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**UNIVERSITÄTS
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HERZZENTRUM**



**Interventionelle Therapie der AFC im
kommen!**

CFA

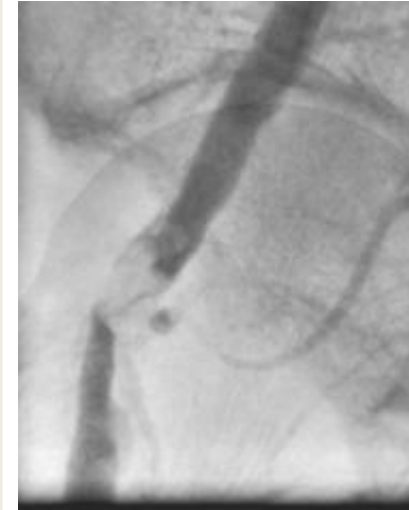
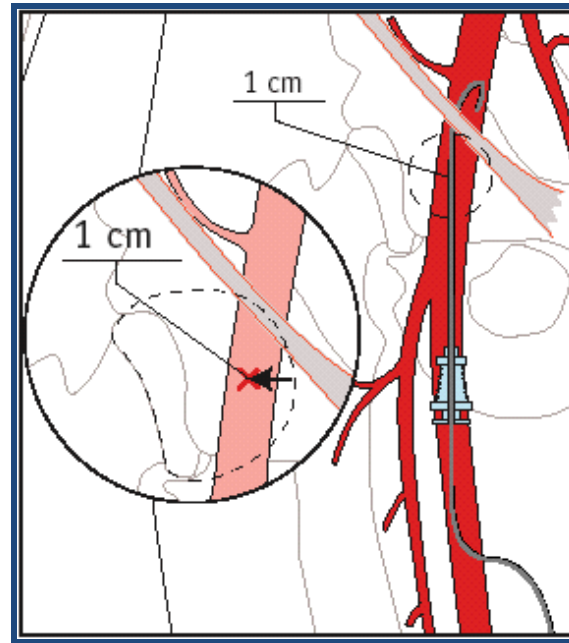
Standard Treatment

Open surgical revascularisation

- Thrombendarterectomy
 - atheromateous lesions
- Embolectomy
 - embolic lesions

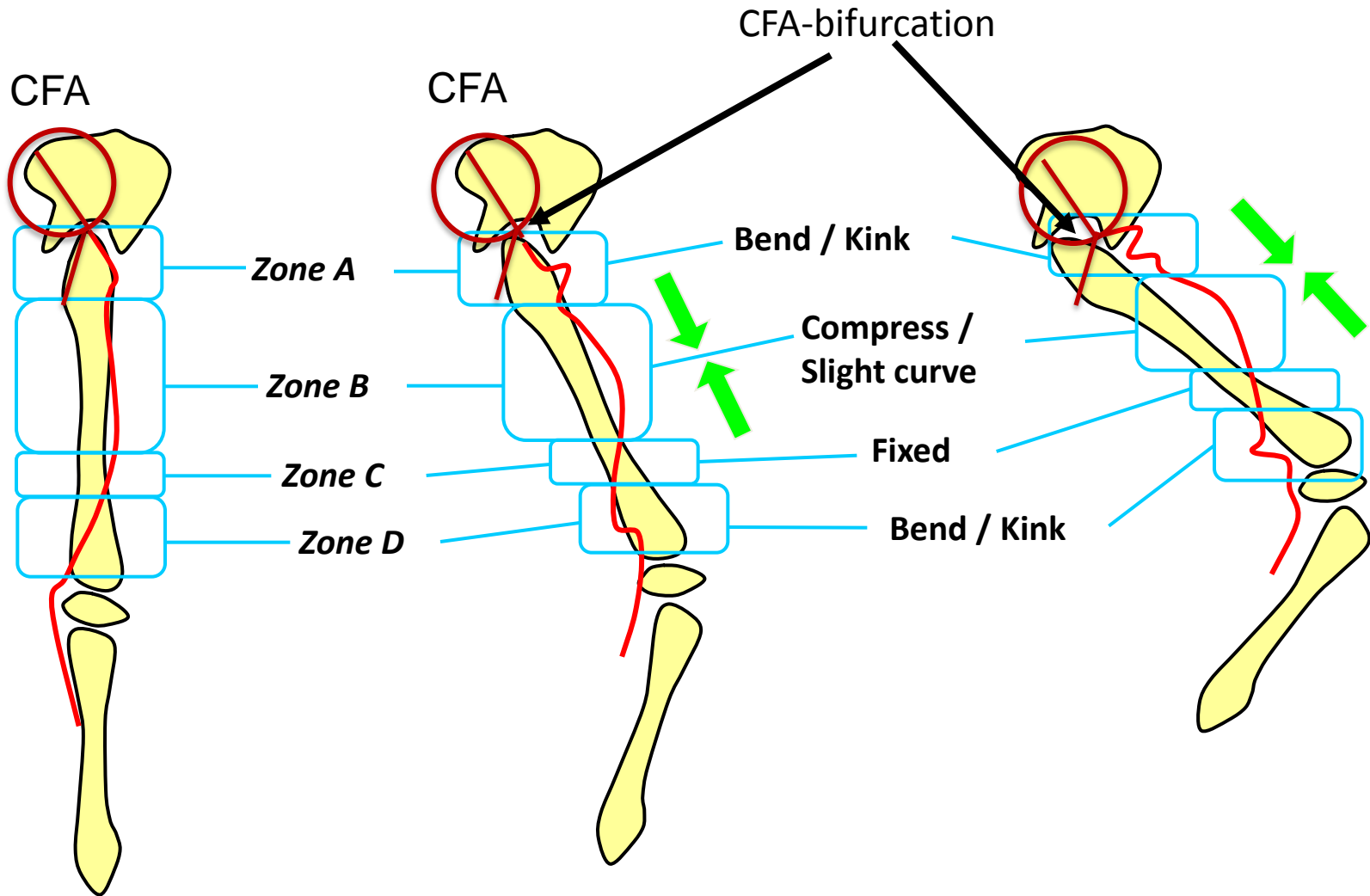
Limitations:

- Scarred tissue
- Obesity
- Morbidity up to 5%:
 - Major hematoma
 - Wound infection
 - Surgical revision



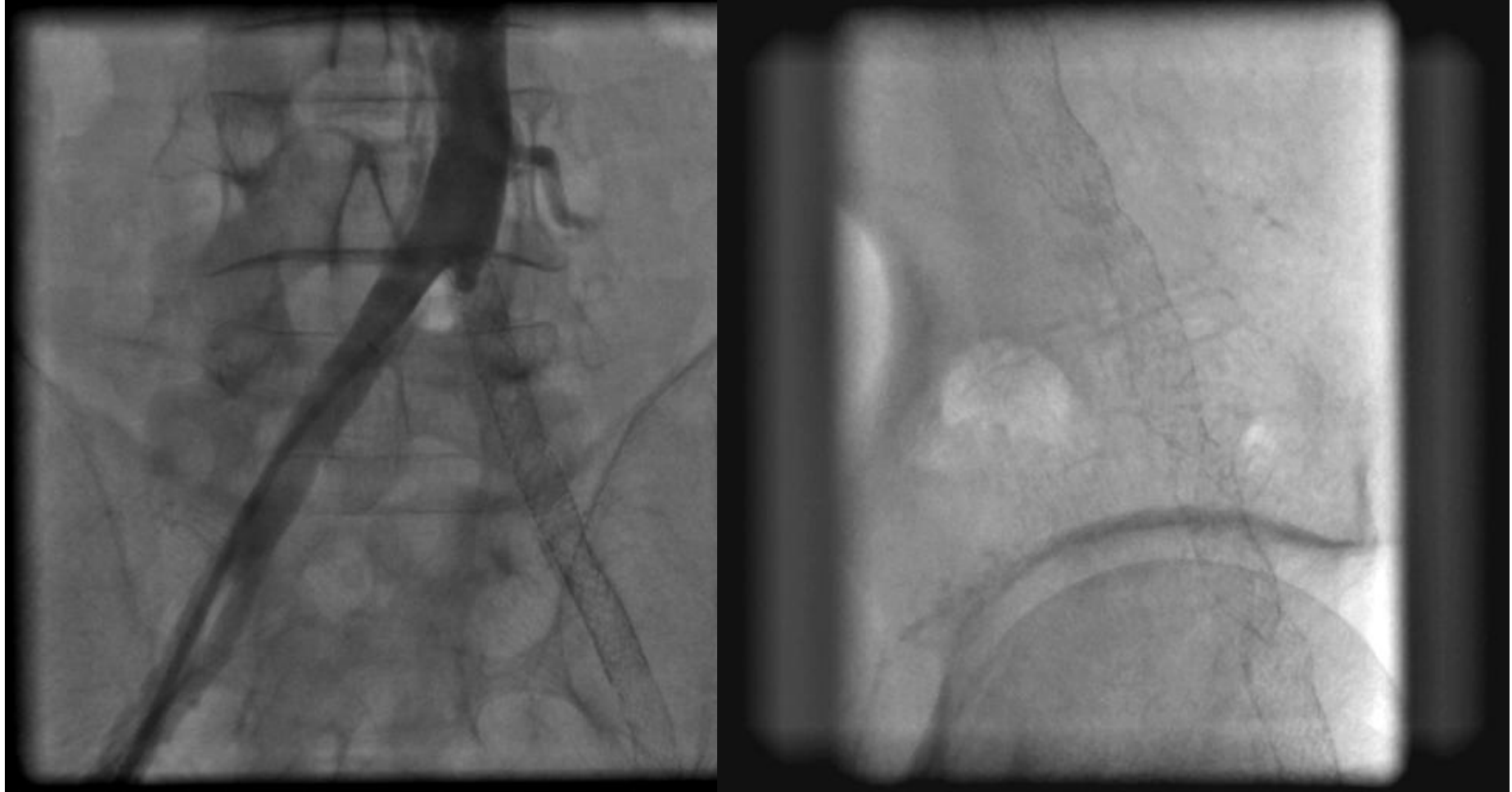
Cardon A et al. Endarteriectomy of the femoral tripod: long-term results and analysis of failure factors. Ann Chir 2001;126:777-82.

Femoro-popliteal Artery - Biomechanics

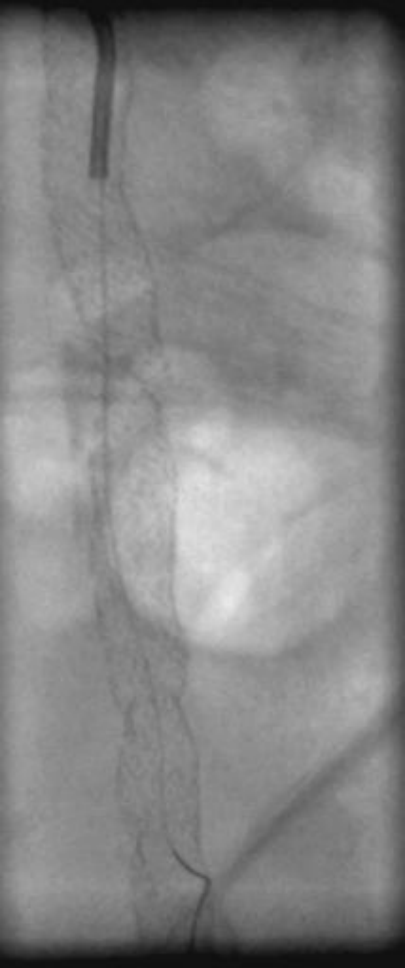


Modified according to Lansky, A; Angiographic Analysis of Strut Fractures in the SIROCCO Trial. TCT 2004

Stent Fractures Distal EIA



Stent Fractures Distal EIA



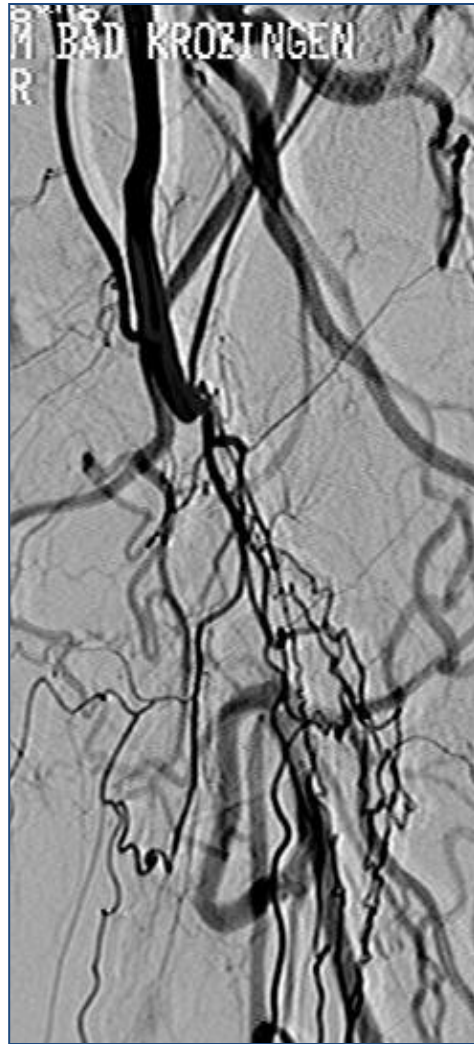
CFA – Angioplasty

Balloon Angioplasty



CFA – Stent

Bail-out Stenting



CFA – Stent

Bail-out Stenting



1: Double balloon-PTA of the CFA-bifurcation. 2: After PTA.

CFA – Stent

Bail-out Stenting



1: Kissing balloon-PTA of the CFA-bifurcation. 2: After PTA. 3: After SMART-stent CFA.

Patients / Lesion Flow-Chart

Total of 11493 patients treated at our center (9.1996 → 12.2007) = mean 958 ± 679 patients/year

466 Patients presenting with a CFA lesion / 516 CFA Interventions

Included Patients / Interventions:
321 Patients / 360 Interventions,
(= 2.8% of all patients treated at our center)

Excluded Patients / Interventions (=145/156):

- 31 VCD-related stenosis
- 9 CFA bleedings
- 64 CFA thrombo-embolic lesions
- 28 stenosis <70% (visual estimation at angio)
- 20 iatrogenic CFA dissections
- 4 other causes

CFA Lesions Characteristics:

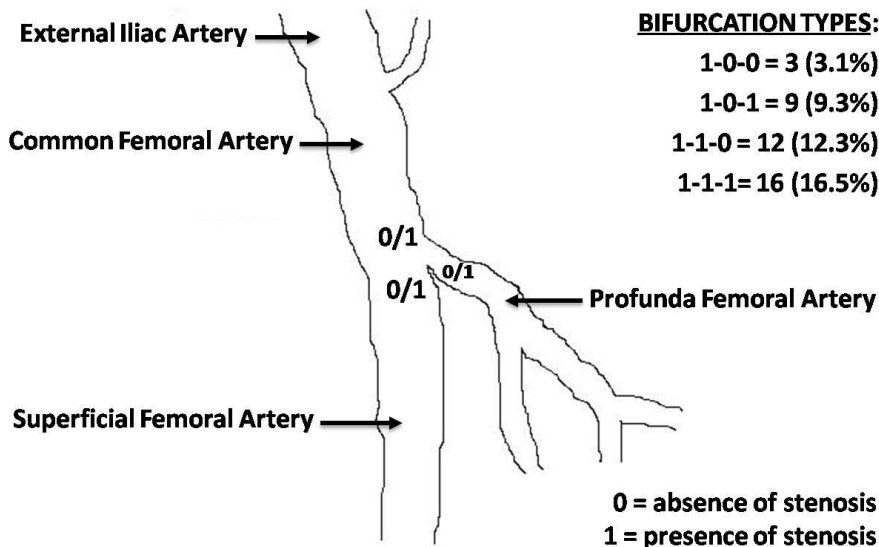
- 64 (17.8%) CFA total occlusion
- 140 (38.9%) CFA bifurcation lesion
 - o 67 (18.6%) 1-1-1 lesion
 - o 27 (7.5%) 1-1-0 lesion
 - o 26 (7.2%) 1-0-1 lesion
 - o 20 (5.6%) 1-0-0 lesion
- 50 (13.9%) post-TEA restenosis
- 79 (21.9%) associated with a SFA occlusion
- 93 (25.8%) associated with a DFA lesion

Interventions :

- 97 (26.9%) isolated CFA Intervention
- 157 (43.6%) CFA + homolateral Iliac Intervention
- 152 (42.2%) CFA + homolateral Fem-pop. Intervention

Performed Interventions :

- 355 (98.6%) PTA
- 133 (36.9%) PTA + stent
 - o 122 (33.9%) one stent
 - o 11 (3.1%) two stents
- 30 (8.3%) special techniques :
 - o 25 (6.9%) Silverhawk Atherectomy device
 - o 5 (1.4%) Kissing Balloon



CFA = Common Femoral Artery
TEA = surgical Thrombendarterectomy
DFA = Deep Femoral Artery
PTA = Percutaneous Transluminal Angioplasty

VCD = Vascular Closure Device
SFA = Superficial Femoral Artery
Fem-pop. = Femoro-popliteal

CFA Angioplasty Bad Krozingen Experience

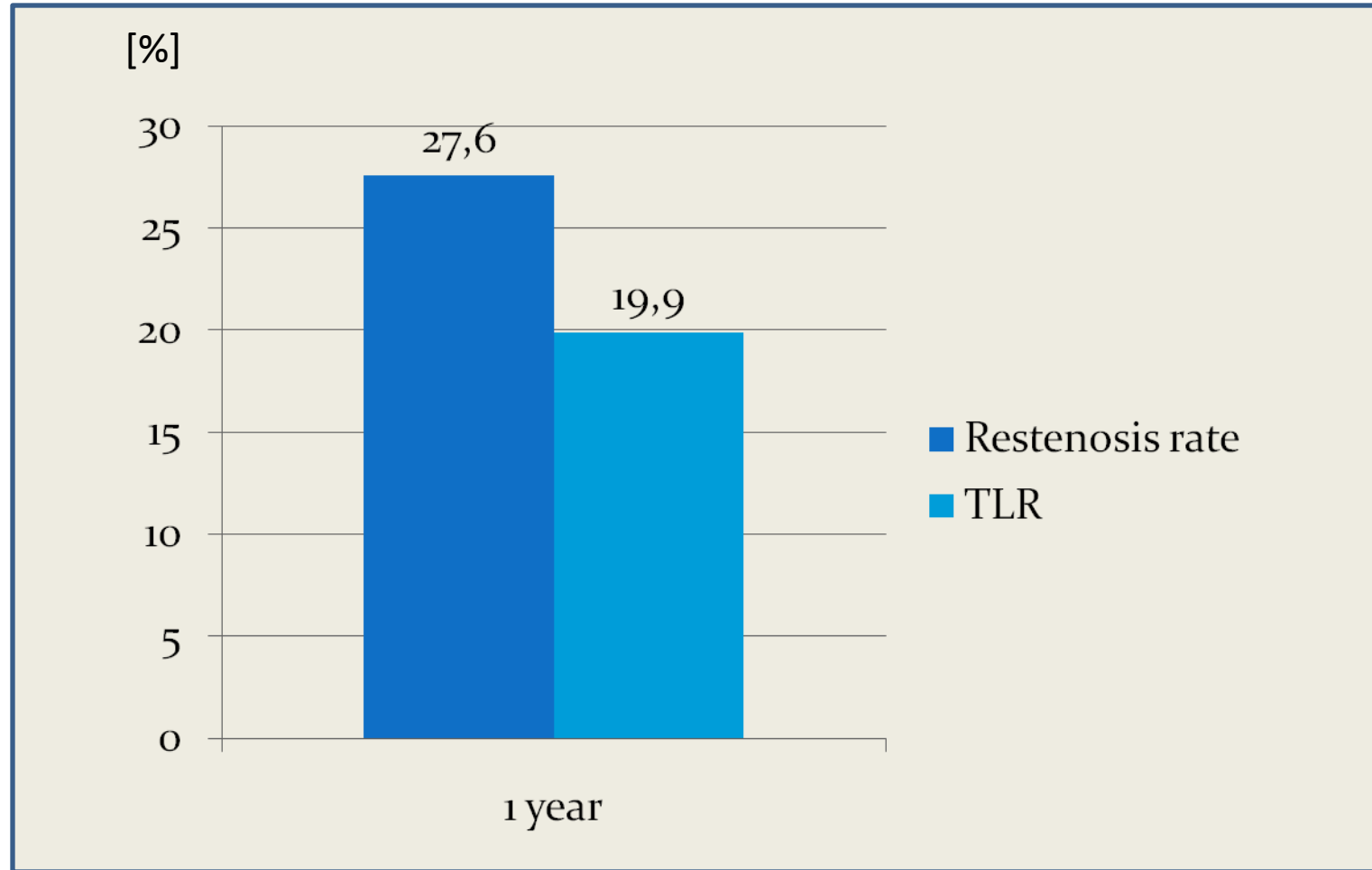
CFA-Angioplasty

Acute Technical Outcomes & In-Hospital Events

| | |
|---|-----------------|
| Procedural success ($\leq 30\%$ stenosis) | 334/360 (92.8%) |
| Peri-procedural complications | 23/360 (6.4%) |
| - Contralateral access site complications | 6/360 (1.7%) |
| - Distal embolization | 6/360 (1.7%) |
| - Thrombotic CFA occlusion | 6/360 (1.7%) |
| In-hospital myocardial infarction | 4 (1.2%) |
| In-hospital minor amputation | 1 (0.3%) |

CFA Angioplasty

1-year Technical Outcomes



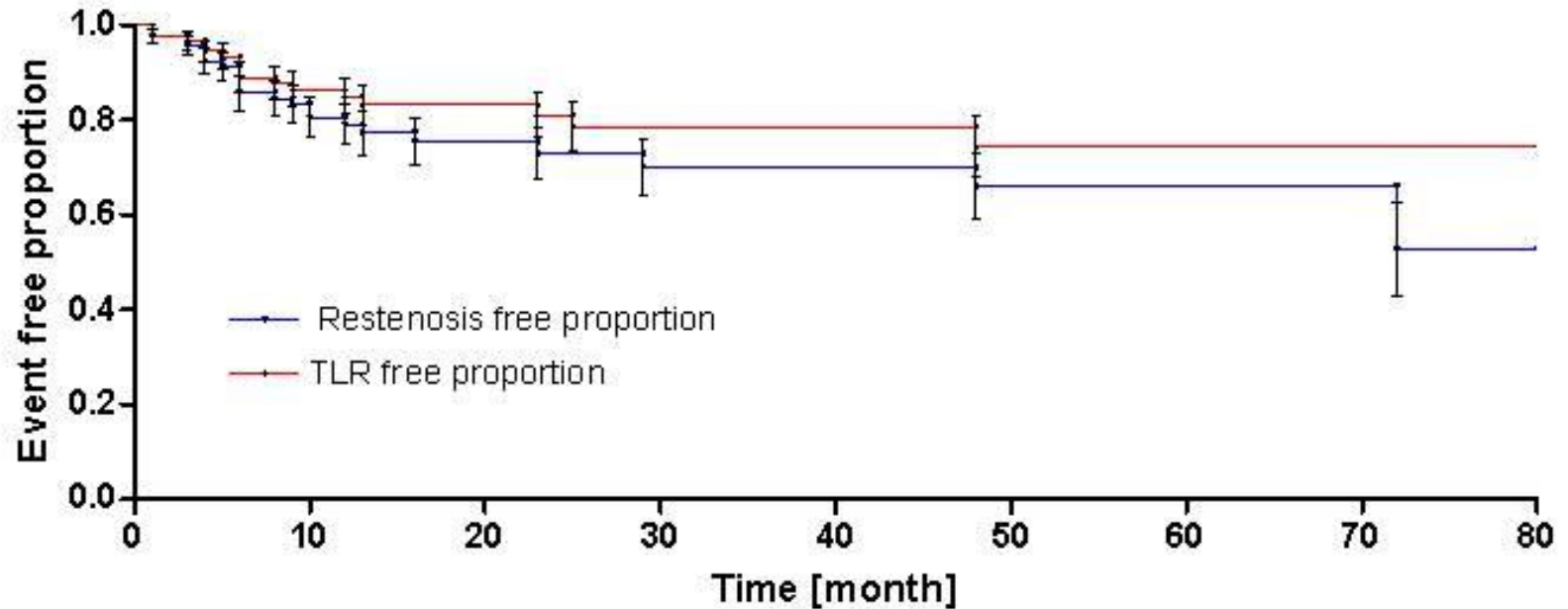
Subgroup Analysis

Stented lesions vs. non-stented lesions

| | Stented (n = 133) | Nonstented (n = 227) | OR 95% CI | P Value |
|----------------------|-----------------------------|--------------------------------|----------------------------|----------------|
| Failure | 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-Year TLR | 13.1% | 23.6% | 0.49 (0.26-0.91) | 0.021 |

CFA Only Cohort

Kaplan Meier curves for cumulative survival rate without restenosis (blue line) and TLR (red line)

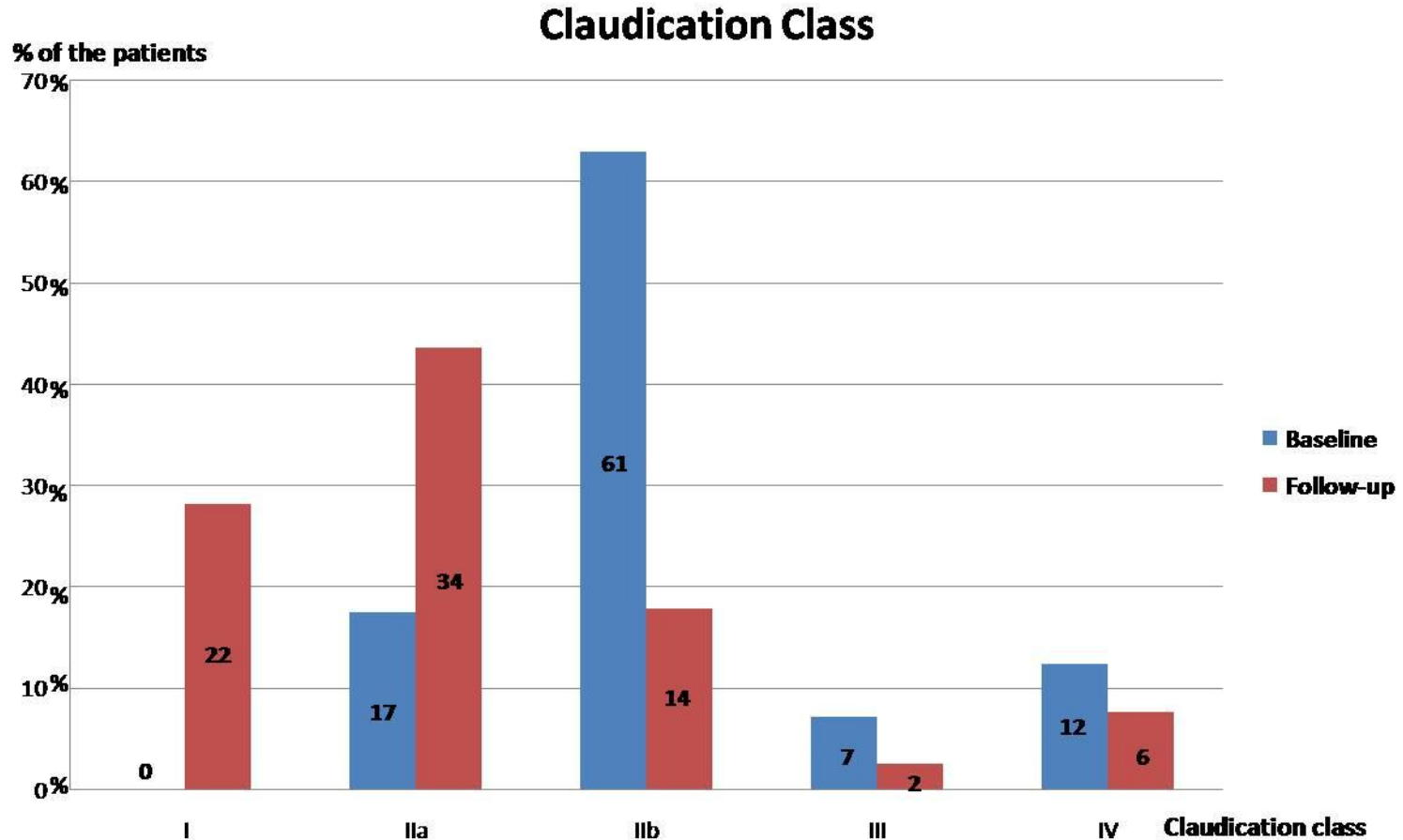


| Number at risk | 0 | 10 | 20 | 30 | 40 | 50 | 60 | 70 | 80 |
|----------------|----|----|----|----|----|----|----|----|----|
| Restenosis | 95 | 32 | 18 | 10 | 4 | | | | |
| TLR | 97 | 38 | 20 | 10 | 4 | | | | |

Points of censor in both curves include death, patients lost of follow-up as well as patients without adequate clinical and duplex-US data.

Clinical Outcomes - Functional Class (Fontaine) Improvements

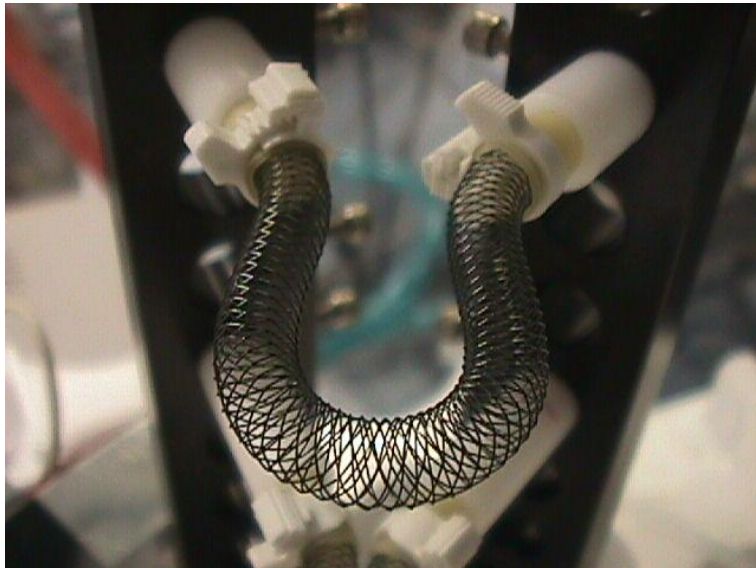
The numbers in the columns correspond to the effective number of the analyzed patients



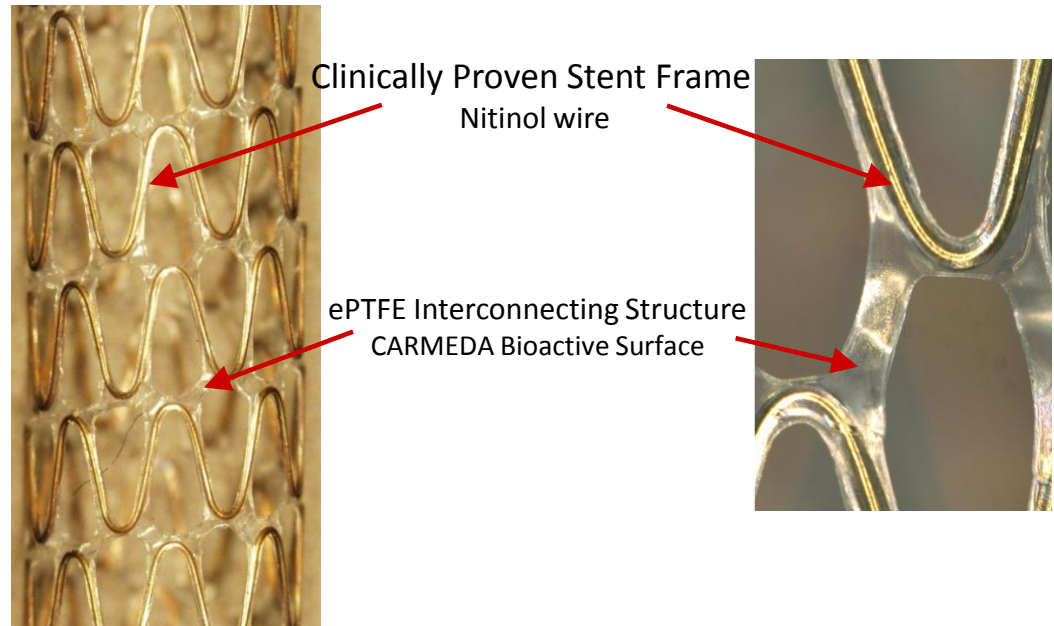
Stent-Angioplasty of CFA

Dedicated Stents

Supera Vascular Stent
Interwoven Nitinol Design



GORE® TIGRIS Vascular Stent
Dual Component Stent Design



Subgroup Analysis

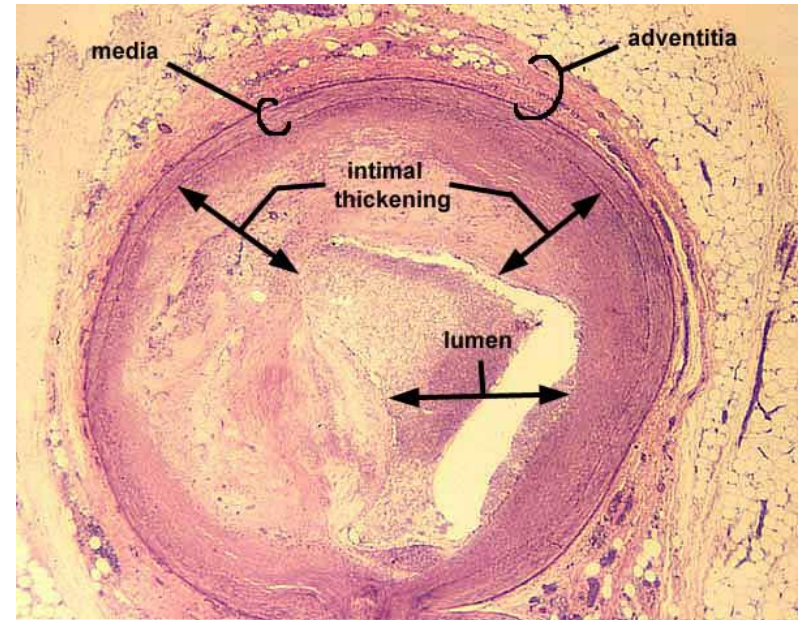
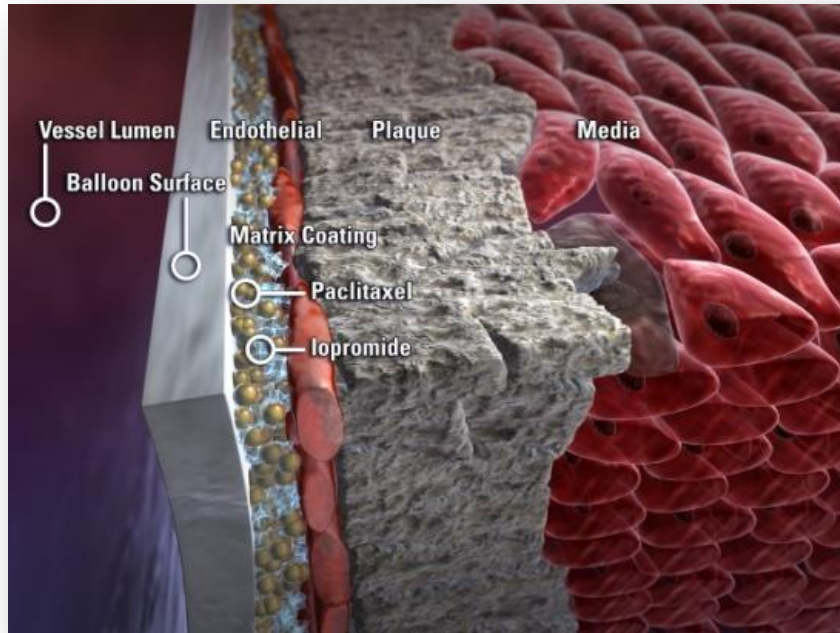
Atherectomy vs. POBA +/- Stent

| | Atherectomy (N=25) % | PTA ±stent (N=335) % | RR | 95% CI | P value |
|-------------------|-------------------------|-------------------------|-------------|--------------------|-------------|
| Failures | 4.0 | 7.5 | 0.51 | 0.07 – 3.98 | 1 |
| Complications | 0. | 6.9 | 0.26 | 0.01 – 4.42 | 0.38 |
| Restenosis | 11.8 | 28.7 | 0.35 | 0.07 – 1.48 | 0.16 |
| 1 yr TLR | 4.8 | 20.9 | 0.18 | 0.02 – 1.42 | 0.09 |

The Potential New Solution:

Drug Coated Balloon angioplasty
with or w/o upfront atherectomy /
mechanical thrombectomy

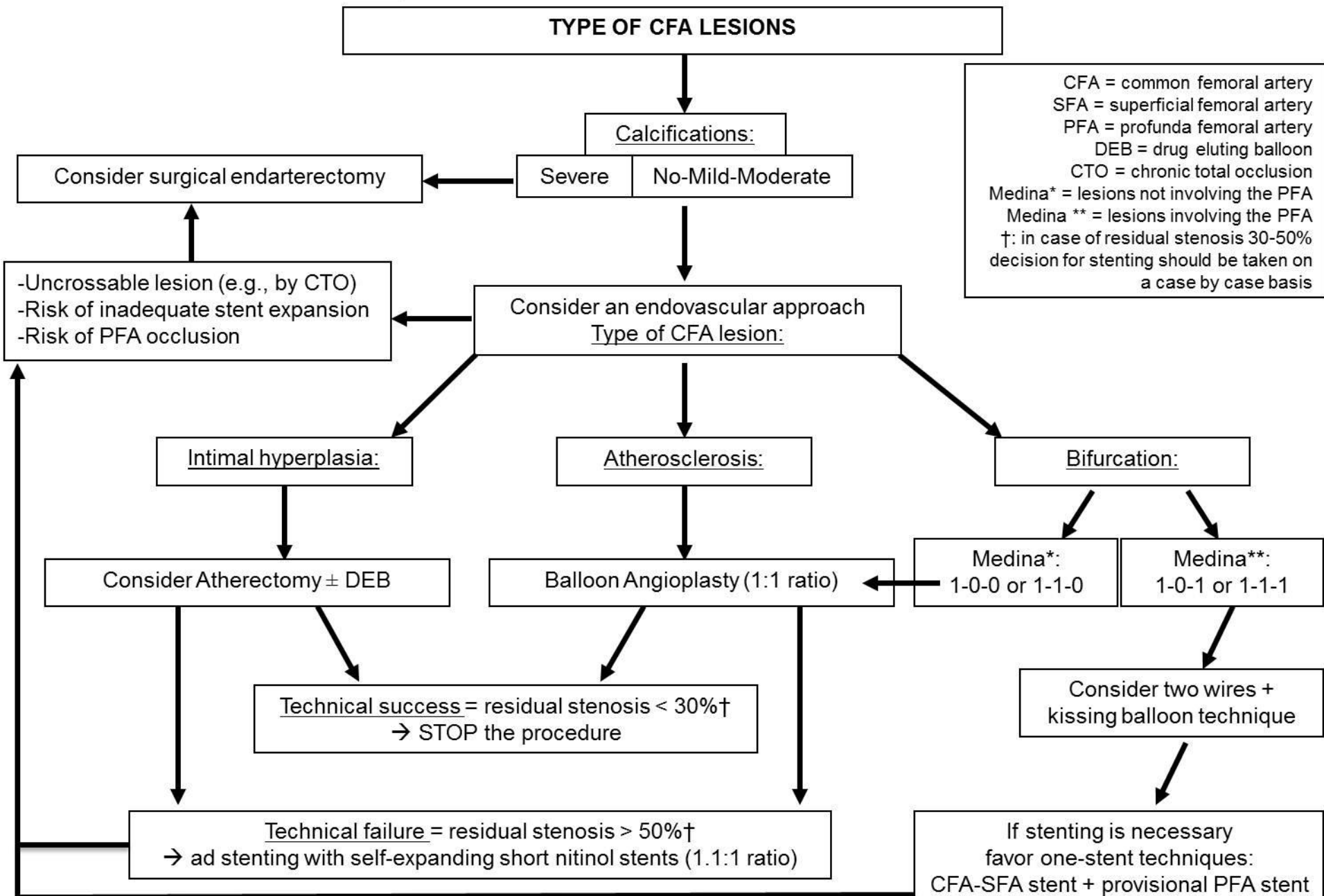
Rationale for plaque excision and drug-delivery as an essential combination



- Mechanically recanalize the vessel without overstretch
- Big artery diameter >> incomplete plaque excision
- Remove the perfusion barrier – better and more homogenous drug uptake?
- Reduce the likelihood of bail-out stenting



Treatment algorithm in case of CFA lesions



Is Endovascular Treatment of CFA Lesions Ready for Primetime?

Summary

- Surgical reconstruction of CFA is still considered the gold standard despite the lack of relevant data.
- However, PTA with or without stenting is a valid alternative in patients being unfit for surgery.
- Stent fractures seem not to play the same role as in the femoro-popliteal segment
- Even calcified lesions can be successfully treated with DA (Turbohawk).
- DCB might further improve the long-term outcome
- An RCT comparing surgery with endovascular therapy including DEB is on the way.

Is Endovascular Treatment of CFA Lesions Ready for Primetime? Future

PESTO-CFA

Percutaneous Intervention versus Surgery in the
Treatment of Common Femoral Artery Lesions

A prospective, multi-centre, randomised study

PESTO-CFA Study

| | |
|----------------------|---|
| Title: | PESTO-CFA |
| Aim: | Non inferiority study comparing DCB based endovascular therapy and suigical therapy in the treatment of atherosclerotic CFA disease |
| Stuidy design: | Prospective, multicenter, randomized, controlled study , 1:1 randomization Follow-up at 6 months, 1, 2 and 5 years |
| Patient recruitment: | 260 patients. Study duration 6.5 years (recruitment time 18 months, follow-up 5 years) |