

Atherectomy-assisted endovascular and Open Repair in Atherosclerotic Common Femoral Artery Lesions

The **ARISTON** Trial

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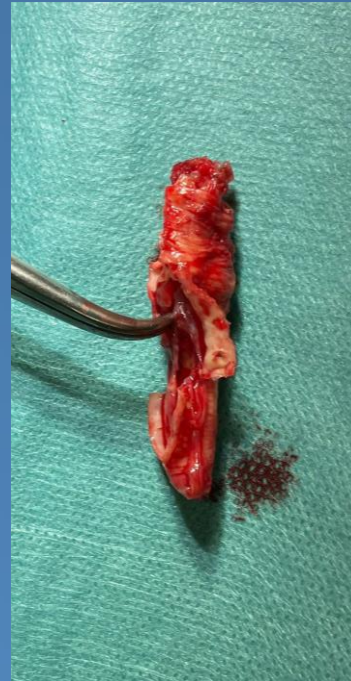
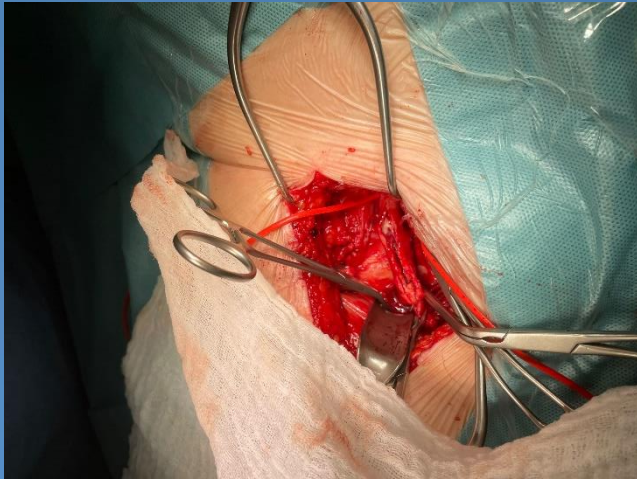
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Surgery as the gold standard for CFA atherosclerotic lesions

- The entire atherosclerotic burden can be desobliterated with high precision.
- Long-term durability without any metal or stent material leaved in place



Is surgical endarterectomy really the gold standard for treating CFA lesions?

Surgical Endarterectomy is the gold standard:

Ballotta et al (Surgery 1010)
8 yr. single center study, n=117 pat.
Primary patency 96% at 7 yrs.

Kang et al (J. Vasc. Surg. 2008)
5 yrs. prospective study, n=58 pat.
Primary patency 91% at 5 yrs.

Kechagia et al (World J Surg 2008)
15 yrs. prospective study, n=111 pat.
Primary patency 85% at 15 yrs.



Surgical Endarterectomy may not be the Non-plus-ultra option for all patients:

Ballotta et al (Surgery 1010)
7% complication rate
Lymph leaks

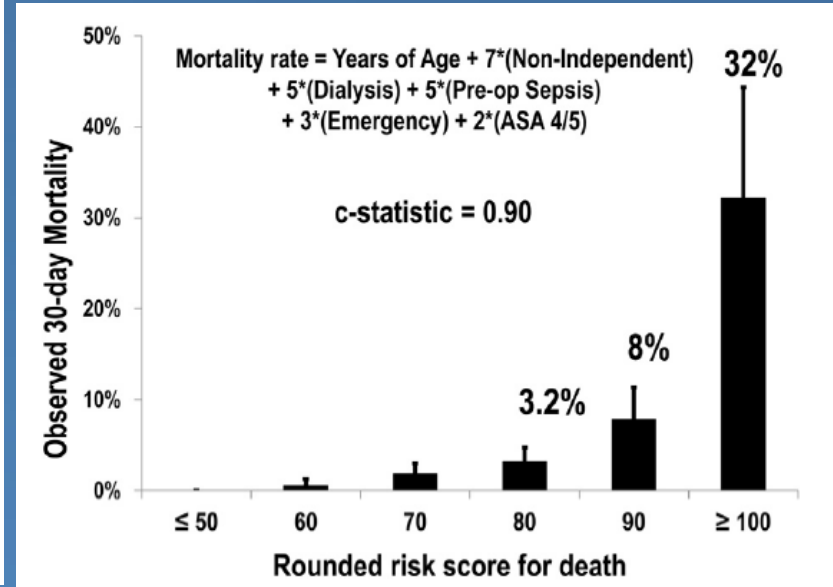
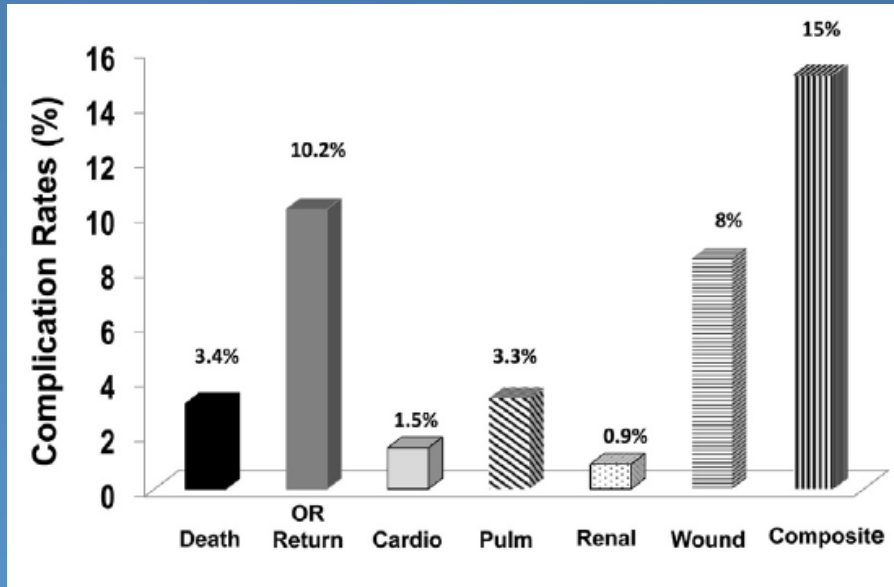
Kang et al (J. Vasc. Surg. 2008)
14% complication rate
5% requiring reintervention

Kechagia et al (World J Surg 2008)
17% **wound infection rate**
9% hematomas

Postoperative complications after common femoral endarterectomy

Bao-Ngoc Nguyen, MD, Richard L. Amdur, PhD, Mustafa Abugideiri, BS, Rodeen Rahbar, MD, Richard F. Neville, MD, and Anton N. Sidawy, MD, MPH, *Washington, D.C.*

Complication & mortality rates may be higher than anticipated
1843 CFEs
Morbi-mortality rates 15%

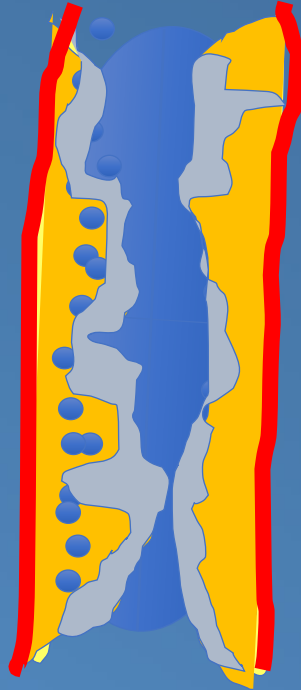


Conclusions: CFE is not as “benign” a procedure as previously believed. The risks of death and wound complications are not insignificant, and a high percentage of these complications occurred after patients were discharged from the hospital. Patients should be carefully selected, especially in the elderly population, and close postoperative follow-up should be considered. (*J Vasc Surg* 2015;61:1489-94.)

Atherectomy removes
atherosclerotic / calcific tissue
similar to surgical techniques,
resulting in
lumen gain without barotrauma



Facilitating low pressure balloon
angioplasty



Simultaneously increasing drug
delivery to the vessel wall



Decreasing the chance for
dissection,
avoiding additional stent
placement
'leave nothing behind'



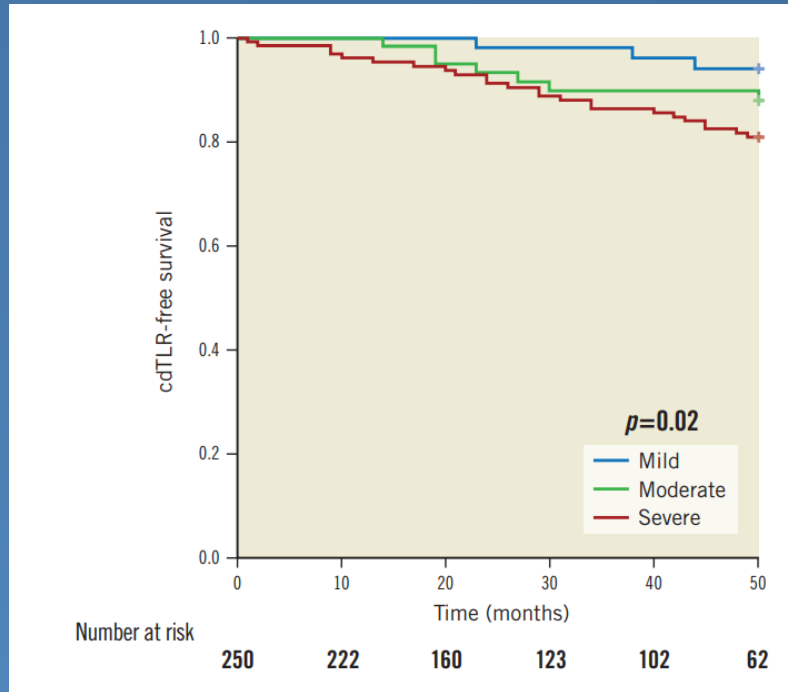
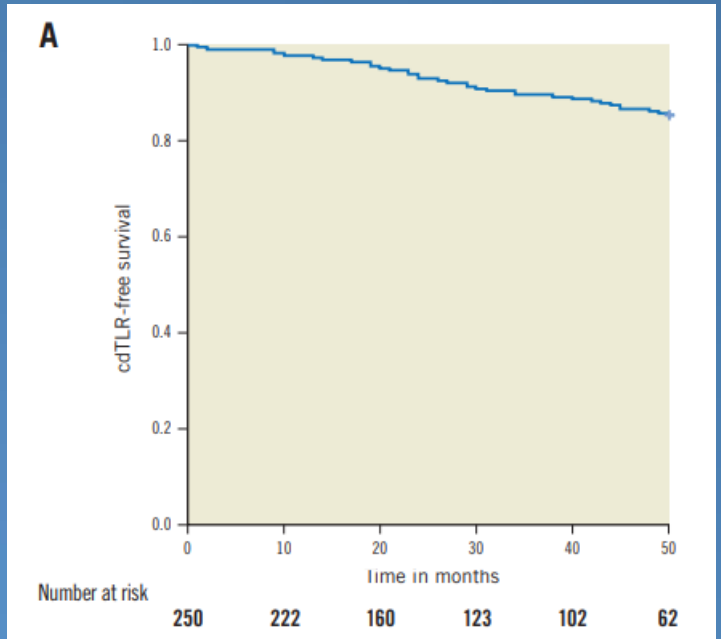
Advantages of Atherectomy-assisted endovascular repair:

- Vessel anatomy and physiology can be preserved.
- Vessel compliance can be improved
- Treatment can be performed minimally invasive without open surgery.
- Re-Interventions may be easier without implanted stents, access sites can be preserved.
- Potential bypass landings zones can be preserved.



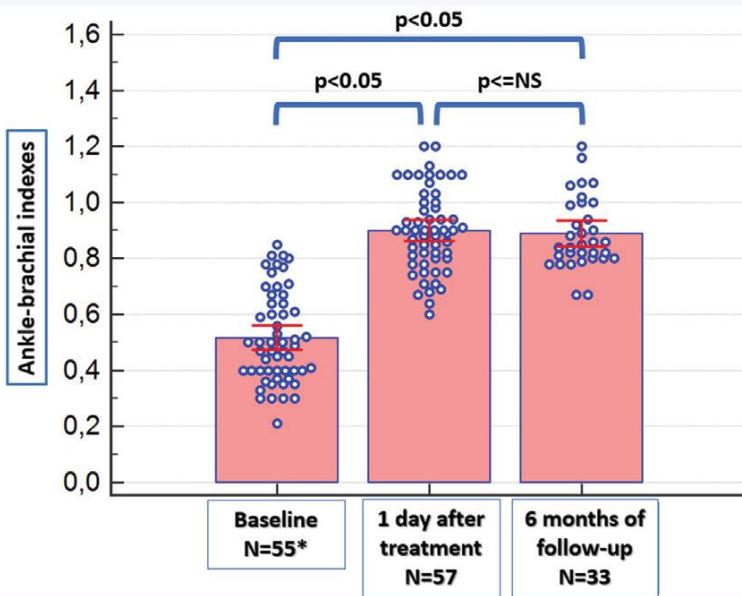
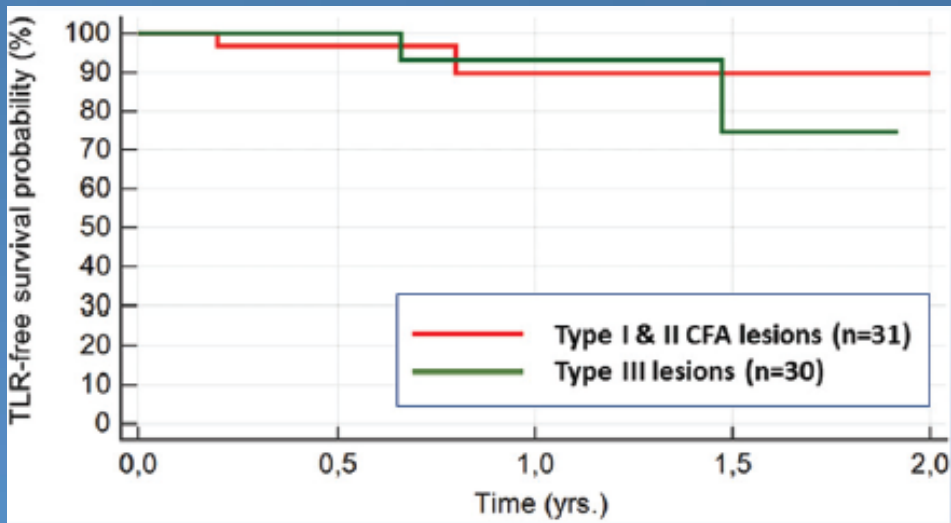
Current evidences for atherectomy:

Retrospective analysis of 250 patients treated with DAART



56 CFA lesions treated with Phoenix

Current evidences for atherectomy:



* 55 measures in 61 limbs available, after exclusion of 2 patients with acute limb ischemia, who did not tolerate pressure cuff before the intervention and 4 additional patients with ABI values > 1.3 due to media sclerosis.

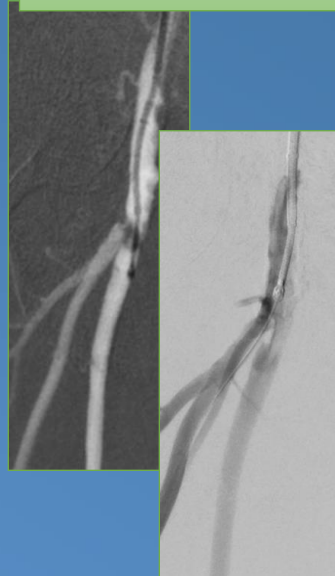


Clinical case 1 (CFA)
7F (2.4mm) deflecting catheter

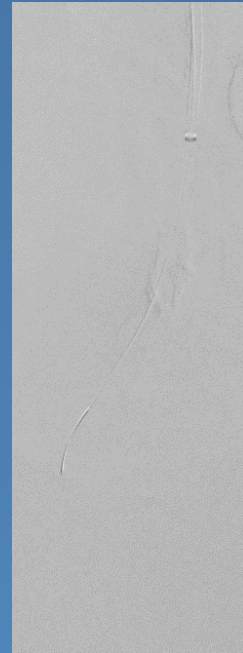
♂, 68 yrs., RF 3

Final result without
stenting

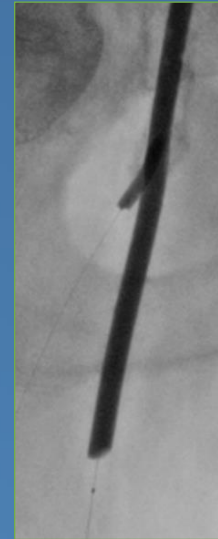
Atherectomy both of
the SFA and DFA



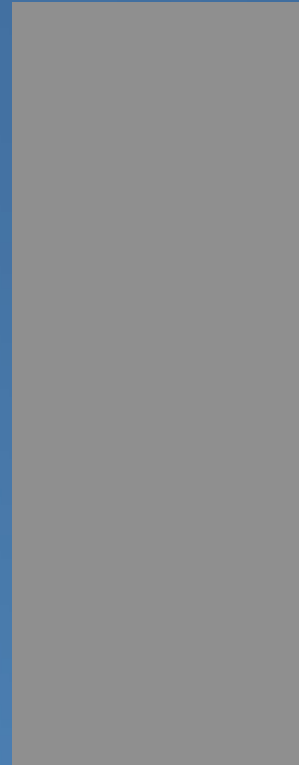
Type III
Lesion at the



After multiple
atherectomy passages



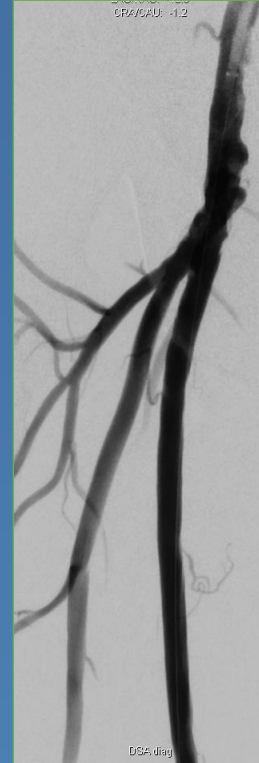
DCB and kissing balloon
angioplasty



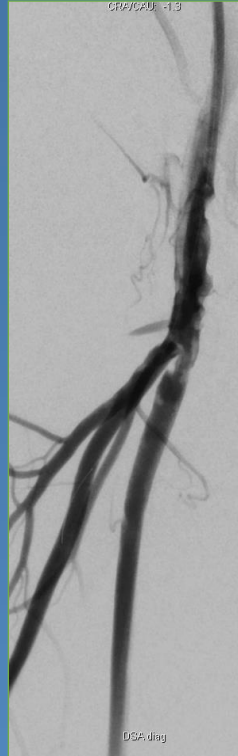
Type III
Lesion at the
Femoral bifurcation



Final result without
stenting



After multiple
atherectomy passages



Objective: To investigate the safety and effectiveness of the endovascular and open revascularization techniques for the treatment of consecutive patients with CFA lesions within a real-world registry. Patients will be included with claudication or rest pain/CLTI RC5 due CFA stenosis or occlusion.

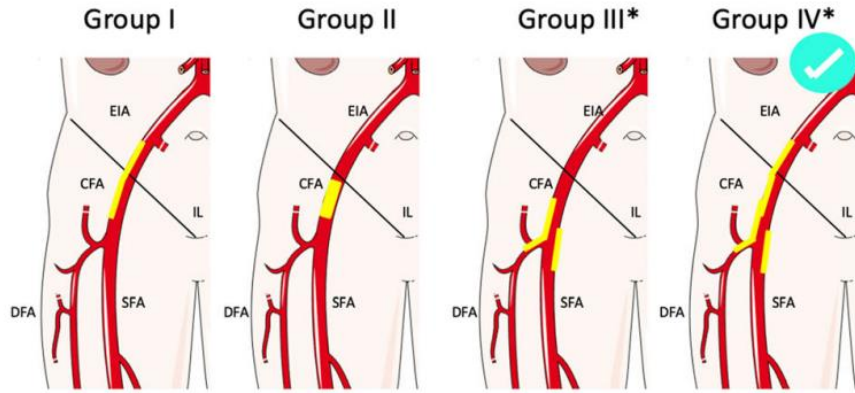
Outcomes: Improvement in terms of Rutherford category, clinically driven TLR

Study design: multi-center, retrospective observational study.

Study period: 01.01.2015 – 31.12.2021

Study population: All comers >18 years with symptomatic PAD.





Assess:

1) Bifurcation lesion

2) Occlusion

3) Calcification

Stenosis

Mild or Moderate Calcification

S

D

B

Occlusion

Heavy Calcification

* Stenosis may affect the SFA, DFA or both

CFA occlusive disease classification, as described by Rabellino et al (1) for type I, II and subclassifying type III CFA lesions. In addition, information is provided on the presence of CTO and on lesion calcification.

1. Rabellino M, Valle Raleigh J, Chiabrando JG, Di Caro V, Chas J, Garagoli F, Bluro I. Novel Common Femoral Artery Lesion Classification in Patients Undergoing Endovascular Revascularization. *Cardiovasc Intervent Radiol*. 2022 Apr;45(4):438-447.



Inclusion criteria

1. Symptomatic PAD RC 2, 3 or 4,5.
2. CFA de novo or after prior surgery (recurrent) stenosis (with or without inclusion of the femoral bifurcation) >70% (visual estimate) or occlusion;
3. Angiographic or CTA evaluation of CFA lesion based on the CFA occlusive disease classification available based on the novel CFA lesion classification, as recently proposed by **Rabellino et al**
4. At least 1 vessel outflow artery.
5. **Endovascular Procedure:** successful target lesion crossing of the guidewire (guidewire passed intraluminally). Isolated POBA, primary stenting, or vessel preparation by all available types of lesion preparation by scoring/cutting balloon, atherectomy in first line or with intravascular lithotripsy and additional use of POBA, DCB, scoring balloon or combination treatment of the above-mentioned options is allowed.
6. **Surgical revascularization** techniques included patch endarterectomy or direct suture of the common femoral artery with or without involvement of the distal portion of the external iliac artery and femoral bifurcation. Hybrid approach with stenting of the common iliac artery to optimize inflow in the CFA is allowed.
7. Ipsilateral treatment of significant iliac disease within or prior to the index session is mandatory. Ipsilateral femoropopliteal disease (only TASC A, B or C lesions) is allowed.



Exclusion Criteria:

Evidence of thrombus within target vessel or thrombolysis within 72 hours prior to the index procedure.

Ipsilateral femoropopliteal TASC D lesions (data will be included in the CFA registry).

Patients with CLTI and Rutherford 6 category (data will be included in the CFA registry).

Predefined subgroups:

Patient specific: Octogenarians >80yrs. of patients >70yrs. with significant comorbidities such as symptomatic heart failure, unstable coronary or carotid disease.

Lesion specific: Patients with CFA lesions including the femoral bifurcation versus isolated CFA lesions.

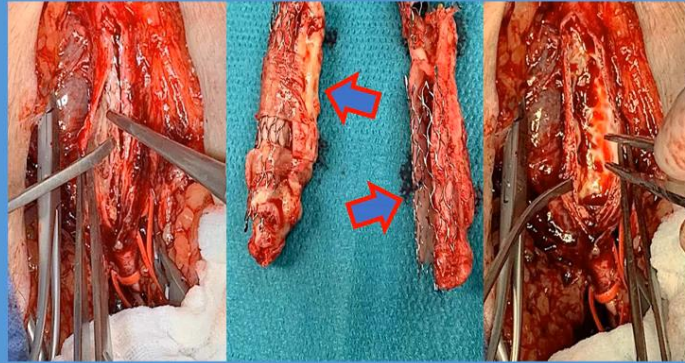


Outcome measures (12 months of follow-up):

- Clinical driven reintervention (TLR).
- Restenosis confirmed by ABI or by duplex sonography.
- Periprocedural and 30-day mortality.
- **Endovascular** (pseudoaneurysm or bleeding requiring surgery, perforation, symptomatic peripheral embolization with clinical impairment in the deep femoral artery or in the popliteal/tibial vessels) and
- **Surgical** complications (wound complications (lymphorrhea, lymphocele) needed re-operations, VAC placement, persistent nerve irritation influencing quality of life).
- Length of hospital stay & major adverse events during hospital stay
- Clinical improvement defined as cumulative improvement of 1 class by RC.



Endarterectomy – when does surgery remain the gold standard?



Atherectomy – When is it an alternative for the groin?

