Endovascular techniques for CFA revascularization

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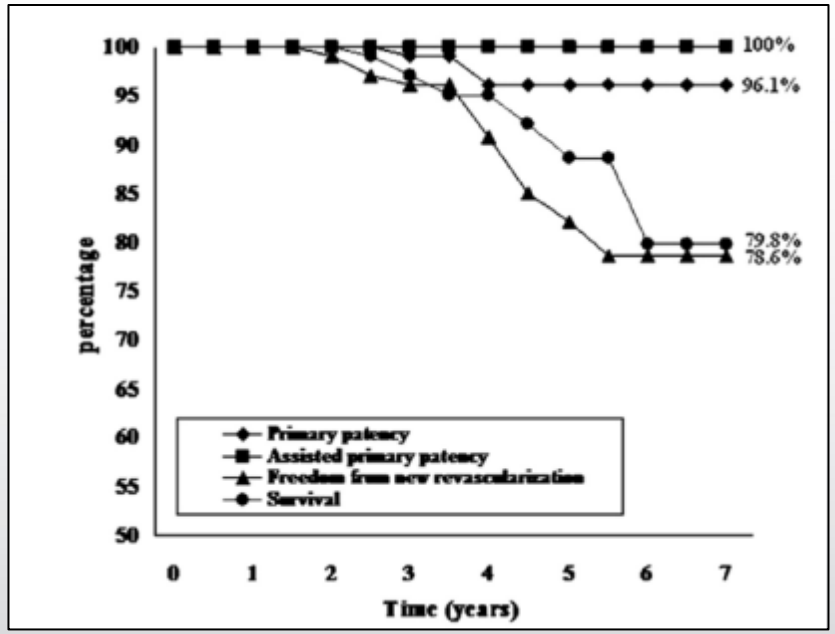
ATHENS HEART CENTER

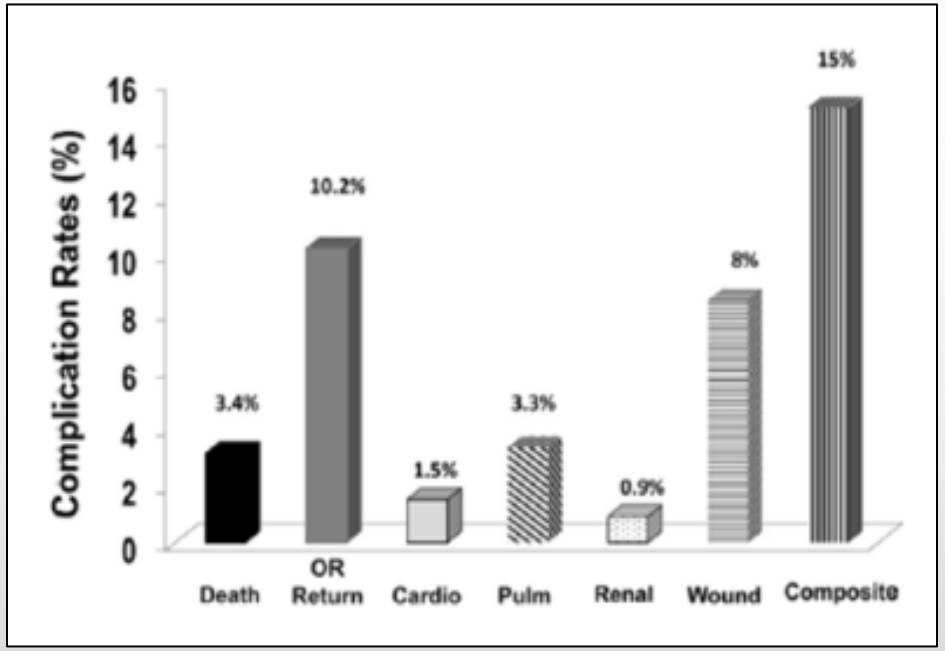
Conflicts of interest

- **Consultancy & Honoraria:**
  - Medtronic, Boston Scientific, Penumbra, Philips, BBraun, Bard, COOK Medical, Profusa, Terumo, Angiodroid, GORE
- **Research grants**:
  - Medtronic, German Society of Vascular Surgery
- **Shareholder:**
  - Vascupedia

Is the open surgical CFA repair still the gold standard?



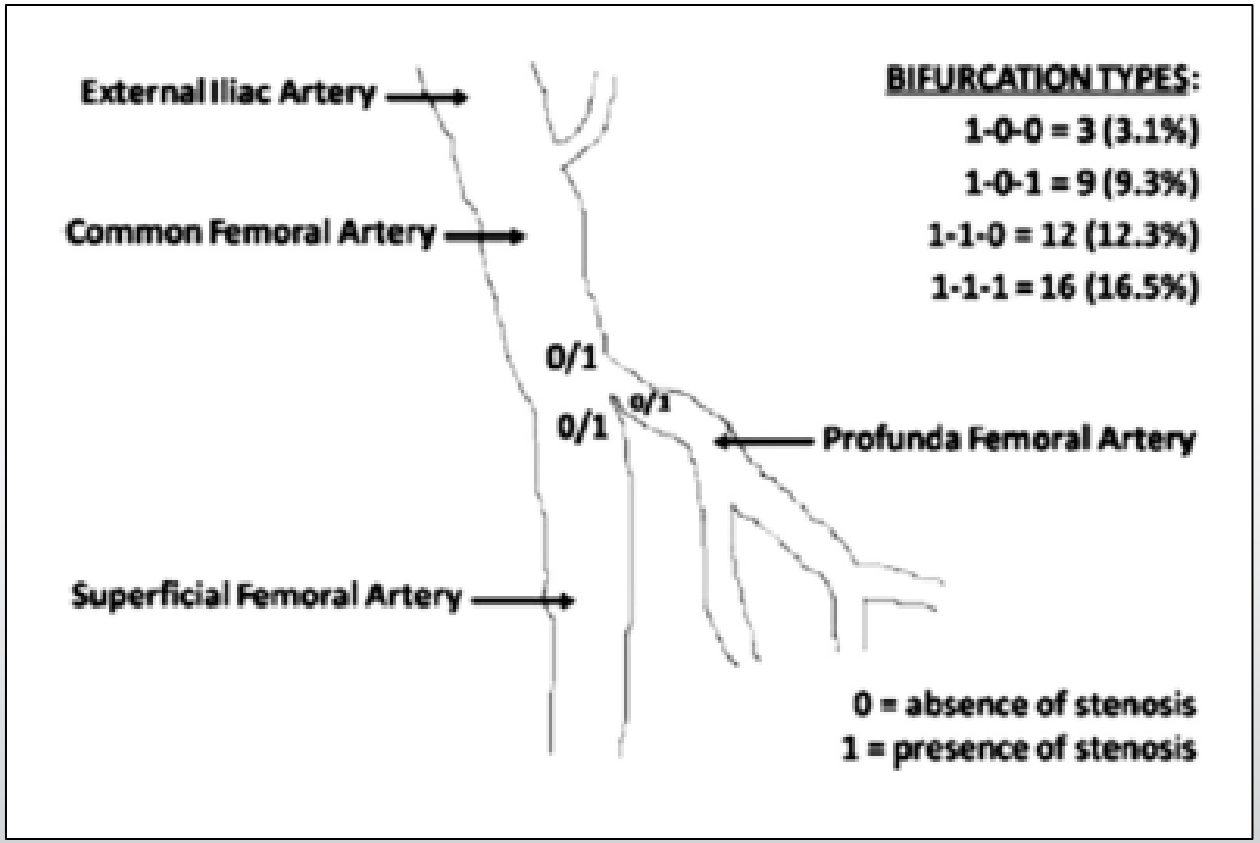
- **Perioperative complication rate**: 16%[1]
- **Perioperative mortality**: 1.5%[1]



1. *Wiecker et al. J Vasc Surg. 2016;64(4):995-1001*
2. *Ballota et al. Surgery 2010;147(2):272*

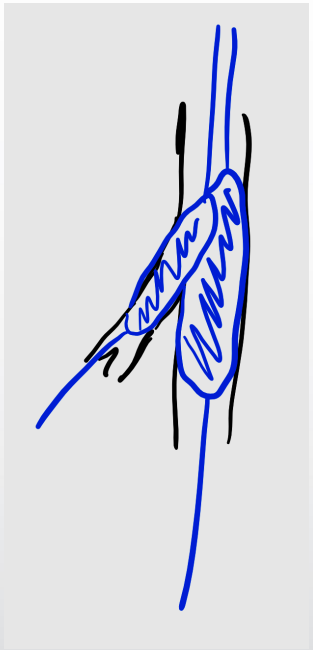
The endovascular technique

The Medina classification

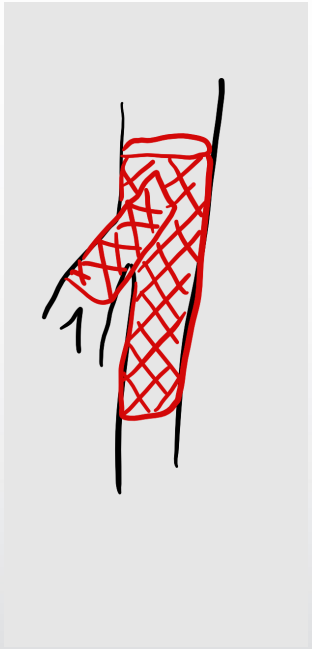


Heo S et al. Intervent Cardiol Clin 2016

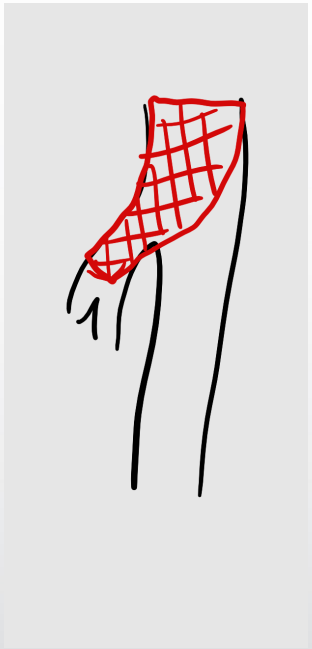
Techniques of endovascular reconstruction for CFA



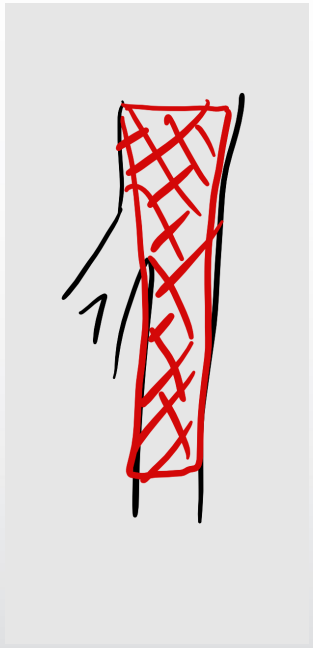
KISSING BALLOON



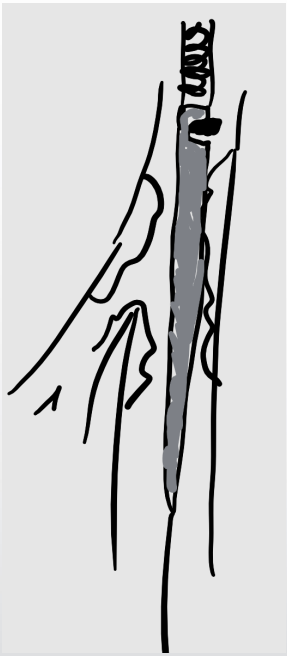
KISSING STENTS



SINGLE STENT, JAILED SFA



SINGLE STENT, JAILED PFA



ATHERECTOMY

Data landscape

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CLINICAL RESEARCH — Interventional Cardiology

Endovascular Treatment of Common Femoral Artery Disease

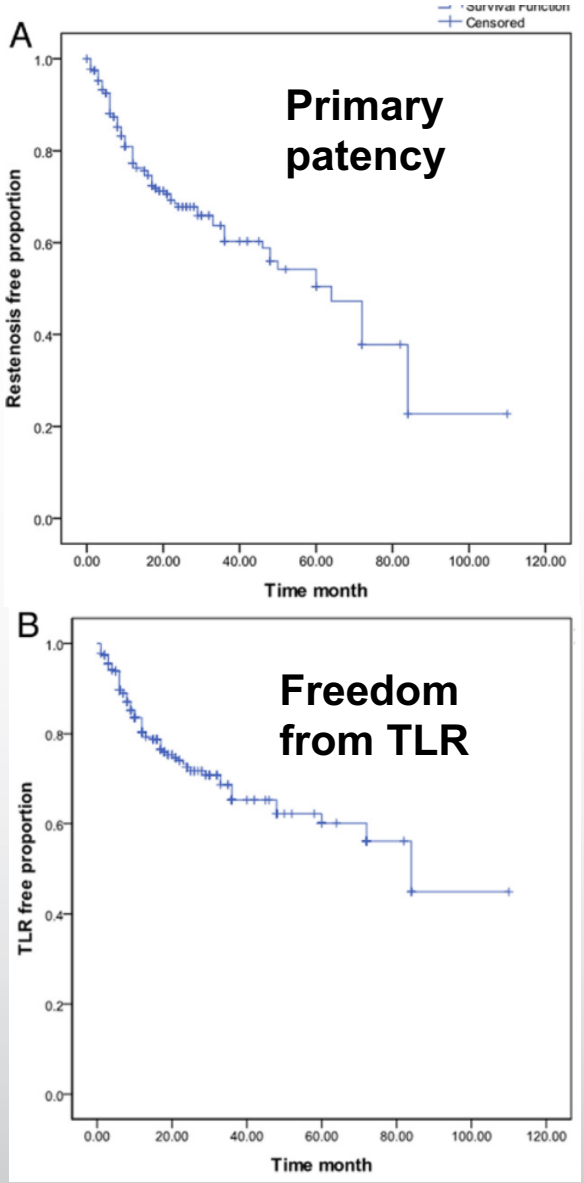
Medium-Term Outcomes of 360 Consecutive Procedures

Robert F. Bonvini, MD,*† Aljoscha Rastan, MD,* Sebastian Sixt, MD,* Elias Noory, MD,* Thomas Schwarz, MD,* Ulrich Frank, MD,‡ Marco Roffi, MD,† Pierre André Dorsaz, PHD,† Uwe Schwarzwälder, MD,* Karlheinz Bürgelin, MD,* Roland Macharzina, MD,* Thomas Zeller, MD*

Bad Krozingen, Germany; and Geneva and Chur, Switzerland

N=360 consecutive patients
27% isolated CFA interventions
39% bifurcation lesions
Primary stenting: 37%

Technical success
93%



Restenosis: 28%

TLR: 20%

Predictors of adverse events during CFA intervention

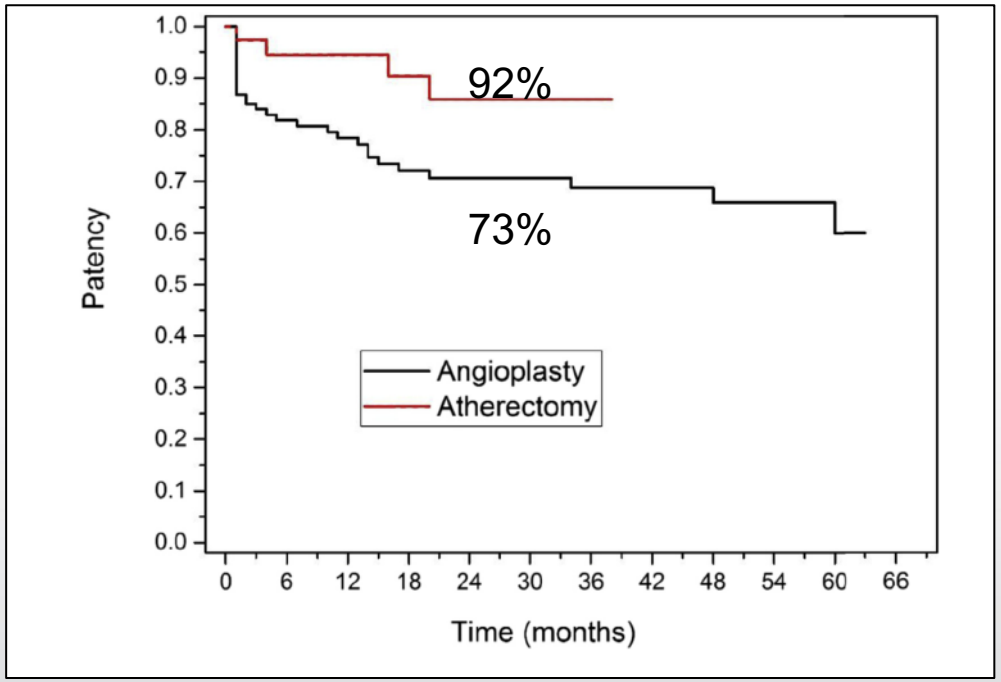
- Isolated CFA > CFA + other vessel ?
- De novo < post-TEA ?
- Stented > Non-stented
- Atherectomy > PTA ± stent ?

Table 5 Multivariate Analysis of Outcomes for 4 Different Patient Subgroups

	Isolated CFA (n = 97), %	CFA + Other Vessel PTA (n = 263), %	OR	95% CI	p Value
Failures	7.2	7.2	1.00	0.40–2.45	1.000
Complications	4.1	7.2	0.55	0.18–1.67	0.340
Restenosis	26.0	28.2	0.89	0.48–1.64	0.760
1-yr TLR	15.9	21.0	0.71	0.37–1.36	0.340
	De Novo (n = 310), %	**Post-TEA (n = 50), %**			
Failures	7.7	4.0	0.49	0.11–2.17	0.550
Complications	5.5	12.0	2.35	0.88–6.28	0.110
Restenosis	29.6	16.7	0.47	0.20–1.12	0.090
1-yr TLR	20.4	14.9	0.68	0.29–1.60	0.430
	Stented (n = 133) %	**Nonstented (n = 227), %**			
Failures	2.2	10.1	0.20	0.06–0.69	0.005
Complications	7.5	5.7	1.34	0.57–3.14	0.510
Restenosis	20.0	31.8	0.53	0.29–0.97	0.046
1-yr TLR	13.1	23.6	0.49	0.26–0.91	0.021
	Atherectomy (n = 25), %	**PTA ± Stent (n = 335), %**			
Failures	4.0	7.5	0.51	0.07–3.98	1.000
Complications	0	6.9	0.26	0.01–4.42	0.380
Restenosis	11.8	28.7	0.35	0.07–1.48	0.160
1-yr TLR	4.8	20.9	0.18	0.02–1.42	0.090

Endovascular repair

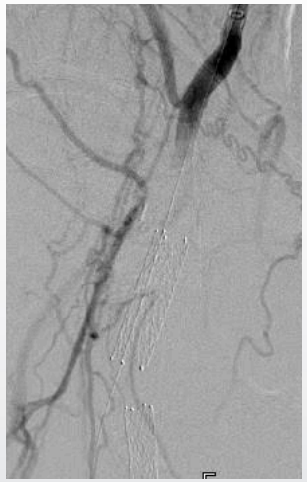
Atherectomy+PTA vs PTA

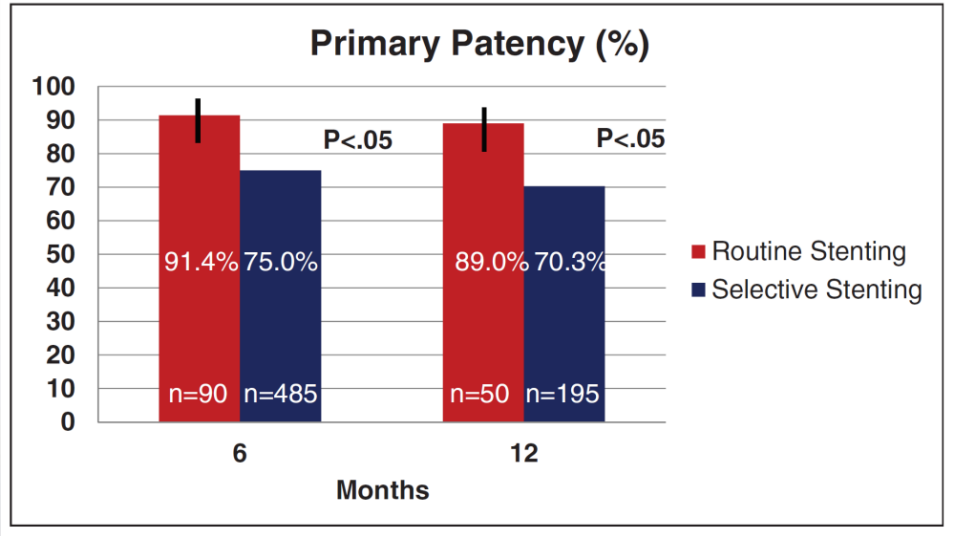


Atherectomy + PTA superior to PTA alone in claudicants

Endovascular repair

Routine vs selective stenting

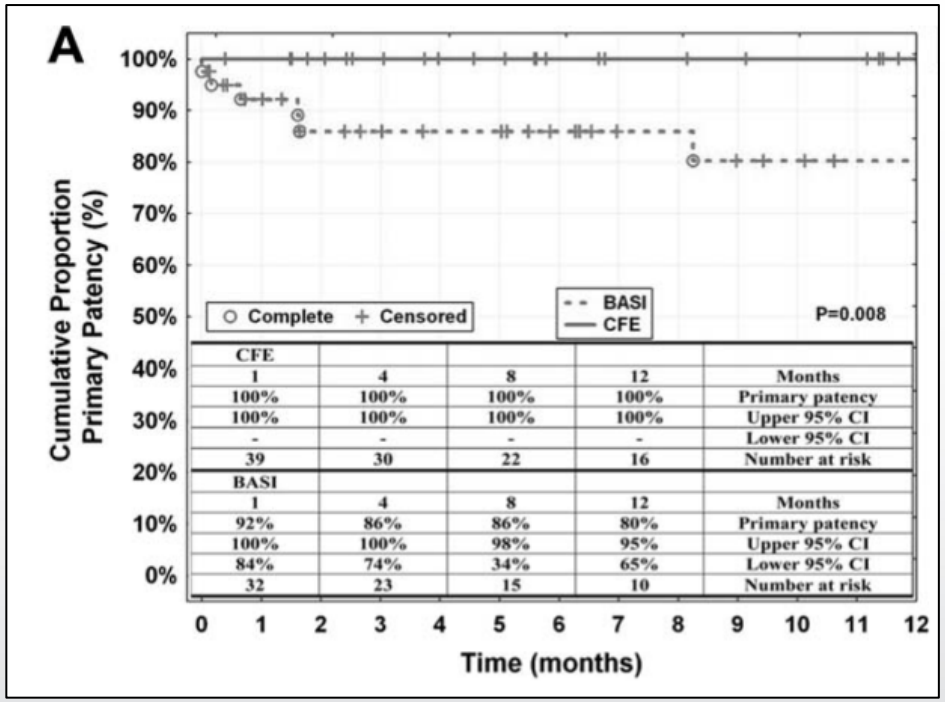


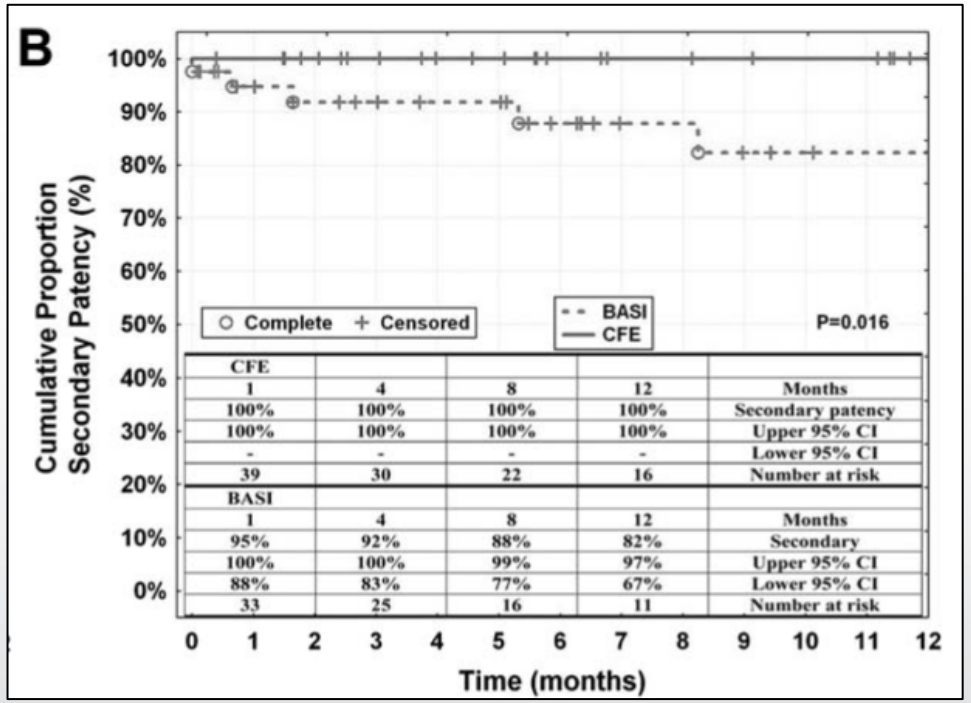


Mid-term patency of selective stenting is good and may be further improved by routine stenting

Endovascular repair

Bioresorbable BMS vs CFA endarterectomy





This interim analysis suggests that BASI is not an option for CFA occlusion and is only a limited option for CFA stenosis.

Endovascular repair
DAART vs DCB alone

eck for updates

Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

Directional Atherectomy With Antirestenotic Therapy vs Drug-Coated Balloon Angioplasty Alone for Common Femoral Artery Atherosclerotic Disease

Journal of Endovascular Therapy
1–8

DOI: 10.1177/1526602817748319
www.jevt.org
SAGE

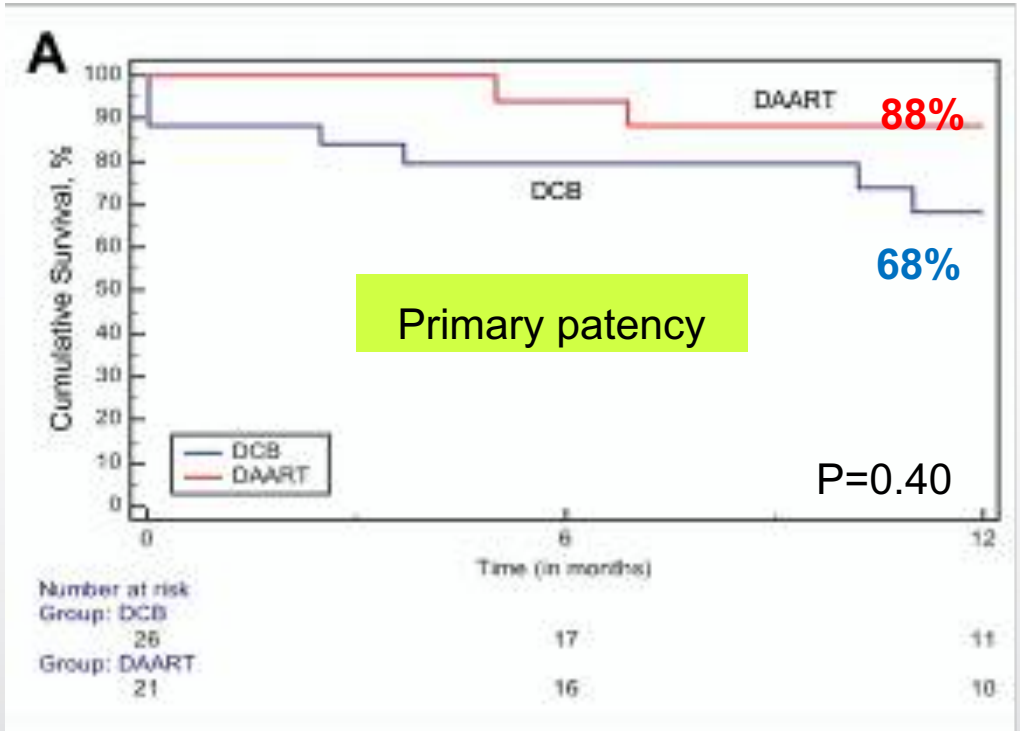
Konstantinos Stavroulakis, MD[I], Arne Schwindt, MD[I], Giovanni Torsello, MD[I], Efthymios Beropoulis, MD[I], Arne Stachmann, MD[I], Christiane Hericks, MD[I], Leonie Bollenberg, MD[I], and Theodosios Bisdas, MD, PhD[I]

Luminal gain
after atherectomy: 62%
after DAART: 73%

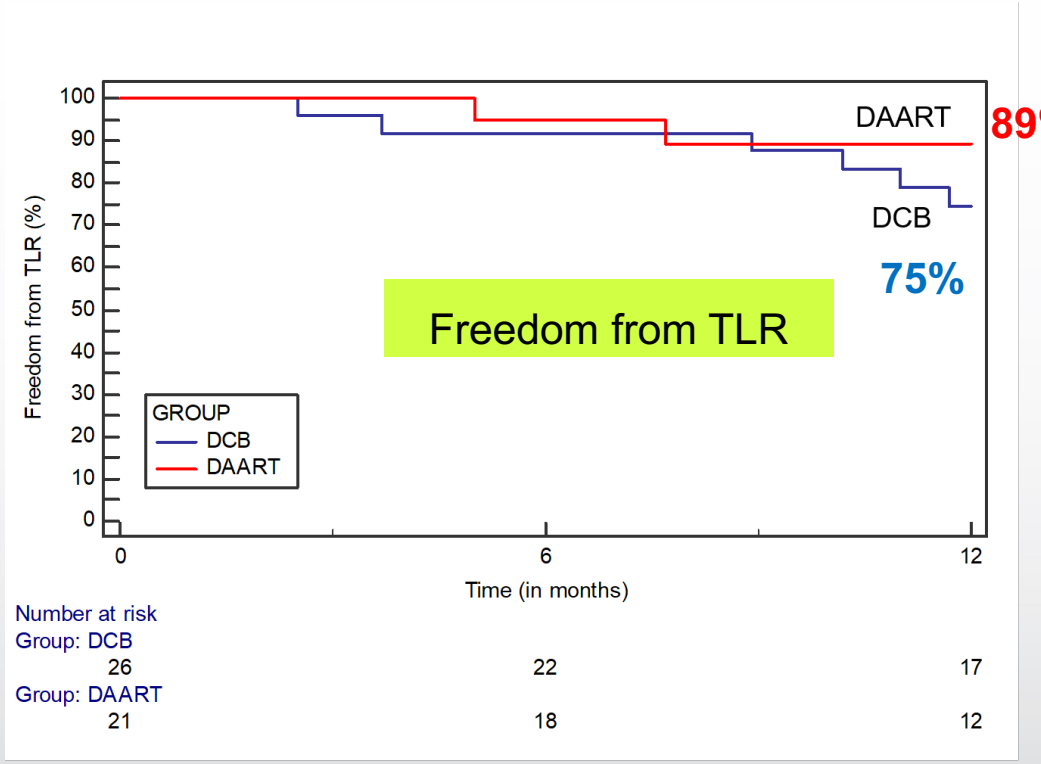
Technical success
after DAART: 88%
after DCB: 75%

Stavroulakis K, Schwindt A, Torsello G, Beropoulis E, Stachmann A, Hericks C, Bollenberg L, Bisdas T.
Directional Atherectomy With Antirestenotic Therapy vs Drug-Coated Balloon Angioplasty Alone for Common Femoral Artery Atherosclerotic Disease.
J Endovasc Therap 2018; in press

Endovascular repair
DAART vs DCB alone



Primary patency



Freedom from TLR

Secondary patency:
DAART: 100%
DCB: 81%, P=0.03

Stavroulakis K, Schwindt A, Torsello G, Beropoulis E, Stachmann A, Hericks C, Bollenberg L, Bisdas T.
Directional Atherectomy With Antirestenotic Therapy vs Drug-Coated Balloon Angioplasty Alone for Common Femoral Artery Atherosclerotic Disease.
J Endovasc Therap 2018; in press

TECCO trial

Stenting vs surgery for de novo CFA

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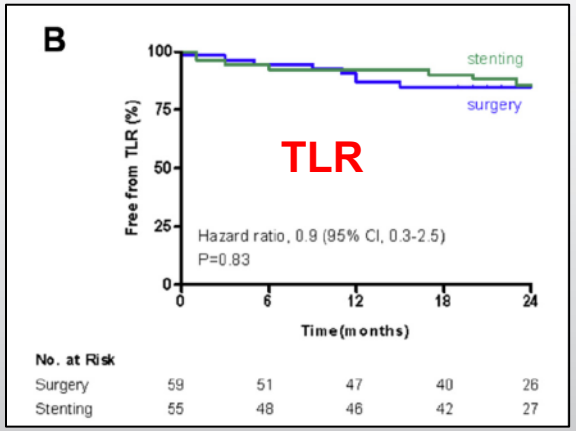
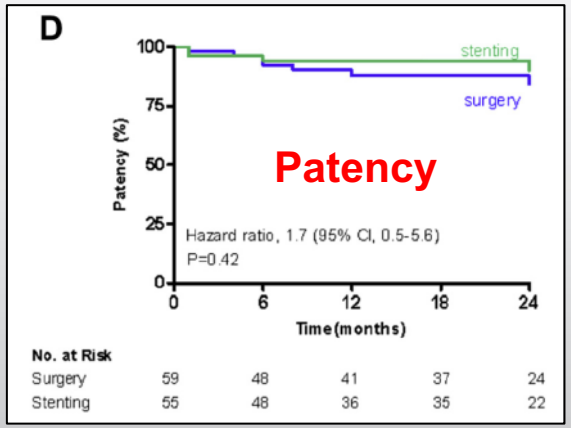
PERIPHERAL VASCULAR

Stenting or Surgery for De Novo Common Femoral Artery Stenosis

Yann Gouëffic, MD, PhD,[a,b,c] Nellie Della Schiava, MD,[d] Fabien Thaveau, MD, PhD,[e] Eugenio Rosset, MD, PhD,[f] Jean-Pierre Favre, MD, PhD,[g] Lucie Salomon du Mont, MD,[h] Jean-Marc Alsac, MD, PhD,[i] Réda Hassen-Khodja, MD,[j] Thierry Reix, MD,[k] Eric Allaire, MD, PhD,[l] Eric Ducasse, MD, PhD,[m] Raphael Soler, MD,[n] Béatrice Guyomarc'h,[o] Bahaa Nasr, MD[p]





Primary endpoint (PPA)

Morbidity and mortality @ 30 days:

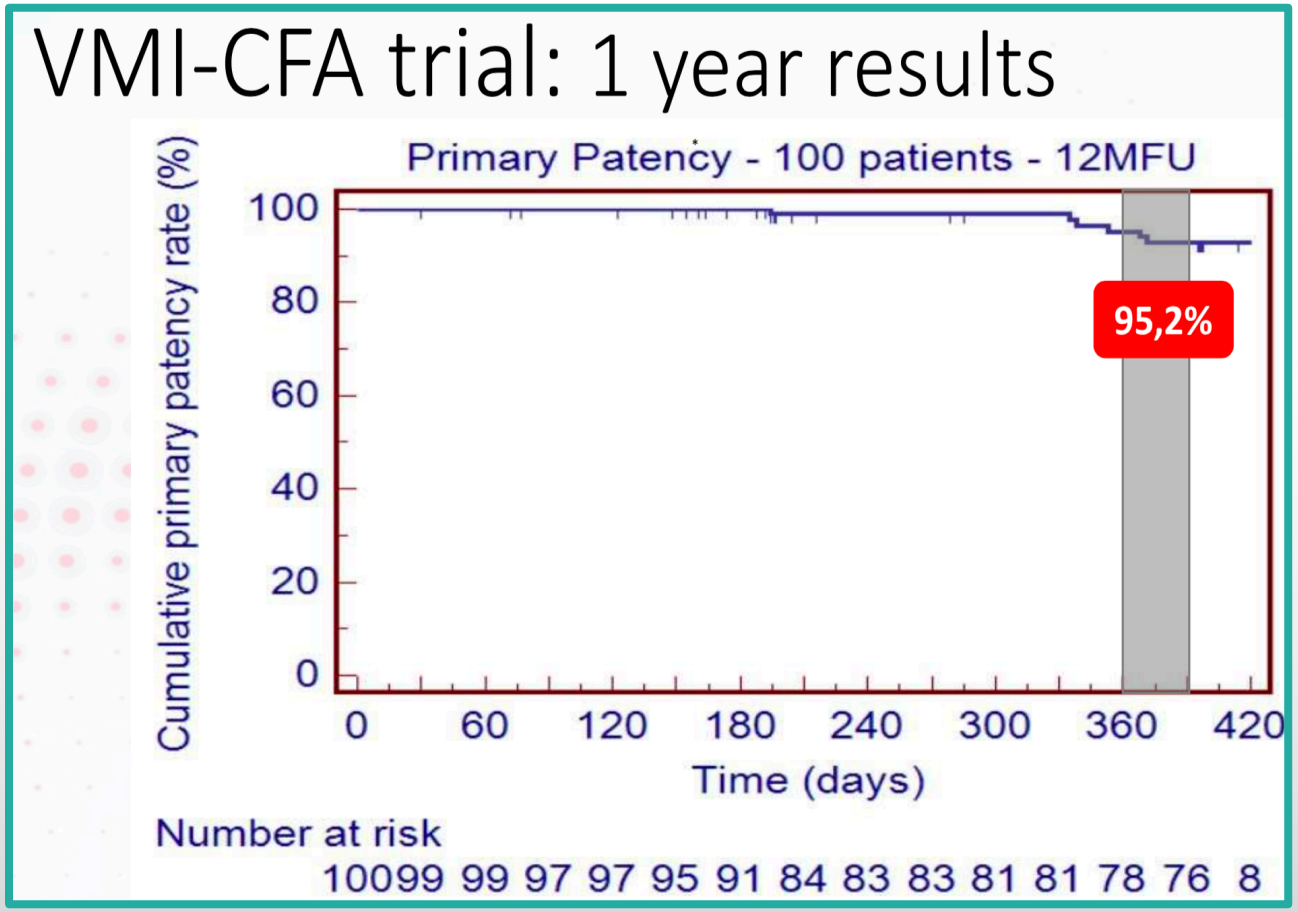
Open: 26%

Stent: 6%, P=0.005

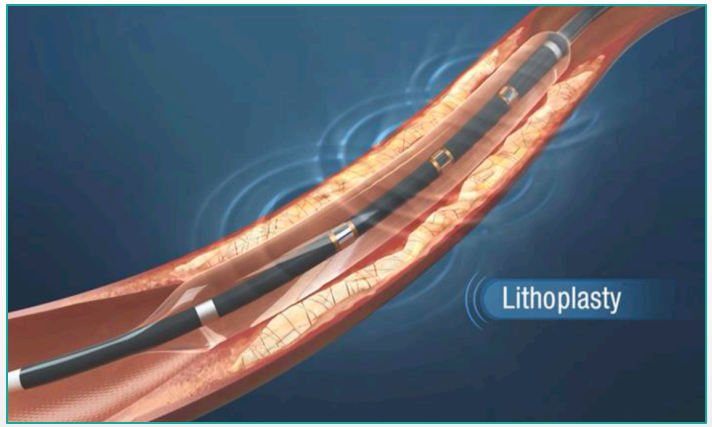
Only 1 stent fracture

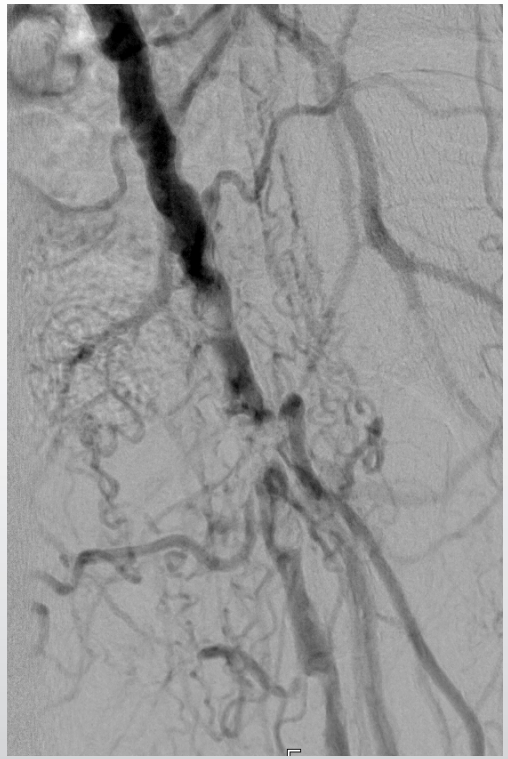
CFA Stent therapy

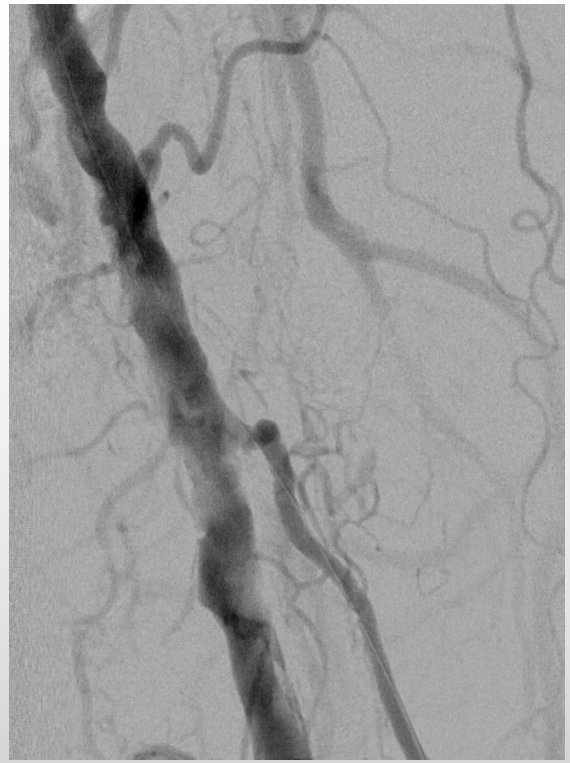
Supera Stent



Shockwave balloon for severely calcified CFA







Common femoral artery

Endovascular lithoplasty

Journal of Endovascular Therapy
1–5

DOI: 10.1177/1526602819844998
www.jevt.org
SAGE

Safety and Feasibility of Intravascular Lithotripsy for Treatment of Common Femoral Artery Stenoses

Marianne Brodmann, MD[1], Arne Schwindt, MD[2], Angeliki Argyriou, MD[2], and Roger Gammon, MD[3]

Abstract

Purpose: To evaluate the safety and feasibility of treating calcified, stenotic common femoral arteries (CFAs) using the Peripheral Intravascular Lithotripsy (IVL) System. **Methods:** An analysis was performed of 21 patients (mean age 71.9±10.1 years; 16 men) across 3 sites with calcified CFA stenoses treated with the Peripheral IVL System. The outcomes of interest were the ability to deliver IVL to the target lesion, the increase in acute gain, the reduction in diameter stenosis, the rate of provisional stenting, and angiographically defined complications. **Results:** Access to the target lesion and delivery of treatment by the IVL catheter were successful in all 21 patients. Post treatment mean diameter stenosis was 21.3%, representing an acute mean lumen gain of 3.1±1.3 mm (range 0.7–5.2). Vascular complications were minimal, with only 5 type B (non-flowing-limiting) dissections reported. The profunda femoris artery was patent in all patients following IVL, and none of the subjects experienced a perforation, distal embolization, thrombus, no reflow, or abrupt closure. **Conclusion:** These early results demonstrate that calcified, stenotic CFA lesions can be safely and successfully treated using the Peripheral IVL System.

Table 2. Characteristics of the 21 Procedures and Outcomes.[a]

Predilation, %	0
Successful IVL delivery	21
IVL pulses	140±58 (60–300)
Pressure, atm	6.3±1.4 (4.0–9.3)
Adjunctive technology	
Drug-coated balloon	18
Atherectomy	1
Standalone IVL	2
Stents	0
Outcomes	
Lumen diameter, mm	4.8±1.1 (2.8–6.5)
Diameter stenosis, %	21.3±10.7 (5.1–40.0)
Acute gain, mm	3.1±1.3 (0.7–5.5)
Dissection (grade B)	5
Perforation	0
Distal embolization	0
Thrombus	0
No reflow	0
Abrupt closure	0

Abbreviation: IVL, intravascular lithotripsy.
[a]Continuous data are presented as the mean ± standard deviation (range); categorical data are given as the number.

What‘s next?

PESTO-AFC trial

- **Percutaneous Intervention versus Surgery in the Treatment of Common Femoral Artery Lesions trial**
- *www.clinicaltrials.org* NCT02517827
- DAART versus open surgery
- Primary Outcome Measures: Primary patency

- Estimated Enrollment: 306
- Study Start Date: November 2016
- Est. Study Completion Date: December 2019
- Est. Primary Completion Date: June 2018

Post DAART

Who are candidates for endo-first for the CFA?

- Elderly and unfit patients
- Redo operations
- Previous radiation
- Multiple lymph nodes at the ultrasound
- Obese and diabetics
- Anastomotic stenoses after fempop Rx

Summary

- The morbidity of CFA endarterectomy is often understated
- Endovascular CFA treatment is a viable and safe treatment
- Retrospective series: High restenosis rate when angioplasty and stent is used
- First RCT data favor endo treatment
- DAART could be the key endovascular option (PESTO AFC will provide more data)
- Lithoplasty and DCB in the CFA requires further research