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Atherectomy and thrombectomy of femoropopliteal occlusions with Rotarex S: The Leipzig experience

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Disclosure

Speaker name:

Sven Bräunlich

I have the following potential conflicts of interest to report:

- 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



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Lower Extremity Arterial CTOs

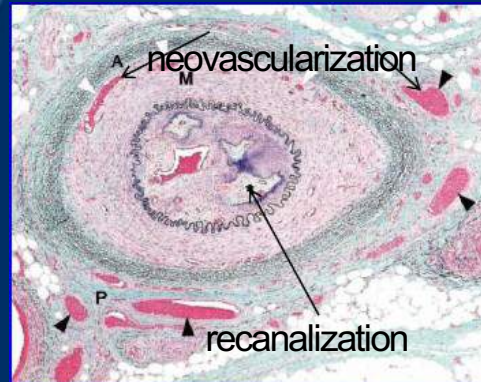
- 40-50% of patients with symptomatic peripheral arterial disease (PAD) have complete occlusion and half of all patients with CLI will undergo some revascularization¹.
- CTOs are most common in the infra-inguinal location².
- Nearly 50% of superficial femoral artery (SFA) lesions present as CTO³.
- CTO is much more common in critical limb ischemia (CLI).

1. Norgren, et al. *J Vasc Surg*. 2007;45 (supp. S): S5–67.
2. Banerjee, et al. *Cardiovasc Revasc Med*. 2011;12(2):134.
3. Banerjee, et al. *JACC*.2012;60(15):1352–359.

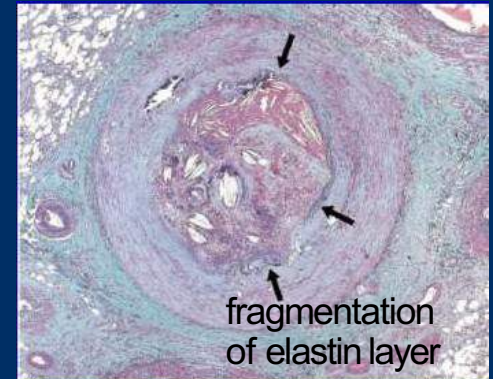


CTOs Histologic Sections from Patients with CLI

CTO with fibrocalcific tissue and atherothrombotic soft tissue



Artery with atheromatous thromboemboli



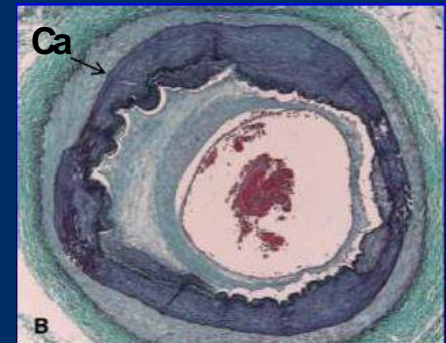
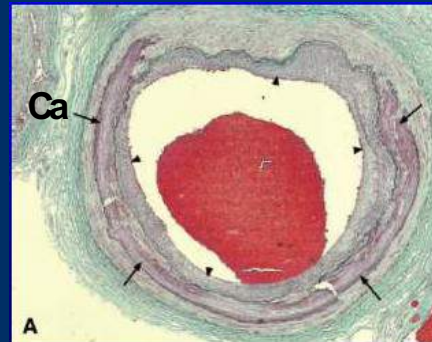
Recent (< 3 months)

- Thrombus/embolus
- Acute limb ischemia (< 2 weeks)

Chronic total occlusion (≥ 3 months)

- Organized thrombus
- Fibrotic tissue
- Calcification
- Microchannels

Artery with circumferential medial calcification





UNDERSTANDING CALCIUM: Prevalence of Calcium in Atherosclerotic Lesions

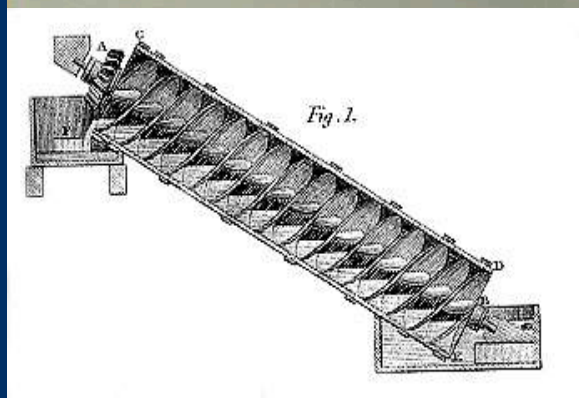
Degree of Intimal Calcium	De Novo – <i>No Thrombus</i>	De Novo – <i>With Thrombus</i>	Restenotic	Total Ca ⁺⁺ Degree
No Intimal Calcium	7.0%	10.75%	45.0%	62.75%
MILD Calcium	6.0%	7.5%	2.0%	15.5%
MODERATE Calcium	6.0%	5.0%	2.0%	13.0%
SEVERE Calcium	4.0%	3.75%	1.0%	8.75%
TOTAL Lesion Type	23.0%	27.0%	50.0%	

LESS THAN 10% OF ALL LESIONS HAVE SEVERE INTIMAL CALCIUM
15.5% of De Novo Atherosclerotic Lesions; 1% Restenotic



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Rotarex S Catheter (Straub-Medical)



Detachment
(up to 1 cm/s)

Suction

Fragmentation

Transport



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Rotarex mechanical debulking: The Leipzig experience in 1.200+ patients

- Single center registry:
 - Use of Rotarex Atherektomie device in PAOD patients
 - Safety and efficacy

- Consecutive patient enrollment
 - Real world scenario
 - 1.809 patients treated (from 1/2005 – 11/2013)
 - 1.572 patients were analyzable (86,9%)



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Rotarex mechanical debulking: The Leipzig experience in 1.200+ patients

Intervention Feature

- Native „virgin“ arteries → 1203 Procedures
- Surgical bypasses
- Redo procedures
- In-stent procedures



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Rotarex mechanical debulking in acute/subacute thrombotic lesions: The Leipzig experience in 525 patients

Intervention Feature

- Native „virgin“ arteries
- Surgical bypasses
- Redo procedures
- In-stent procedures



525
Acute/Subacute

Rotarex Mechanical Debulking in Acute and Subacute Arterial Lesions: Single-Center Experience With 525 Patients

Bruno Freitas, MD^{1,2}, Sabine Steiner, MD¹, Yvonne Bausback, MD¹, Daniela Branzan, MD³, Matthias Úlrich, MD¹, Sven Bräunlich, MD¹, Andrej Schmidt, MD¹, and Dierk Scheinert, MD¹

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Rotarex S® Atherothrombectomy in native FemPop arteries: The Leipzig experience

Intervention Feature

- Native „virgin“ FemPop arteries treated with Rotarex S → 658 Procedures
- Surgical bypasses
- Redo procedures
- In-stent procedures

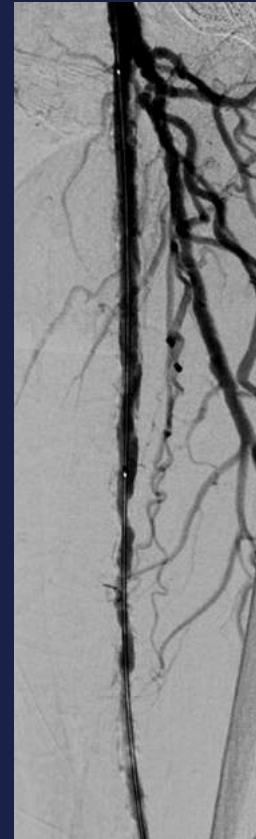
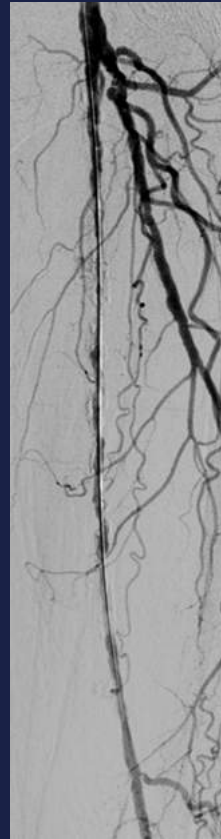
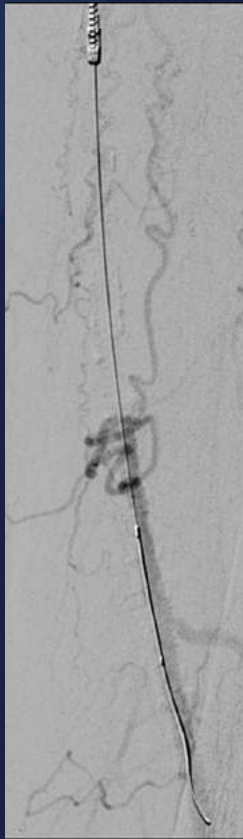
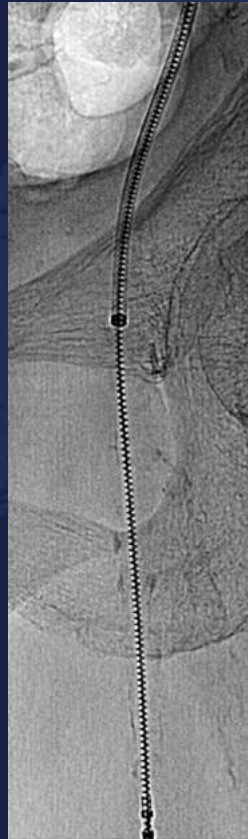
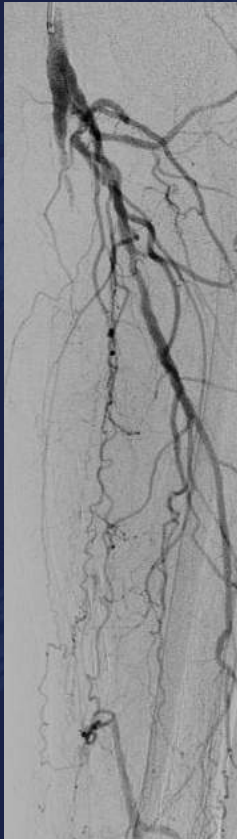
From January 2011 to November 2013



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CTO of the left SFA, 8 Fr Rotarex



First pass

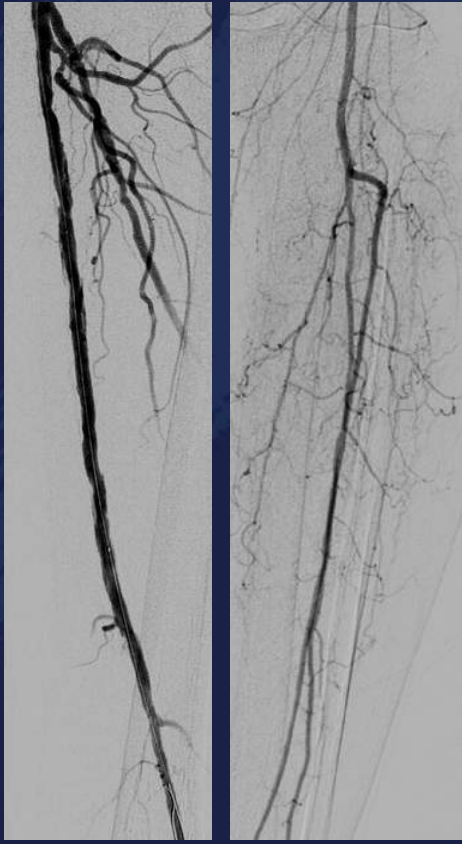
Several passes



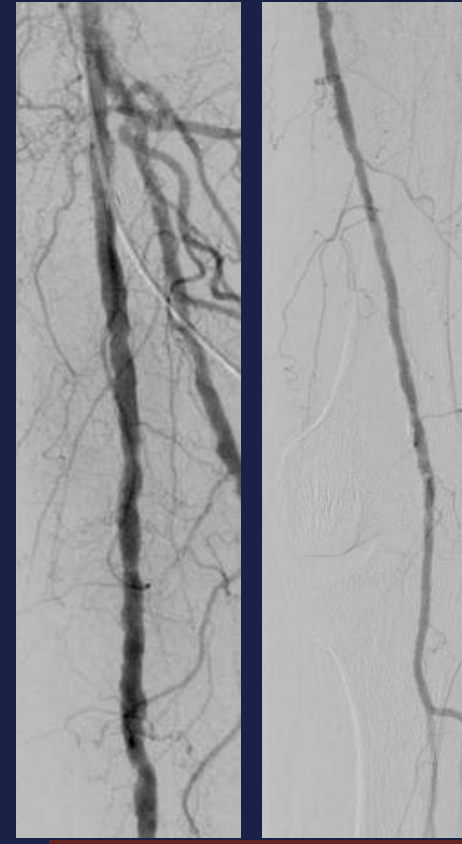
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Rotarex for Chronic SFA-CTOs



2 x 5.0/120 mm DCB



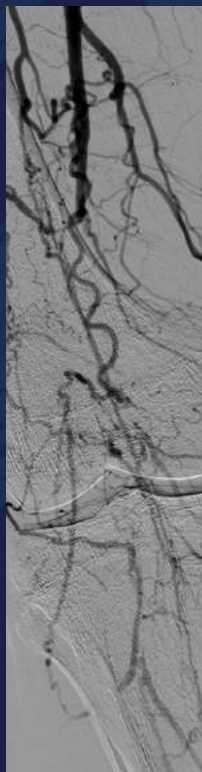
12 months FU results



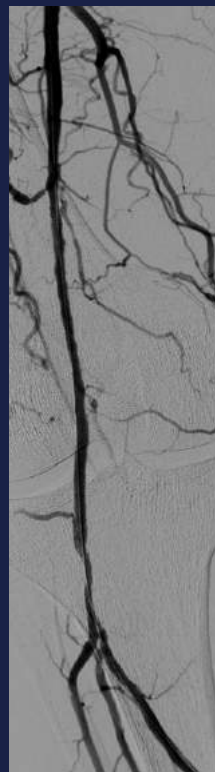
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Rotarex + DCB Registry Femoropopliteal Lesions



Clinically chronic Apop-occlusion



6 Fr Rotarex



After DCB



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Rotarex S Atherothrombectomy in native FemPop arteries:

Demographic characteristics (n=658)

Age, Mean ± SD (n)	67.4 ± 11.6 (658)
Male gender, n(%)	428 (65.1)
Medical History, n(%)	
Obesity	188 (29.6)
Smoking	294 (44.7)
Dyslipidemia	437 (66.4)
Diabetes	244 (37.1)
Insulin-dependent DM	37 (15.2*)
Hypertension	512 (77.8)
Coronary Artery Disease	208 (31.6)
Cerebrovascular disease	71 (10.8)
Renal Impairment	75 (11.4)
Dialysis	8 (1.2)
Previous anticoagulation	43 (6.5)

Table 1. Clinical characteristics of 658 patients treated with Mechanical Atherothrombectomy for "plain" FemPop native arteries. * among diabetic patients



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Rotarex S Atherothrombectomy in native FemPop arteries:

Onset of symptoms (n=658)

Acute (<14 days)	126 (19.1)
Subacute (< 3 months)	159 (24.1)
Chronic (> 3 months)	373 (56.7)



Clinical status – Rutherford class on admission

Rutherford Score	Patient with events, n(%)
0	0
1	8 (1.2)
2	88 (13.4)
3	165 (25.1)
4	258 (39.2)
5	110 (16.7)
6	29 (4.4)
Total	658 (100)

60.3% CLI

Table 2. Baseline Rutherford scores among patients at enrollment Atherothrombectomy Devices in native FemPoparteries



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Rotarex S Atherothrombectomy in native FemPop arteries: Angiographic and procedural characteristics

Total Vascular access sites			658
	Antegrade		373 (56.7%)
	Crossover		285 (43.3%)
Sheath diameter device (French)			
	6		445 (67.6)
	8		213 (32.4)
Mean lesion length (cm)			14.8 (2-27.4)
Intervention area			
	SFA		419 (63.7%)
	Popliteal		85 (12.9%)
	SFA + Popliteal		154 (23.4%)

Table 3. Overall Angiographic and procedural characteristics among 568 patients treated with Mechanical atherothrombectomy devices for "plain" native arteries.



Rotarex S Atherothrombectomy in native FemPop arteries:

Angiographic and procedural characteristics

Type of lesion (complain symptoms)	n(%)
Calcification	658
No/mild	321 (48.8)
Moderate	224 (34.0)
Severe	113 (17.2)
Intervention Feature	658
De-novo lesions	449 (68.2)
Lesion Type Previous Balloon Angioplasty	209 (31.8)

82.8%



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Rotarex S Atherothrombectomy in native FemPop arteries: Acute results

- Procedural success rate: 631 (95.9%)
- Main performed procedure
 - Rotational Atherothrombectomy alone: 139 (21.1%)
 - Rotational Atherothrombectomy + PTA: 354 (53.8%)
 - Additional Stenting: 165 (25.1%)
 - Additional Thrombolysis: 59 (9.0%)
- Mean time follow-up: 12 ± 2.4 months
- Filter usage percentage: 41 patients (6.2%)



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Rotarex S Atherothrombectomy in native FemPop arteries: Acute results

Stenting-rate:

165

(25.1%)

Full lesion stenting:

44 (6.8 %)

Focal stenting:

121 (18.3
%)



Spot Stenting vs. Long Stenting after Subintimal Approach in FP Artery CTOs

PERIPHERAL

Outcomes of Spot Stenting Versus Long Stenting After Intentional Subintimal Approach for Long Chronic Total Occlusions of the Femoropopliteal Artery

Sung-Jin Hong, MD, Young-Guk Ko, MD, Dong-Ho Shin, MD, MPH, Jung-Sun Kim, MD, Byoung-Keuk Kim, MD, Donghoon Choi, MD, Myeong-Ki Hong, MD, Yungoo Jang, MD

ABSTRACT

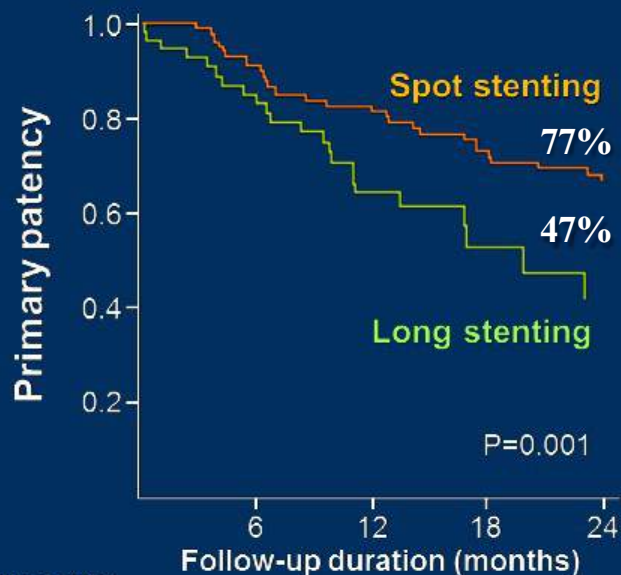
OBJECTIVES This study sought to compare the outcomes of spot stenting versus long stenting after intentional subintimal approach for long femoropopliteal chronic total occlusions (CTO).

BACKGROUND The optimal stenting strategy following the subintimal recanalization of long femoropopliteal chronic total occlusions has not been investigated.

METHODS A total of 196 limbs in 163 patients, implanted with bare nitinol stents after subintimal approach in long femoropopliteal occlusions (lesion length 25 ± 8 cm), were retrospectively analyzed. The primary patency was compared between spot stenting ($n = 129$) and long stenting ($n = 67$).

RESULTS Baseline characteristics and immediate procedural results were similar between groups. Adjusted primary patency (47% vs. 77%, $p < 0.001$) and adjusted freedom from target lesion revascularization (52% vs. 84%, $p < 0.001$) at 2 years were significantly lower in the long stenting group than in the spot stenting group. The incidence of stent fracture, fracture type, and restenosis pattern did not differ between groups. Long stenting was an independent predictor of restenosis (hazard ratio [HR], 2.0) along with other risk factors such as nonuse of clopidogrel (HR, 3.3) or cilastazol (HR, 2.2), small stent diameter (HR, 0.6), poor run-off (HR, 1.9), and post-procedural ankle-brachial index (HR, 0.1). Compared with spot stenting after adjustment using inverse probability of treatment weighting, long stenting, especially involving the P2 or P3 segment of the popliteal artery, was independently associated with 7.5-fold increases in restenosis risk ($p < 0.001$).

CONCLUSIONS The primary patency was significantly higher with spot stenting than with long stenting following subintimal approach for long femoropopliteal chronic total occlusions. The risk of restenosis was especially higher when long stenting was extended to the distal popliteal artery. (*J Am Coll Cardiol Interv* 2015;8:472-80) © 2015 by the American College of Cardiology Foundation.



Number at risk	0	6	12	18	24
Spot	129	103	81	68	61
Long	67	47	29	15	8

J Am Coll Cardiol Interv 2015;8:472



Rotarex S Atherothrombectomy in native FemPop arteries: Acute results - Complications

**Table 6. Major Adverse Events (MAE) to 12-months
post-intervention**

MAE	All events
	n (%)
Perforation	9 (1.4)
Bleeding	18 (2.7)
Dissection	49 (7.4)
Acute closure	19 (2.9)
Emboli	21 (3.2)
Infection	12 (1.8)



Rotarex SAtherothrombectomy in native FemPop arteries:

Clinical Follow-up: 30-day results

Major Adverse Events (MAE) to 30 postoperative day		
MAE	Events	(%)
Death	9	<u>1.4</u>
MI *	11	1.7
TLR **	11	<u>1.7</u>
TVR ***	4	0.6
Major Amputation	8	<u>1.2</u>
Total	43	6.5

Table 4. Major Adverse Events (MAE) to 30 postoperative day. Values are rate numbers (%) of observations

• Myocardial infarction

** Target-lesion revascularization

*** Target-vessel revascularization



Rotarex SAtherothrombectomy in native FemPop arteries:

Clinical Follow-up: 12 months results

Major Adverse Events (MAE) up to 12 month		
MAE	Events	(%)
Death	59	<u>9.0</u>
MI *	17	2.6
TLR **	65	<u>9.9</u>
TVR ***	21	3.2
Major Amputation	24	<u>3.7</u>

Table 5. Major Adverse Events (MAE) at 12 months FU. Values are rate numbers (%) of observations

• Myocardial infarction

** Target-lesion revascularization

*** Target-vessel revascularization



Rotarex SAtherothrombectomy in native FemPop arteries:

Clinical Follow-up: 12 months results

Major Adverse Events (MAE) up to 12 month		
MAE	Events	(%)
Death	59	<u>9.0</u>
MI *	17	2.6
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TVR ***	21	3.2
Major Amputation	24	<u>3.7</u>

Table 5. Major Adverse Events (MAE) at 12 months FU. Values are rate numbers (%) of observations

• Myocardial infarction

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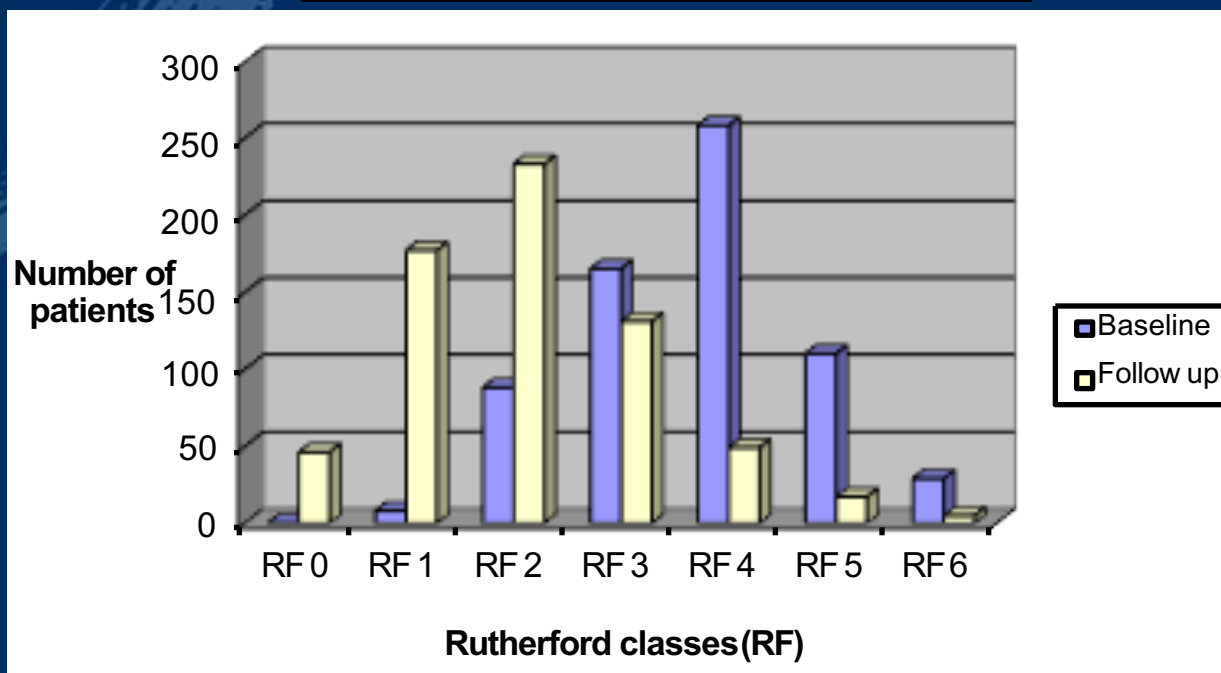


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Rotarex SAtherothrombectomy in native FemPop arteries:

Clinical Follow-up: 12 months results

**78.7% of patients with
improvement in Rutherford class**





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Rotarex SAtherothrombectomy in native FemPop arteries:

The Leipzig experience in 568 patients

Summary

- The use of the Rotarex-catheter in native peripheral arteries with acute, subacute and chronic lesions resulted in a high procedural success rate of 95.9%
- The low rate of procedural complications and 30 day clinical events supports the safety of the device in a broad range of lesions
- The 12-months TLR rate of 9.9% together with a marked improvement of the clinical status demonstrates the clinical effectiveness at 1 year.
- Despite of a reasonable number of cases, it's a Single Center experience, retrospective analysis.
- Effective tool for removing soft atherothrombotic lesions and highlighting uncovered "guilty" lesions – less stenting