The versatility of directonal atherectomy to address challenges of multi-level disease in CLTI

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Disclosure

Speaker name:

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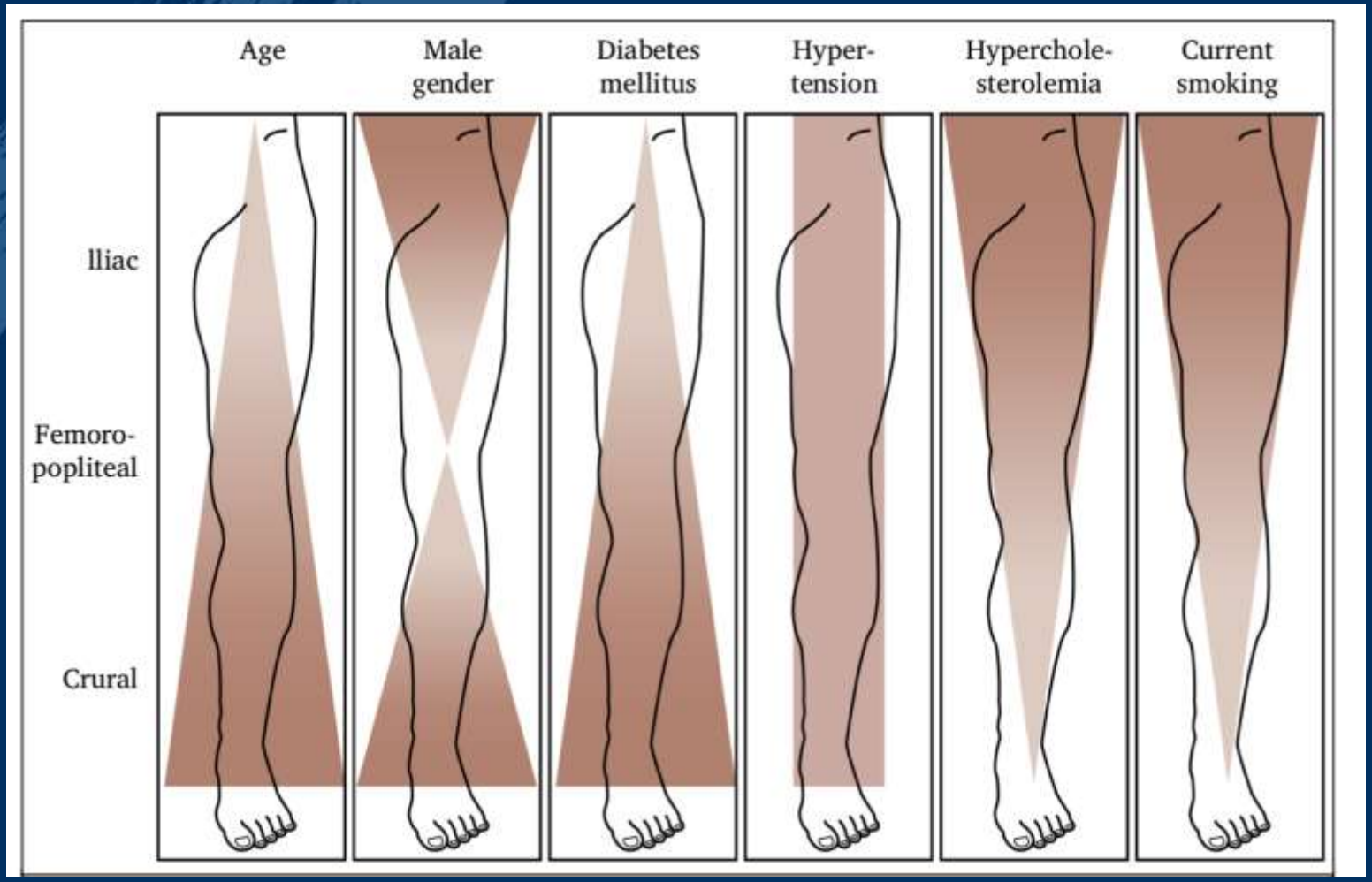
I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

The CLTI pattern



Conte et al, JVS 2019

The Hawk Devices

	H1-M	H1-S
Sheath Compatibility	6F	6F
Vessel Diameter (mm)	3.0-7.0	2.0-4.0
Crossing Profile (mm)	2.2	2.2
Working Length (cm)	135	151
Effective Length (cm)	129	145
Tip Length (cm)	5.9	5.9
Max Cut Length (mm)	40	40
Packing Device	Yes	Yes

6F Device*	Cutter Height	Cut Depth
HawkOne 6F	0.009" (0.23 mm)	0.36 mm (H1-M) 0.34 mm (H1-S)
TurboHawk SX-C	0.009" (0.23 mm)	0.37 mm

7F Device*	Cutter Height	Cut Depth
HawkOne 7F	0.011" (0.28 mm)	0.45 mm
TurboHawk 7F	0.012" (0.30 mm)	0.47 mm

DEFINITVE LE trial: CLTI Cohort

Lower Extremity Revascularization Using Directional Atherectomy

12-Month Prospective Results of the DEFINITIVE LE Study

James F. McKinsey, MD,* Thomas Zeller, MD,† Krishna J. Rocha-Singh, MD,‡ Michael R. Jaff, DO,§ Lawrence A. Garcia, MD,‖ on behalf of the DEFINITIVE LE Investigators

ABSTRACT

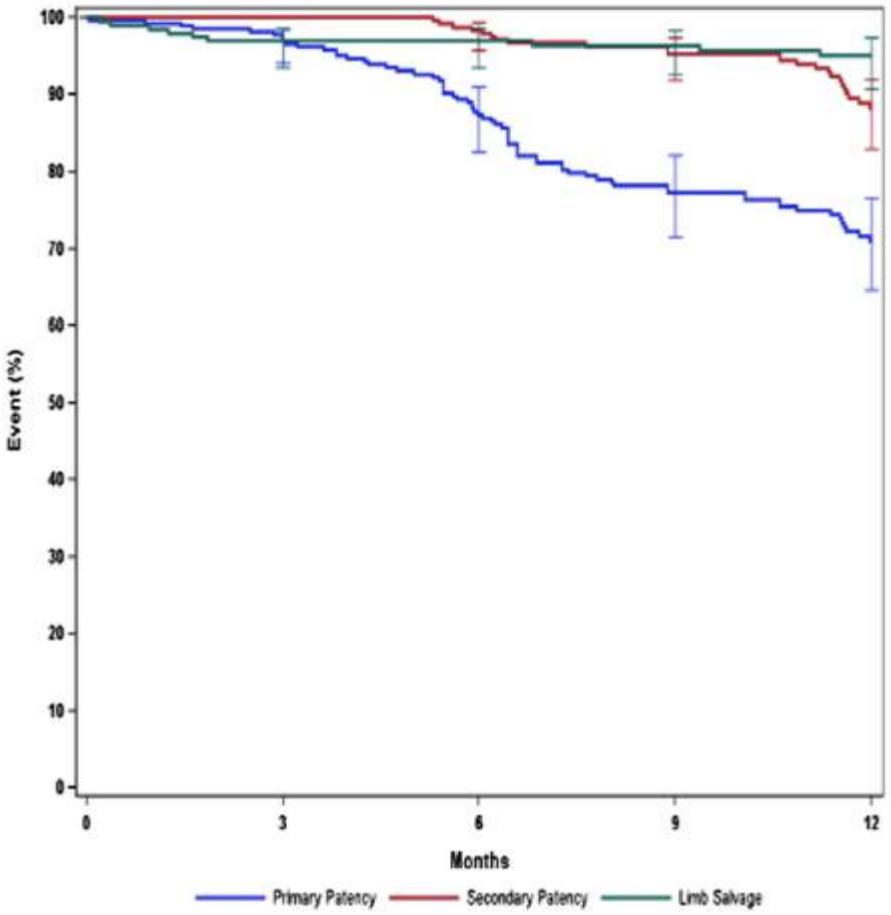
OBJECTIVES The aim of this study was to assess the safety and effectiveness of directional atherectomy (DA) for endovascular treatment of peripheral arterial disease (PAD) in infrainguinal arteries in patients with claudication or critical limb ischemia.

BACKGROUND To date, no prospective, multicenter, independently-adjudicated study has evaluated the effectiveness and durability of DA in the treatment of PAD. Previous DA studies have not been prospectively powered to evaluate any differences in outcomes in patients with and without diabetes.

METHODS DEFINITIVE LE (Determination of EFfectiveness of the SilverHawk® Peripheral Plaque ExcisioN System (SilverHawk Device) for the Treatment of Infrainguinal VEssels / Lower Extremities) prospectively enrolled subjects at 47 multinational centers with an infrainguinal lesion length up to 20 cm. Primary endpoints were defined as primary patency at 12 months for claudicants and freedom from major unplanned amputation for critical limb ischemia (CLI) subjects. A pre-specified statistical hypothesis evaluated noninferiority of primary patency in diabetic versus nondiabetic claudicants. Independent angiographic and sonographic core laboratories assessed outcomes, and events were adjudicated by a clinical events committee.

RESULTS A total of 800 subjects were enrolled. The 12-month primary patency was 78% (95% confidence interval: 74.0% to 80.6%) in claudicants, with a 77% rate in the diabetic subgroup versus 78% in the nondiabetic subgroup (noninferior, $p < 0.001$). The rate of freedom from major unplanned amputation of the target limb at 12 months in CLI subjects was 95% (95% confidence interval: 90.7% to 97.4%). Periprocedural adverse events included embolization (3.8%), perforation (5.3%), and abrupt closure (2.0%). The bail-out stent rate was 3.2%.

CONCLUSIONS The DEFINITIVE LE study demonstrated that DA is a safe and effective treatment modality at 12 months for a diverse patient population with either claudication or CLI. Furthermore, DA was shown to be noninferior for treating PAD in patients with diabetes compared with those without diabetes. (Study of SilverHawk/TurboHawk in Lower Extremity Vessels [DEFINITIVE LE]; NCT00883246). (J Am Coll Cardiol Intv 2014;7:923-33) © 2014 by the American College of Cardiology Foundation.



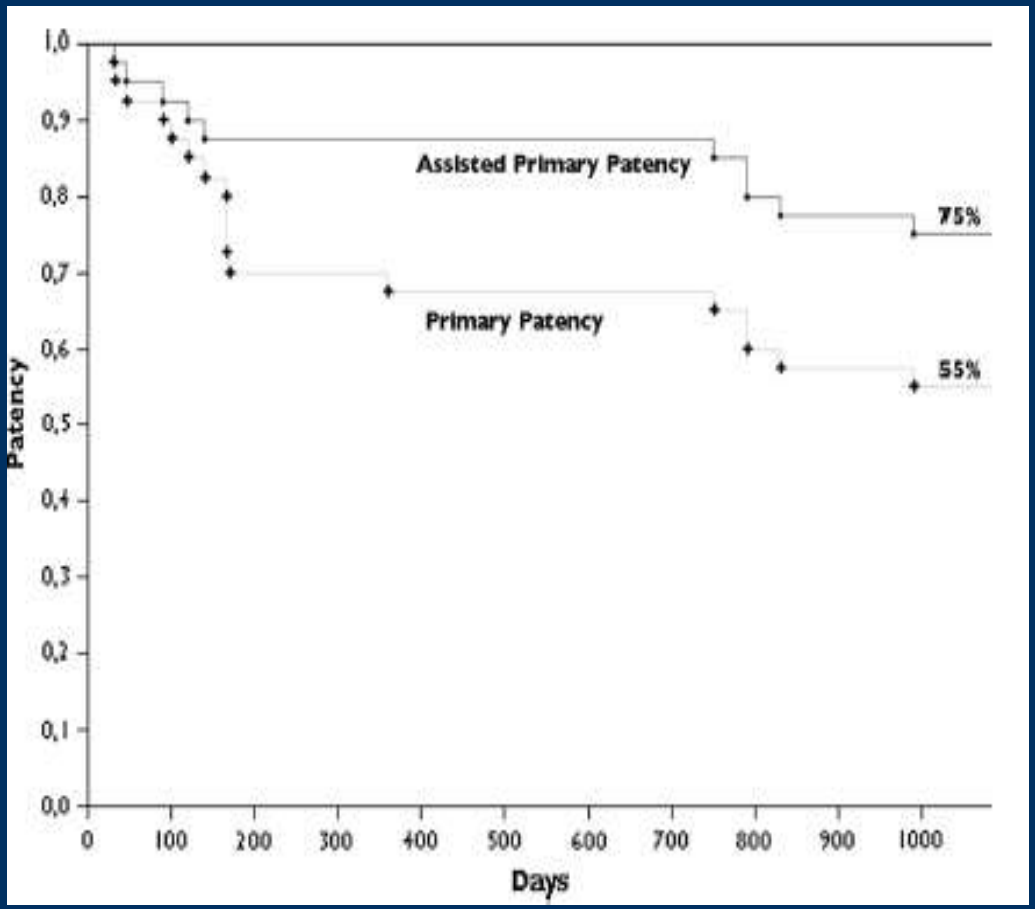
J Am Coll Cardiol Intv 2014;7:923–33

Directional atherectomy as stand alone therapy

CLINICAL INVESTIGATION ARTERIAL INTERVENTION

Three-Year Results After Directional Atherectomy of Calcified Stenotic Lesions of the Superficial Femoral Artery

P. Minko · A. Boehler · S. Jaeger · M. Kaufs



Minko et al, Cardiovasc Intervent Radiol (2014) 37:1165–1170

Directional Atherectomy + Anti-Restenotic Therapy

The DAART Concept

DA: Vessel Preparation

+

Anti-restenotic treatment

Directional Atherectomy +DCB (DAART)

Baseline Lesion Characteristics

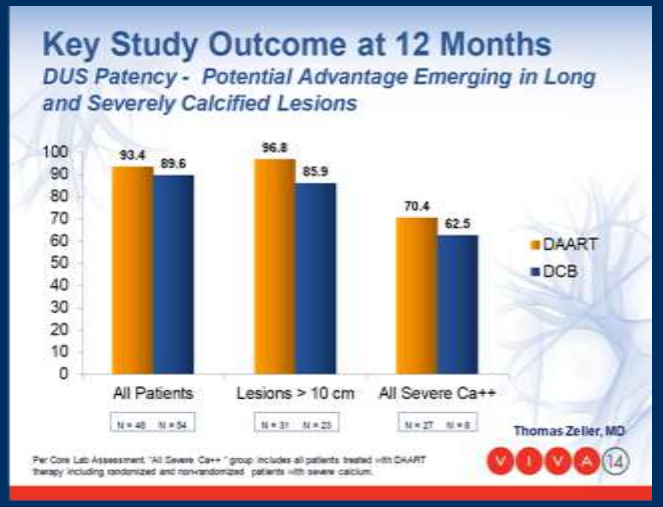
Per Core Lab

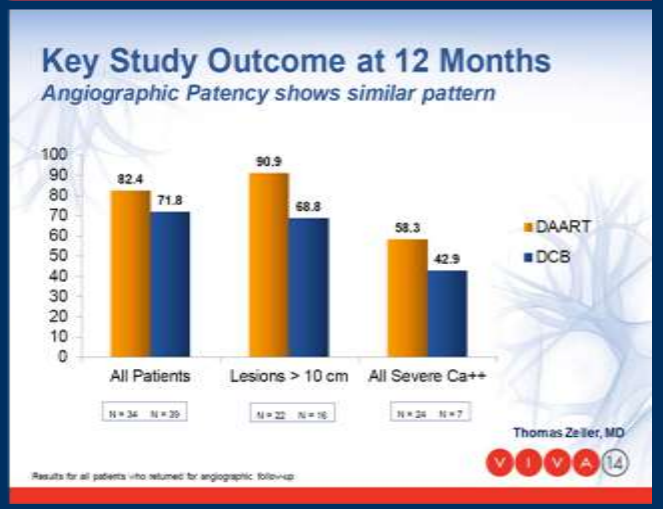
Baseline Characteristics	DAART (N= 48)	DCB (N = 54)	*p*-Value*	DAART Severe Ca++ Arm (N=19)
Lesion Length (cm)	11.2	9.7	0.05	11.9
Diameter Stenosis	82%	85%	0.35	88%
Reference vessel diameter (mm)	4.9	4.9	0.48	5.1
Minimum lumen diameter (mm)	1.0	0.8	0.34	0.7
Calcification	70.8%	74.1%	0.82	94.7%
Severe calcification	25.0%	18.5%	0.48	89.5%

Thomas Zeller, MD

VIVA 14

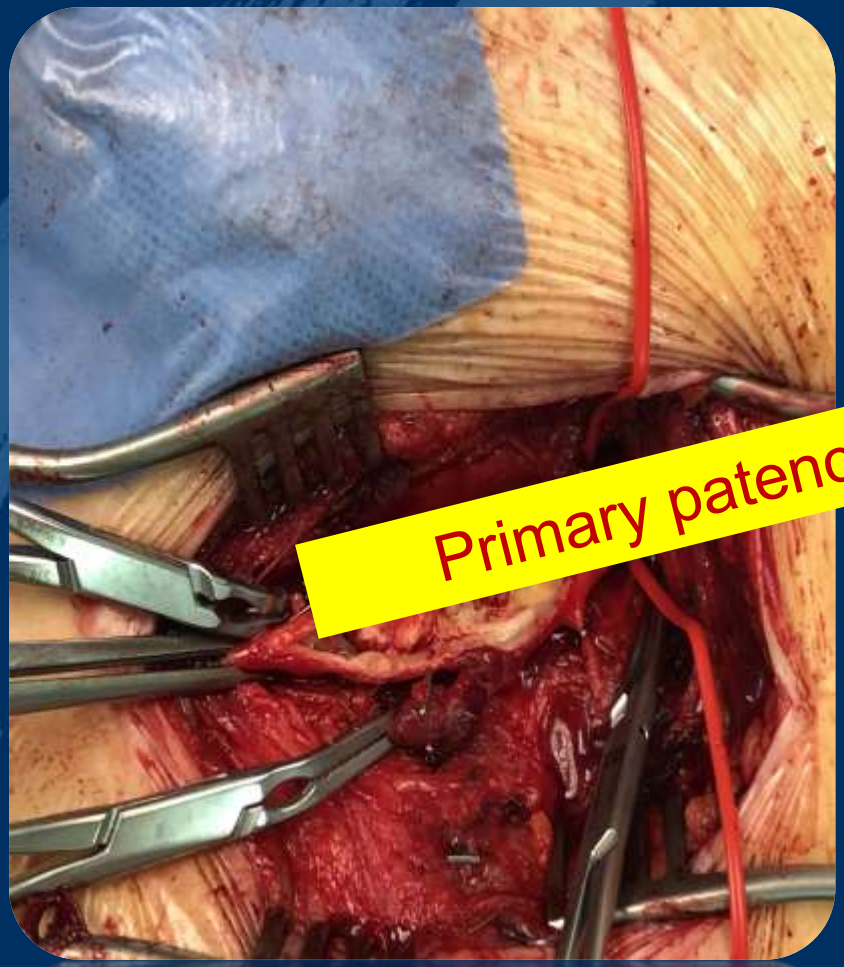
* *p*-value for DAART and DCB groups





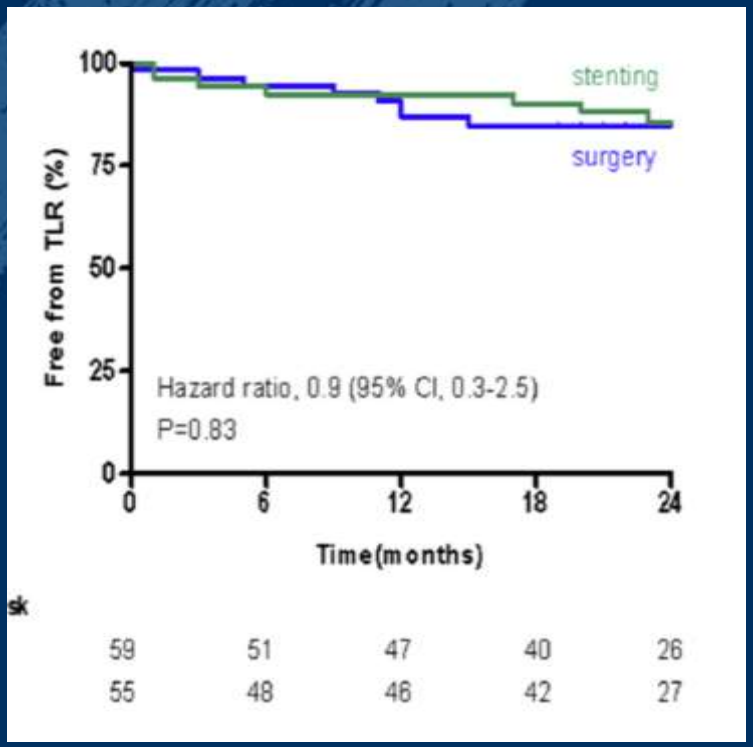
Zeller et al, Circ Cardiovasc Interv. 2017;10:e004848.

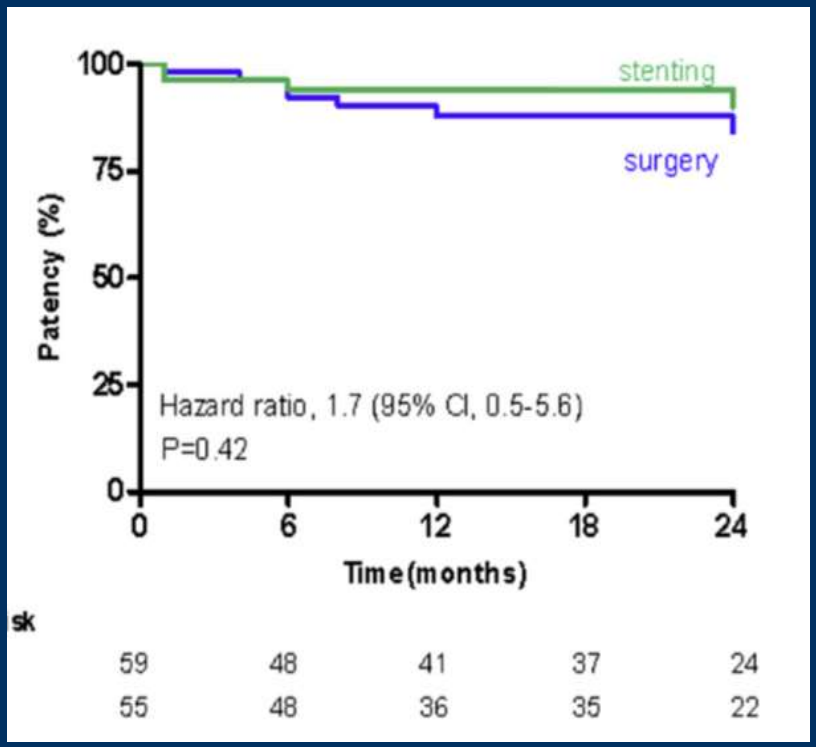
CFA disease



Primary patency: 96% @ 7 years

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

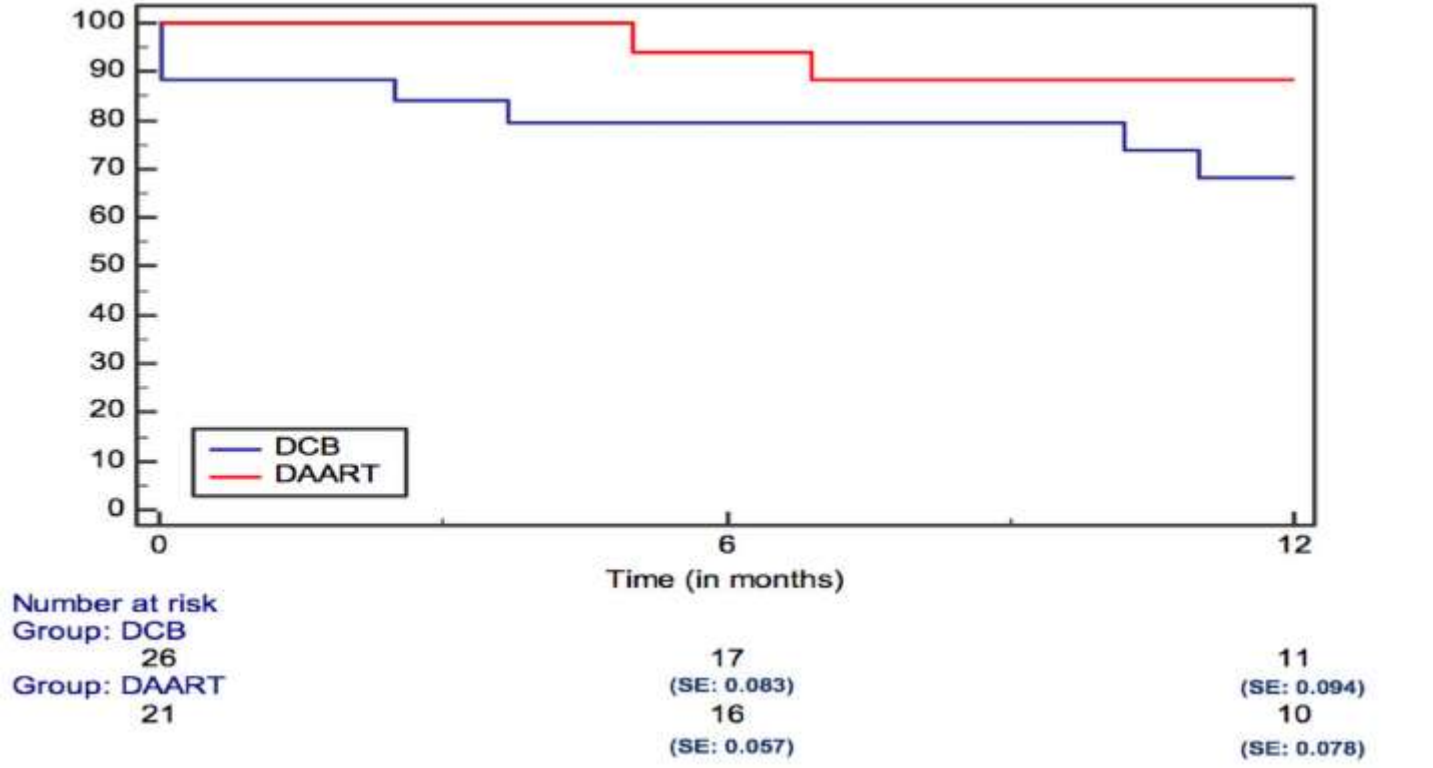
6.30 Avoid stents in the CFA and do not place stents across the origin of a patent deep femoral artery.

Grade	Level of evidence	Key references
Good practice statement		-

Conte et al, JVS 2019

DAART for CFA

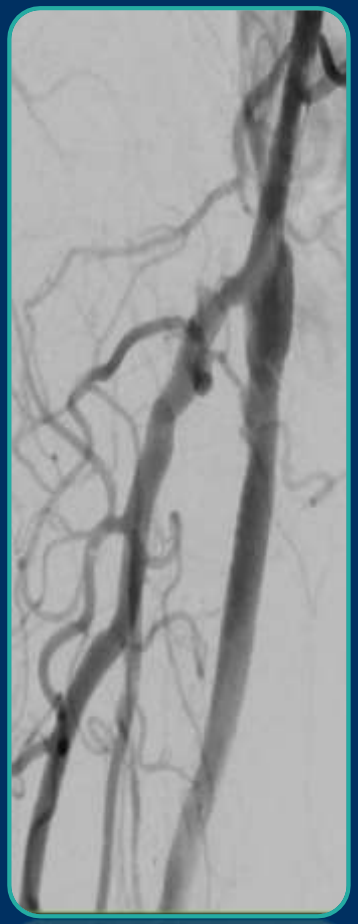
68% vs 88%, (HR): 0.64; 95 CI: 0.22 to 2.81, P= .40



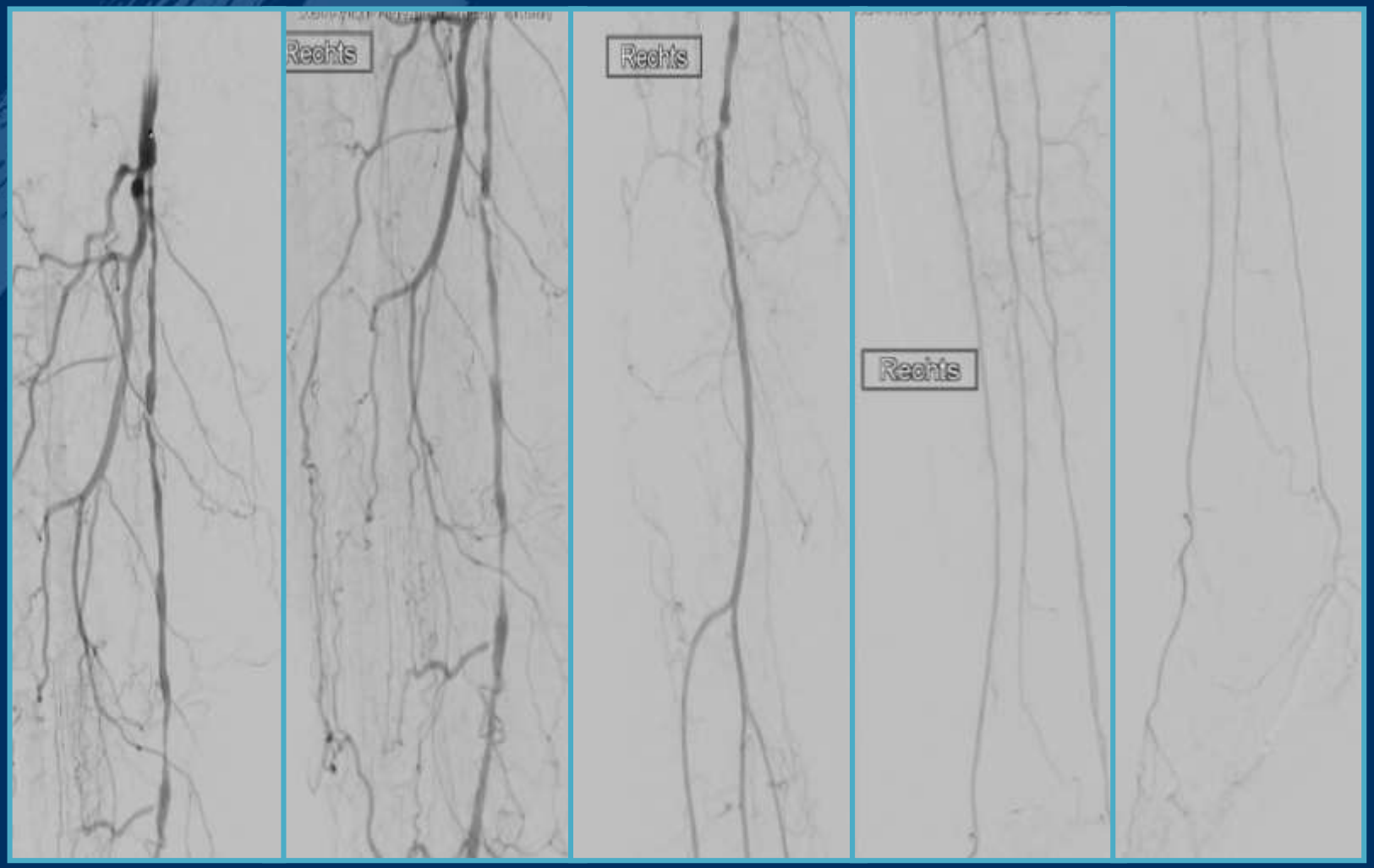
Stavroulakis et al. J Endovasc Ther. 2018 Feb;25(1):92-99

DAART for CFA Restenosis after Surgery

DAART for Bypass anastomosis stenosis



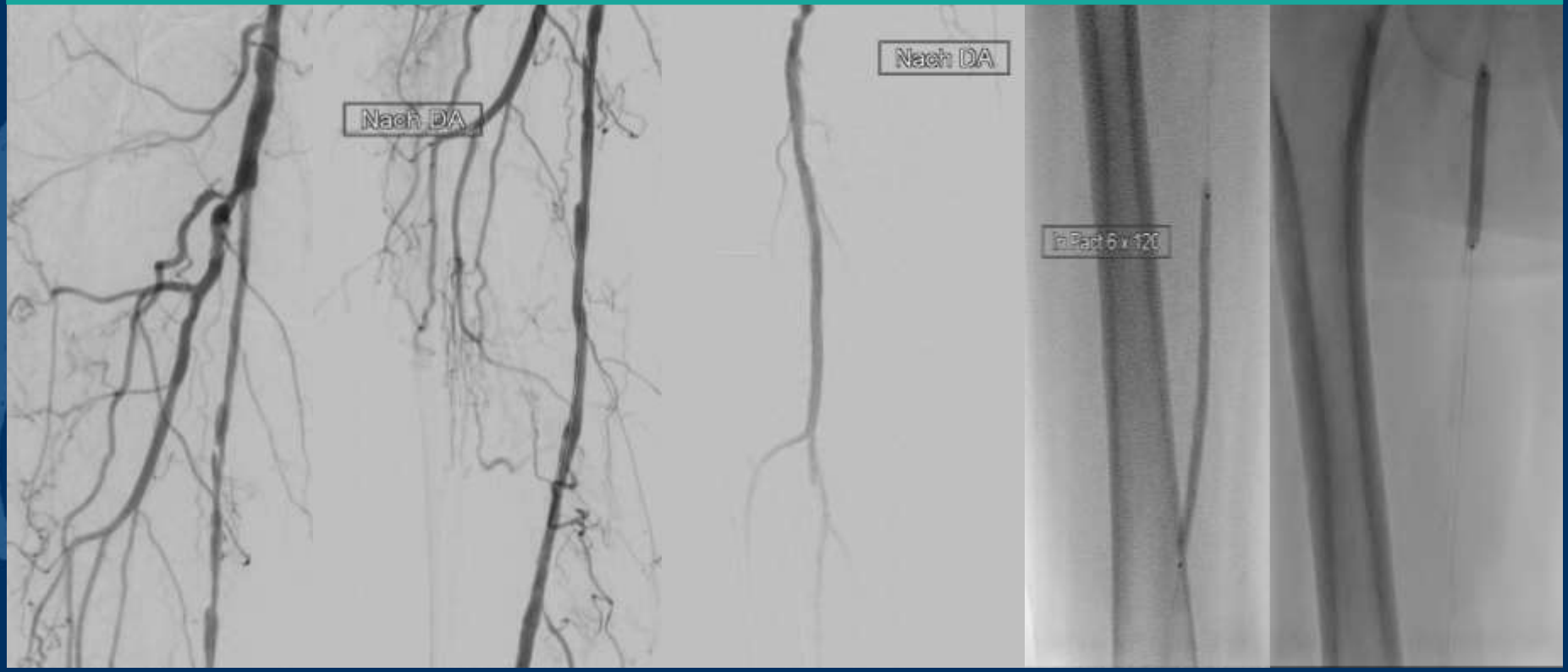
DAART long SFA lesion



DAART long SFA lesion

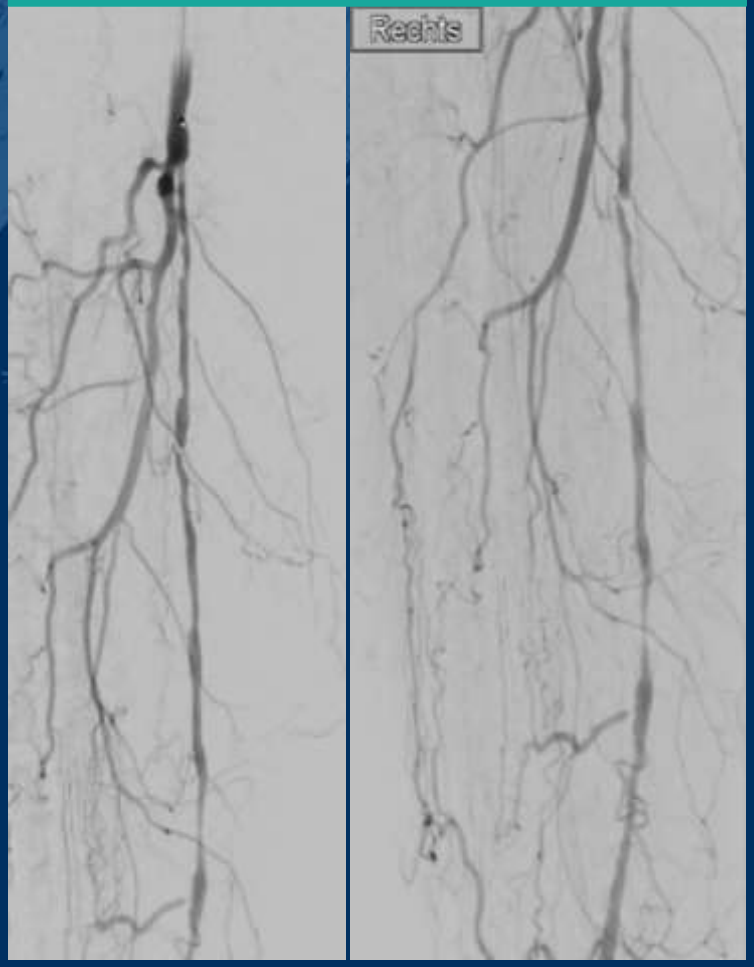
After Directional Atherectomy

DCB Angioplasty

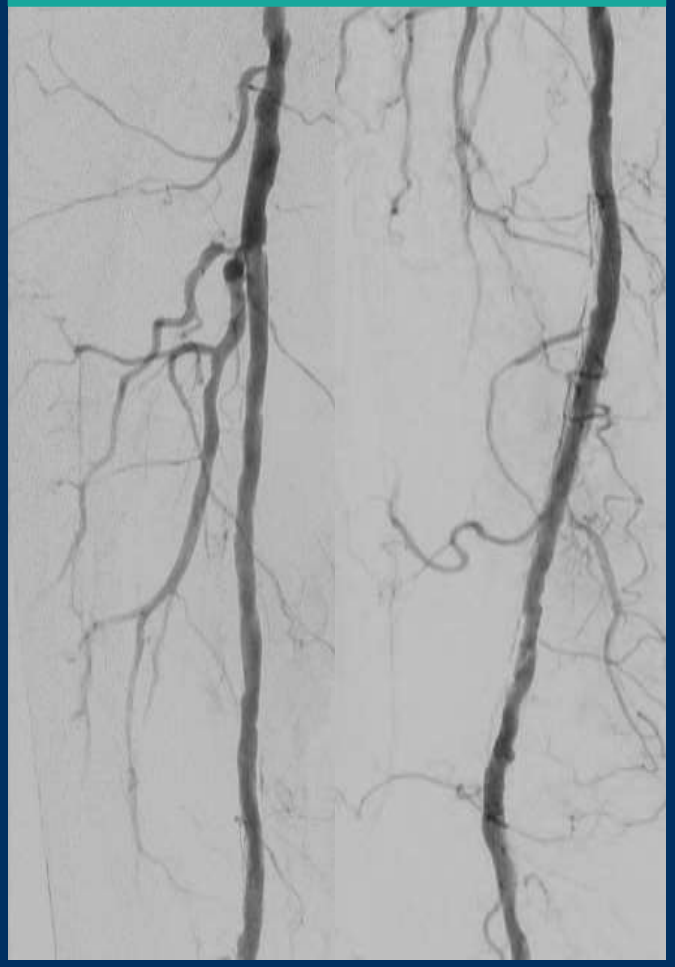


DAART long SFA lesion

Baseline



Final Result



The pitfalls of stent therapy for popliteal disease

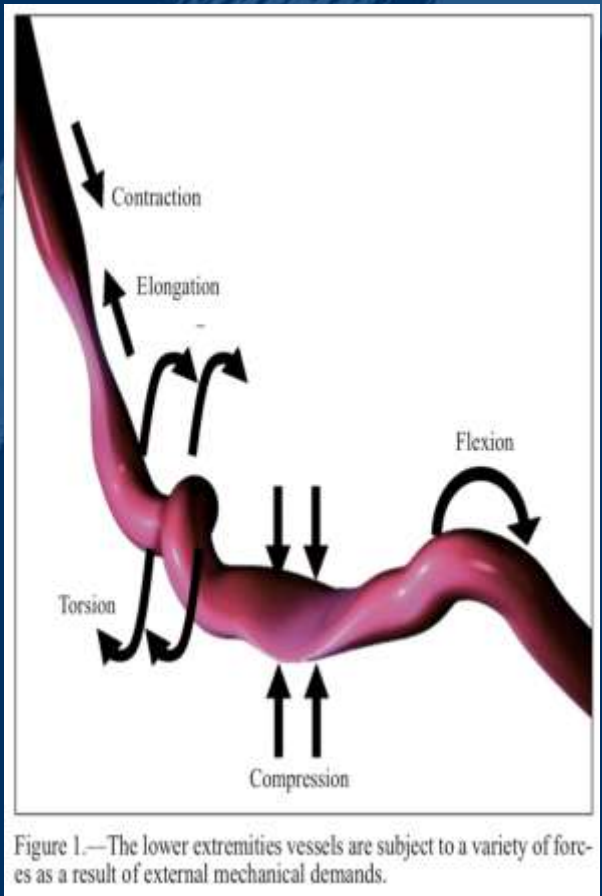
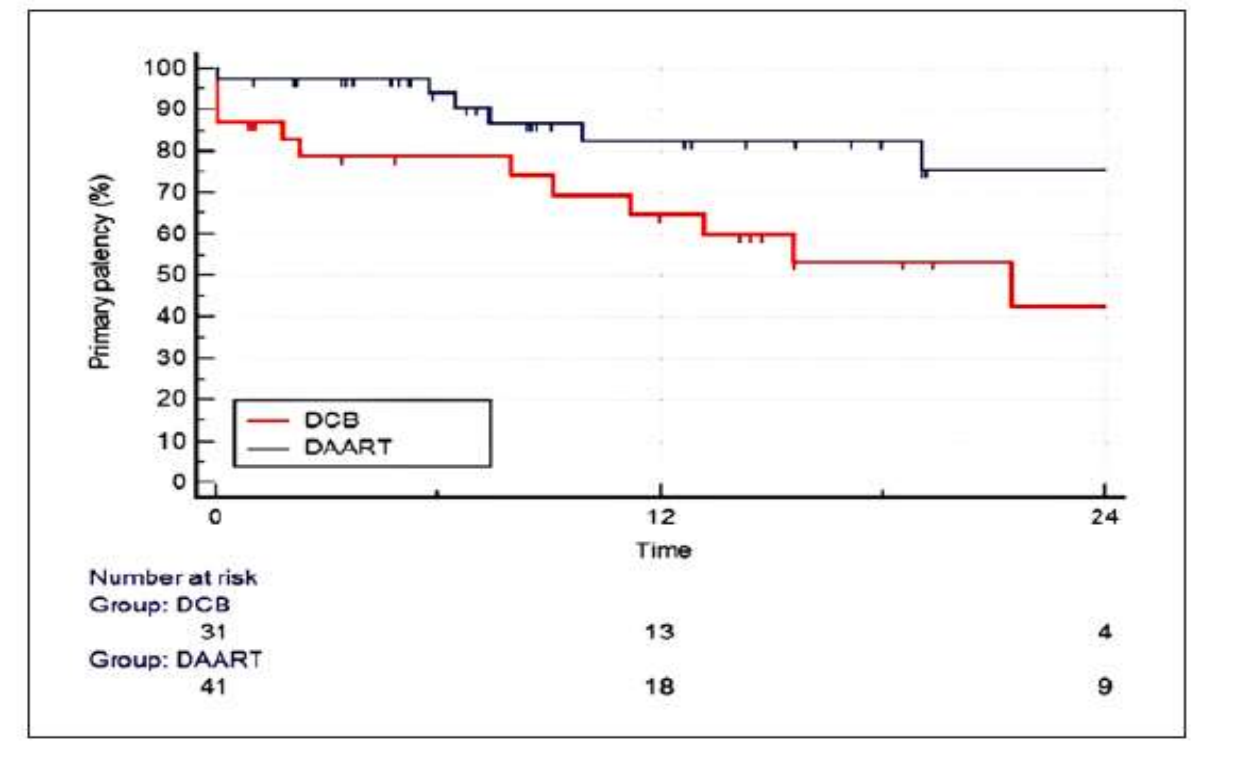


Figure 1.—The lower extremities vessels are subject to a variety of forces as a result of external mechanical demands.

Li et al, J Cardiovasc surg 2017;58:698-714

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 BTK Disease: The ADCAT Trial

- 80 subjects
- 1:1 Randomization (DCB vs DAART)
- BTK long de- novo lesions (≥6cm)
- Repeat angiography at 3 months
- Primary endpoint: in-Segment Binary Restenosis
- Follow-up visits scheduled at 3, 6, 12 months

ClinicalTrials.gov Identifier: NCT01763476

Conclusions

- CLTI multivessel disease pattern
- DA can effectively remove calcium and minimize the risk for dissections and bailout stenting
- No clear long-term benefit
- DA valuable vessel prep tool for
  - CFA disease
  - Popliteal disease
  - Long/Calcified lesions
- Waiting for BTK data

Thank you!

The versatility of directonal atherectomy to address challenges of multi-level disease in CLTI

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