Use of directional atherectomy where stenting is not an option

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- ☒ Consulting:Medtronic, Cook, Cordis, Gore, Boston
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

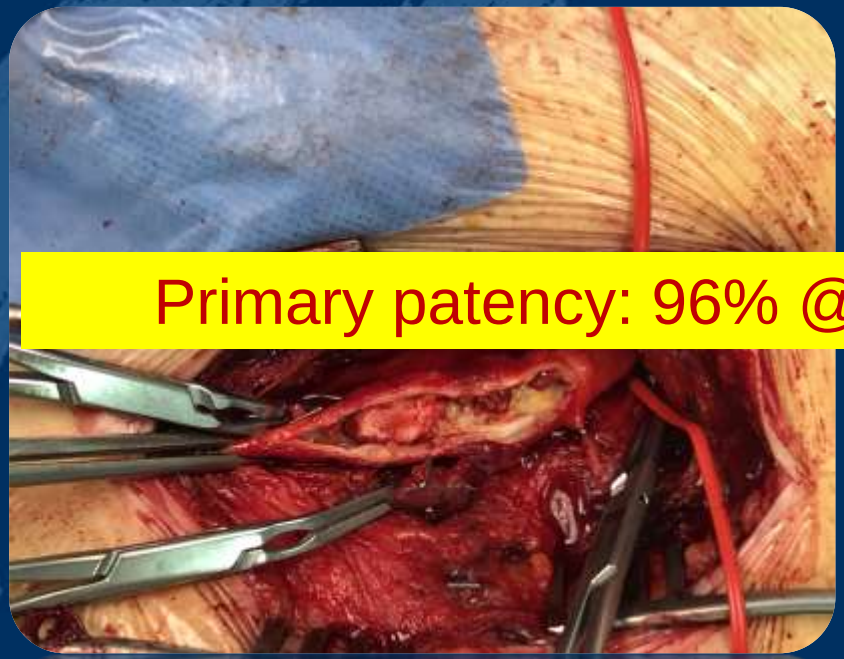
☐ I do not have any potential conflict of interest

So-called non-stenting zones Background

A decade ago, the CFA and PA were viewed as a “no stent zone.”

Due to the high flexion of knee and hip and the concern for possible stent fracture surgical rather than endovascular therapy has been historically recommended

Surgical therapy: Gold standard



Primary patency: 96% @ 7 years

Surgery is associated with excellent, durable patency and long-term freedom from reintervention

Surgical therapy: Gold standard?

Complication	%	Risk factors
30 days mortality	1.5-3.4%	Age
Local complications	8%	COPD
Combined	15%	ESRD
30 days re-operation	10%	SIRS/MODS
At least 1 complication	7.9%	ASA 4-5

Role of endovascular therapy?

Nguyen et al, J Vasc Surg. 2015;61(6):1489-94.
Siracuse et al, Vasc Endovascular Surg. 2014;48(1):27-33

As periop morbidity is significant, endovascular TX may represent an alternative if patency is comparable

CFA PTA with provisional stenting

CLINICAL RESEARCH — Interventional Cardiology

Endovascular Treatment of Common Femoral Artery Disease

Medium-Term Outcomes of 360 Consecutive Procedures

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Bad Krozingen, Germany; and Geneva and Chur, Switzerland

Objectives — The purpose of this study was to evaluate the technical feasibility, safety, and 1-year efficacy of the endovascular treatment of atherosclerotic common femoral artery (CFA) obstructions.

Background — Atherosclerotic CFA obstruction is a known cause of symptomatic peripheral arterial disease. Although surgical endarterectomy is considered the therapy of choice for this condition, little is known about the percutaneous options.

Methods — During a prospectively maintained single-center database, we retrospectively analyzed the outcomes of 360 consecutive percutaneous interventions of the CFA for atherosclerotic disease and assessed procedural success, in-hospital complications, and 1-year patency and target lesion revascularization rates.

Results — Ninety-seven procedures (26.9%) were isolated CFA interventions, whereas 137 (43.6%) and 122 (42.2%) also involved inflow and outflow vessels, respectively. Bifurcation lesions were present in 340 cases (94.4%), and concomitant treatment of the profunda femoral artery was performed on 93 occasions (25.8%). Chronic total CFA occlusions were recanalized in 40 cases (10.7%). Balloon angioplasty was performed as the primary intervention in virtually all cases (98.6%), whereas stenting was needed for suboptimal angioplasty results in 123 procedures (34.9%). Failure—defined as a final angiographic result with a >30% residual stenosis—was observed on 26 occasions (7.2%). In-hospital major (i.e., requiring surgery) and minor (i.e., treated percutaneously or conservatively) complications occurred in 5 (1.4%) and 18 (5.0%) procedures, respectively. One-year follow-up data were available for 282 patients (87.6%). Restenosis >50% by duplex scanning and target lesion revascularization were observed in 74 of 288 (27.6%) and 44 of 322 (13.9%) procedures, respectively.

Conclusions — This large series suggests that the percutaneous approach may be a valid alternative to surgery for CFA atherosclerotic obstructions. (J Am Coll Cardiol 2011;58:792–8) © 2011 by the American College of Cardiology Foundation

Table 4 Multivariate Analysis of Clinical and Procedural Predictors of Adverse Events for CFA Interventions

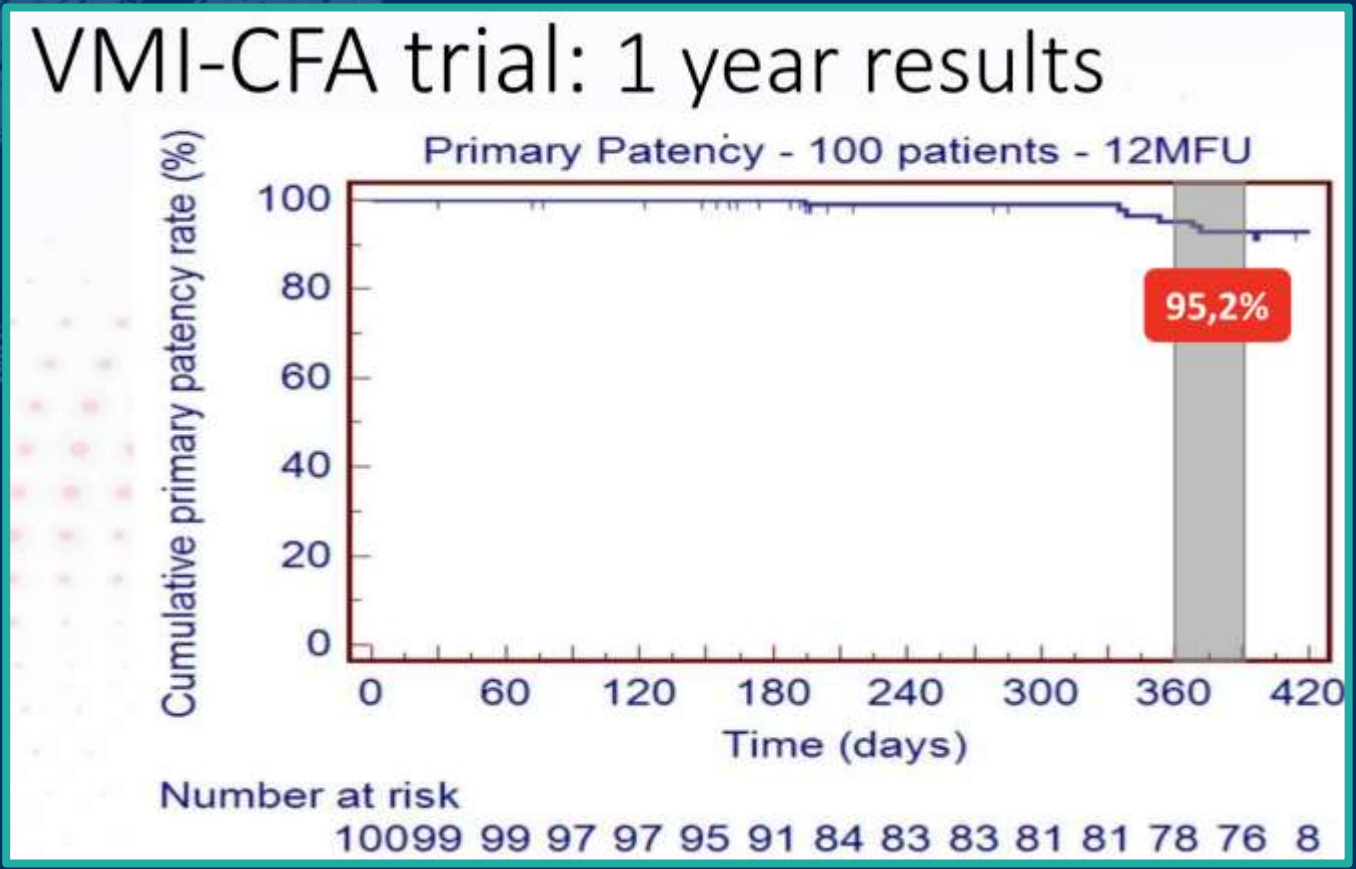
Endpoint	Variable	% Present vs. Absent	OR	95% CI	p Value
Procedural failure*	IDDM	0 vs. 9.0	0.11	0.006–1.90	0.040
	Bifurcation	11.4 vs. 4.5	2.71	1.19–6.15	0.013
	Stent use	2.2 vs. 10.1	0.20	0.06–0.69	0.005
	>2001 vs. ≤2001	5.5 vs. 14.1	0.35	0.15–0.83	0.013
Peri-procedural complications	IDDM and NIDDM	2.8 vs. 8.6	0.31	0.10–0.93	0.028
	Chronic total occlusion	11.7 vs. 5.3	2.34	0.92–5.97	0.067
Restenosis >50%†	Stent use	20.0 vs. 31.8	0.53	0.29–0.97	0.046
	Bifurcation	34.3 vs. 24.7	1.68	0.97–2.91	0.066
	Medina 1-0-0	8.3 vs. 37.9	0.15	0.02–1.20	0.043
TLR‡	CFA + infrainguinal intervention	25.9 vs. 15	1.97	1.12–3.44	0.015
	Bifurcation	24 vs. 16.8	1.56	0.89–2.72	0.115
	Medina 1-0-0	5.3 vs. 27.3	0.15	0.02–1.15	0.038
	Stent use	13.1 vs. 23.6	0.49	0.26–0.91	0.021

*Procedural failure defined as final angiographic result with >30% residual stenosis. †Restenosis >50% at 12 months' follow-up (duplex or angiographic evaluation). ‡TLR at 12 months' follow-up. CI = confidence interval; CTO = chronic total occlusion; IDDM = insulin-dependent diabetes; NIDDM = non-insulin-dependent diabetes; OR = odds ratio; other abbreviations as in Table 2.

Bonvini et al J Am Coll Cardiol 2011;58:792–8

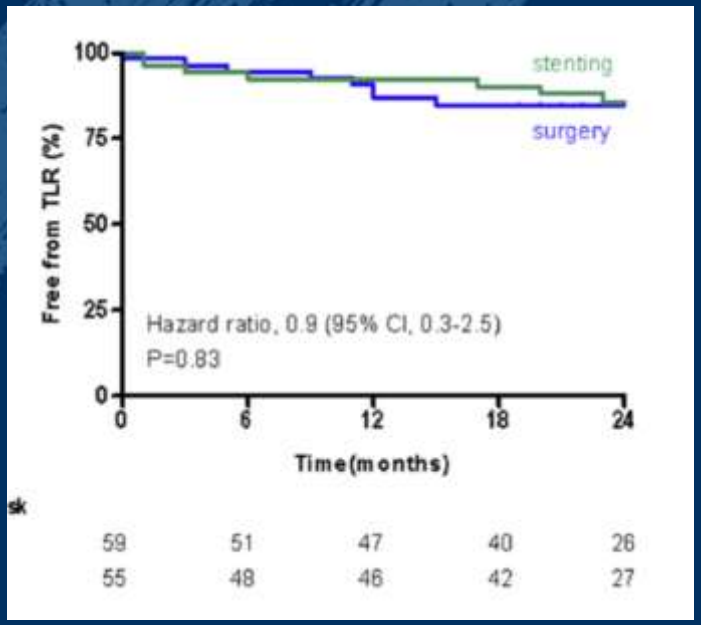
Observational studies have suggested that PTA is associated with acceptable short- and mid-term patency

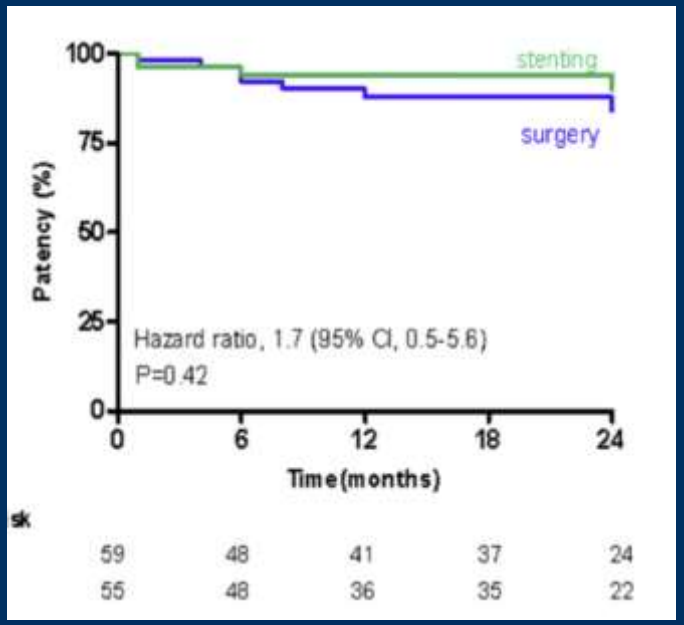
CFA Stent therapy: Supera Stent



DeLoose LINC 2019

CFA Stent therapy vs Surgery: Tecco trial





Gouëffic et al J Am Coll Cardiol Intv 2017;10:1344–54

CLTI Guidelines

CLINICAL PRACTICE GUIDELINE DOCUMENT

Global vascular guidelines on the management of chronic limb-threatening ischemia

Michael S. Conte, MD (Co-Editor),[a] Andrew W. Bradbury, MD (Co-Editor),[b] Philippe Kolh, MD (Co-Editor),[c] John V. White, MD (Steering Committee),[d] Florian Dick, MD (Steering Committee),[e] Robert Fitridge, MBBS (Steering Committee),[f] Joseph L. Mills, MD (Steering Committee),[g] Jean-Baptiste Ricco, MD (Steering Committee),[h] Kalkunte R. Suresh, MD (Steering Committee),[i] M. Hassan Murad, MD, MPH,[j] and the GVG Writing Group.[k] *San Francisco, Calif; Birmingham, United Kingdom; Wallonia, Belgium; Niles, Ill; St Gallen, Switzerland; Adelaide, South Australia; Houston, Tex; Poitiers, France; Bangalore, India; and Rochester, Minn*

Joint guidelines of the Society for Vascular Surgery, European Society for Vascular Surgery, and World Federation of Vascular Societies

Endorsed by the American Podiatric Medical Association, British Cardiovascular Society, British Society for Endovascular Therapy, British Society of Interventional Radiology, Circulation Foundation, College of Podiatry, Society of Interventional Radiology, Society for Vascular Nursing, the Society for Vascular Technology of Great Britain and Ireland, and the Vascular Society of Great Britain and Ireland

ABSTRACT

Chronic limb-threatening ischemia (CLTI) is associated with mortality, amputation, and impaired quality of life. These Global Vascular Guidelines (GVG) are focused on definition, evaluation, and management of CLTI with the goals of improving evidence-based care and highlighting critical research needs. The term CLTI is preferred over critical limb ischemia, as the latter implies threshold values of impaired perfusion rather than a continuum. CLTI is a clinical syndrome defined by the presence of peripheral artery disease (PAD) in combination with rest pain, gangrene, or a lower limb ulceration >2 weeks duration. Venous, traumatic, embolic, and nonatherosclerotic etiologies are excluded. All patients with suspected CLTI should be referred urgently to a vascular specialist. Accurately staging the severity of limb threat is fundamental, and the Society for Vascular Surgery Threatened Limb Classification system, based on grading of Wounds, Ischemia, and foot Infection (WIfI) is endorsed. Objective hemodynamic testing, including toe pressures as the preferred measure, is required to assess CLTI. Evidence-based revascularization (EBR) hinges on three independent axes: Patient risk, Limb severity, and ANatomic complexity (PLAN). Average-risk and high-risk patients are defined by estimated procedural and 2-year all-cause mortality. The GVG proposes a new Global Anatomic Staging System (GLASS), which involves defining a preferred target artery path (TAP) and then estimating limb-based patency (LBP), resulting in three stages of complexity for intervention. The optimal revascularization strategy is also influenced by the availability of autogenous vein for open bypass surgery. Recommendations for EBR are based on best available data, pending level 1 evidence from ongoing trials. Vein bypass may be preferred for average-risk patients with advanced limb threat and high complexity disease, while those with less complex anatomy, intermediate severity limb threat, or high patient risk may be favored for endovascular intervention. All patients with CLTI should be afforded best medical therapy including the use of antithrombotic, lipid-lowering, antihypertensive, and glycemic control agents, as well as counseling on smoking cessation, diet, exercise, and preventive foot care. Following EBR, long-term limb surveillance is advised. The effectiveness of nonrevascularization therapies (eg, spinal stimulation, pneumatic compression, prostanoids, and hyperbaric oxygen) has not been established. Regenerative medicine approaches (eg, cell, gene therapies) for CLTI should be restricted to rigorously conducted randomized clinical trials. The GVG promotes standardization of study designs and end points for clinical trials in CLTI. The importance of multidisciplinary teams and centers of excellence for amputation prevention is stressed as a key health system initiative. (J Vasc Surg 2019;69S:3S-125S.)

Keywords: Chronic limb-threatening ischemia; Critical limb ischemia; Peripheral artery disease; Diabetes; Foot ulcer; Endovascular intervention; Bypass surgery; Practice guideline; Evidence-based medicine

6.29 Consider endovascular treatment of significant CFA disease in selected patients who are deemed to be at high surgical risk or to have a hostile groin.

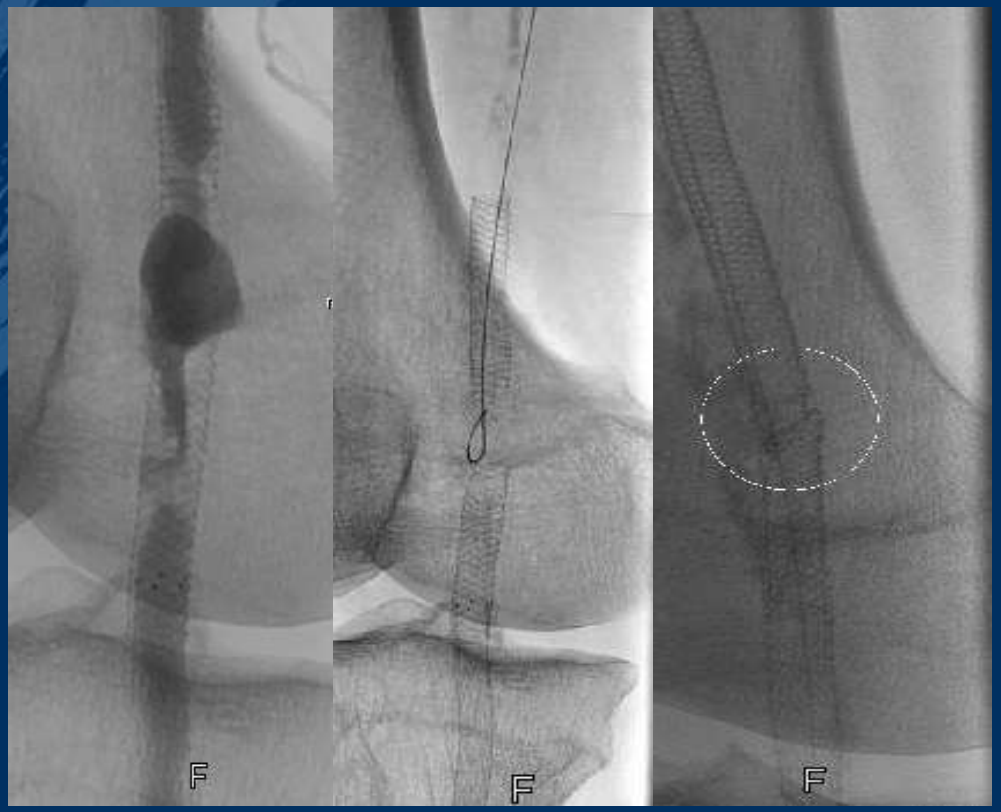
Grade	Level of evidence	Key references
2 (Weak)	C (Low)	Baumann,[91] 2011 Bonvini,[92] 2011 Gouëffic,[93] 2017 Siracuse,[94] 2017

6.30 Avoid stents in the CFA and do not place stents across the origin of a patent deep femoral artery.

Grade	Level of evidence	Key references
Good practice statement		-

Conte et al, JVS 2019

The pitfalls of stent therapy

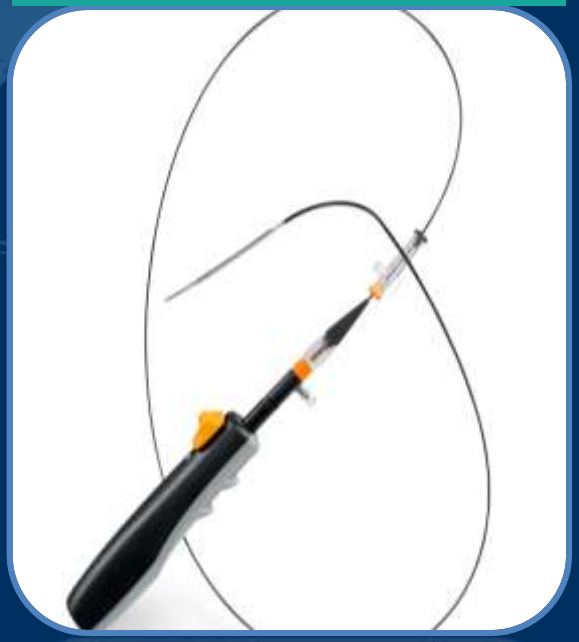


Stenting has not been widely adopted, due to concerns regarding stent durability in this vessel segment

Directional Atherectomy + Anti-Restenotic Therapy

The DAART Concept

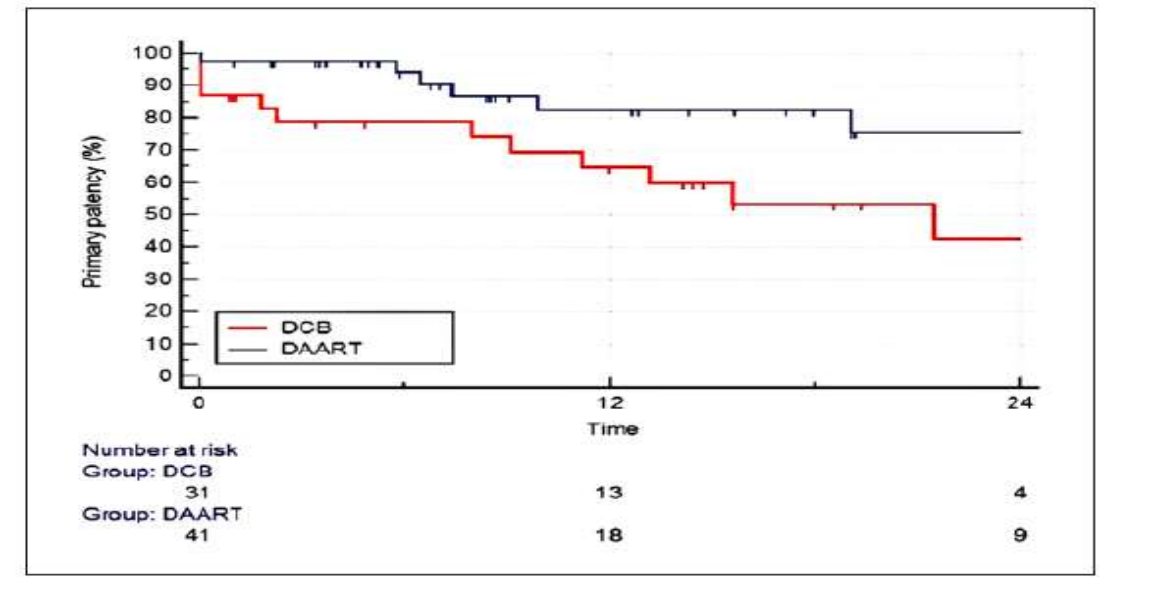
DA: Vessel Preparation



+

Anti-restenotic treatment

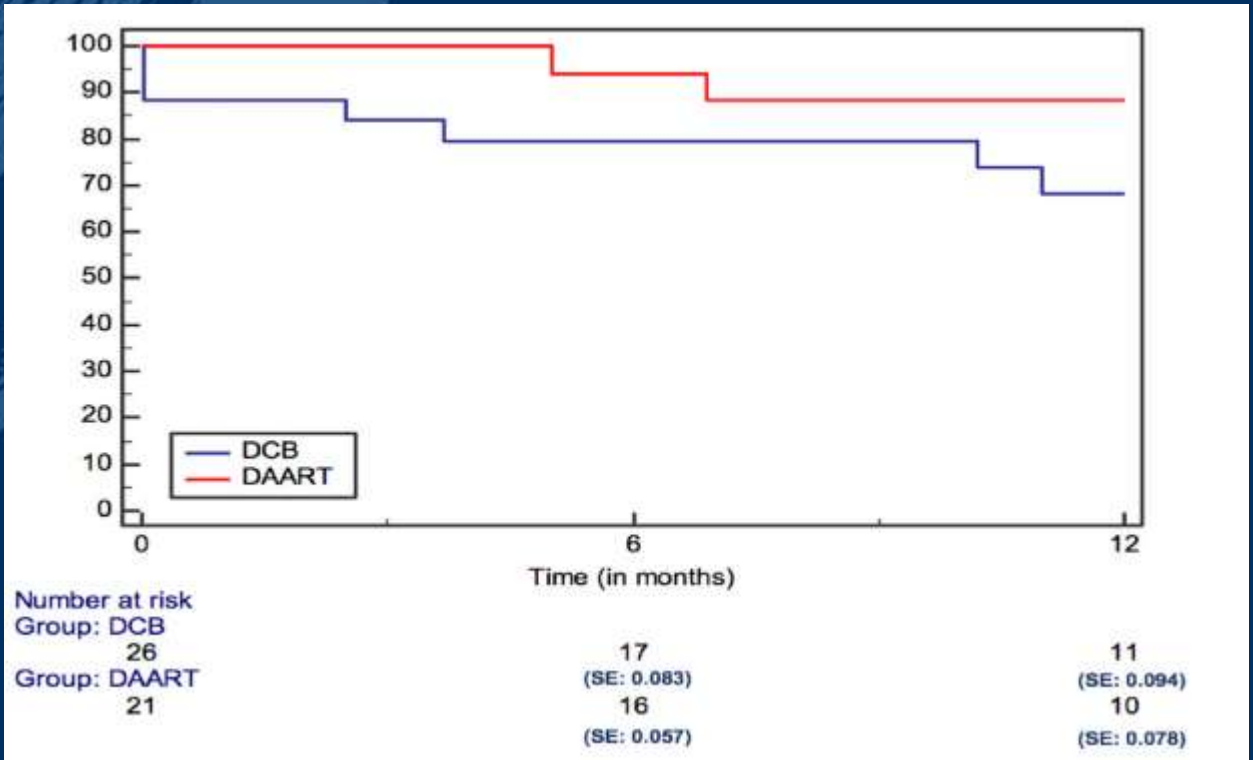
DAART for popliteal disease



	DCB	DAART	P Wert
Primary patency	65%	82%	**0.021**
Freedom from TLR	82%	94%	0.7

Stavroulakis et al JEVT. 2017;24(2):181-188

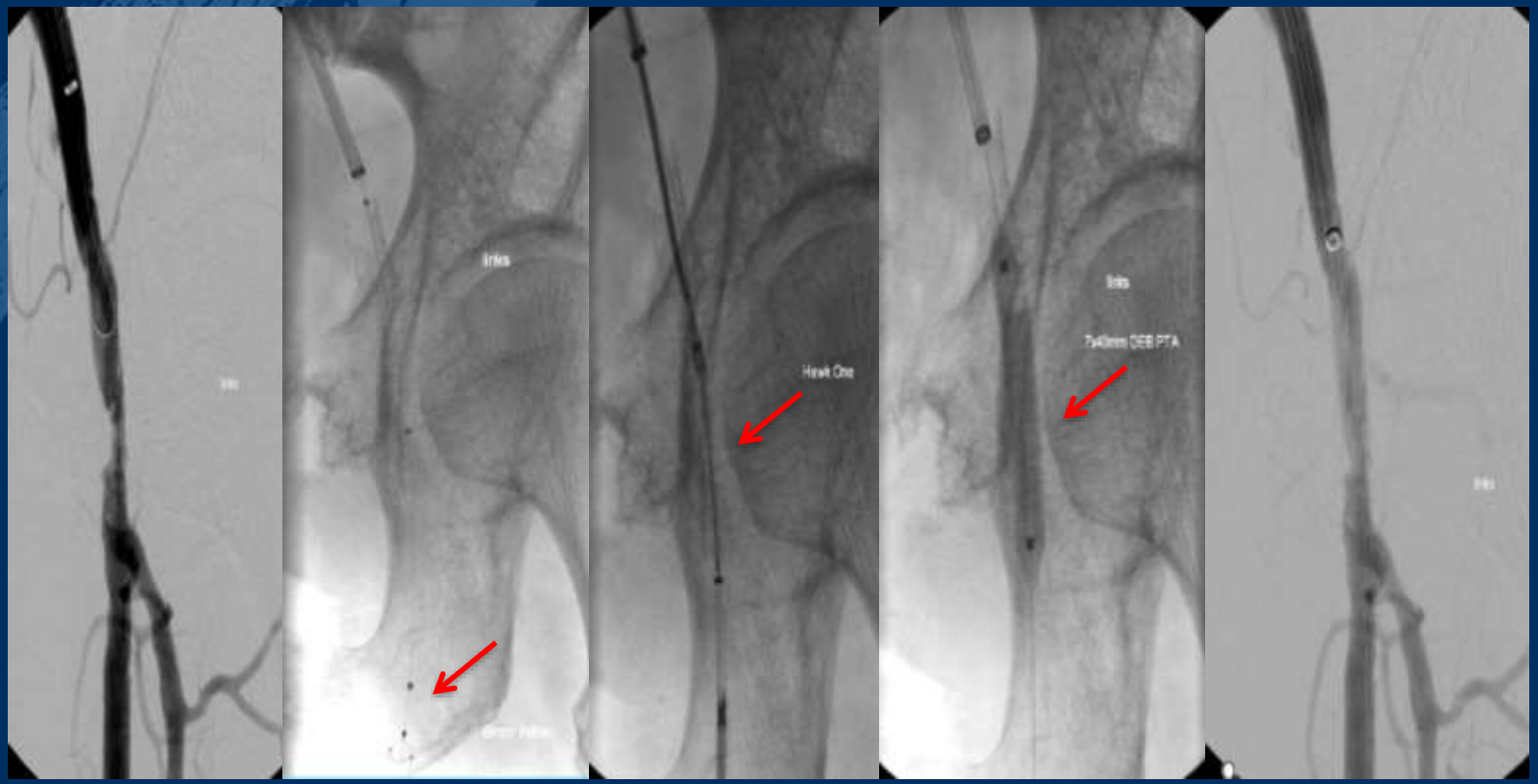
DAART for CFA



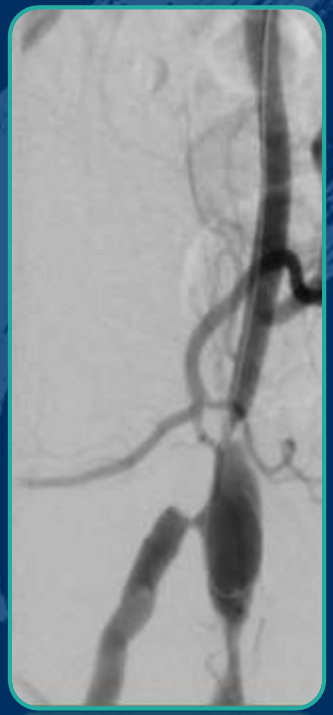
68% vs 88%, (HR): 0.64; 95 CI: 0.22 to 2.81, P= .40

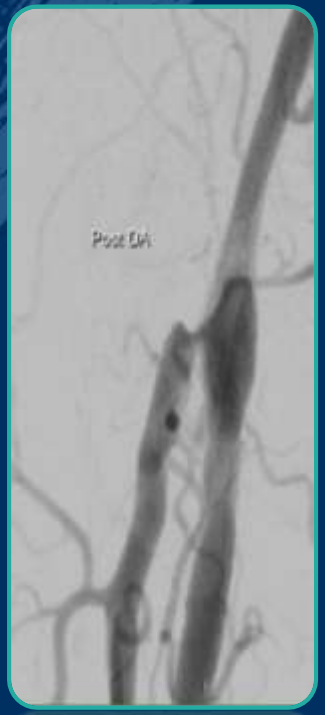
Stavroulakis et al. J Endovasc Ther. 2018 Feb;25(1):92-99

DAART for CFA

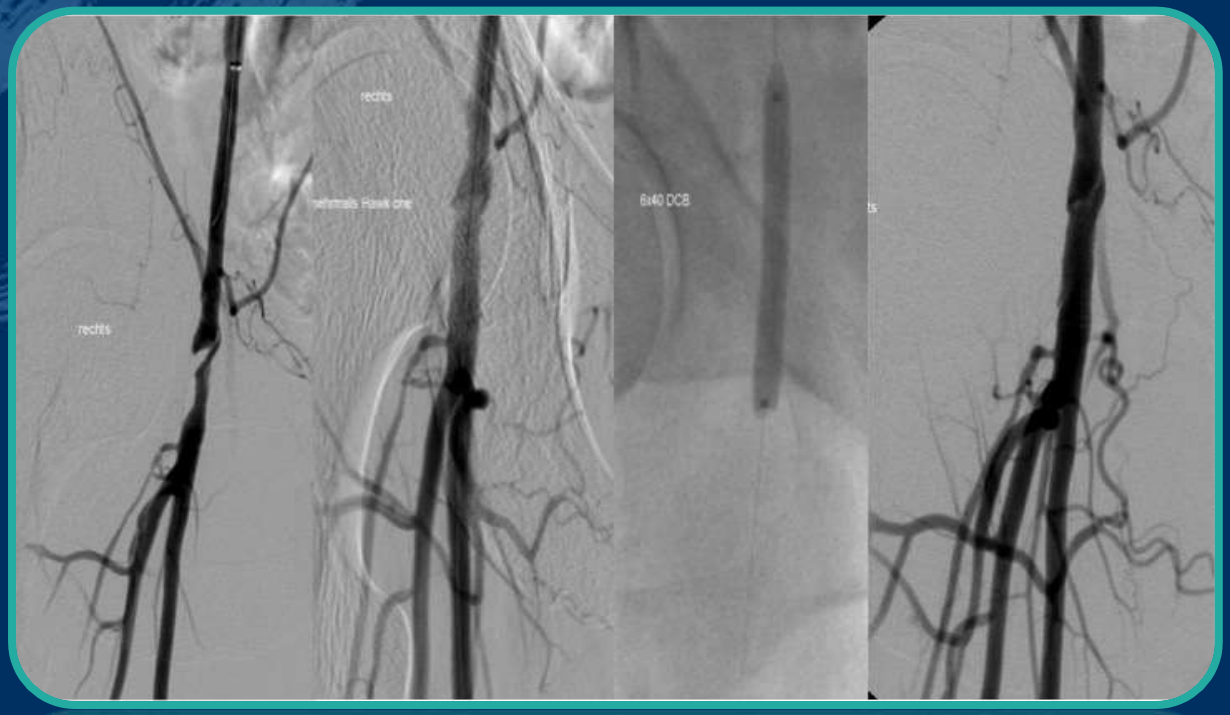


DAART for Bypass anastomosis stenosis

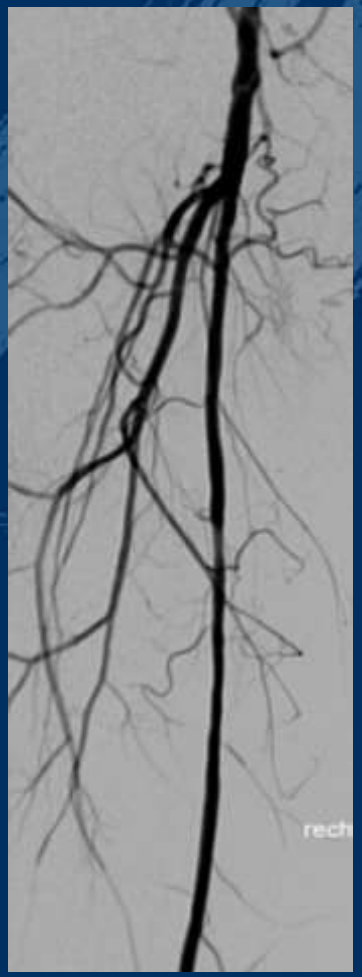


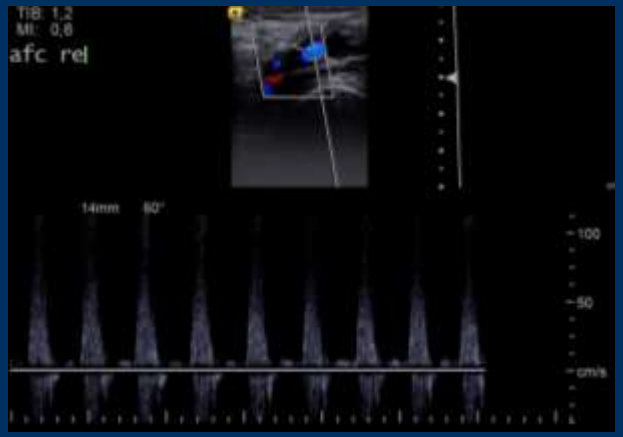


DAART for CFA dissection after punction



18 Months Follow UP





DAART for CFA: PESTO-AFC Trial

Percutaneous Intervention Versus Surgery in the Treatment of Common Femoral Artery Lesions (PESTO-AFC)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT02517827

Recruitment Status: Recruiting
First Posted: August 7, 2015
Last Update Posted: August 3, 2018

See Contacts and Locations

Study Design Go to

Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	306 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Percutaneous Intervention Versus Surgery in the Treatment of Common Femoral Artery Lesions A Prospective, Multi-centre, Randomised Study
Actual Study Start Date:	August 1, 2017
Estimated Primary Completion Date:	December 2019

Conclusions

- Surgery still the gold standard in nonstenting zones
- Significant morbidity and mortality
- Endo therapy useful in patients unfit for surgery, re-stenosis after surgery, high-risk for complications
- Stent therapy comparable results with surgery at 2 years (RCT data)
- Vessel prep and DCB might be an alternative
- Additional long-term data are necessary

homepage: www.gefaesschirurgie-muenster.de

Thank you!

St. Franziskushospital Münster

Use of directional atherectomy where stenting is not an option

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