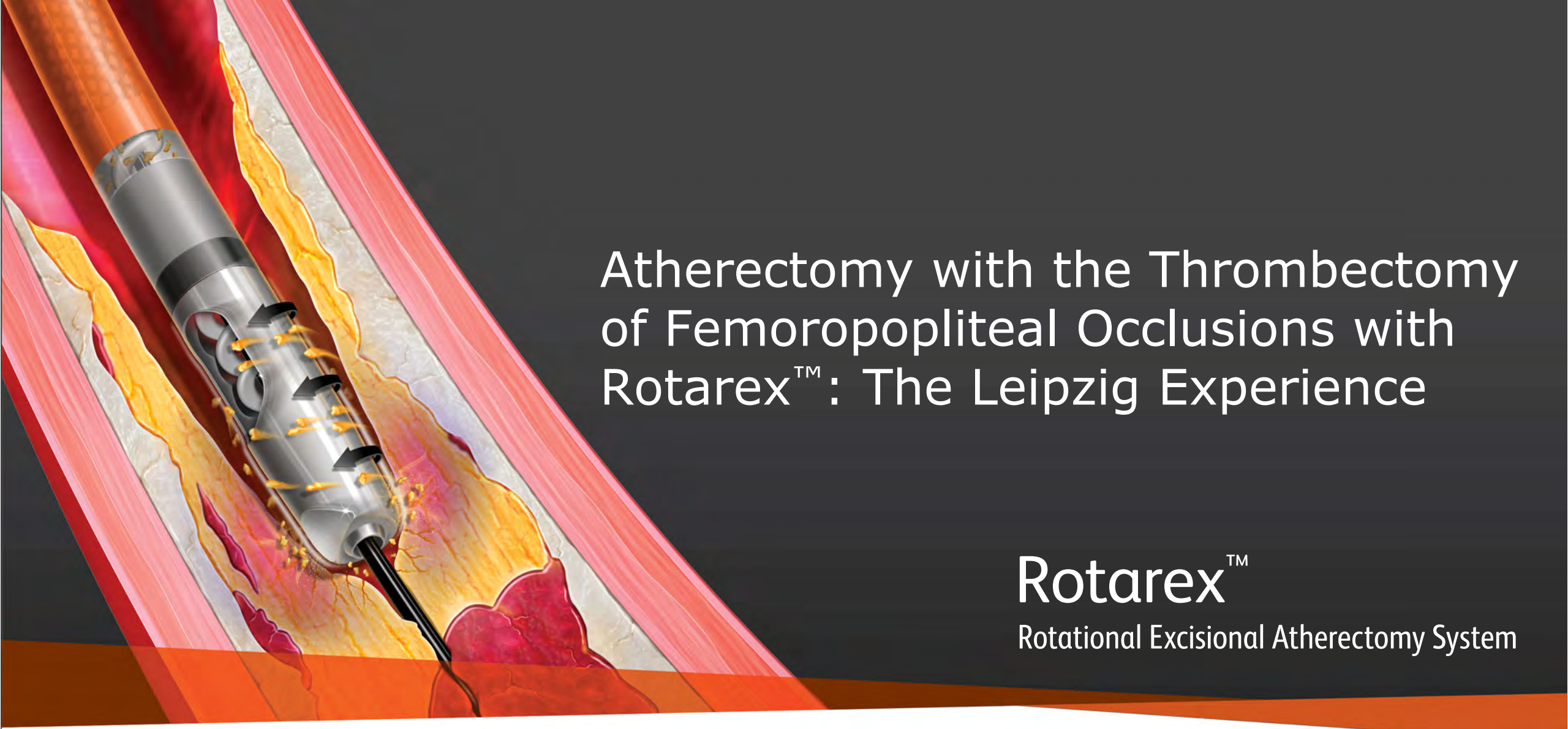


Atherectomy with the Thrombectomy of Femoropopliteal Occlusions with Rotarex™: The Leipzig Experience

Rotarex™

Rotational Excisional Atherectomy System

BD

Real-World Clinical Results

Retrospective review in a real-world scenario with consecutive patient enrollment between January 2011 and November 2013.[1]

Total Procedures Studied: 658

Revascularization at 12-months	**90.1%** Freedom from Target Lesion Revascularization	
Clinical Success at 12-months	**78.7%** Clinical Success (% of N=658 patients with improvement of ≥1 Rutherford Class)	
Challenging Lesions	**51.2%** Calcified Lesions[2]	**14.8 cm** Average Lesion Length
	60.3% Rutherford 4-6 at Admission	**56.7%** Chronic Lesions

[1] The clinical experiences presented herein are for informational and educational purposes only. The results presented may not be predictive for all studies and patients. Results may vary depending on a variety of experimental and clinical parameters, as well as patient specific attributes. The treatments described in this presentation represent those of the presenting physician. Please consult product labeling for appropriate use. 3.2% distal embolization rate at 12 months, distal embolic protection used in 6.2% of cases

[2] The use of Rotarex™ System Catheters are contraindicated in vessels in which the target lesion is heavily calcified.

Objective & Methods

Objective

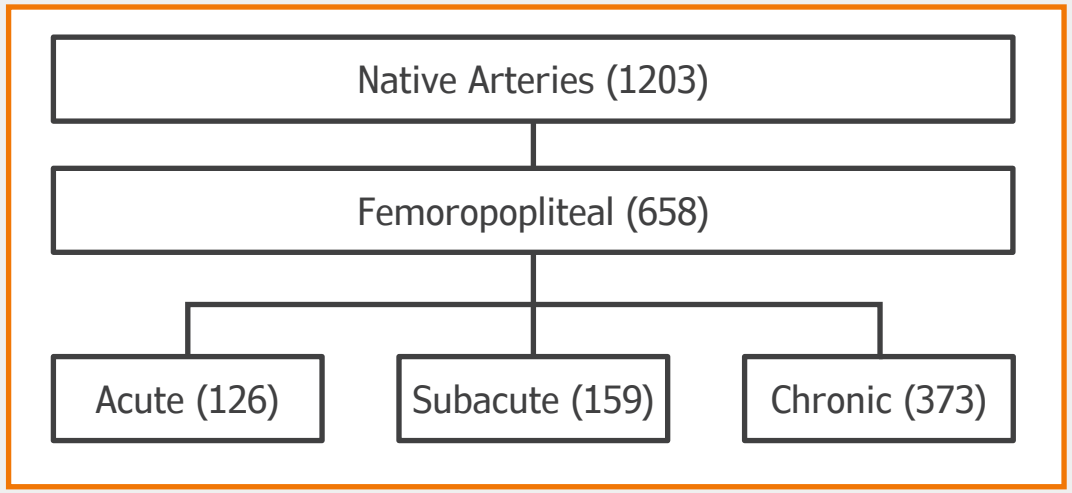
To evaluate the use of the Rotarex™ Rotational Excisional Atherectomy Device in acute, subacute, and chronic femoropopliteal artery occlusions.

Outcome Measures:

- Procedural success
- Need for thrombolysis
- Stenting rate
- Stent length vs lesion length
- MAE (including distal embolization, perforation, amputation, bleeding) at 1 month/12 months follow-up
- Freedom from clinically-driven TLR (cd-TLR) within 12 months follow-up
- Clinical success as improvement in Rutherford Class (RC) and ABI at 12 months follow-up

Methods

Retrospective, single-center, investigator-initiated registry. A cohort of 1203 patients “native” lower limb arteries were treated with the Rotarex™ Atherectomy Device of which 658 were “native” femoropopliteal. Analysis was performed for each of the subgroups.



Patient & Lesion Characteristics

- 60.3% CLI patient
- 14.8 cm mean lesion length
- 100% occlusions
- 56.7% chronic lesions

Patient Demographics	
Age (years ± SD)	67.4 ±116
Gender (m)	65.1%
Obesity	29.6%
Hyperlipidemia	66.4%
Diabetes mellitus	37.1%
Smoker	44.7%
Mean ABI	0.31 ± 0.19
CLI	60.3%
Calcification	51.2%

Lesion Characteristics	
Mean lesions length	14.8 cm
Occlusions	100%
Isolated popliteal artery	12.9%

Onset of Symptoms	
Acute	19.1%
Subacute	24.1%
Chronic	56.7%

The use of Rotarex™ System Catheters are contraindicated in vessels in which the target lesion is heavily calcified.

1-Month Safety Results

- Low distal embolization rate (3.2%) despite rare use of distal protection filters
  - 93.8% of cases did not include a distal protection filter
- Low rate of procedural complications in a broad range of lesions

1-Month Safety Rates	
Distal Embolization	3.2%
Perforation	1.4%
Bleeding	2.7%
30-day death	1.4%
30-day amputation	1.2%

12-Month Outcomes

- High rate of procedural success
- 1 in 5 patients treated with ONLY the Rotarex™ Atherectomy System
- 53.8% adjunctive PTA use
- 90.1% freedom from TLR at 12 months
- 78.7% of patients improved by ≥1 RC

Immediate Results	
Procedure success	95.9%
Rotarex™ alone	21.1%
Adjunctive thrombolysis	9.0%
Adjunctive PTA	53.8%
Adjunctive stenting	25.1%

12-Month Efficacy Rates	
Freedom from TLR	90.1%
Improvement in RC ≥1	78.7%

Summary

Atherectomy with Thrombectomy of Femoropopliteal Occlusions with Rotarex™: The Leipzig Experience

Presented by Bruno Freitas, MD at Charing Cross 2019

- High procedural success rate of 95.9% in challenging lesions
- 90.1% freedom from TLR at 12 months
- 21.1% of patients did not receive adjunctive therapies
- 78.7% of patients improved by ≥1 RC
- Low distal embolization rate (3.2%) despite rare use of distal protection filters
- Low rate of procedural complications and 30-day clinical events