Le stenting est le traitement de référence des lésions athéromateuses de novo de l'artère fémorale commune

Y. Gouëffic, MD, PhD

Department of vascular surgery, University hospital of Nantes, France

Disclosure

Research grants /Consulting/Honoraria for

Abbott
Bard
Biotronik
Boston Scientific
Cook
Medtronic
Perouse
Spectranetics
Terumo
WL Gore

Patient history in 2004

Symptomatology

- CLI of the left foot (Rutherford 4)

Medical history

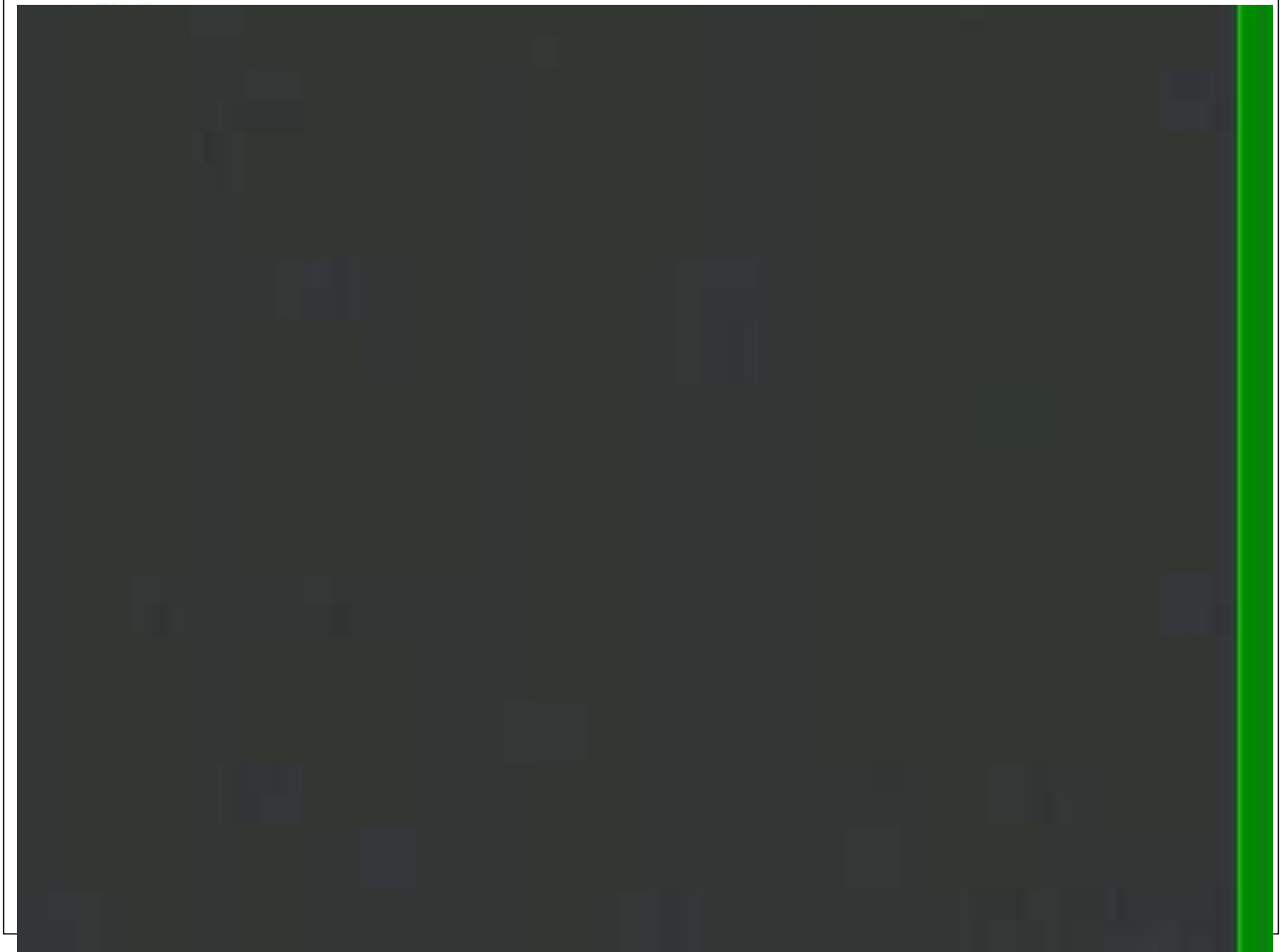
- Dislipidemia, HTA, active smoking
- Peripheral arterial disease
- Coronaropathy
- Heart failure (30%)

Duplex scan

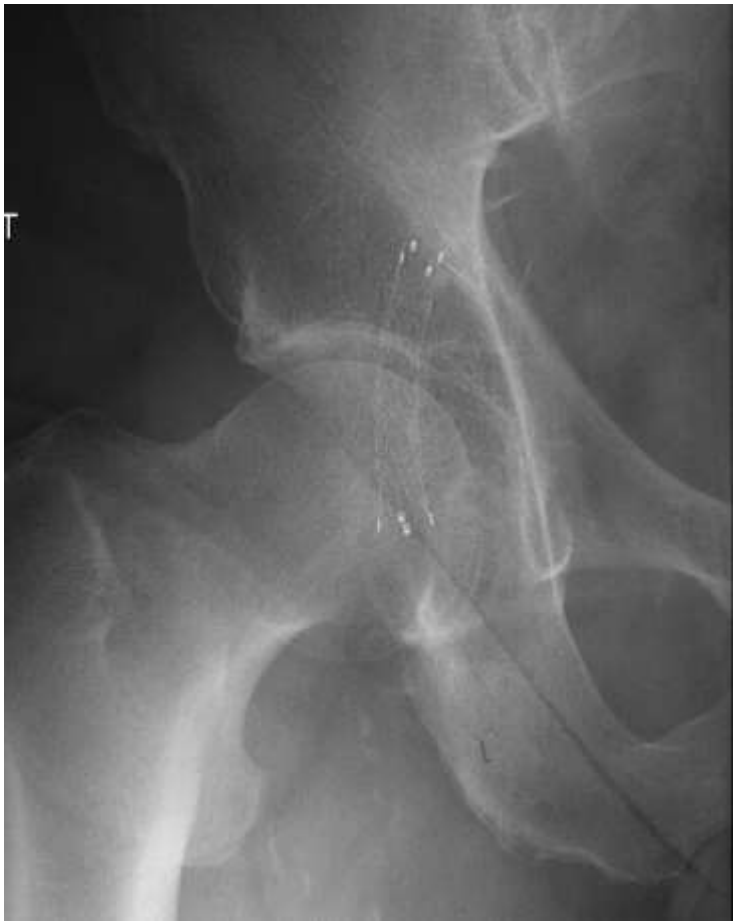
- Common femoral stenosis

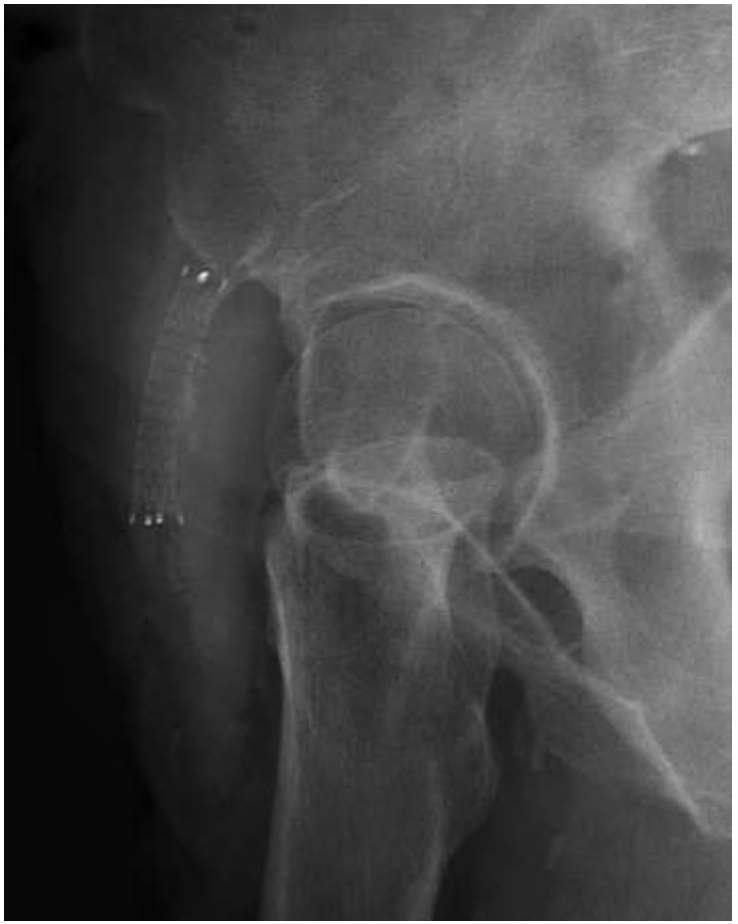
Procedure

- Stenting of the common femoral artery

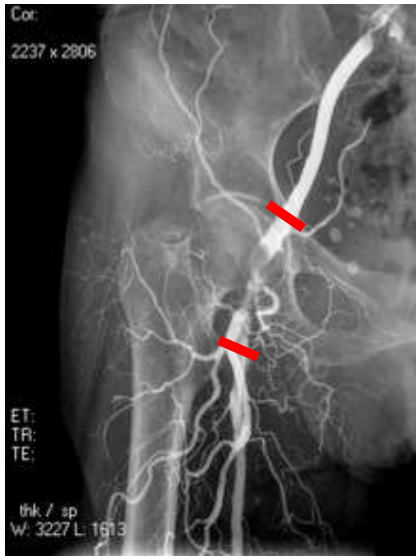
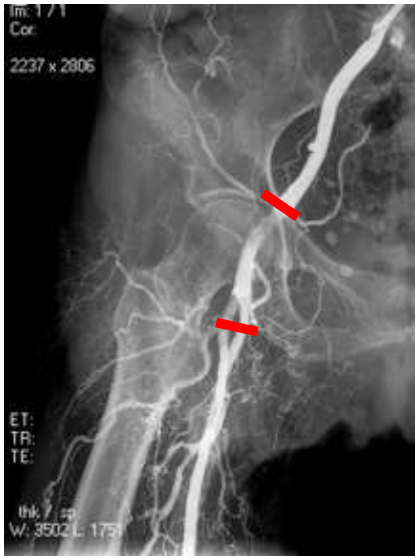
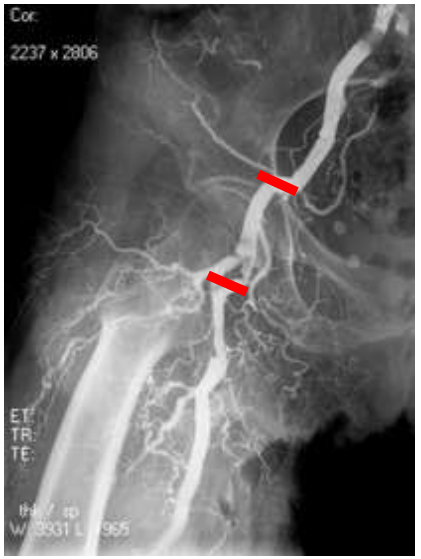
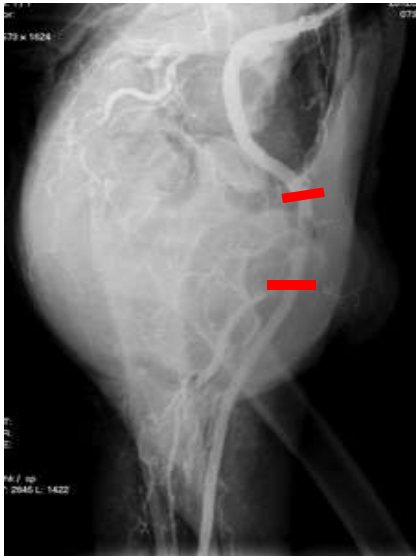
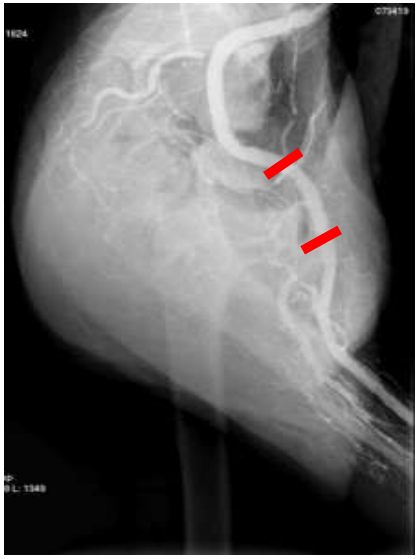
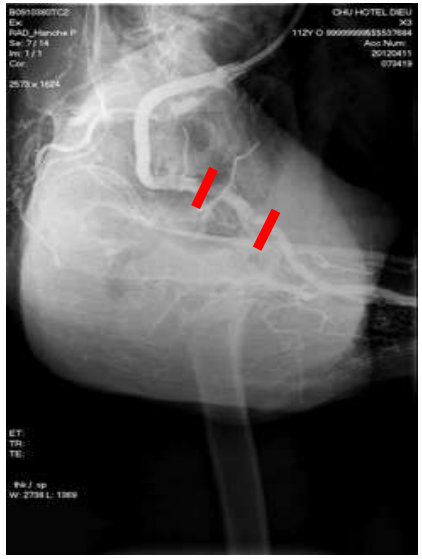


2 years later...





CFA is fixed

	Extension	45° flexion	90° flexion
FACE			
PROFILE			

Scaffolding to avoid crush

Contents lists available at ScienceDirect

Atherosclerosis

journal homepage: www.elsevier.com/locate/atherosclerosis

Carotid and femoral atherosclerotic plaques show different morphology☆

Fanny Hérisson[a,b,c,1], Marie-Françoise Heymann[a,b,d,1], Maud Chétiveaux[b,e], Céline Charrier[a,b], Séverine Battaglia[a,b], Paul Pilet[b,e], Thierry Rouillon[b,e], Michel Krempf[b,f,g], Patricia Lemarchand[b,g,h], Dominique Heymann[a,b], Yann Gouëffic[b,f,g,h,i,*]

Eur J Vasc Endovasc Surg (2015) ■, 1–9

Bone Like Arterial Calcification in Femoral Atherosclerotic Lesions: Prevalence and Role of Osteoprotegerin and Pericytes

L-M. Davaine[a,b,c,1], T. Quillard[a], M. Chatelais[a,d], F. Guilbaud[a,e], R. Brion[a,e], B. Guyomarch[a,f], M.Á. Brennan[a], D. Heymann[a,g], M.-F. Heymann[a,g,*], Y. Gouëffic[a,f,*]

WHAT THIS PAPER ADDS

Arterial calcification is very common in arterial lesions and has a major clinical impact. Though recognized as being a highly regulated process, most knowledge is based on studies at the coronary or carotid levels. This work provides detailed analysis of the presence of bone like arterial calcification—known as osteoid metaplasia (OM)—at the femoral level and suggest a high prevalence of OM in femoral atherosclerotic lesions. It further suggests that vascular pericytes and the osteoprotegerin/receptor activator for the nuclear factor kappa B ligand (RANKL)/RANK axis are implicated in the regulation of arterial calcification.

Objective/Background: Arterial calcification, a process that mimics bone formation, is an independent risk factor of cardiovascular morbidity and mortality, and has a significant impact on surgical and endovascular procedures and outcomes. Research efforts have focused mainly on the coronary arteries, while data regarding the femoral territory remain scarce.

Methods: Femoral endarterectomy specimens, clinical data, and plasma from a cohort of patients were collected prospectively. Histological analysis was performed to characterize the cellular populations present in the atherosclerotic lesions, and that were potentially involved in the formation of bone like arterial calcification known as osteoid metaplasia (OM). Enzyme linked immunosorbent assays and cell culture assays were conducted in order to understand the cellular and molecular mechanisms underlying the formation of OM in the lesions.

Results: Twenty-eight of the 43 femoral plaques (65%) displayed OM. OM included osteoblast and osteoclast like cells, but very few of the latter exhibited the functional ability to resorb mineral tissue. As in bone, osteoprotegerin (OPG) was significantly associated with the presence of OM ($p = .04$). Likewise, a high plasma OPG/receptor activator for the nuclear factor kappa B ligand (RANKL) ratio was significantly associated with the presence of OM ($p = .03$). At the cellular level, there was a greater presence of pericytes in OM+ compared with OM− lesions (5.59 ± 1.09 vs. 2.42 ± 0.58, percentage of area staining [region of interest]; $p = .04$); *in vitro*, pericytes were able to inhibit the osteoblastic differentiation of human mesenchymal stem cells, suggesting that they are involved in regulating arterial calcification.

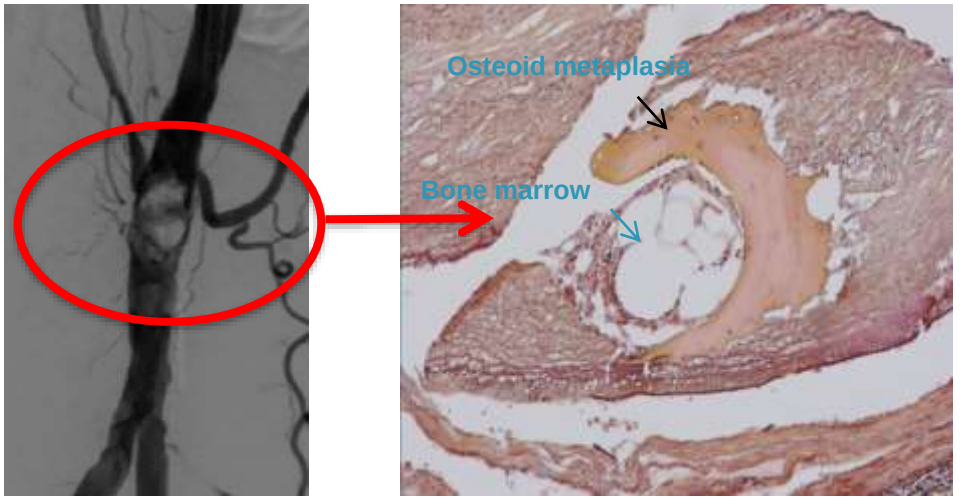
Conclusion: These results suggest that bone like arterial calcification (OM) is highly prevalent at femoral level. Pericyte cells and the OPG/RANK/RANKL triad seem to be critical to the formation of this ectopic osteoid tissue and represent interesting potential therapeutic targets to reduce the clinical impact of arterial calcification.

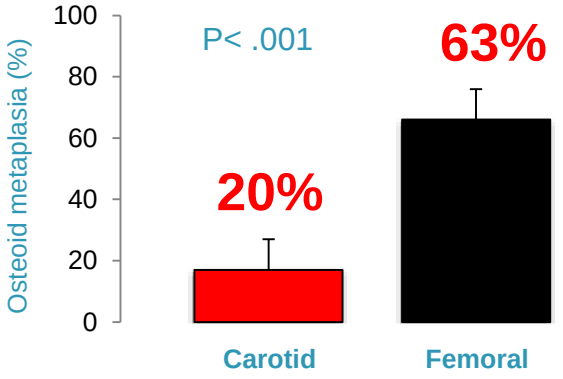
Article history: Received 12 May 2015, Accepted 5 October 2015, Available online XXX

Keywords: Atherosclerosis, Femoral artery, Osteoprotegerin, Peripheral arterial disease, Vascular calcification, Vascular pericytes

INTRODUCTION

The prevalence of arterial calcification in atherosclerotic lesions has been reported to be as high as 90% and is identified as an independent risk factor for cardiovascular mortality.[1,2] Arterial calcification also has an impact on





Hérisson, Atherosclerosis, 2011

Davaine, Eur J Vasc Endovasc Surg, 2015

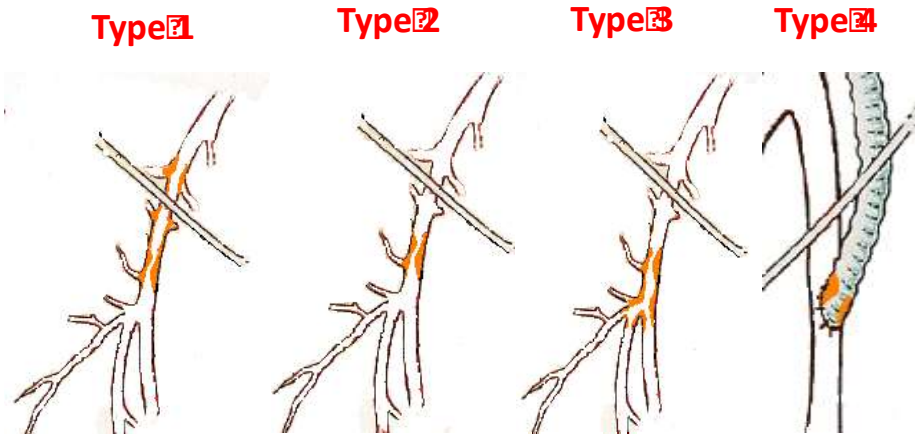
Pilot study 2006-2008

40 limbs – Primary stenting

Endovascular Repair of Common Femoral Artery and Concomitant Arterial Lesions

L. Azéma [a], J.M. Davaine [a], B. Guyomarch [b], P. Chaillou [a], A. Costargent [a], P. Patra [a], Y. Gouëffic [a,*]

Azéma, Eur J Vasc Endovasc Surg, 2011



Perioperative morbi-mortality rate: 5%

Iy clinical improvement @ 1y: 80%

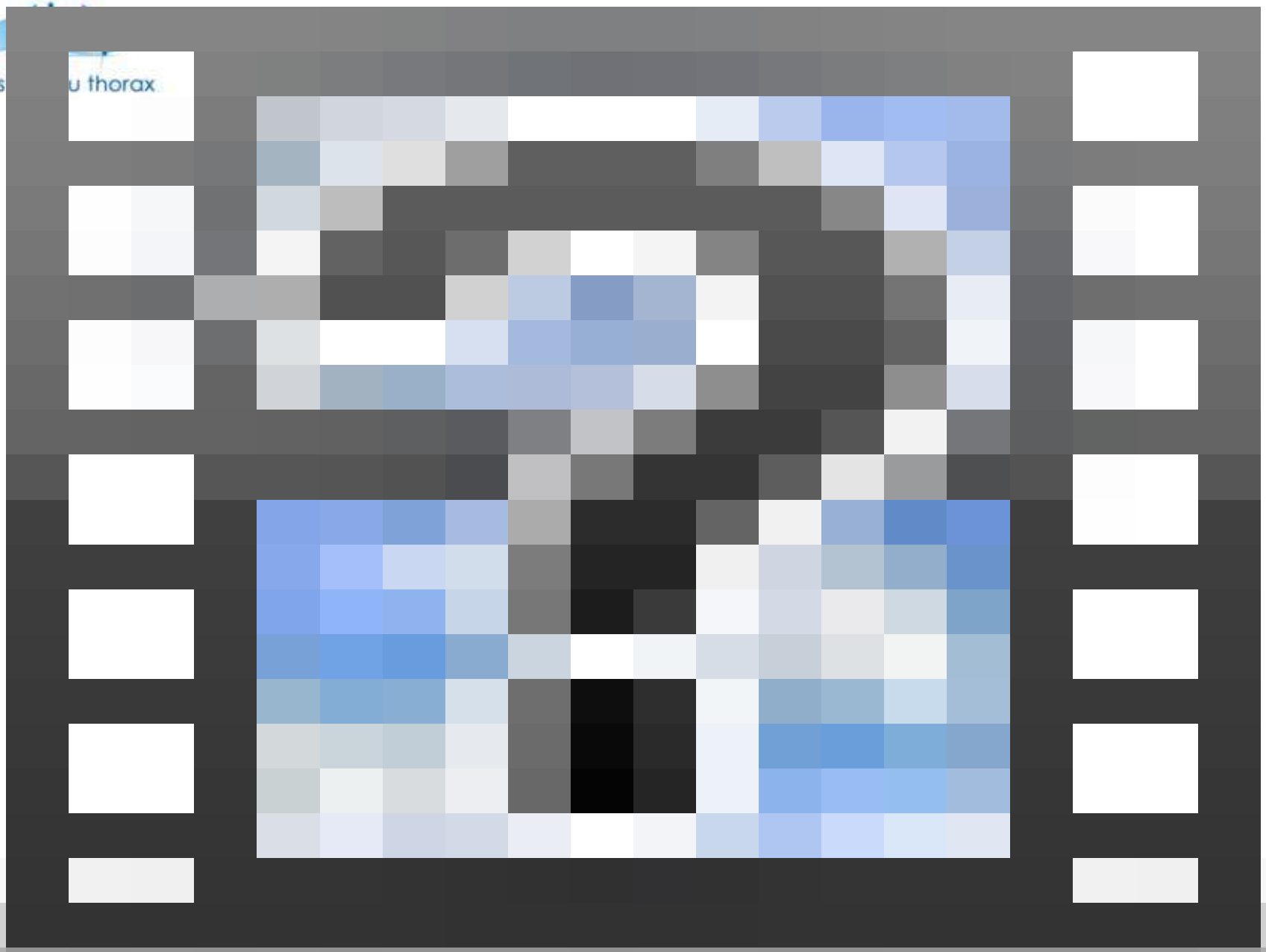
TLR free @ 1-y: 85%

In-stent restenosis rate*: 20%

Stent fracture: 2.5%**

**** Defined systolic velocity peak index > 2.4***

***** according Jaff M., Catheter Cardiovasc Interv 2007***



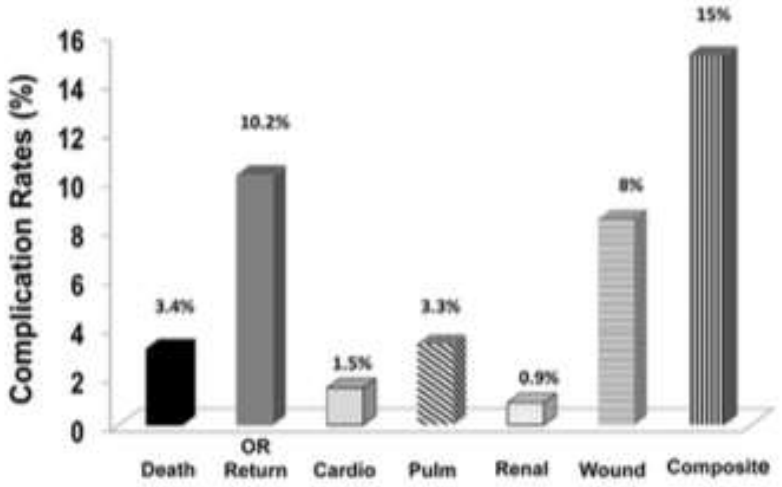
CFA stenting, why not ?

- Surgery is « easy »
- Angioplasty alone ?
- Stent fracture, durability ?
- Calcifications ?
- No compromise future approaches

Postoperative complications after common femoral endarterectomy

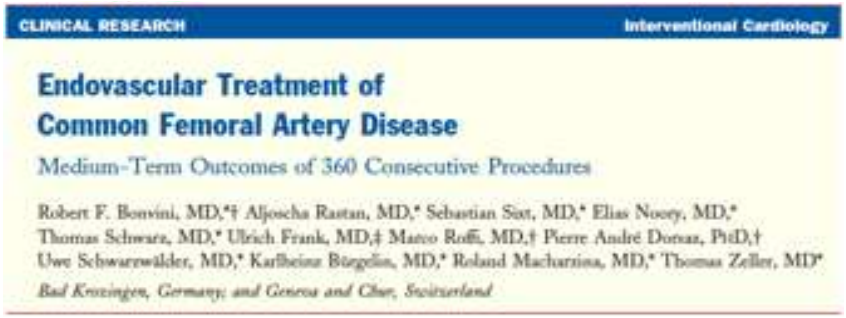
Bao-Ngoc Nguyen, MD, Richard L. Amdur, PhD, Mustafa Abugideiri, BS, Rodeen Rahbar, MD, Richard F. Neville, MD, and Anton N. Sidawy, MD, MPH, *Washington, D.C.*

- **1843 CFEs, Diabetes: 33%; CLI: 36%**
- **CFE between 2005-2010 from the ACS-NSQIP database**
- **Perioperative morbimortality outcomes before and after hospital discharge**
- **Morbi-mortality rates 15%**
- **Average length of stay : 4.6 ± 7.5 d**



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.)

Bao-Ngoc, J Vasc Surg, 2015



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 Donzas, PhD,† Uwe Schwarzwälder, MD,* Karlheinz Bürgelin, MD,* Roland Macharzina, MD,* Thomas Zeller, MD*

Bad Krozingen, Germany, and Geneva and Chur, Switzerland

Journal of Vascular Surgery

Volume 53, Issue 4, April 2011, Pages 1000–1006

ELSEVIER

Endovascular treatment of common femoral artery obstructions

Frederic Baumann, MD,* Mirka Ruch,* Torsten Willenberg, MD,* Florian Dick, MD,† Dai-Do Do, MD,* Hak-Hong Kee, MD,* Iris Baumgartner, MD,* and Nicolas Diehm, MD,* *Berne, Switzerland*

Key findings:

- 360 limbs / CLI: 22.1%
- Lost of FU @ 10mo: 12.2%
- Perioperative complications: **6.4%**
- Restenosis rate: 27.6%
- TLR: 19.9%

The use of stents was identified as the only independent protective factor against procedural failure, TLR and 1-year restenosis

Bonvini, JACC, 2011

Key findings:

- 98 limbs / CLI: 19%
- De novo / restenosis: 85/15%
- Perioperative complications: **6.4%**
- Bailout stenting: 27%
- TLR: 17/46%

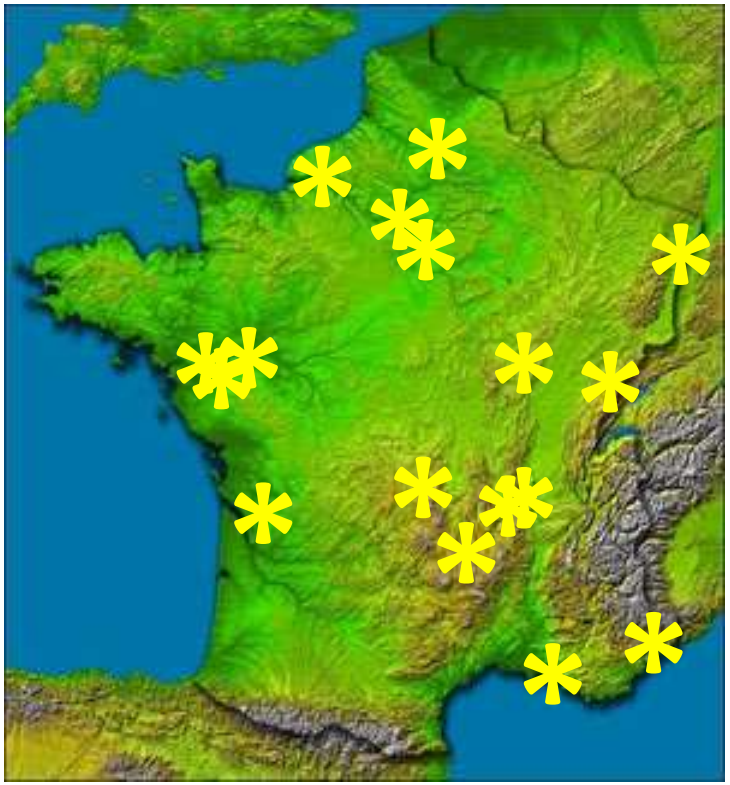
Primary sustained clinical improvement was significantly better in patients in whom stents had been implanted

Baumann, J Vasc Surg, 2011

TECCO trial

French multicenter randomized trial comparing surgery versus stenting for the treatment of CFA atherosclerotic lesion ***(From 2011 to 2015)***

(NCT01353651)



Gouëffic, JACC Interv, 2017

TECCO trial, NCT01353651
Sponsor Nantes University Hospital
PHRC 2010 DGOS 20-03

17 centers : CHU de Nantes (N° 1), CHU de Amiens (N° 2), CHU Besançon (N° 3), CHU de Strasbourg (N° 4), CHU de Dijon (N° 5), CHU de Clermont-Ferrand (N° 6), CHU de Nice (N° 7), CHU de Marseille (La Timone) (N° 8), CHU de Bordeaux (N° 9), CHU de Lyon (N° 10), CHU de St Etienne (N° 11), CHU de Rouen (N° 12), Clinque du Tonkin (N° 13), Nouvelles Cliniques Nantaises (N° 14), Clinique St Augustin (N° 15), HEGP (N° 16),) Hopital Henri Mondor (N° 17)

TECCO trial protocol

Sponsor Nantes University Hospital - *TECCO trial, NCT01353651*

- **Investigator initiated study**
- **RCT multicenter and controlled**
- **Rigorous data collection process, independent**
- **Adjudication by:**
  - *Duplex ultrasound core laboratory*
  - *Data safety monitoring board*
- **Follow-up includes**
  - 1, 6, 12, and 24-month clinical assessment
  - 1, 12 and 24-month stent x-ray
- **Monitoring with 100% source data verification**

- **Modified intent to treat analysis / Per protocol analysis**
- **Sample size calculation: 120 patients**
- **Randomly assigned in a 1:1 ratio**
- **80% power** ***to detect a between-group difference of 20% percentage points in the morbid-mortality rate at a two-sided alpha level of 0.05 (25% in the surgery group and 5% in the stenting group).***

Population

Main inclusion criteria

- Age between 40 and 90 years-old
- De novo atheromatous common femoral artery stenosis
-Rutherford stages 3 to 6

Main exclusion criteria

-Restenosis

-Thrombosis

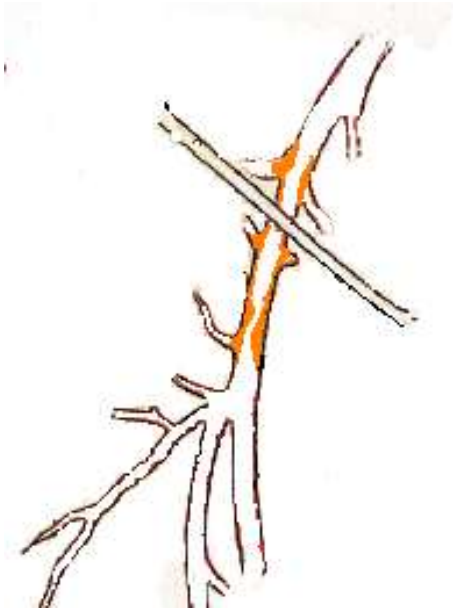
- No atheromatous disease

- Asymptomatic lesion

-Life expectancy < 1 year

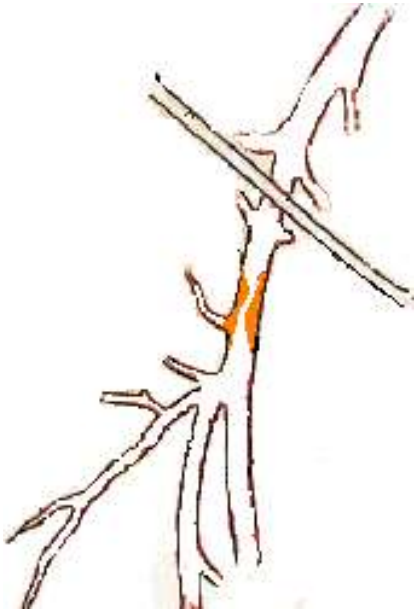
CFA lesions classification

Type 1



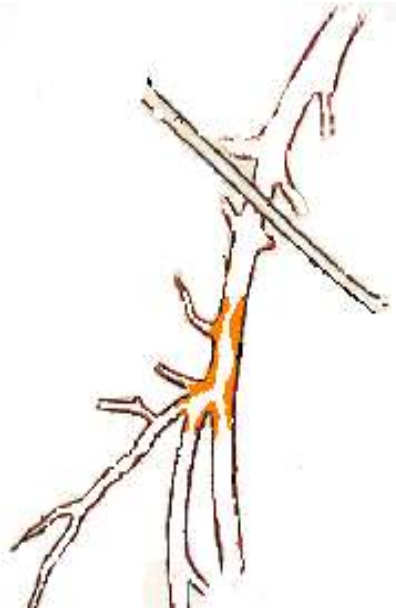
Nitinol

Type 2



Nitinol

Type 3



Nitinol and/or BES

Type 4

Nitinol

Azema, Eur J Vasc Endovasc Surg, 2011

Procedures

Open repair

At the discretion of the physician (bypass, endarteriectomy…)

Endovascular repair

- Anaesthesia: at the discretion

- Over the bifurcation, ipsilateral or brachial approaches

- Primary stenting

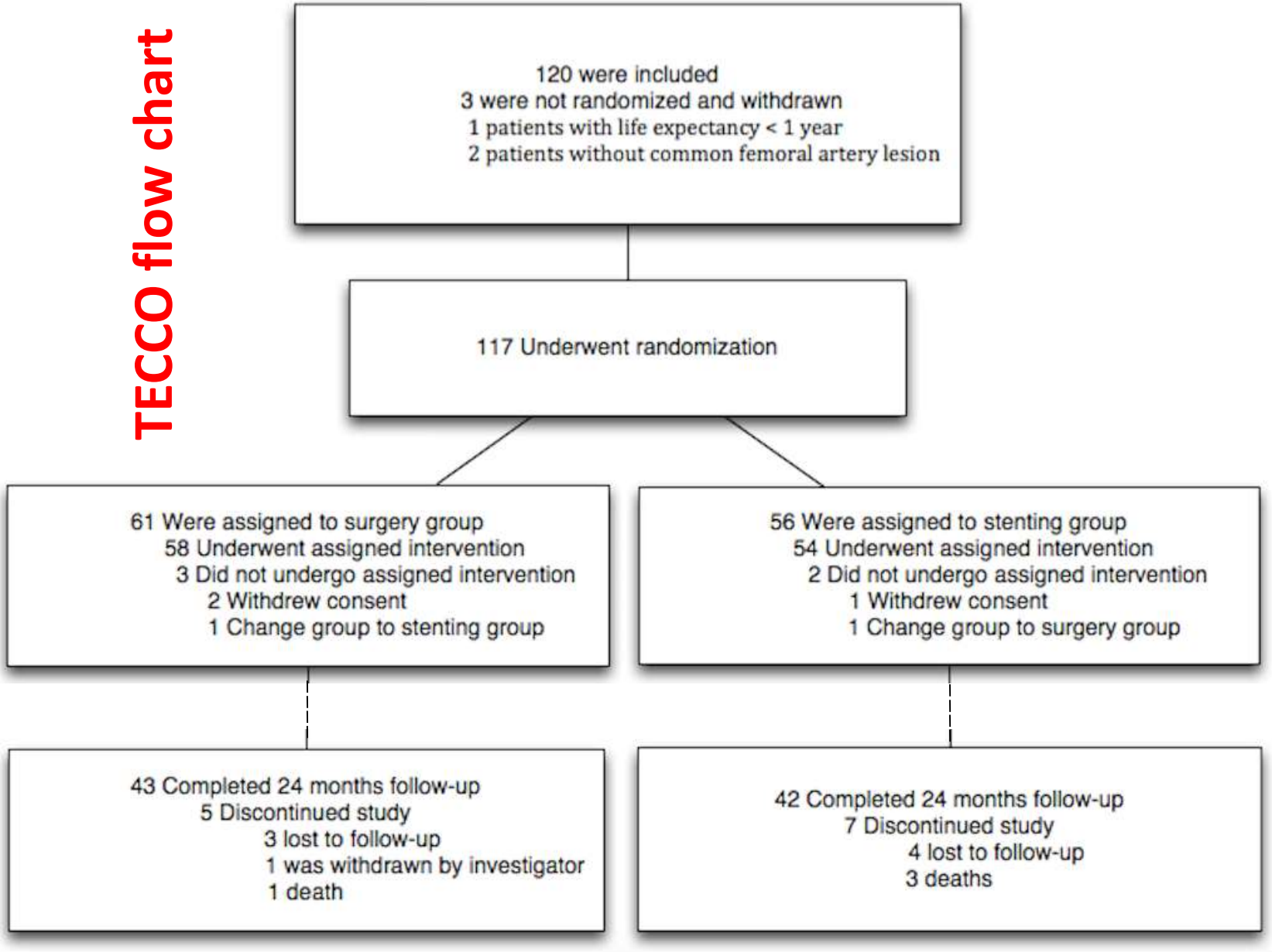
- Antiplatelet treatment: at the discretion

TECCO primary endpoint

Morbid-mortality rate at 1 month

- General complications: *death, MACEs, major amputation*
- Local complications that required rehospitalization and/or reintervention: *hematoma, thrombosis, lymphorrhea, delayed wound healing, false aneurysm, AVF*
- Paresthesia that required drugs

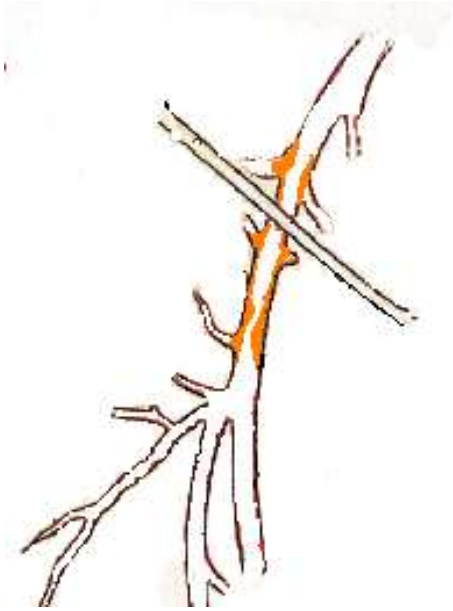
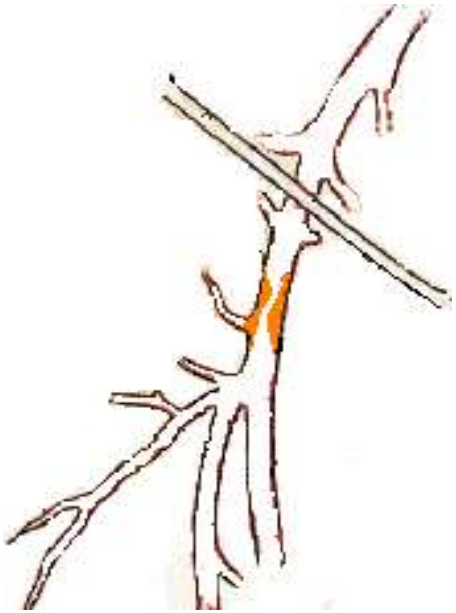
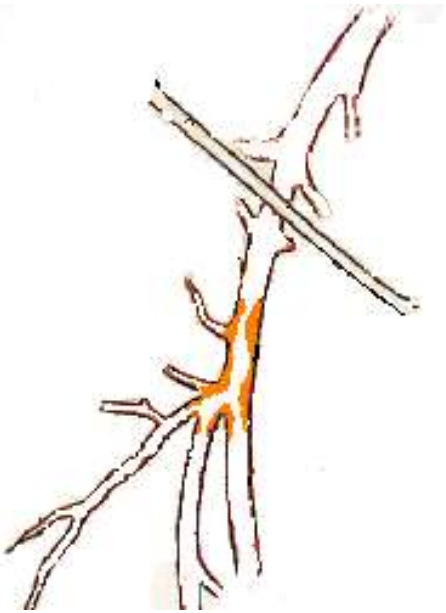
TECCO flow chart



Demographic data

Characteristic	*Surgery (N=61)*	*Stenting (N=56)*
Age – yr	**68 ± 8**	**68 ± 9**
Male sex – no. (%)	51 (84)	48 (86)
Hypertension – no (%)	44 (72)	45 (80)
Hyperlipidemia – no (%)	40 (66)	37 (66)
Diabetes mellitus – no (%)	**25 (41)**	**17 (31)**
Smoking at baseline – no (%)	28 (46)	26 (46)
Coronary artery disease – no (%)	28 (46)	27 (48)
Renal insufficiency – no (%)	**8 (13)**	**6 (11)**
On dialysis – no (%)	1 (13)	1 (17)	
Obesity (BMI > 25) – no (%)	39 (64)	31 (58)
Statin treatment – no (%)	50 (82)	38 (68)
Antiplatelet drug – no (%)	57 (93)	50 (89)
ACE inhibitor – no (%)	19 (31)	22 (39)
Rutherford stage of PAD – no (%)		
???? 2	**2 (3)**	**1 (2)**
???? 3	**54 (89)**	**44 (80)**
???? 4	5 (8)	7 (13)
???? 5	0 (0)	3 (5)

TECCO lesions characteristics

	Type 1	Type 2	Type 3
			
Surgery (%):	**6 (10)**	**21 (34)**	**34 (56)**
Stenting (%):	**9 (16)**	**13 (23)**	**34 (61)**

Intraoperative data

Surgery (N=58)	
Endarterectomy	46 (69)
with venous patch (%)	7 (12)
with prosthetic patch (%)	37 (64)
direct suture (%)	2 (3)
Bypass with a prosthesis	11 (19)
Eversion	1 (2)

Stenting (N=54)	
Crossover access – no. (%)	43 (78)
Brachial access – no. (%)	7 (13)
Femoral ipsilateral – no. (%)	4 (7)

Primary endpoint

Modified intent to treat analysis

	Surgery (n=61)	Stenting (n=56)	p
Morbid-mortality rate @ 1 month, n (%)	16 (26)	7 (12.5)	0.05

Per protocol analysis

	Surgery (n=58)	Stenting (n=47)	p
Morbid-mortality rate @ 1 month, n (%)	16 (26)	3 (6.4)	0.005

General complications

(Modified intent to treat analysis)

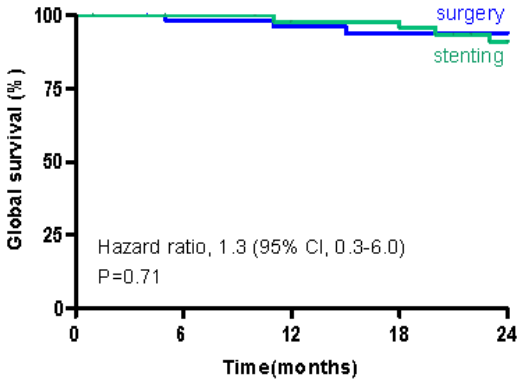
	Surgery (N=61)	*Stenting (N=56)*
Death, n(%)	***0 (0)***	***0 (0)***
Stroke, n(%)	***0 (0)***	***1 (1.8)***
Myocardial infarction, n(%)	***0 (0)***	***0 (0)***
Major amputation, n(%)	***0 (0)***	***0 (0)***

Local complications

(Modified intent to treat analysis)

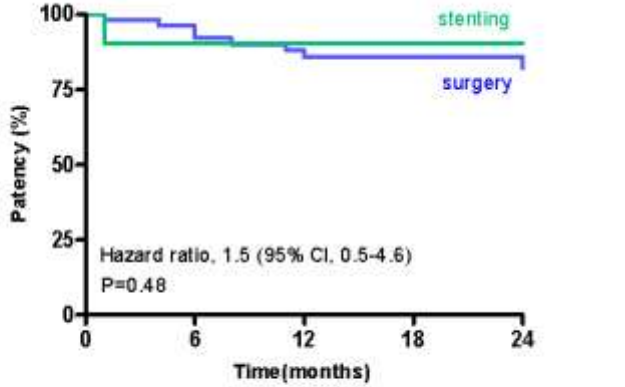
	Surgery (N=61)	*Stenting (N=56)*
Hematoma	*3 (5)*	*0 (0)*
Thrombosis	*0 (0)*	*1 (1.8)*
Lymphorrhea	*2 (3.2)*	*0 (0)*
Delayed wound healing	*10 (16.4)*	*0 (0)*
False aneurysm	*0 (0)*	*0 (0)*
Arteriovenous fistula	*0 (0)*	*0 (0)*
Paresthesia	*4 (6.5)*	*0 (0)*
Local infection	*3 (5)*	*1 (1.8)*
Vascular perforation	*0 (0)*	*1 (1.8)*

Survival @ 24 months



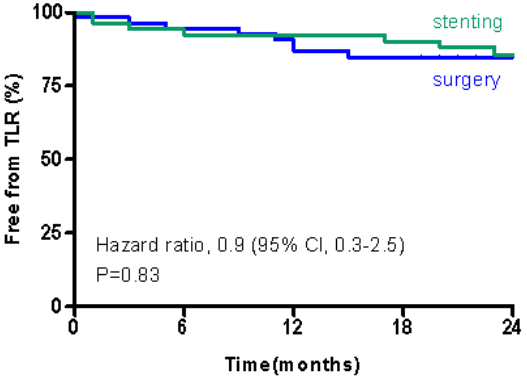
No. at Risk					
Surgery	59	52	48	44	30
Stenting	55	55	46	45	31

Patency @ 24 months



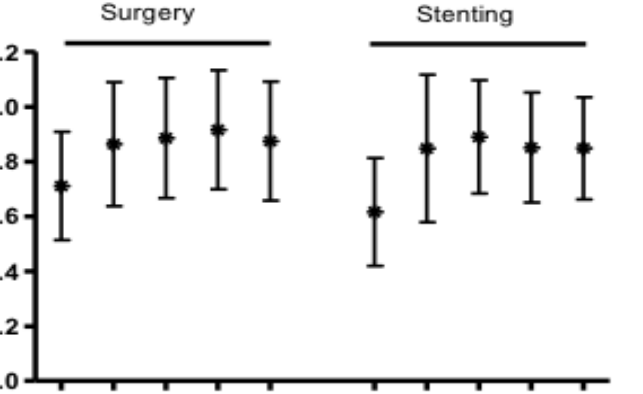
No. at Risk					
Surgery	59	48	41	37	24
Stenting	55	48	36	35	22

Freedom from TLR @ 24 months

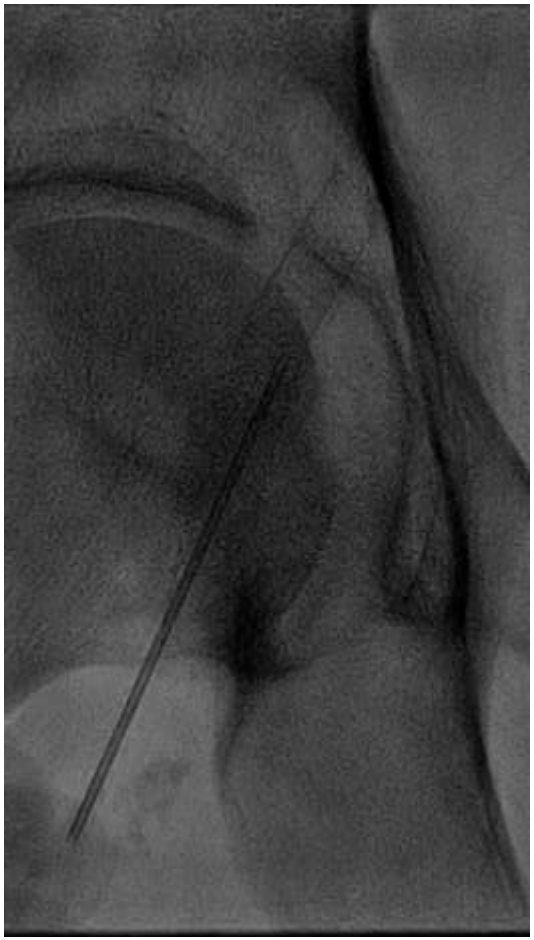


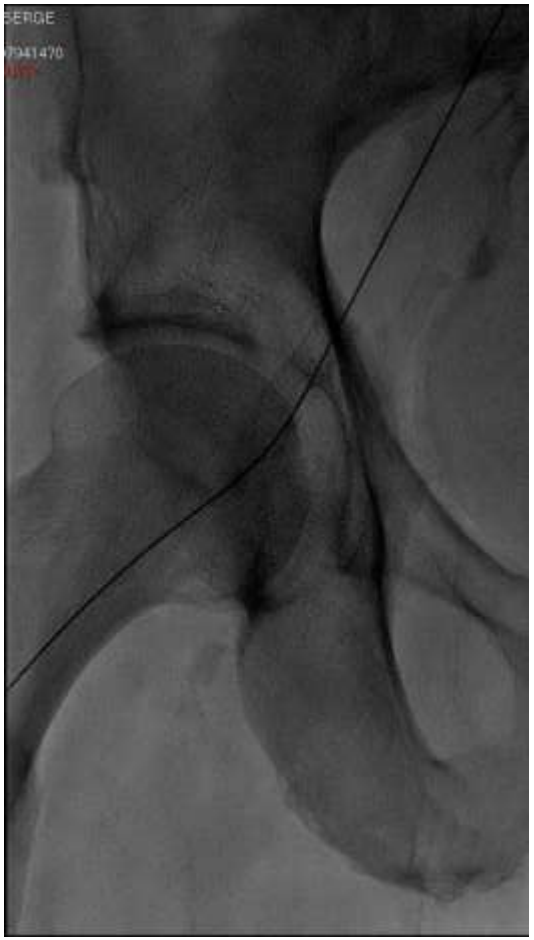
No. at Risk					
Surgery	59	51	47	40	26
Stenting	55	48	46	42	27

Haemodynamic improvement @ 24 months



Stented CFA puncture is possible and safe





l'institut du thorax

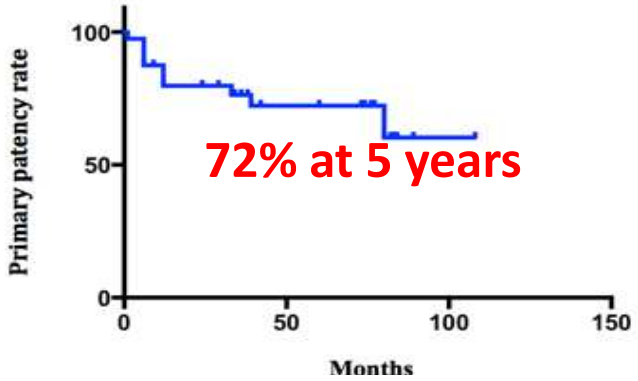
Long-Term Outcomes of Common Femoral Artery Stenting

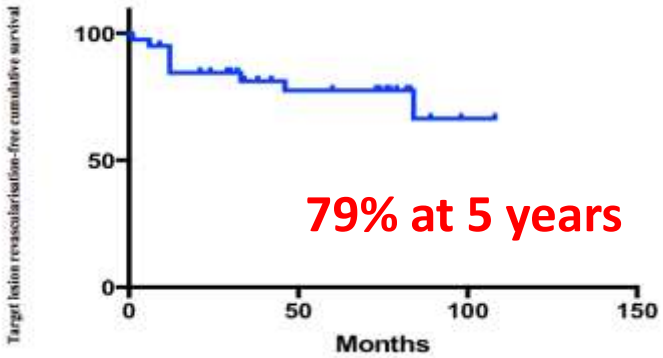
Bahaa Nasr, Adrien Kaladji, Pierre-Alexandre Vent, Philippe Chaillou, Alain Costargent, Thibault Quillard, Yann Gouëffic

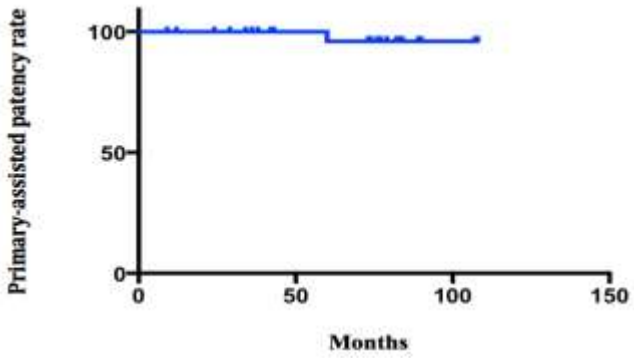
PlumX Metrics

DOI: http://dx.doi.org/10.1016/j.avsg.2016.07.088 | CrossMark

At 5 years of FU:
Iy clinical improvement was 73%
Freedom from TLR: 79%
7 open reinterventions
4 endo reinterventions







Conclusions: Endovascular repair of the common femoral artery and its bifurcation seems to provide sustained clinical and morphological long-term results. Fear of stent fracture and local complications due to hip mobility are no longer relevant.

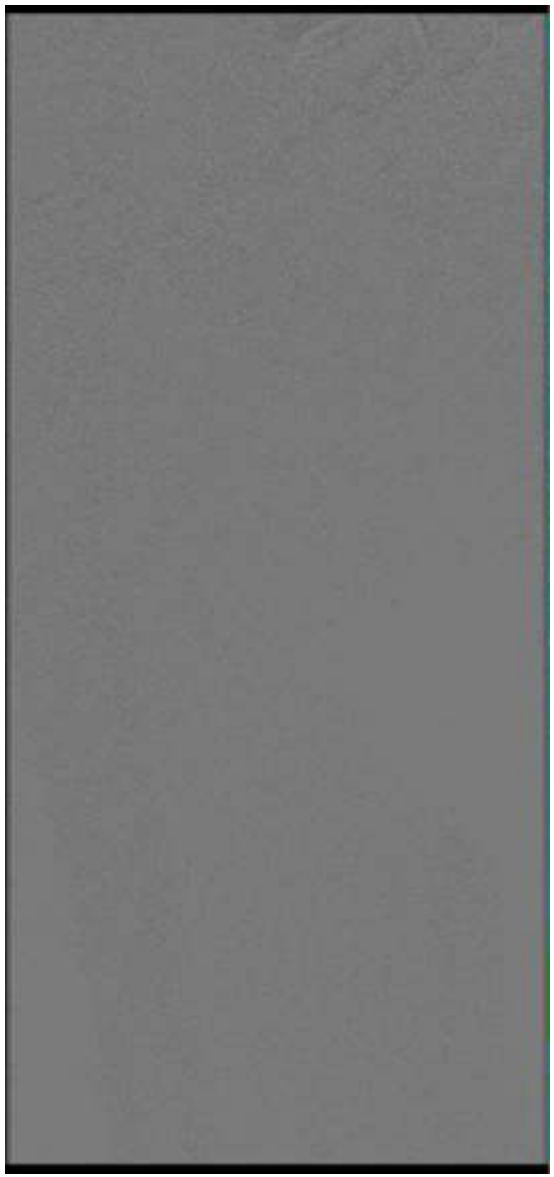
Nasr, Ann Vasc Surg, 2016

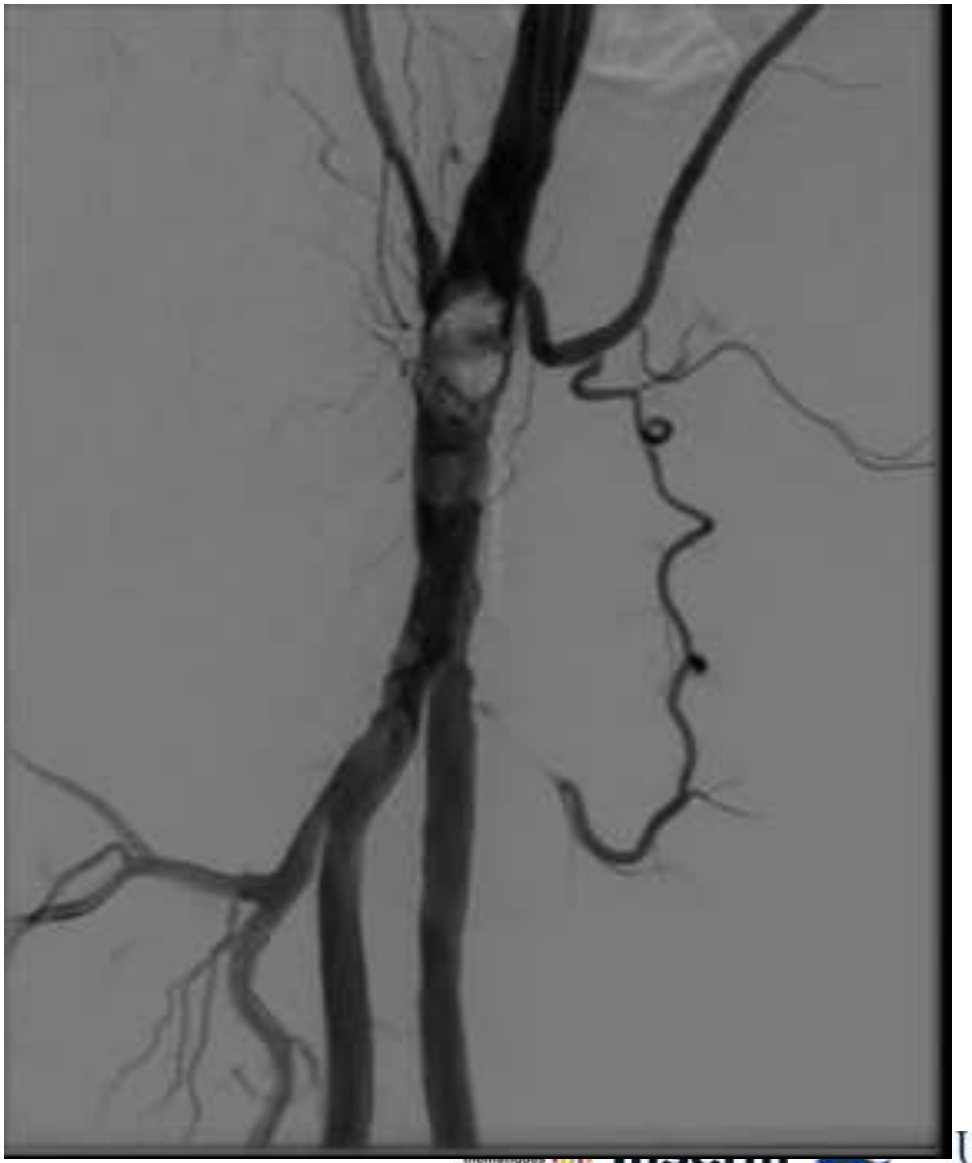
TECCO
Take home message

- **In patients with de novo atherosclerotic lesions of common femoral artery, the perioperative morbi-mortality rate was significantly lower among patients who underwent endovascular therapy by stenting rather than surgery.**

- **At 2 years of follow-up, clinical, morphological and hemodynamic outcomes are comparable.**

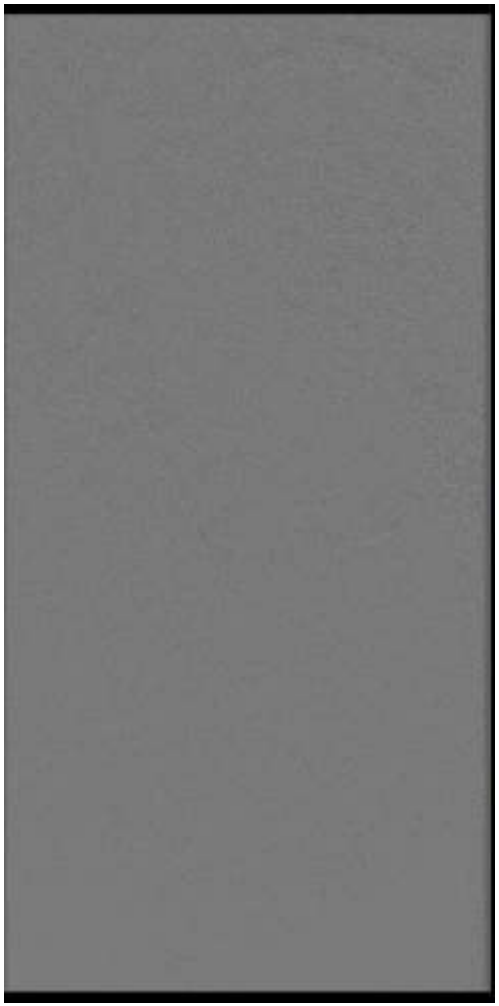
Male, 68 years-old, rutherford 3





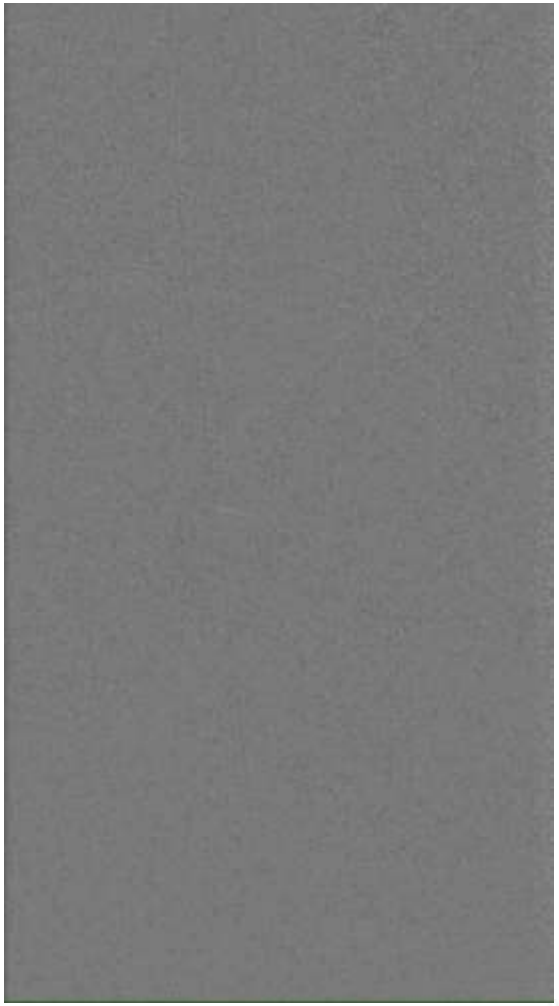
Male, 71 years-old, rutherford 3

Pre operative angiogram



Pre-inflation

9-40mm



Supera

8-40mm

VMI-CFA

Physician initiated, prospective, multicenter, single arm trial to evaluate the Supera® Peripheral Vascular Mimetic Implant Device (Abbott Vascular) for symptomatic (R 2-4) CFA disease treatment

Participating centers

Belgium

- AZ. Sint Blasius Hospital Dendermonde
  - **K. Deloose (PI)**, J. Callaert, M. Bosiers
- OLV Hospital Aalst
  - L. Maene, R. Beelen
- ZNA Stuivenberg Hospi
  - P. Gov
- Imelda Hos
  - J. ide

100 out of 100 patients are enrolled

France

- Hôpital Nord Laennec, CHU, Nantes
  - Y. Gouëffic
- Clinique Rhône Durance, Avignon
  - C. Brunet