE (%)	100 ± 0.00	97.0 ± 2.98	97.0 ± 2.98	97.0 ± 2.98	90.5 ± 5.22	83.7 ± 6.70	83.7 ± 6.70	76.1 ± 7.96	76.1 ± 7.96
DCB at risk	33	32	31	28	27	26	21	20	17
Events	0	2	3	5	5	6	11	12	14
FF TLR ± SE (%)	100 ± 0.00	93.9 ± 4.15	90.9 ± 5.00	84.8 ± 6.24	84.8 ± 6.24	81.6 ± 6.80	65.3 ± 8.50	62.0 ± 8.68	55.5 ± 8.91

113 patients (63 DCB vs 50 OA + DCB)

Propensity score matching

Bail-out stenting: 67% vs 39%, p=0.02

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Directional atherectomy before paclitaxel coated balloon angioplasty in complex femoropopliteal disease: The VIVA REALITY study

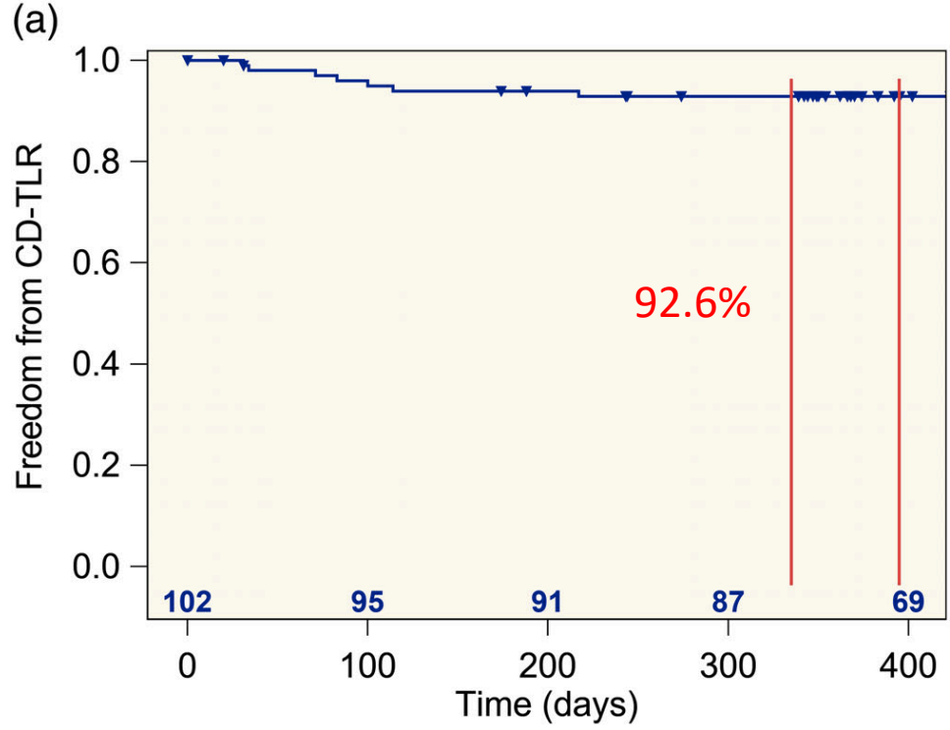
Krishna J. Rocha-Singh MD[1] | Ravish Sachar MD[2] | Brian G. DeRubertis MD[3] | Claus C. A. Nolte-Ernsting MD[4] | John G. Winscott MD[5] | Prakash Krishnan MD[6] Eric C. Scott MD[7] | Lawrence A. Garcia MD[8] | Jean-Luc Baeriswyl MSc[9] | Gary Ansel MD[10] | Kenneth Rosenfield MD[11] | Thomas Zeller MD[12] | The REALITY Investigators

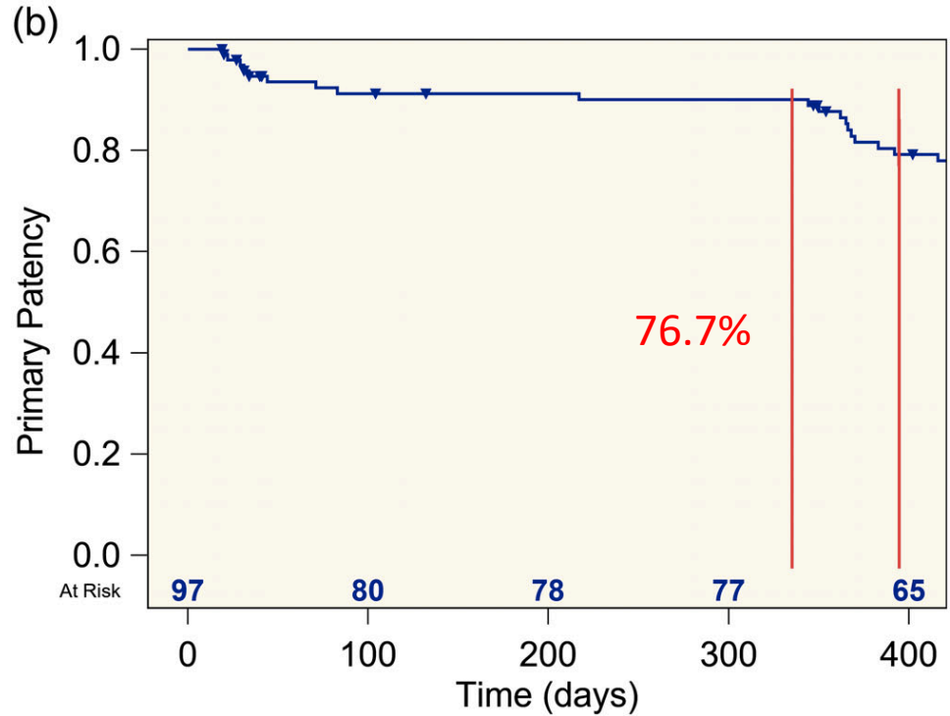
13 multinational centers

Mean lesion lenght 17.9 ± 8.1 cm, PACSS 3 / 4, 39% CTO

102 patients, DA + DCB

Bailout stenting 8.8%





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Intravascular Lithotripsy for Peripheral Artery Calcification: Mid-term Outcomes From the Randomized Disrupt PAD III Trial

Gunnar Tepe, MD [a], Marianne Brodmann, MD [b], William Bachinsky, MD [c], Andrew Holden, MD [d], Thomas Zeller, MD [e], Sarang Mangalmurti, MD [f], Claus Nolte-Ernsting, MD [g], Renu Virmani, MD [h], Sahil A. Parikh, MD [i], William A. Gray, MD [j,*], for the Disrupt PAD III Investigators

Disrupt PAD III RCT
306 patients: IVL vs PTA prior to DCB or stenting
Endpoint: PP at 1 year (freedom from TLR + freedom from restenosis

Acute PTA failure requiring stent placement during the procedure was prespecified as a loss of PP

Bailout stenting: 4.6% vs 18.3%, p<0.0001
PP 1 year: 80.5% vs 68%, p=0.01

Freedom from TLR (95.7% vs 98.3%, p=0.94) and freedom from restenosis rates (90% vs 88.8%, p=0.48) were similar

SYSTEMATIC REVIEW

Systematic Review and Network Meta-analysis of Vessel Preparation Techniques With Plain Balloon Angioplasty, Atherectomy, or Intravascular Lithotripsy Before Application of a Drug Coated Balloon to Treat Atherosclerotic Femoropopliteal Disease

Janice Yiu [a,‡], **Ravali Tippireddy** [a,‡], **Lukla Biasi** [a], **Sanjay Patel** [a], **Prakash Saha** [a], **Athanasios Saratzis** [b], **Konstantinos Katsanos** [c], **Hany Zayed** [a,*]

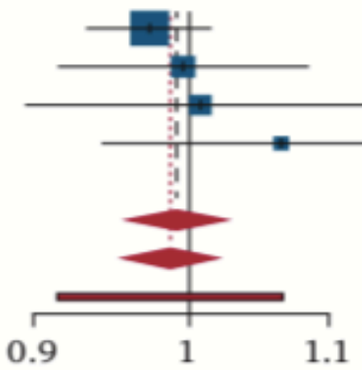
[a] Department of Vascular Surgery, Guy's and St. Thomas' Hospital NHS Foundation Trust and King's College London, London, United Kingdom
[b] NIHR Leicester Biomedical Research Centre, Leicester, United Kingdom
[c] Patras University Hospital, Rion, Greece

Objective: To compare one year outcomes after atherectomy, intravascular lithotripsy *vs.* plain balloon angioplasty before application of drug coated balloons for treating femoropopliteal atherosclerotic disease.

Freedom from TLR

Study	Experimental Events	Experimental Total	Control Events	Control Total	RR	95% CI	Weight (fixed)	Weight (random)
Tepe *et al.* 2022[25]	132	138	114	116	0.97	[0.93–1.02]	54.1%	66.4%
Cai *et al.* 2020[23]	43	45	47	49	1.00	[0.91–1.09]	19.6%	16.8%
Zeller *et al.* 2017[24]	38	41	46	50	1.01	[0.89–1.13]	18.1%	8.7%
Shammas *et al.* 2022[22]	27	27	15	16	1.06	[0.94–1.20]	8.2%	8.2%
Fixed effect model	**240**	**251**	**222**	**231**	**0.99**	**[0.96–1.03]**	**100.0%**	--
Random effects model					**0.99**	**[0.95–1.02]**	--	**100.0%**
Prediction interval						**[0.91–1.07]**		

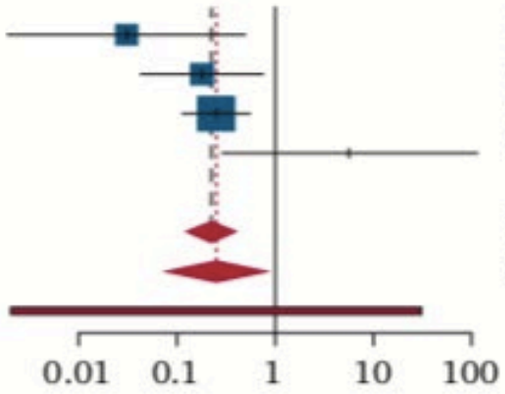
Heterogeneity: $I^2 = 0\%, \tau^2 = 0, p = .55$



Bailout stenting

Study	Experimental Events	Experimental Total	Control Events	Control Total	RR	95% CI	Weight (fixed)	Weight (random)
Shammas *et al.* 2022[22]	0	31	8	16	0.03	[0.00–0.50]	21.1%	14.6%
Cai *et al.* 2020[23]	2	45	12	49	0.18	[0.04–0.77]	23.0%	30.4%
Tepe *et al.* 2022[25]	7	153	28	153	0.25	[0.11–0.55]	56.0%	41.9%
Zeller *et al.* 2017[24]	2	48	0	54	5.62	[0.28–114.17]	0.0%	13.1%
Fixed effect model	**11**	**277**	**48**	**272**	**0.22**	**[0.12–0.41]**	**100.0%**	--
Random effects model					**0.25**	**[0.07–0.89]**	--	**100.0%**
Prediction interval						**[0.00–30.39]**		

Heterogeneity: $I^2 = 54\%, \tau^2 = 0.8268, p = .090$



"All the News That's Fit to Print"

The New York Times

LATE EDITION
Today, showers and thunderstorms, downpours may lead to flooding, high 82. Tonight, thunderstorms, low 72. Tomorrow, humid with sun, high 89. Weather map, Page 20.

VOL. CLXXII . . . No. 59,851 NEW YORK, SUNDAY, JULY 16, 2023 $6.00

CYDNI ELLEDGE FOR THE NEW YORK TIMES

Kelly Hanna, whose leg was amputated in 2020, received at least 18 artery-opening procedures on her legs from a Michigan doctor.

Patients Lost Limbs as Doctors and Health Care Giants Prospered

This article is by Katie Thomas, Jessica Silver-Greenberg and Robert Gebeloff.

Kelly Hanna's leg was amputated on a summer day in 2020, after a Michigan doctor who called himself "the leg saver" had damaged her arteries by snaking metal wires through them to clear away plaque.

OPERATING PROFITS
'The Leg Saver'

It started with a festering wound on her left foot. Her podiatrist referred Ms. Hanna to Dr. Jihad Mustapha. Over 18 months, he performed at least that many artery-opening procedures on Ms. Hanna's legs, telling her they would improve blood flow and prevent amputations.

They didn't — for Ms. Hanna or many of his other patients. Surgeons at nearby hospitals had seen so many of his patients with amputations and other problems that they complained to Michigan's medical board about his conduct. An insurance company told state authorities that 45 people had lost limbs after treatment at his clinics in the past four years.

Dr. Mustapha is no back-alley operator working in the shadows of the medical establishment, an investigation by The New York Times has found. With the financial backing of medical device manufacturers, he has become a leader of a booming cottage industry that peddles risky procedures to millions of Americans — enriching doctors and device companies and sometimes costing patients their limbs.

Device Makers Finance Cottage Industry for Risky Procedures

The industry targets the roughly 12 million Americans with peripheral artery disease, in which plaque, a sticky slurry of fat, calcium and other materials, accumulates in the arteries of the legs. For a tiny portion of patients, the plaque can choke off blood flow, leading to amputations or death.

But more than a decade of medical research has shown that the vast majority of people with peripheral artery disease have mild or no symptoms and don't require treatment, aside from getting more exercise and taking medication. Experts said even those who do have severe symptoms, like Ms. Hanna, shouldn't undergo repeated procedures in a short period of time.

Continued on Page 14

Beijing Targets Canada Critics From Overseas

Meddling With Ottawa Part of Global Aims

By NORIMITSU ONISHI

RICHMOND, British Columbia — The polls predicted a re-election victory, maybe even a landslide.

But a couple of weeks before the vote, Kenny Chiu, a member of Canada's Parliament and a critic of China's human rights record, was panicking. Something had flipped among the ethnic Chinese voters in his British Columbia district.

"Initially, they were supportive," he said. "And all of a sudden, they just vanished, vaporized, disappeared."

Longtime supporters originally from mainland China were not returning his calls. Volunteers reported icy greetings at formerly friendly homes. Chinese-language news outlets stopped covering him. And he was facing an onslaught of attacks — from untraceable sources — on the local community's most popular social networking app, the Chinese-owned WeChat.

The sudden collapse of Mr. Chiu's campaign — in the last federal election, in 2021 — is now drawing renewed scrutiny amid mounting evidence of China's interference in Canadian politics.

Mr. Chiu and several other elected officials critical of Beijing were targets of a Chinese state that has increasingly exerted its influence over Chinese diaspora communities worldwide as part of an aggressive campaign to expand its global reach, according to current and former elected officials, Canadian intelligence officials and experts on Chinese state disinformation campaigns.

Canada recently expelled a Chinese diplomat accused of conspiring to intimidate a lawmaker from the Toronto area, Michael Chong, after he successfully led efforts in Parliament to label China's treatment of its Uyghur Muslim community a genocide. Canada's intel-

VAST FIELDS FULL OF MINES HINDER UKRAINE'S FORCES

GRIM PICTURE IN SOUTH

Array of Trip Wires and Booby Traps Slows Counteroffensive

By ANDREW E. KRAMER

ORIKHIV, Ukraine — It was a grisly scene of bloody limbs and crumpled vehicles as a series of Russian mines exploded across a field in southern Ukraine.

One Ukrainian soldier stepped on a mine and tumbled onto the grass in the buffer zone between the two armies. Nearby lay other Ukrainian troops, their legs in tourniquets, waiting for medical evacuation, according to videos posted online and the accounts of several soldiers involved.

Soon, an armored vehicle arrived to rescue them. A medic jumped out to treat the wounded and knelt on ground he deemed safe — only to trigger another mine with his knee.

Five weeks into a counteroffensive that even Ukrainian officials say is off to a halting start, interviews with commanders and soldiers fighting along the front indicate the slow progress comes down to one major problem: land mines.

The fields Ukrainian forces must cross are littered with dozens of types of mines — made of plastic and metal, shaped like tins of chewing tobacco or soda cans, and with colorful names like "the witch" and "the leaf."

Ukraine's army is also hindered by a lack of air support and the deep network of defensive structures the Russians have built. But it is the vast array of mines, trip wires, booby traps and improvised explosive devices that has Ukrainian forces bogged down only a few miles from where they started.

"I couldn't imagine something like this," said a Ukrainian private

Take home message

- Calcium still a challenge for endovascular treatment
- Vessel Prep can improve the outcomes of drug coated devices
- Drug coated devices seems to provide the best outcomes
- Benefict from the use of scaffolds