Angioplastie au ballon simple ou actif, ou stent nu ou actif?
Que faire pour la fémorale superficielle ?

Y. Gouëffic, MD, PhD

Department of vascular surgery, University hospital of Nantes, France

l'institut du thorax

Inserm UNIVERSITÉ DE NANTES

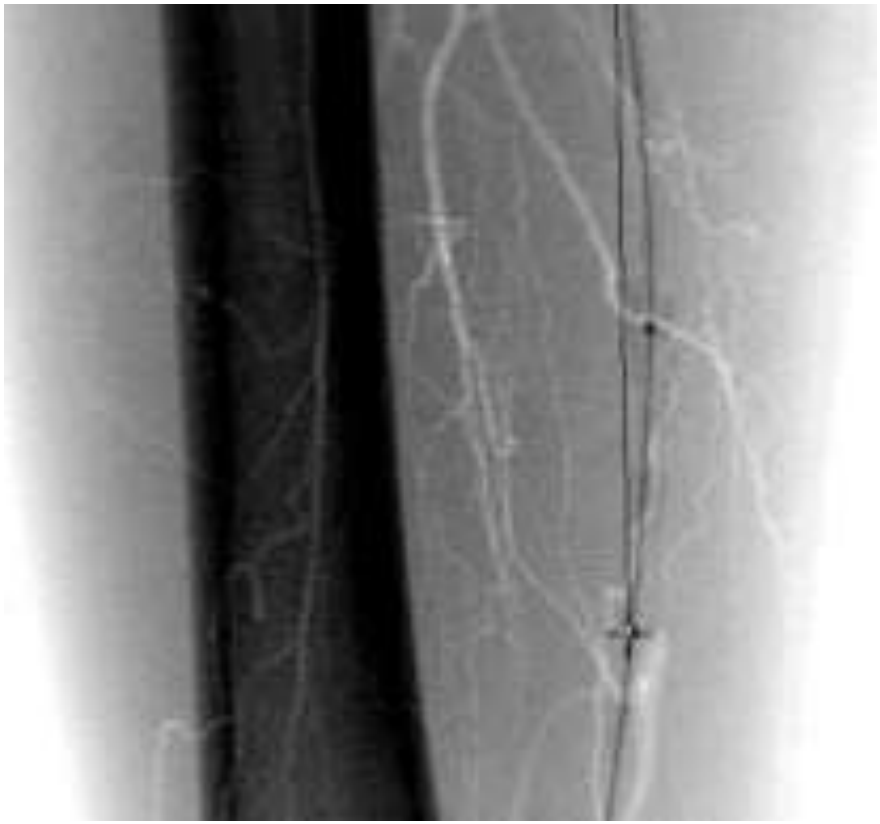
Inserm UNIVERSITÉ DE NANTES l'institut du thorax

Disclosures

Research grants /Consulting/Honoraria for

- Abbott
- Bard
- Boston Sc
- Cook
- Medinol
- Medtronic
- Perouse
- Spectranetics
- Terumo
- WL Gore

What is the best strategy for femoropopliteal lesions?



POBA

Bare metal stent

Drug eluting stent

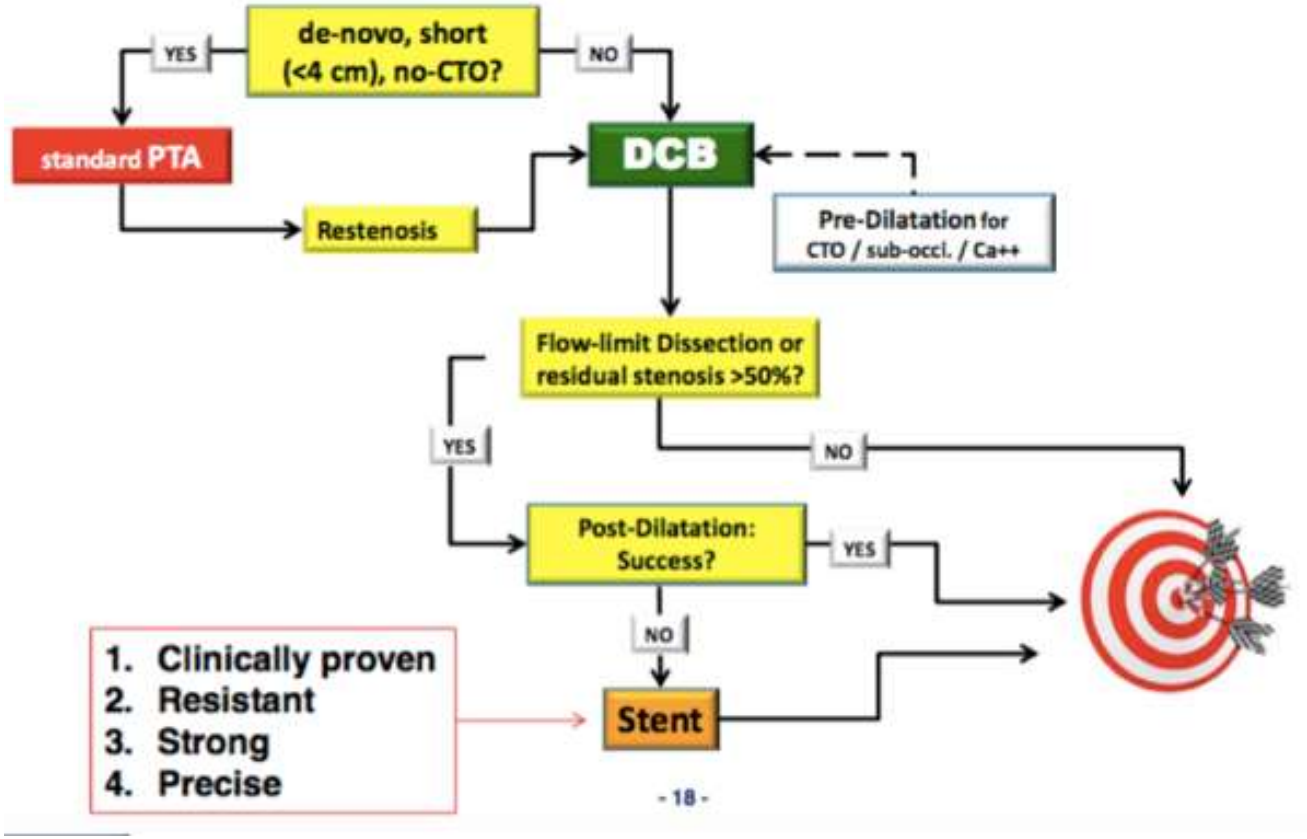
Drug eluting balloon

Covered stent

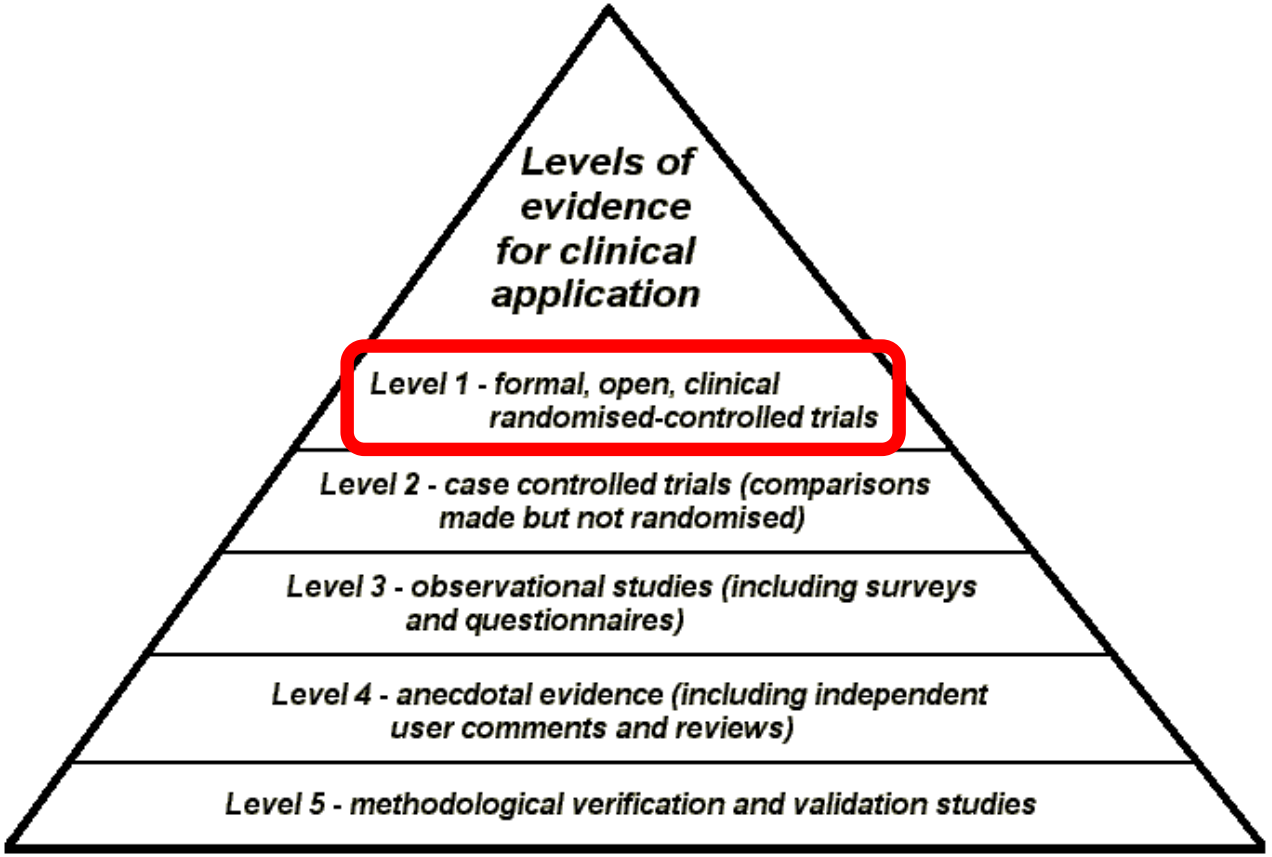
Bioresorbable stent

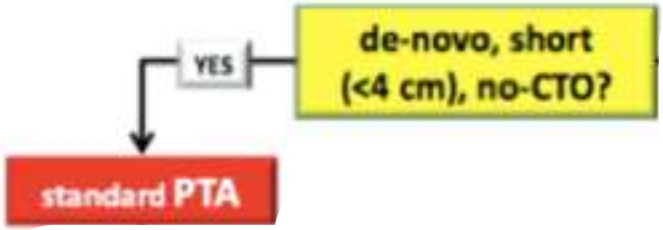
…

Algorythm


de-novo, short (<4 cm), no-CTO?
YES
NO
standard PTA
DCB
Restenosis
Pre-Dilatation for CTO / sub-occl. / Ca++
Flow-limit Dissection or residual stenosis >50%?
YES
NO
Post-Dilatation: Success?
YES
NO
Stent
1. Clinically proven
2. Resistant
3. Strong
4. Precise
- 18 -

5 levels of evidence





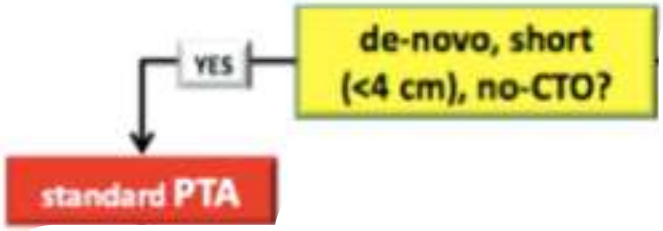
Systematic versus selective stent placement after superficial femoral artery balloon angioplasty: A multicenter prospective randomized study

Jean-Pierre Becquemin, MD,[a] Jean-Pierre Favre, MD,[b] Jean Marzelle, MD,[c] Chantal Nemoz, PhD,[d] Caroline Corsin,[d] and Alain Leizorovicz, MD,[d] *Créteil, St Etienne, Annecy, and Lyon, France*

Nitinol Stent Implantation Versus Percutaneous Transluminal Angioplasty in Superficial Femoral Artery Lesions up to 10 cm in Length : The Femoral Artery Stenting Trial (FAST)

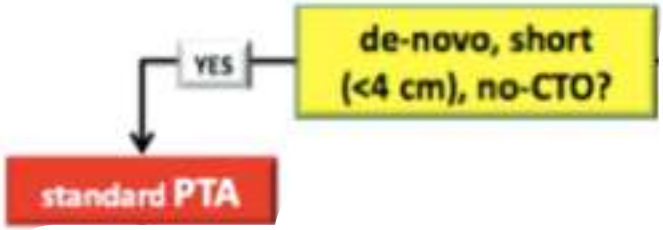
Hans Krankenberg, Michael Schlüter, Hermann J. Steinkamp, Karlheinz Bürgelin, Dierk Scheinert, Karl-Ludwig Schulte, Erich Minar, Patrick Peeters, Marc Bosiers, Gunnar Tepe, Bernhard Reimers, Felix Mahler, Thilo Tübler and Thomas Zeller

Becquemin, J Vasc Surg, 2003
Krankenberg, Circulation, 2007



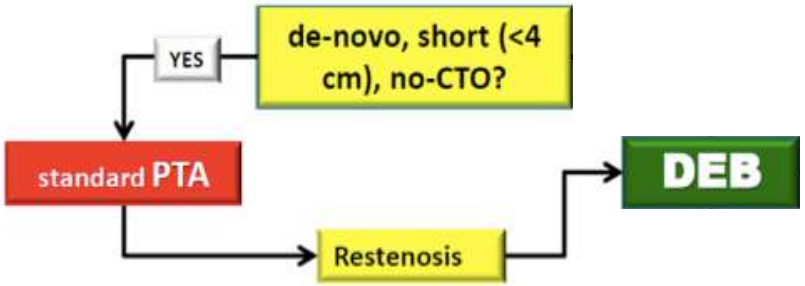
	Zilver PTX	MAJESTIC
Length	≤14-cm	≥30 mm and ≤110 mm
Mean treated length (cm)	61.8mm	70.8±28.1

Dake, Circ Cardiovasc Interv. 2011
Müller-Hülsbeck, J Endovasc, Ther, 2016



	IN-PACT SFA	LEVANT 2	ILLUMINATE RCT
Length (Inclusion criteria)	4-18 cm length or occulsion with lengths of ≤10 cm	≤15 cm	3-20 cm
Mean treted length (cm)	8.94±4.89	6.28±4.10	7.2± 5.2

Tepe, Circulation, 2014; Rosenfield, NEJM, 2015;
Schroeder, Circulation, 2017



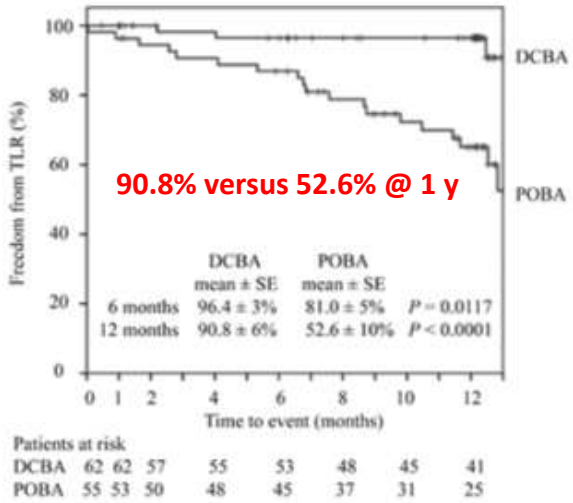
Interventional Cardiology

Drug-Coated Balloon Versus Standard Balloon for Superficial Femoral Artery In-Stent Restenosis

The Randomized Femoral Artery In-Stent Restenosis (FAIR) Trial

Hans Krankenberg, MD*; Thilo Tübler, MD*; Maja Ingwersen, DVM; Michael Schlüter, PhD; Dierk Scheinert, MD; Erwin Blessing, MD; Sebastian Sixt, MD; Arne Kieback, MD; Ulrich Beschorner, MD; Thomas Zeller, MD

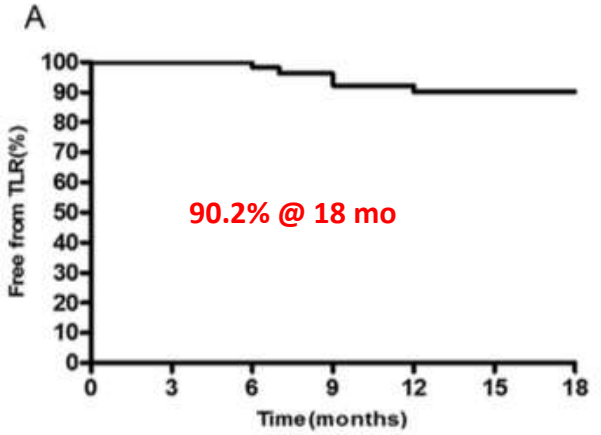
Mean lesion length: 82.2±68.4 mm
Complete occlusion: 28.6%



Femoropopliteal In-stent Restenosis Repair: Midterm Outcomes After Paclitaxel Eluting Balloon Use (PLAISIR Trial)

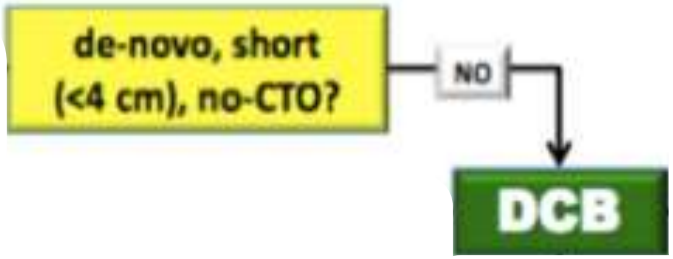
N. Bague [a], P. Julia [b], A. Sauguet [c], J.M. Pernès [d], P. Chatelard [e], J.F. Garbé [f], S. Penillon [g], J.M. Cardon [h], P. Commeau [i], O. Planché [j], B. Guyomarch [a], Y. Gouëffic [a,k,l,*]

Prospective registry (In Pact Admiral,Medtronic)
53 patients



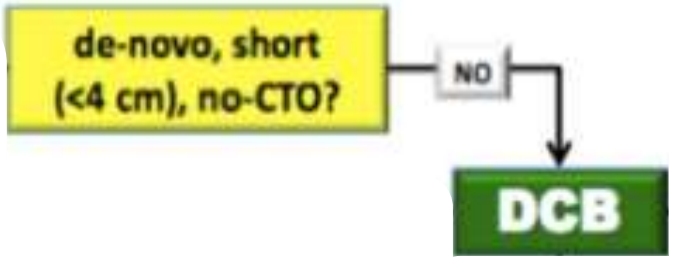
Months	0	3	6	12	18
Patients at risk (n)	55	54	53	44	40
Rate (%+/-SD)	100	100	98.1+/-1.9	90.2+/-4.2	90.2+/-4.2

Krankenberg, Circulation, 2015
Bague, Eur J Vasc Endovasc Surg, 2016



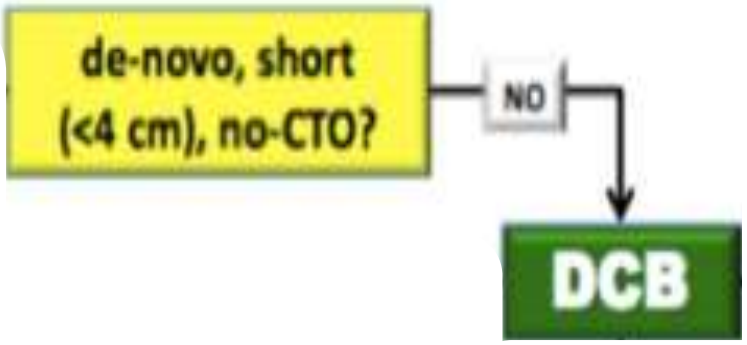
	IN-PACT SFA (DEB arm)	LEVANT 2 (DEB arm)	ILLUMINATE RCT (DEB arm)
Patients (n)	220/111	316/160	222/72
Mean age	67.5±9.5	67.8±10.0	67±9
Intermittent claudication (%)	91	92.1	98
Mean length (cm)	8.94±4.89	6.28±4.10	7.2± 5.2
Severe calcifications (%)	8.1	10.4	13
Occlusions	25.8	21	19

Tepe, Circulation, 2014
Rosenfield, NEJM, 2015
Schroeder, Circulation, 2017



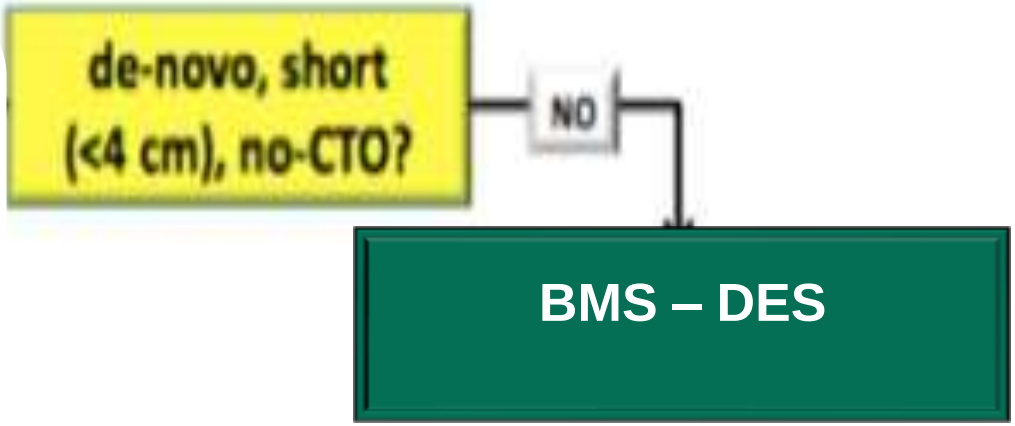
	IN-PACT SFA	LEVANT 2	ILLUMINATE RCT
Provisionnal stenting (%)	7.3	2.5	15
ly patency rates at 12 months (%) (proportional rate)	82.2 vs. 52.4 p <0.001	65.2 vs. 52.6 p <0.02	83.9 vs. 60.6 p <0.001
ly patency rates at 24 months (%)	78.9 vs. 50.1 p < 0.001	58.6 vs. 53.0 p=0.05	89 vs 65 p <0.001

Tepe, Circulation, 2014
Rosenfield, NEJM, 2015
Schroeder, Circulation, 2017



In/Ex critieria ?

- Long lesions
- Failure of vessel prep
- Severe calicification


de-novo, short
(<4 cm), no-CTO?
NO
BMS – DES

?

Trials for TASC A-B femoropopliteal lesions

	Vienna	Durability	Fast	Resilient	Astron	Misago 2	Supera SFA registry
Stent	Absolute (Abbott)	Everflex (Covidien)	Luminexx (Bard)	Lifestent (Bard)	Astron (Biotronik)	Misago (Terumo)	Supera (Abbott)
Design	RCT	Registry	RCT	RCT	RCT	Registry	Registry
Lesion length criteria (mm)	>30	≤ 140	1-100	<150	3-200	< 180	NA

Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

Journal of Endovascular Therapy
2016, Vol. 23(5) 701–707
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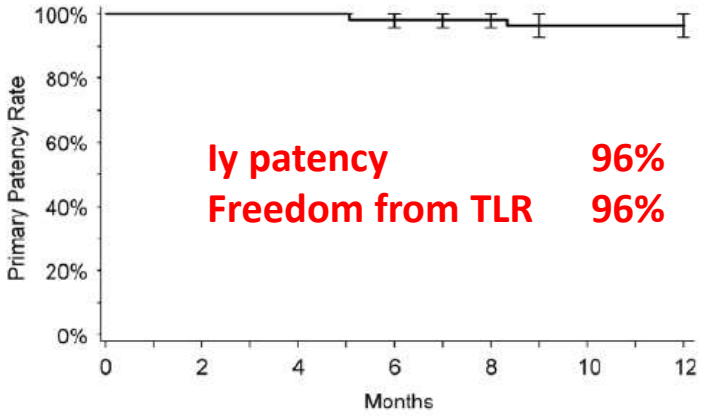
DOI: 10.1177/1526602816650206
www.jevt.org
SAGE

Twelve-Month Results From the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Treatment of Obstructive Femoropopliteal Disease

Stefan Müller-Hülsbeck, MD[1], Koen Keirse, MD[2], Thomas Zeller, MD[3], Herman Schroë, MD[4], and Juan Diaz-Cartelle, MD[5]

Prospective, multicentre, single-arm, open label (n= 57)

Mean age	69±9 years
Diabetes	35%
Restenotic lesions	-
Mean lesion length	70.8±28.1 mm
Occlusions	46%
TASC A/B	90%

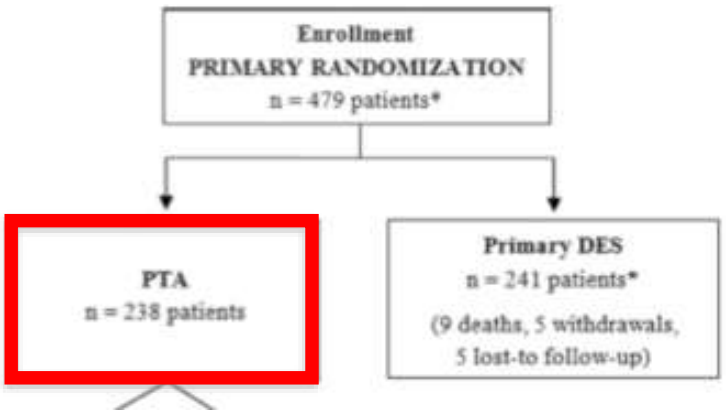


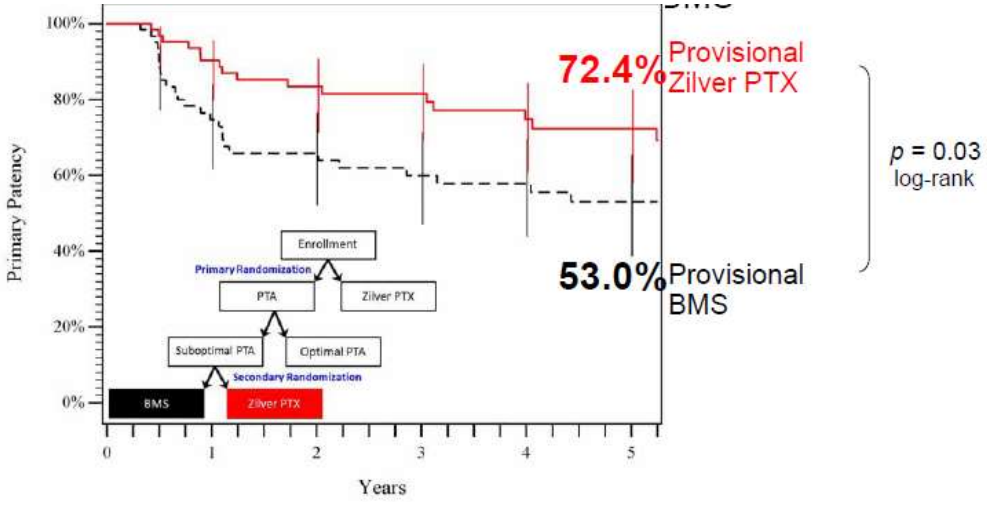
Number of patients:	Time from index procedure (months)				
	0	1	6	9	12
At Risk	57	56.5	56	54.5	37
Censored	0	1	0	1	32
Events	0	0	1	1	0
Patency Rate	100%	100%	98.2%	96.4%	96.4%

Müller-Hülsbeck, J Endovasc ther, 2016

Zilver PTX RCT

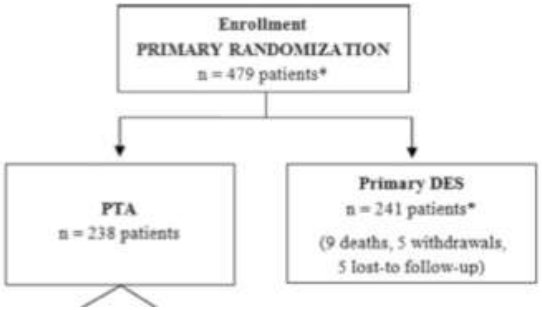
Zilver PTX vs POBA for TASC A/B femoropopliteal lesions
At 5 years, sustained clinical, morphological and hemodynamic outcomes





Dake, Circ Cardiovasc Interv. 2011
Dake, Circulation, 2016

Samples size calculation of Zilver-PTX RCT



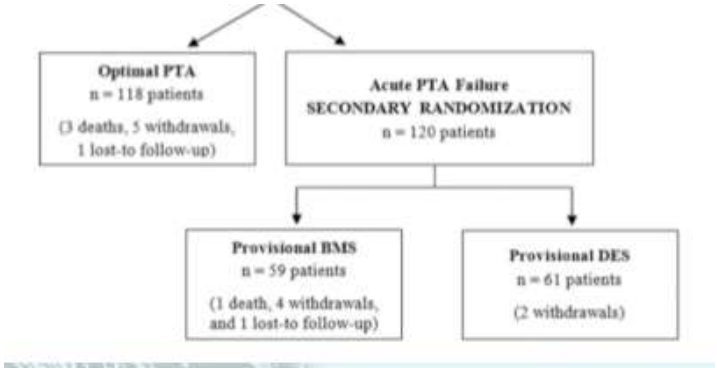
First arm of randomization

Primary end point

12-month rates of event-free survival and patency in the primary DES and PTA groups

describing femoropopliteal PTA outcomes.[21–26] The calculation assumed the 12-month primary patency rates were 65% and 80% in the PTA and DES groups, respectively. Power analysis was performed

479 patients to include



Second arm of randomization

- Sub groups
- Secondary endpoints

Dake, Circ Cardiovasc Interv. 2011

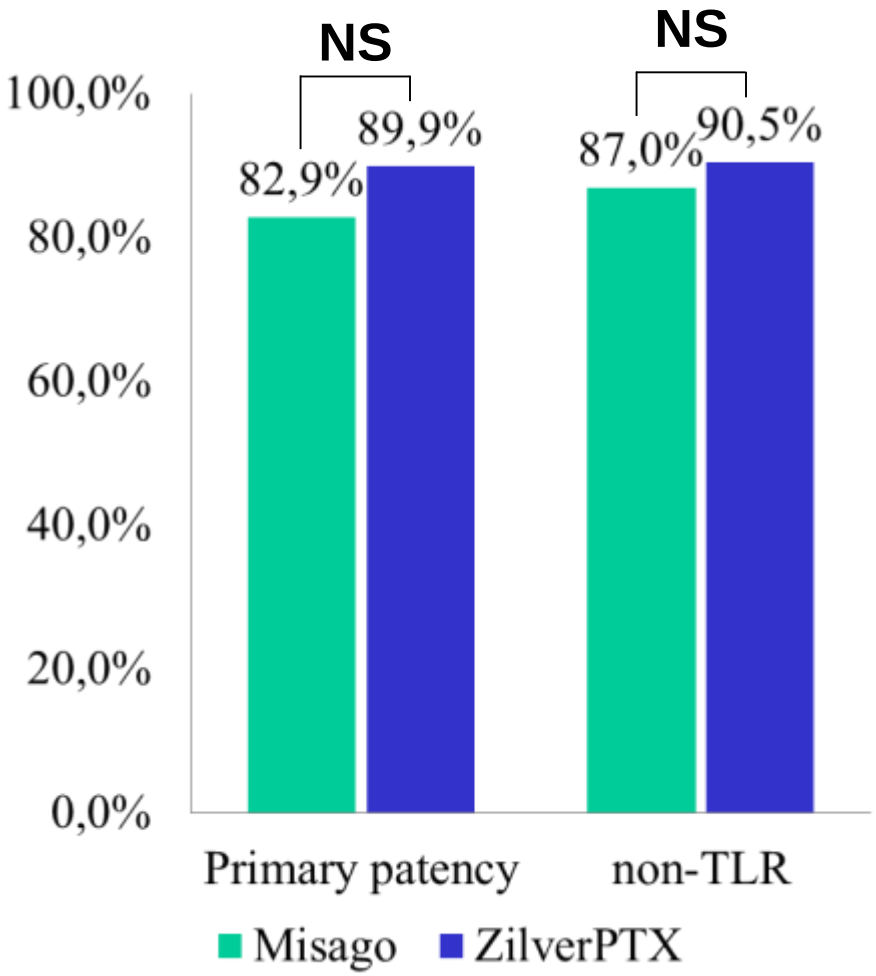
Sub groups and secondary endpoints analysis

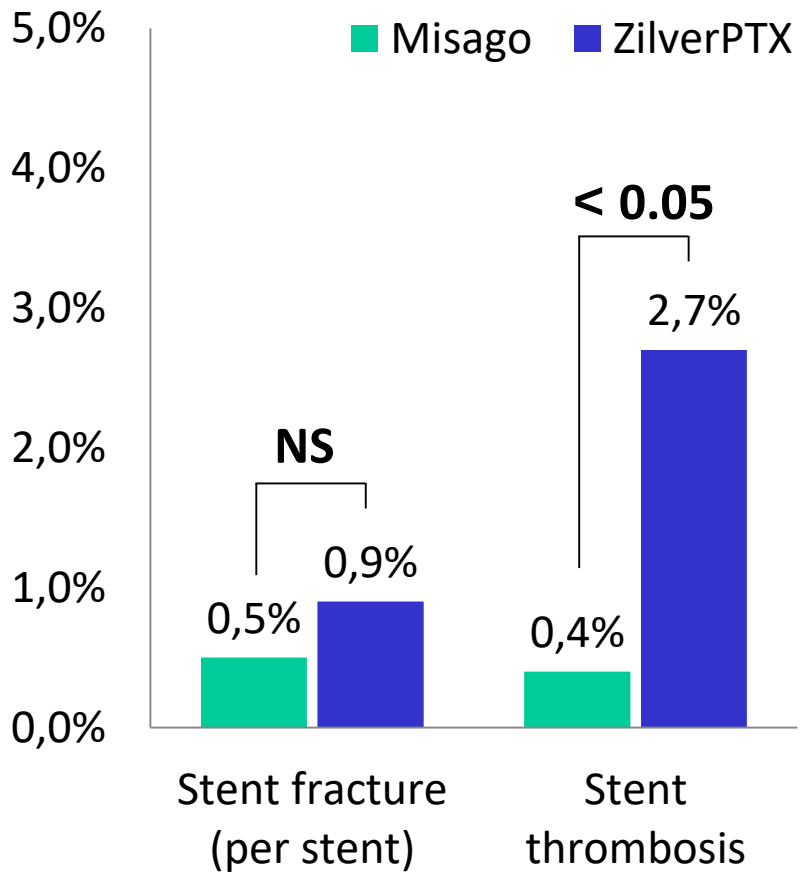
We can not draw any conclusions from the second arm of randomization

MeReC Briefing (2005);30:1-7.
Best Pract Res Clin Obstet Gynaecol. 2005;19(1):15-26.
Wiebe S. The principles of evidence-based medicine.Cephalalgia. 2000;20 Suppl 2:10-3.
Drug and Therapeutics Bulletin 2006; 44(3):21.

Bare metal stent

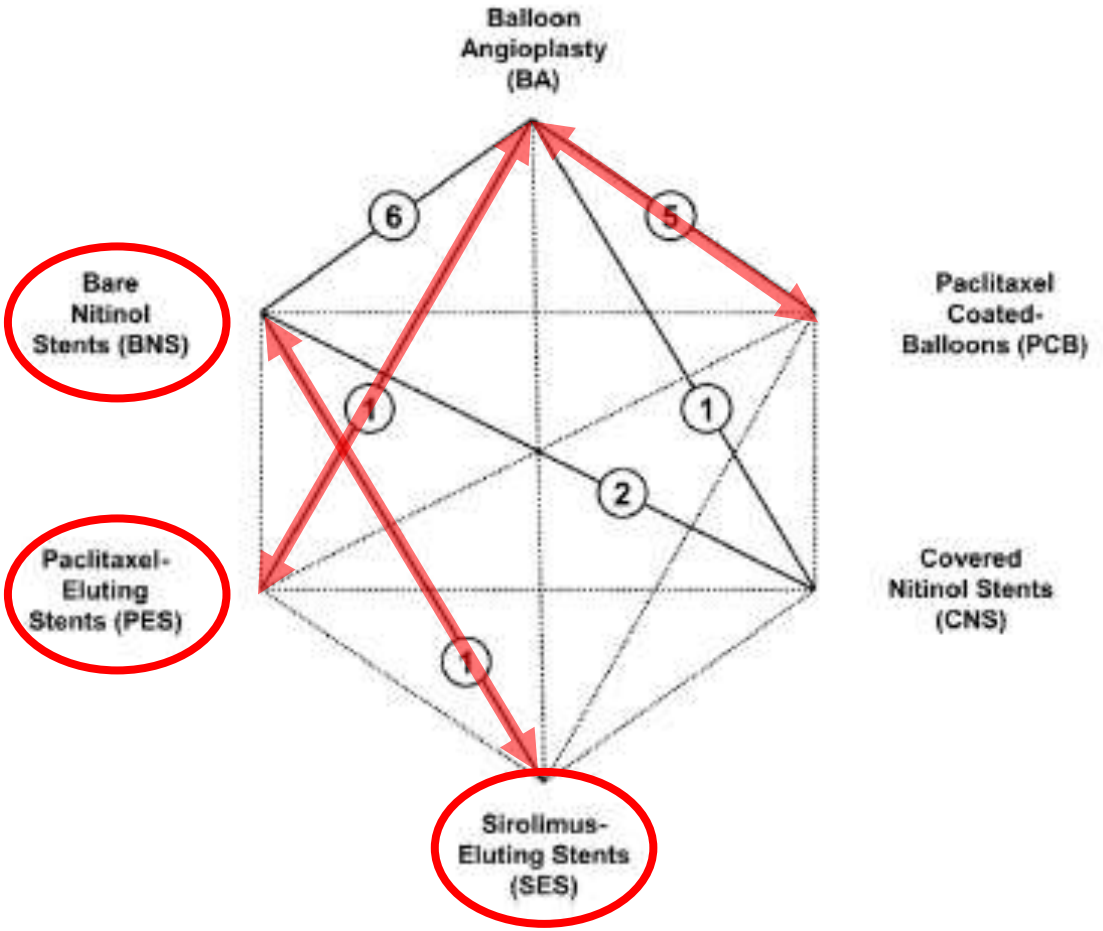
Indirect Comparison between Misago and Zilver PTX** - Results @ 12months -*





Ohki A. et al. Journal of Vascular Surgery 2016
**Dake, Circ Cardiovasc Interv. 2011

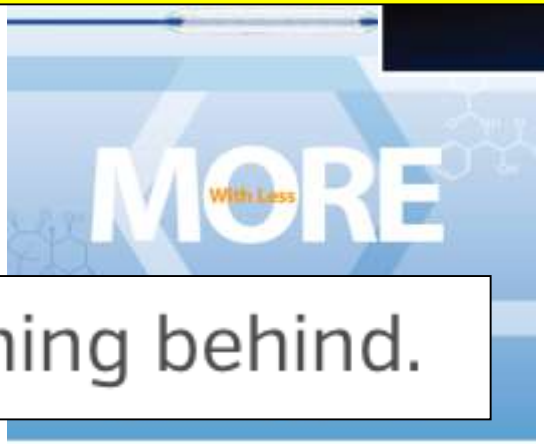
Few head to head comparison between devices for FP lesions treatment



Katsanos, J Vasc Surg, 2014

POBA
the weakest competitor

No high level evidence support an algorythm to treat femoropopliteal lesions > 4-cm



leaving nothing behind.

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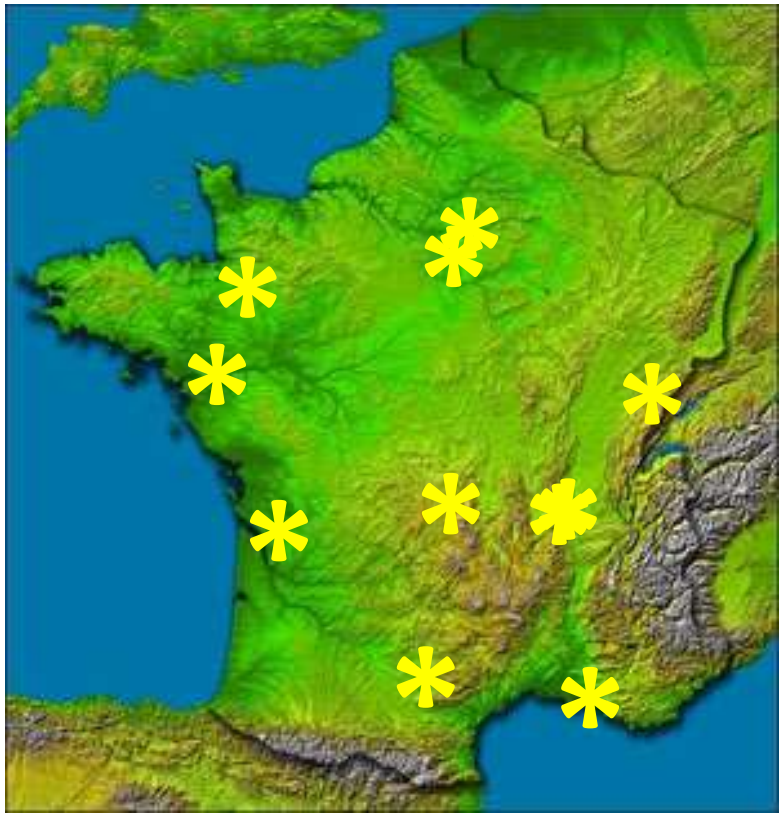
CLASH OF THE TITANS

BATTLE trial

(ClinicalTrials.gov number, NCT02004951)

French multicentric randomized clinical trial comparing MISAGO vs. ZILVER PTX for the treatment of intermediate femoropopliteal lesions



10 centers: Clinique d'Antony (Jean-Marc PERNES); CHU de Besançon (Simon RINCKENBACH); CHU de Bordeaux (Eric DUCASSE) ; CHU de Clermont Ferrand (Eugenio ROSSET) ; AP-HP, Hôpital Henri Mondor (Pascal DESGRANGES) ; CH de Lyon (Patrick FEUGIER) ; CH de Bourgouin (Patrick LERMUSIAUX); Clinique Ollioules (Philippe COMMEAU) ; CHU de Rennes (Alain CARDON) ; Clinique Pasteur (Antoine SAUGUET); CHU de Nantes (Yann GOUËFFIC)

Principal investigator: Pr Gouëffic
Sponsor: **Nantes University Hospital**
Granted from the French ministry of health (PHRC 2010 DGOS 20-03)

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BATTLE Trial

Perioperative interim analysis

-Enrollment completed: **186 patients**

-Primary endpoint completion date: **September 2017**

-12-months interim analysis with **186 patients** will be communicated **in 2018**

-BATTLE trial completion date: **September 2018**

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IMPERIAL trial

Clinical Study Overview: IMPERIAL	Enrollment completed
Title	A randomIzed trial coMParing the ELUVIA dRug-elutIng stent versus Zilver PTX stent for treatment of superficiAL femoral and/or proximal popliteal arteries
Primary Investigators	Global: William A. Gray, MD European: Prof. Dr. med Stefan Müller-Hülsbeck
Objective	To evaluate the safety and effectiveness of the ELUVIA Drug-Eluting Vascular Stent System (ELUVIA Stent) for treating Superficial Femoral Artery (SFA) and/or Proximal Popliteal Artery (PPA) lesions up to 140 mm in length.
Study Design	The trial consists of the following: •A prospective, multicenter, 2:1 randomized (ELUVIA vs Zilver PTX), controlled, single-blind, non-inferiority trial (RCT) •A concurrent, non-blinded, non-randomized, single-arm, pharmacokinetic (PK) substudy A subject may be enrolled in the RCT or the substudy; but not in both

EMINENT Clinical Study

Clinical Study Overview: EMINENT	Ongoing
Title	A Randomized Trial Comparing the ELUVIA™ Drug-Eluting Stent versus Bare Metal Self-Expanding Nitinol Stents in the Treatment of Superficial Femoral and/or Proximal Popliteal Arteries
Coordinating Principal Investigators	Prof. Yann Goueffic, Nantes, France Prof. Giovanni Torsello, Münster, Germany
Objective	To confirm superior effectiveness of the ELUVIA Drug-Eluting Vascular Stent System (ELUVIA Stent) for treating Superficial Femoral Artery (SFA) and/or Proximal Popliteal Artery (PPA) lesions up to 140 mm in length when compared against bare metal stents, and collect additional data including health economics data.
Study Design	Prospective, multi-centre, single-blind, superiority trial (RCT) Randomized 2:1 (Eluvia : Self Expanding BMS)
Subjects	750 subjects to receive treatment •Test Device – Eluvia Drug Eluting Vascular Stent System • N=500 subjects •Control device N=250 • Self Expanding Bare Nitinol Stents with US approval and CE marking

Caution: Eluvia is an investigational device limited under US law for investigational use only. Not available for sale in the U.S.

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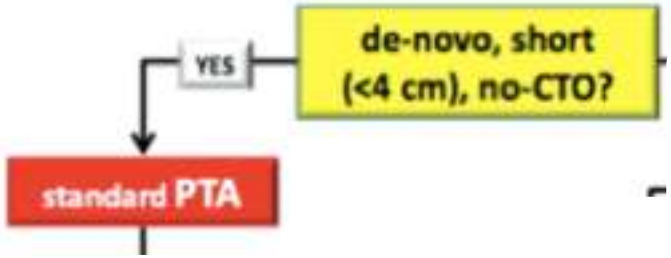
Take home message

- **Lesions de novo < 4-cm: POBA**
- **Restenosis: DCB**
- **Lesions de novo > 4-cm: BMS, DES, DCB BUT POBA**



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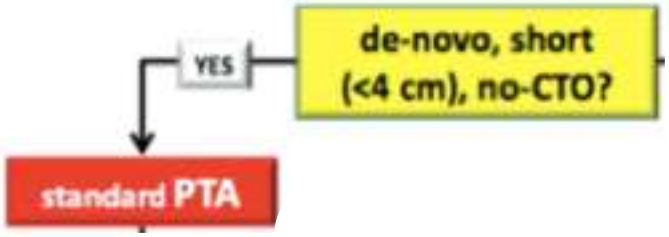
Tepe, Circulation, 2014; Rosenfield, NEJM, 2015; Schroeder, Circulation, 2017



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Dake, Circ Cardiovasc Interv. 2011
Müller-Hülsbeck, J Endovasc, Ther, 2016

2-Year Results of Paclitaxel-Coated Balloons for Long Femoropopliteal Artery Disease

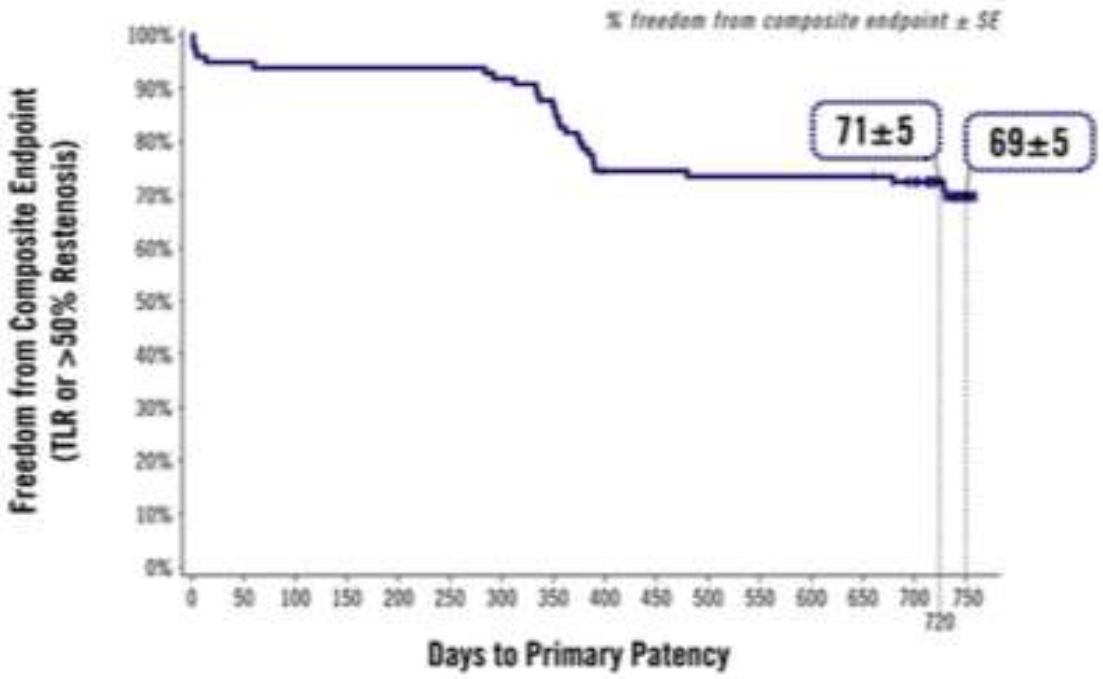
Evidence From the SFA-Long Study

Antonio Micari, MD, PhD,[a] Roberto Nerla, MD,[a] Giuseppe Vadalà, MD,[b] Fausto Castriota, MD,[a] Chiara Grattoni, MD,[a] Armando Liso, MD,[c] Paolo Russo, MD,[d] Paolo Pantaleo, MD,[e] Giuseppe Roscitano, MD,[f] Alberto Cremonesi, MD[a]

Prospective,multicenter,single-arm study

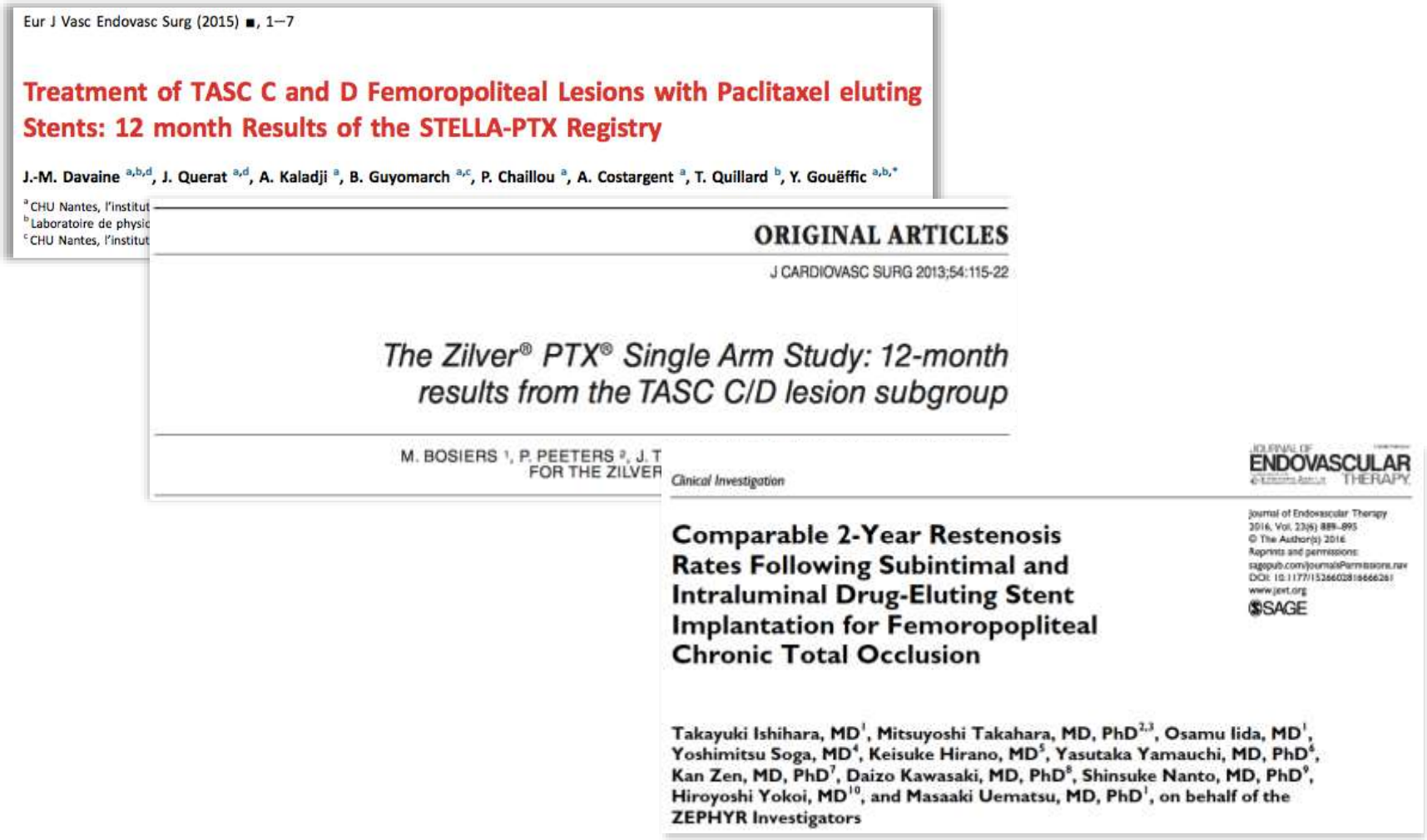
Age 68±9 years;
Limbs: 105
IC/CLI: 89.5/10.5
Diabetes: 57.2%
De novo lesions: 91.4%
Lesion length (mm)251.71±78.9mm
Total occlusions: 49.5%

Bailout stenting rate was 10.9%.



Micari, J Am Coll Cardiol Intv 2017

Drug eluting stent trials for TASC C/D femoropopliteal lesions



Eur J Vasc Endovasc Surg (2015) ■, 1—7

Treatment of TASC C and D Femoropoliteal Lesions with Paclitaxel eluting Stents: 12 month Results of the STELLA-PTX Registry

J.-M. Davaine [a,b,d], J. Querat [a,d], A. Kaladji [a], B. Guyomarch [a,c], P. Chaillou [a], A. Costargent [a], T. Quillard [b], Y. Gouëffic [a,b,*]

[a] CHU Nantes, l'institut
[b] Laboratoire de physic
[c] CHU Nantes, l'institut

ORIGINAL ARTICLES

J CARDIOVASC SURG 2013;54:115-22

The Zilver® PTX® Single Arm Study: 12-month results from the TASC C/D lesion subgroup

M. BOSIERS [1], P. PEETERS [2], J. T
FOR THE ZILVER

Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

Comparable 2-Year Restenosis Rates Following Subintimal and Intraluminal Drug-Eluting Stent Implantation for Femoropopliteal Chronic Total Occlusion

Journal of Endovascular Therapy
2016, Vol. 23(6) 889–895
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Davaine, Eur J Vasc Endovasc Surg, 2015
Bosiers, J Cardiovasc Surg, 2013
Ishihara, J Endovasc Ther, 2016

Original report

Bare metal versus paclitaxel eluting stents for long femoropopliteal lesions: prospective cohorts comparison using a propensity-score matched analysis.

Pierre-Alexandre Vent[1], Adrien Kaladji[2], Jean-Michel Davaine[1], Béatrice Guyomarch[3-4-5-6], Philippe Chaillou[1], Alain Costargent[1], Thibaut Quillard[7], Yann Gouëffic[1, 6, 7]

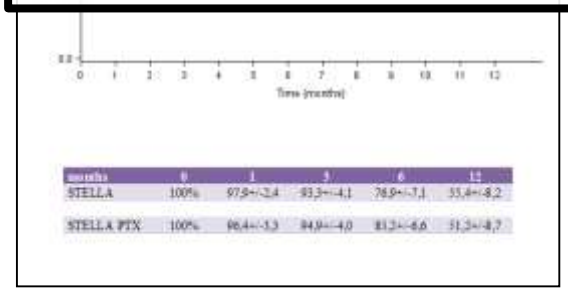
Sustained primary clinical improvement with adjusted data

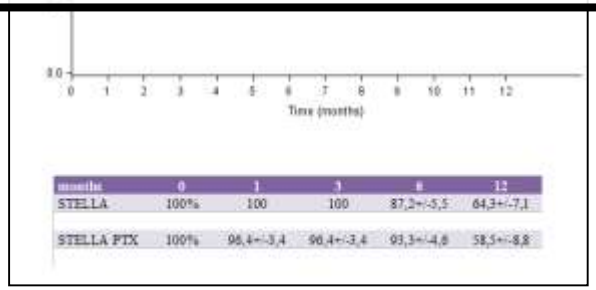
TLR-free cumulative survival with adjusted data

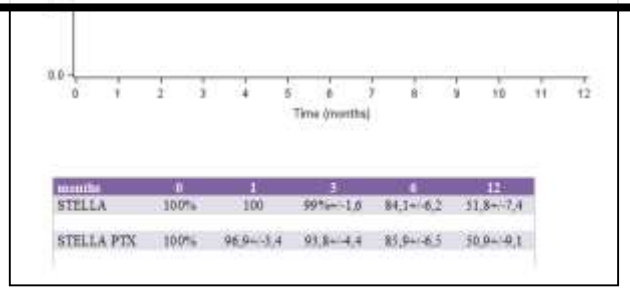
Patency cumulative survival with adjusted data

CONCLUSION

Paclitaxel eluting stents do not seem to provide benefits in terms of clinical and morphological outcomes for TASC C/D lesions compared to BMS.







Vent PA, Ann Vasc Surg, 2017