

# How do I use mechanical debulking for the treatment of arterial occlusions



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# Disclosure

Speaker name:

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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

# Mechanical debulking

Specific endovascular strategies  
are needed to open the artery

**AND**

to avoid distal embolization

# Rotarex S Catheter (Straub-Medical)

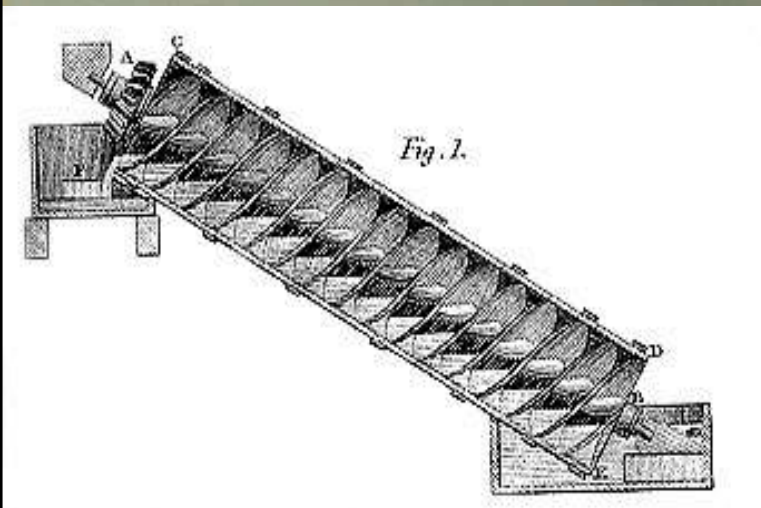


Detachment  
(up to 1 cm/s)

Suction

Fragmentation

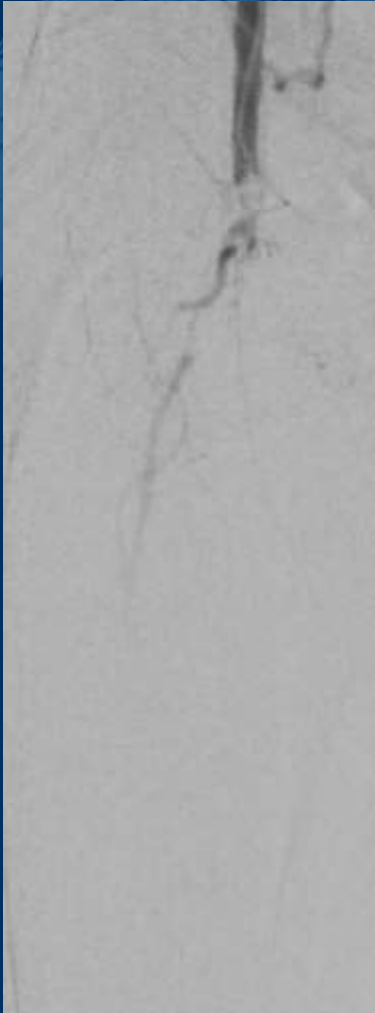
Transport



# Thrombus-Containing Lesions

## Acute Occlusions

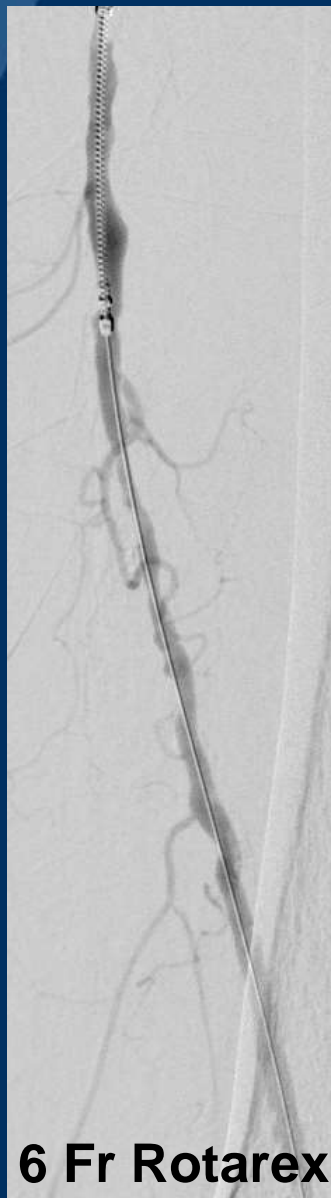
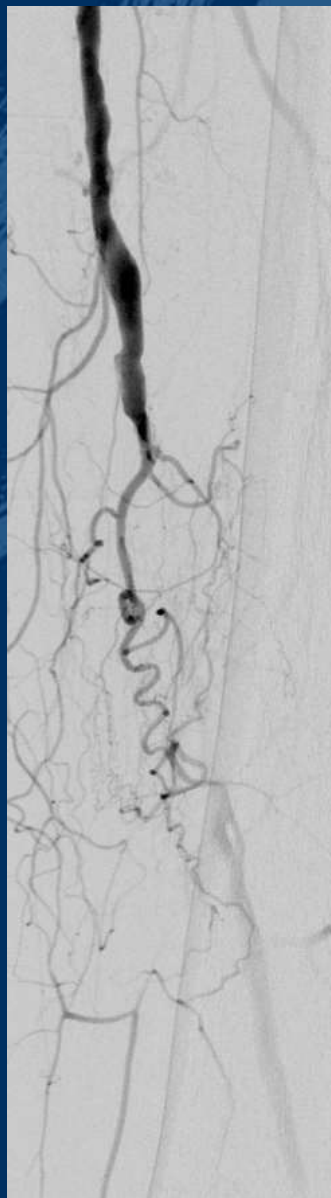
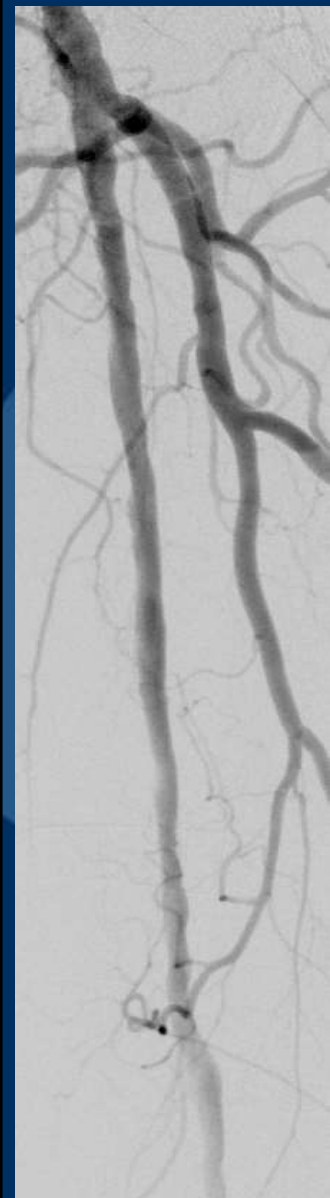
82 year, female, acute onset of pain right leg, Atrial Fibrillation



2 passages Rotarex 8F  
activation-time 45 sec.



# Rotarex for CHRONIC occlusions



6 Fr Rotarex

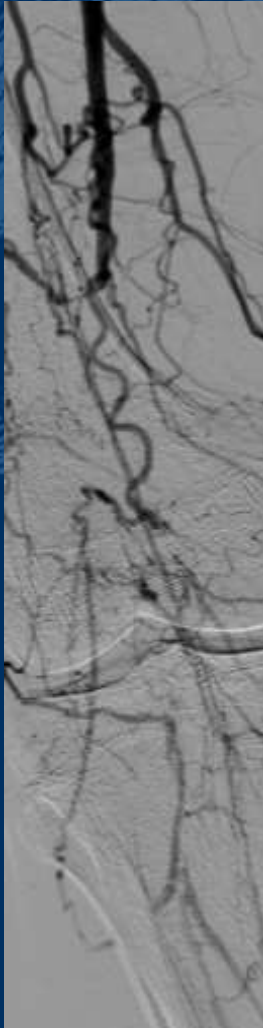


DCB

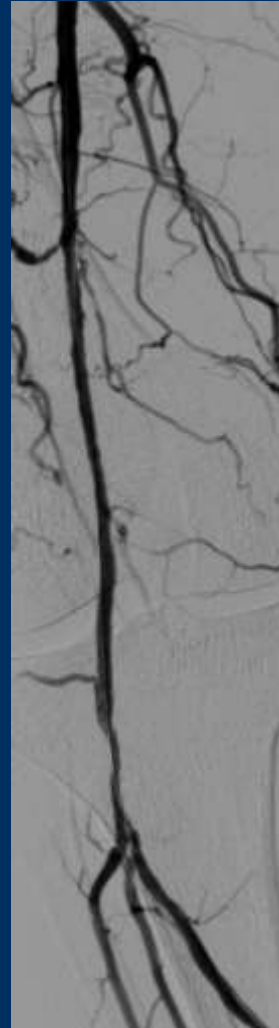


Result

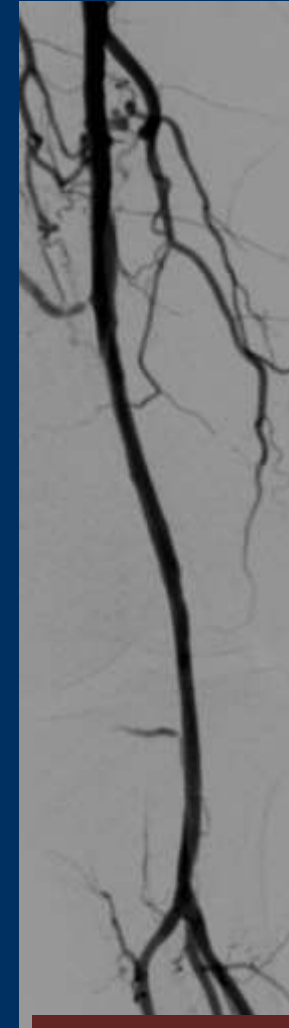
# Rotarex for chronic occlusions



Clinically chronic Apop-occlusion

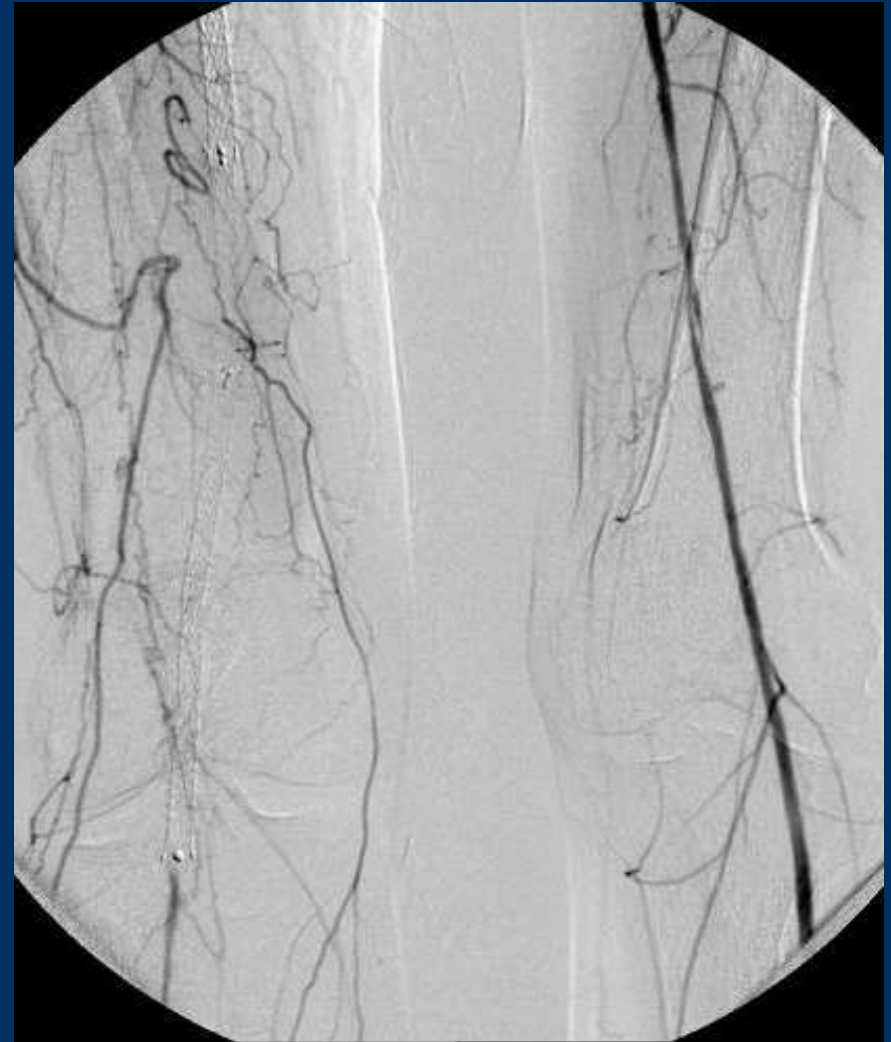


6 Fr Rotarex



After DCB

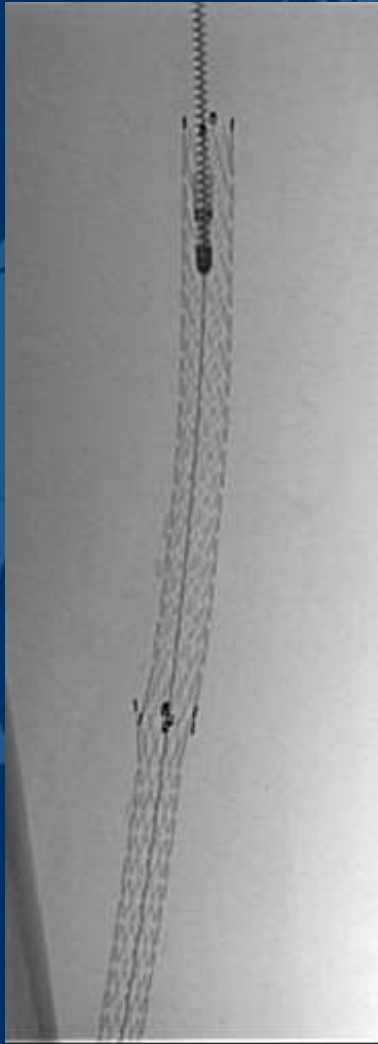
# Rotarex for chronic ISR



In-stent occlusion right SFA and PA

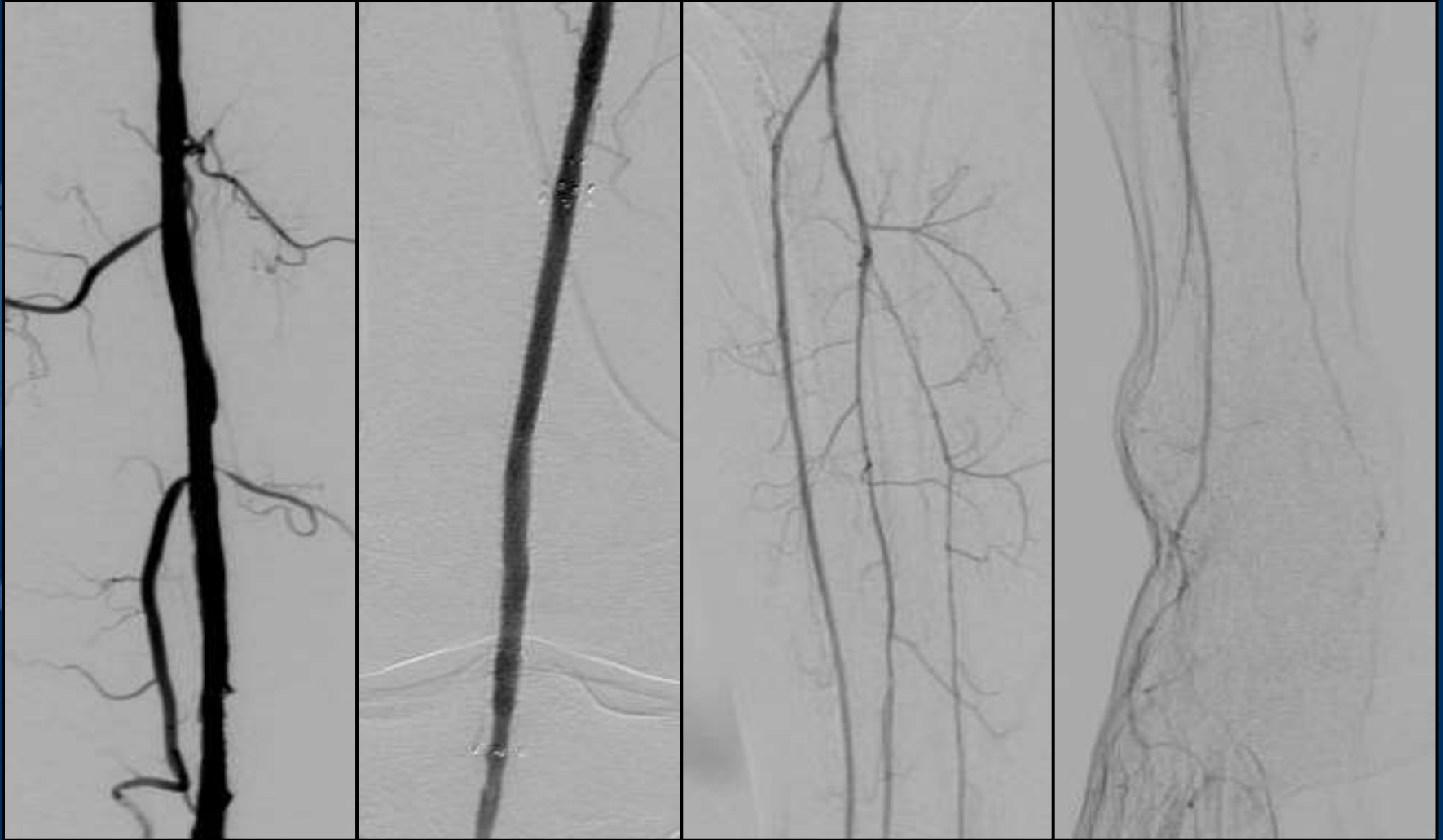


# Rotarex for chronic ISR



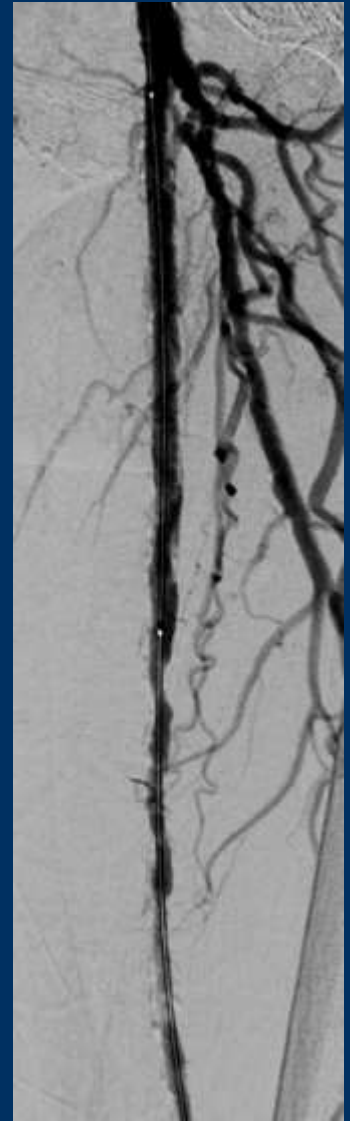
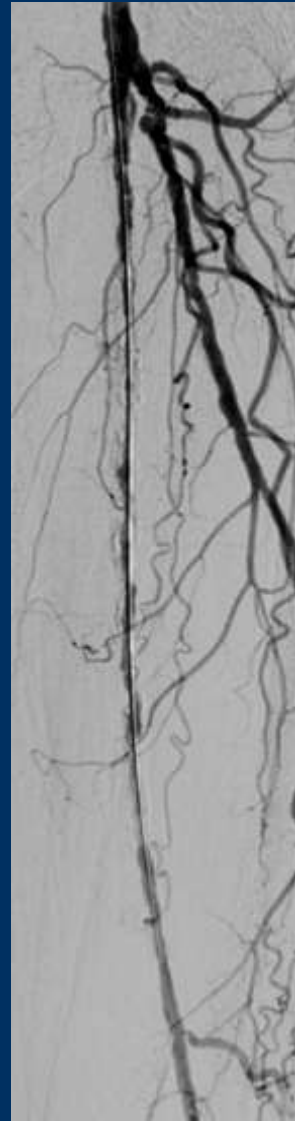
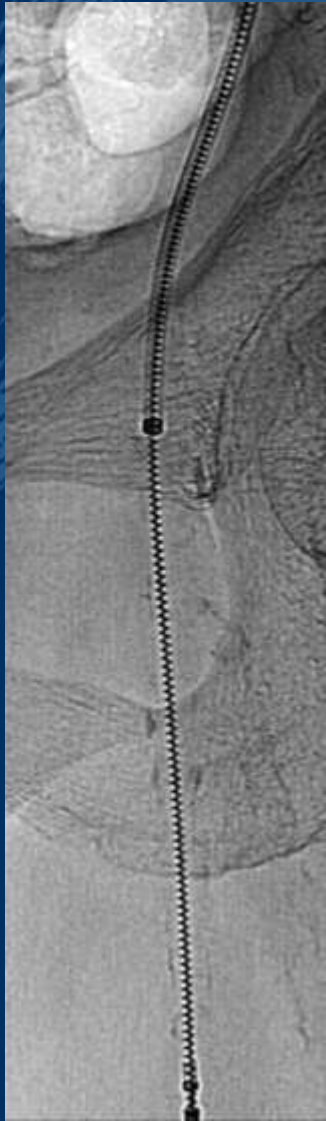
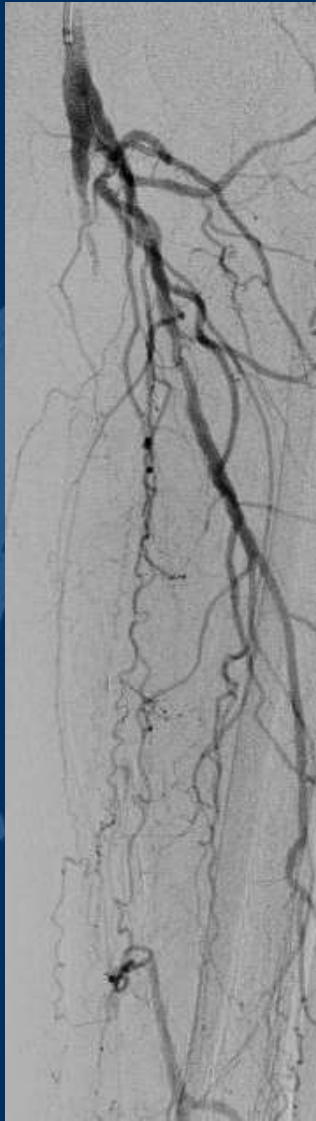
Result after Rotarex-thrombectomy

# Rotarex for chronic ISR



Result after additional DCB angioplasty

# Rotarex for chronic SFA-CTO

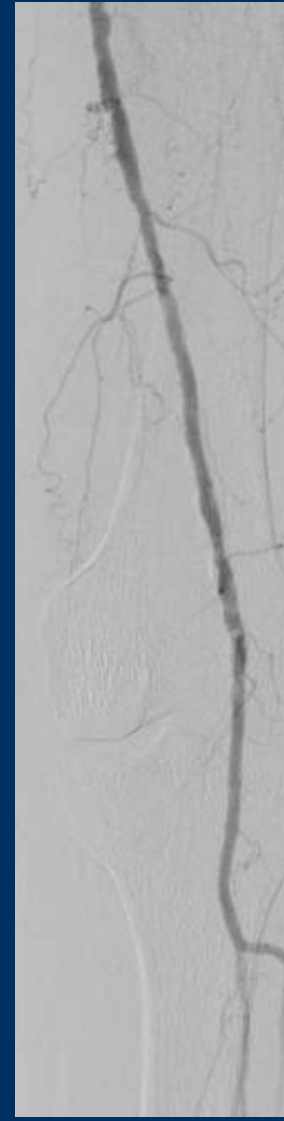
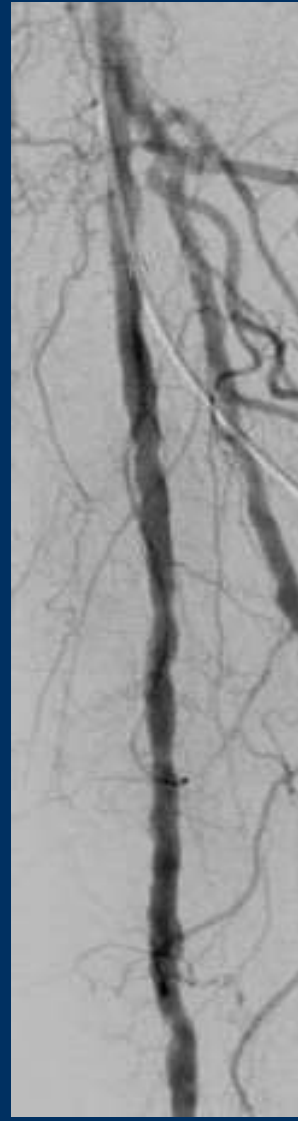
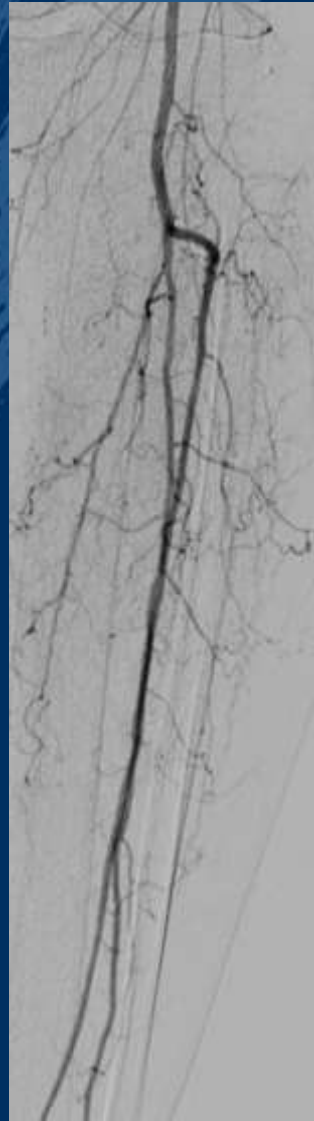


CTO of the left SFA, 8 Fr Rotarex

First pass

Several passes

# Rotarex for Chronic SFA-CTO



2 x 5.0/120 mm DCB

12 months FU results

# Rotarex mechanical debulking: The Leipzig experience in 1.200+ patients

- Single center registry:
  - Use of Debulking 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%)

# Rotarex mechanical debulking: The Leipzig experience in 1.200+ patients

## Intervention Feature

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

# Rotarex mechanical debulking in native arteries:

## Demographic characteristics (n=1203)

<b>Age, Mean ± SD (n)</b>	66.7 ± 12.1 (1203)
<b>Male gender, n(%)</b>	805 (66.9)
<b>Medical History, n(%)</b>	
<b>Obesity</b>	396 (32.9)
<b>Smoking</b>	573 (47.6)
<b>Dyslipidemia</b>	795 (66.1)
<b>Diabetes</b>	482 (40.1)
<b>Insulin-dependent DM</b>	85 (17.6*)
<b>Hypertension</b>	957 (79.6)
<b>Coronary Artery Disease</b>	360 (29.9)
<b>Cerebrovascular disease</b>	122 (10.1)
<b>Renal Impairment</b>	146 (12.1)
<b>Dialysis</b>	18 (1.5)
<b>Previous anticoagulation</b>	87 (7.2)

Table 1. Clinical characteristics of 1203 patients treated with Mechanical Debulking for “plain” native arteries. \* among diabetic patients

# Rotarex mechanical debulking in native arteries:

## Onset of symptoms

Acute ( <14 days ) 211 (17.5)

Subacute ( < 3 months ) 314 (26.1)

Chronic ( > 3 months ) 678 (56.4)



# Rotarex mechanical debulking in native arteries: **Angiographic and procedural characteristics**

Total Vascular access sites		1203
	Antegrade	739 (61.5%)
	Crossover	413 (34.3%)
	Retrograde	51 (4.2%)
Sheath diameter device (French)		
6		844 (70.2)
	8	359 (29.8)
Mean lesion length (cm)		11.7 (2-24.8)
Intervention area		
	Iliac	13 (1.1%)
	SFA	835 (69.4%)
	Popliteal	114 (9.5%)
	SFA + Popliteal	169 (14.0%)
	Proximal BTK	49 (4.1%)
	Other	23 (1.9%)

Table 3. Overall Angiographic and procedural characteristics among 1203 patients treated with Mechanical debulking devices for “plain” native arteries.

# Rotarex mechanical debulking in native arteries: Angiographic and procedural characteristics

Type of lesion (complain symptoms)		n(%)
Calcification		1169 *
	No/mild	396 (33.9)
	Moderate	464 (39.7)
	Severe	309 (26.4)
Intervention Feature		1203
	De-novo lesions	789 (65.6)
	Previous Balloon Angioplasty	414 (34.4)

\* Loss of 34 patients, due to inadequate images

# Rotarex mechanical debulking in native arteries:

## Acute results

- Procedural success rate: 1139 (94.7% )
- Main performed procedure
  - Rotarex Debulking alone: 255 (21.2%)
  - Rotarex Debulking + PTA: 597 (49.6%)
  - Additional Stenting: 251 (29.2%)
  - Additional Thrombolysis: 113 (9.4%)
- Mean time follow-up: 12  $\pm$  2.4 months

# Rotarex mechanical debulking in native arteries: Acute results - Complications

**Table 6. Major Adverse Events (MAE) to 30 postoperative day**

MAE	All events
	n (%)
Perforation	22 (1.8)
Bleeding	29 (2.4)
Dissection	108 (9)
Acute closure	27 (2.2)
Emboli	87 (7.2)
Infection	14 (1.2)

# Rotarex mechanical debulking in native arteries:

## Results

- Procedural success rate 94.7%
- Stenting-rate: 29.2 %
- Full lesion stenting: 7.6 %
- Focal stenting: 21.6 %
- Clinical follow-up: 12 months TLR 10.6%

# Rotarex mechanical debulking

## Summary

- Mechanical debulking with the Rotarex-catheter resulted in a high procedural success rate of 94.7%
- The Rotarex device is safe and effective in a broad range of lesions, including CTO
- The 12-months TLR rate of 10.6% in a real world scenario demonstrates the clinical effectiveness of Rotarex mechanical debulking in arteries



**Thank you!**

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