Real World Results, The Leipzig Experience

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Rotarex™

Rotational Excisional Atherectomy System

BD

Disclaimer

The speaker's presentation today is on behalf of BD. Any discussion regarding BD products during the presentation today is limited to information that is consistent with the BD labeling for those products. Please consult BD product labels and inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use.

The opinions and clinical experiences presented herein are for informational purposes only. The results from these case studies may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes. The physician has been compensated by BD.

Disclosure

Speaker name: **Dierk Scheinert, MD**

I have the following potential conflicts of interest to report:

- **X** 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

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

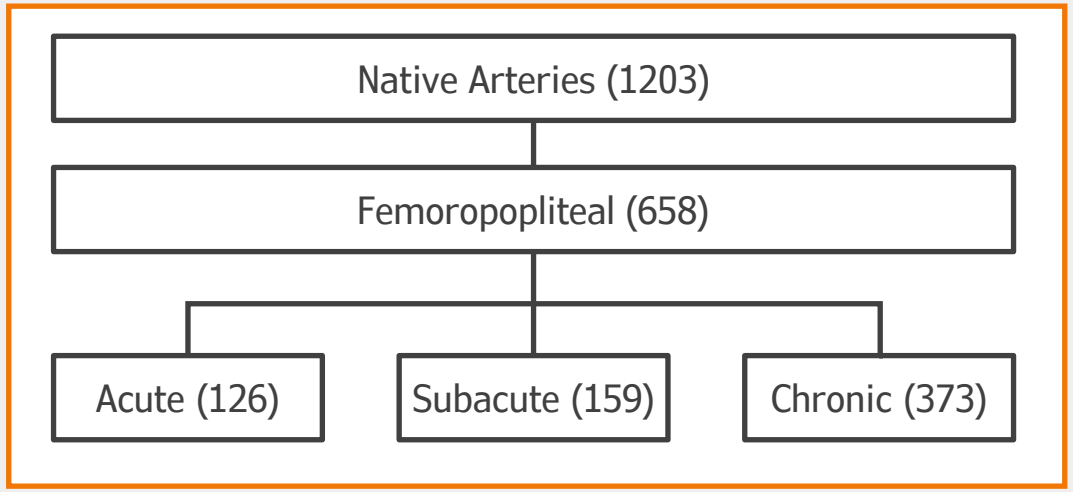
To evaluate the use of the Rotarex™ Rotational Excisional Atherectomy Device in acute, subacute, and chronic femoropopliteal artery occlusions.

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™ Atherectomy Device: 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

Rotarex™

Rotational Excisional Atherectomy System

The Straub Endovascular System is herein referred to as the BD Rotarex™ Rotational Excisional Atherectomy System

Indication For Use: When operated with a Rotarex™ single use catheter, the Straub Endovascular System is intended for use as an atherectomy device and to break up and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, pulmonary, iliac or renal vasculature.

Contraindications: Use of the Rotarex™ family of catheters is contraindicated in the following situations and locations: · In the cardiopulmonary, coronary, cerebral, iliac and renal vasculature · In the venous vasculature · In instances of persistent vasospasm · In patients not suitable for atherectomy/ thrombectomy · In patients with known or suspected allergies to any component of the Straub Endovascular System · In patients with haemodynamic instability, shock or severe coagulatory disorders · In patients where it is impossible to achieve sufficient anticoagulation and platelet aggregation inhibition · In areas of known or suspected infection, especially at the puncture site or target vessel segment · In vessels which are oversized or undersized for the particular Rotarex™ catheter used In stents, stent grafts or bypass grafts · Without the use of a Straub provided guidewire · When the Straub provided guidewire cannot completely cross the target lesion · Where the Straub provided guidewire is in a subintimal position of any length · Where the Straub provided guidewire has become threaded or entangled in the wire mesh of a stent, stent graft or the lining of a stent graft · Where the target lesion is located in a region of marked vessel tortuosity (has a radius of curvature ≤2 cm) or is heavily calcified · Where pre-existing damage is present in the vessel wall at or near the target lesion from prior surgery, aneurysms or other disease · During MRI procedures or where electrical current may be passed to an undesired location via the catheter, e.g., during electrocautery, electrosurgery or defibrillation. The Rotarex™ catheter and guidewire must be entirely removed before these therapies are administered, even in an emergency situation · Where the recommended separation distances from Radio Frequency and Electro- Magnetic Interference (EMI) sources cannot be maintained (Reference the manual for the Drive System) · Where any component of the Straub Rotarex™ Endovascular System has sustained damage, including any breech of the sterile barrier

Warnings: Rotarex™ catheters and the Drive System are intended for use only by suitably qualified medical personnel experienced in the diagnosis and treatment of peripheral vascular disease by percutaneous methods · The Rotarex™ family of catheters may only be used in conjunction with the Drive System · The Rotarex™ family of catheters may only be used with the Straub provided guidewire with which they are packaged · Rotarex™ catheters are supplied sterile for single-use only. Do not reprocess or resterilize. Resterilization or reconditioning may severely impair the function of the product · Do not use Rotarex™ catheters whose packaging is damaged or whose sterilization expiration date has passed · Position the flexible tip of the guidewire as far distally as possible from the vessel occlusion being treated to avoid the tip being aspirated into the rotating helix. Recommended distance is >10 cm (4 in). Operators should take care that manipulations of the catheter do not alter the desired position of the guidewire · Risk of distal embolization is greatly increased if the operator attempts to advance the catheter faster than the recommendations in these instructions, especially near the distal end of the occlusion · Failure to ensure sufficient blood flow to the catheter head could result in vessel collapse · Monitor the blood flow to the collecting bag continuously throughout the procedure · Do not operate the Rotarex™ catheter near fractured areas of broken stents or stent grafts. If a protruding stent strut penetrates into the side window of the catheter head, the stent, stent graft or vessel may become severely damaged, destroyed and/or dislodged, or the catheter head may become entrapped in the stent or stent graft in such a manner that the catheter and the stent or stent graft must be surgically recovered · Rotarex™ catheters should only be used under adequate visual monitoring with suitable radiographic techniques

Cautions: Rotarex™ catheters do not contain any parts that can be maintained or serviced by the end-user. Do not repair or change the configuration of the product · Use of the Rotarex™ catheter through a kinked or damaged introducer or where the catheter itself has become kinked or bent, may cause erratic function and or device failure · Rotarex™ catheters must not be allowed to operate "dry" and must be primed and flushed using heparinized saline before and during use per the instructions in this IFU. Throughout catheter use, always ensure there is a sufficient blood flow to the catheter head. Allowing the catheter to operate without heparinized saline solution priming and flushing or without adequate amounts of aspirated blood, will cause the device to operate erratically and or cease functioning · Failure to manipulate the catheter slowly in a back and forth motion as described in the instructions may result in fracture of the helix and/or guidewire · Insufficient blood flow through the catheter may result in intra-catheter clotting, slow or absent therapeutic function, fracture of the helix and/or guidewire, and/or overheating of the catheter · The guidewire adaptor must be in the working position (pulled back) when the motor is active · When active, the handle of the Rotarex™ Catheter and the portion of the catheter outside the patient's body must be kept at the same height as the introducer sheath and straight at all times with the outlet tube to the collecting bag hanging vertically below the motor in a straight line. Failure to position the catheter and outlet tube in this manner may result in catheter blockage, helix fracture and/or guidewire fracture

Potential Adverse Effects: Potential adverse effects include, but are not limited to: · Embolization, especially distal embolization · Pulmonary embolisms of all degrees of severity · Thrombosis, especially recurrent thrombosis · Re-occlusion · Vessel wall injury · Vessel dissection / perforation / rupture · Perforation as a result of mural calcium being torn out of the vessel wall · Arteriovenous fistula / pseudo-aneurysm · Hematoma, bleeding, hemorrhage · Organ perforation · Implants such as stents / stent grafts / bypass grafts getting damaged, caught or dislodged · Disruption of the catheter: debris remaining in the body · Allergic reactions · Infections or necrosis at the puncture site · Catheter-induced sepsis · Death

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Please consult product labels and instructions for use for indications, contraindications, hazards, warnings, and precautions.