Leipzig's Experience Using Rotarex™ Rotational Excisional Atherectomy for In-Stent Reocclusion in Peripheral Arterial Occlusive Disease

CLD talks with Andrej Schmidt, MD, PhD.

Can you tell us about your practice?

The clinic for Angiology at the University Hospital Leipzig, Germany is probably one of the largest centers for interventional therapy of peripheral arterial occlusive disease (PAOD) in Europe. I am a senior interventionalist specializing in internal medicine, cardiology, and vascular disease at this clinic, and have been performing endovascular procedures for more than 20 years. At our clinic, PAOD is the main focus. The clinical spectrum involves severe intermittent claudication, chronic limb-threatening ischemia, and acute limb ischemia due to disease of the iliac arteries, and of course, infrainguinal disease down to the digital arteries of the foot. I primarily focus on treating complex lesions, including those requiring special techniques such as a double retrograde and antegrade approach. Since stenting is necessary in a substantial number of cases, especially when treating complex PAOD lesions, we are also facing the problem of in-stent reocclusion. The Rotarex™ Atherectomy Device (Becton, Dickinson and Company) is certainly our first choice in these cases.

Can you tell us more about your experience with the Rotarex™ Atherectomy Device?

We started using the Rotarex™ Atherectomy Device more than 15 years ago. Today, after several technical optimizations, the latest generation, based on our experience through the years, doesn't need any further improvements. The Rotarex™ Atherectomy Device works both as a thrombectomy and atherectomy device for acute, subacute, and chronic occlusions. However, the most typical cases for use are acute to subacute occlusions and especially in-stent reocclusions. Regardless of whether the in-stent restenosis is acute or chronic, the results are impressive. The main location after stenting and therefore, for use of the Rotarex™ Atherectomy Device, is the femoropopliteal segment. Iliac in-stent reocclusion certainly occurs less frequently, but does also occur in this segment and here, too, the Rotarex™ Atherectomy Device is our first choice of device. We also use the Rotarex™ Atherectomy Device in occlusions of native arteries, for example, if we have the impression that at least partially fresh or subacute thrombotic material is present. This could be a long femoropopliteal total occlusion, not too calcified, that is showing signs of a rather acute occlusion like paucity of collaterals, visible thrombus at the proximal or distal ends of the occlusion, or cases where a focal stenosis might have led to thrombosis of the whole segment. In these cases, the advantage of the Rotarex™ Atherectomy Device is in its ability to treat different kinds of occlusive disease (fresh or already organized thrombus, as well as atherosclerotic material). In very chronic, severely calcified chronic total occlusions (CTOs), the Rotarex™ Atherectomy Device may not be suited. However, if the calcification pattern is rather circumferential and the guidewire passed centrally through that calcification, a Rotarex™ Atherectomy Device can be a good choice, since this type of CTO not infrequently has a partially thrombotic core.

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Where do you mostly see thrombus in PAOD patients? Have you seen an influx in thrombotic lesions with COVID-19?

In the iliac arteries, thrombus is mainly seen in the infrequent case of in-stent reocclusion. Here we use the Rotarex™ Atherectomy Device as an 8 French device. However, native iliac occlusions may also harbor thrombus; for example, in external iliac occlusions, often starting at the proximal end as arteriosclerotic stenosis and progressing to an occlusion, and with thrombosis formation over the full length of the artery. An 8 French Rotarex™ Atherectomy Device system can effectively be used in this situation.

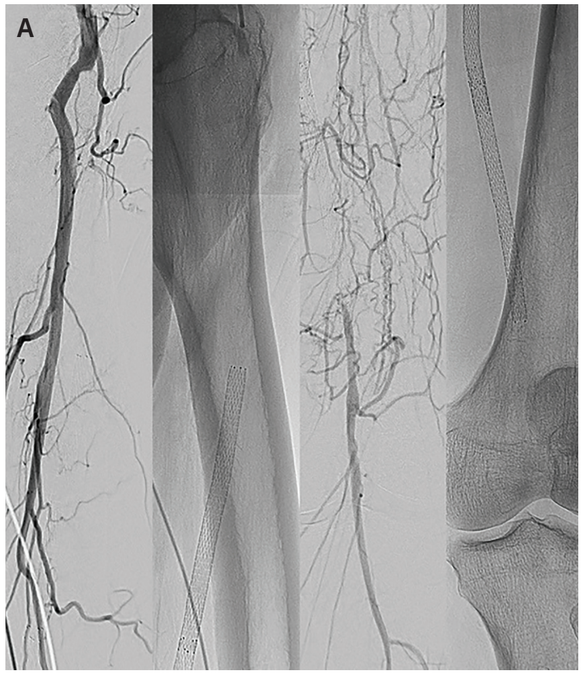
It must be assumed that most in-stent reocclusions of the femoropopliteal segment consist, at least partially, of thrombus. In the native femoropoliteal artery occlusions, in my experience, I see thrombus presence in about 20-30% of my cases.Patient history, Duplex ultrasound, and the angiographic appearance, as mentioned above, certainly all help to select the appropriate case for a Rotarex™ Atherectomy Device in this arterial segment.

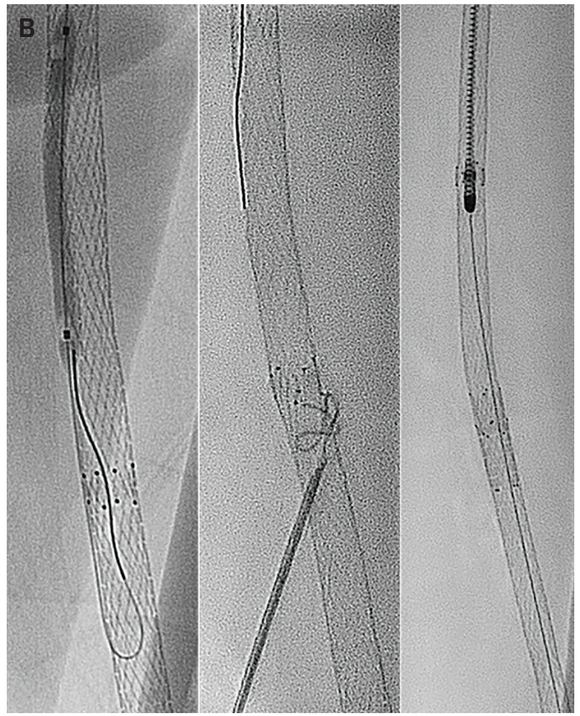
Thromboembolic occlusions are another scenario well suited for treatment with the Rotarex™ Atherectomy Device. Depending on the location, an 8 French is the best match for a femoral bifurcation (surgery is usually the standard treatment, but we have moved to Rotarex™ Atherectomy Device treatment for these lesions), and a 6 French system is used in distal popliteal or infrapopliteal trifurcation emboli. Since peripheral emboli are often of cardiac origin and at least partially organized, thrombolysis may be ineffective and Rotarex™ Atherectomy Device thrombectomy is our first-choice treatment.

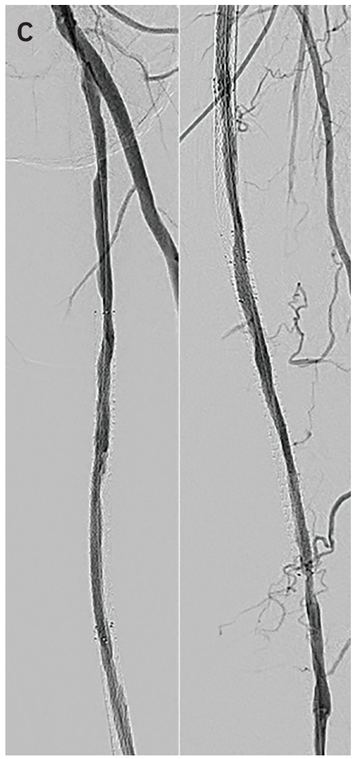
The lesions we choose for treatment with the Rotarex™ Atherectomy Device are manifold and since we are treating approximately 7-10 PAOD patients every day in our cath labs, at least once a day, the Rotarex™ Atherectomy Device is in use.

Since the COVID-19 pandemic, significantly more cases of acute limb ischemia due to thrombotic occlusions are also seen at our center. These cases often involve the whole infrainguinal arterial tree, and appear to be a result of in situ thrombus formation rather than embolic in nature. These occlusions are more difficult to treat. Fogarty thrombectomy is often only partially effective, since the thrombus often reaches into the infrapopliteal area. Thrombolysis after cut-down is no longer an option. We tend to treat endovascularly using the Rotarex™ Atherectomy Device, and additionally using thrombolysis/aspiration for the tibial and pedal segments. Unfortunately, young patients in their 50s or 60s are also affected and some succumb to their COVID-19 illness.

Can you describe the mechanism of action for the Rotarex™ Atherectomy Device?







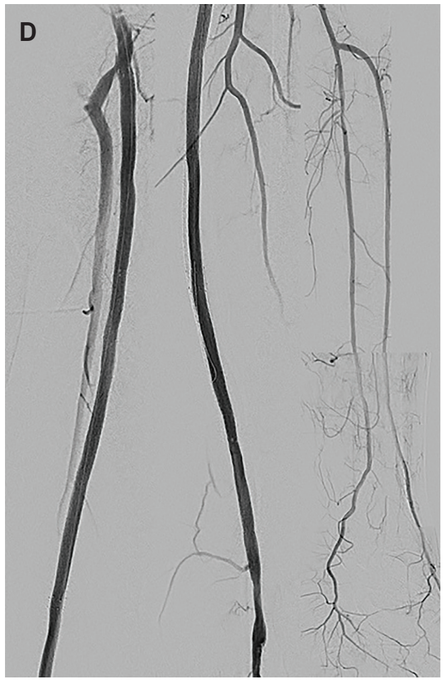


Figure 1A-D. Case Study: Rotarex™ Atherectomy Device for a Chronic In-Stent Reocclusion in the Left Leg.

(A) A 67-year-old male patient received treatment with implantation of a drug-eluting stent (diameter 7 mm) for a long superficial femoral artery (SFA) chronic total occlusion 3.5 years ago. Restenosis/reocclusion developed gradually, with total reocclusion starting 5 months prior to the current presentation. The patient suffered from severe claudication in the left leg, with a maximal walking capacity of 150 meters, and had an ankle-brachial index in the left leg of 0.65. Angiography showed a long reocclusion of the left SFA. Angiography of the left femoral bifurcation was performed in a right anterior oblique 60° view. The first 10 cm of the proximal SFA was not treated with stents. (B) Guidewire passage was difficult due to chronic hyperplastic disease within the stent. Antegrade passage was impossible, even after predilatation. Guidewire insertion from retrograde was also difficult due to the in-stent fibrosis. Finally, atherectomy with an 8 French Rotarex™ Atherectomy Device was performed. (C) Result after 2 passes with the 8 French Rotarex™ Atherectomy Device. (D) Final result after additional stenting of the proximal native SFA and percutaneous transluminal angioplasty with adjunctive therapy for the mid and distal part of the in-stent lesion. Outflow angiography ruled out any peripheral embolization.

The device consists of a long spiral inside of the catheter that rotates at up to 40-60,000 revolutions per minute, depending on the device size, and in doing so, creates a very powerful suction force. The head of the device is beveled at the tip and spins as well, detaching the material from the arterial wall and fragmenting it into small pieces that are then transported out of the artery through two openings within the catheter tip. The observation of the stent walls moving towards the catheter tip during activation demonstrates how powerful the aspiration force of the catheter is. Occasionally, the Rotarex™ Atherectomy Device may stop automatically in these scenarios due to a safety mechanism engineered into the device when too much resistance occurs. A second safety mechanism is a return button that if pressed, spins the spiral in the opposite direction for a very short time, releasing any material blocking the catheter tip/spiral. Over the past 15 years that we have used the Rotarex™ Atherectomy Device, we have never experienced the catheter becoming hooked in a stent, making retrieval of the catheter impossible, an event which can, for example, occur when using a directional atherectomy system within a stent. The Rotarex™ Atherectomy Device has been shown safe to use inside a stent at our institution.

How often do you see in-stent restenosis in your PAOD patients?

Roughly 50-60% of our Rotarex™ Atherectomy Device cases are in-stent reocclusions, approximately 20% are native femoropopliteal occlusions, and 10-20% are patients with acute limb ischemia due to embolic occlusions.

The problem of femoropopliteal in-stent reocclusion certainly has been ameliorated since the introduction of drug-coated devices like drug-coated balloons and drug-eluting stents, but it definitely still exists. The shift from surgery to endovascular treatment, increasing the complexity of the cases we see now in our cath labs, consecutively increased the necessity for stenting, and again, as a consequence, the problem of in-stent occlusion. Management of in-stent acute or subacute occlusions before the availability of the Rotarex™ Atherectomy Device was often pre-dilation and local thrombolysis overnight. Complications due to thrombolysis were not infrequent. We still sometimes have to utilize thrombolysis after using the Rotarex™ Atherectomy Device for in-stent reocclusions. However, the duration of local thrombolysis is significantly shorter. We try to start these cases as the first ones of the day, which allows us to finish them within the same day, avoiding overnight thrombolysis. With this strategy, it is possible to diminish the complication rates of thrombolysis tremendously.

Do you use the Rotarex™ Atherectomy Device in occluded bypass grafts?

Yes, indeed, the Rotarex™ Atherectomy Device works well in bypass grafts. A prosthetic bypass often reoccludes because of hyperplastic or neoarteriosclerotic disease at the anastomosis areas. The material within the occluded graft is usually nearly fluid or at least soft, and the Rotarex™ Atherectomy Device is very efficient in this type of lesion. Similar to this, the Rotarex™ Atherectomy Device is our first choice for reoccluded Viabahns (Gore) in the femoropopliteal segment. Other scenarios of graft occlusions include, for example, a lower limb occlusion that occurs after endovascular aneurysm repair (EVAR). Standard treatment usually is either local thrombolysis or Fogarty thrombectomy via a cut-down of the femoral artery, with the risk of displacing thrombotic material into the hypogastric artery.

How do you find the device setup and time for use?

The setup is very easy; the catheter is flushed with saline using a syringe held to the tip of the device and then is ready for use. For in-stent reocclusions, where usually one or two passes are sufficient, the activation time, of course depending on the length of the lesion, is two to five minutes. After use, it is recommended to flush the device, activating it in saline to avoid thrombosis of the catheter. Treatment following use, for example, ballooning, may cause a peripheral embolization, depending on the amount of residual thrombus. The Rotarex™ Atherectomy Device catheter is then used to extract this embolus, which is usually hanging in the distal popliteal artery or infrapopliteal trifurcation. I have found in my practice that the Rotarex™ Atherectomy Device differentiates itself through its powerful aspiration, which allows me to treat the lesion in less time. Furthermore, this powerful aspiration force helps to reduce the risk of peripheral embolization and we seldom use peripheral filter protection. Finally, depletion of blood volume to a hazardous level, which can occur during classical aspiration with thrombectomy catheters for acute thrombotic or embolic lesions, has not been observed in my practice for the 6 or 8 French Rotarex™ Atherectomy Device. Certainly, very small patients with a low body mass index are at higher risk for volume depletion.

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How many runs of the device are typically required?

While it is patient dependent, in many of cases that I perform, the first pass is effective enough to proceed with ballooning or stenting. The efficacy certainly depends largely on the choice of device diameter. For femoropopliteal in-stent occlusions, the diameter of the stents implanted is usually 6 or 7 mm and then use of an 8 French Rotarex™ Atherectomy Device is definitely our first choice. In this situation, 6 French is only used if access arteries (for complete superficial femoral artery in-stent occlusions, we usually go cross-over) are too small to allow the safe insertion of an 8 French sheath.

Certainly, femoropopliteal in-stent occlusion cases can be encountered, in which thrombotic material seems to remain adjacent to the stent after the treatment with the Rotarex™ Atherectomy Device. We use thrombolysis for a few hours if the remaining thrombus is very apparent, or we continue with balloon treatment and repeat the Rotarex™ Atherectomy Device treatment if the thrombus is dislodged from the arterial wall after ballooning, being either still adjacent to the stent or having embolized.

Do you have advice for other physicians who might be interested in using the Rotarex™ Atherectomy Device?

There are, of course, several tips and tricks to learn for an optimal performance of the Rotarex™ Atherectomy Device. The learning curve is, however, not too long. I would start with rather acute or subacute in-stent reocclusions of the femoropopliteal segment. As mentioned, we prefer an 8 French device cross-over approach in this type of lesion. We prefer relatively stiff, braided sheaths. Advancement of the device through the lesion is slow, and movements are back and forth. Have an eye on the filling of the bag, which is attached by a tube to the device and should hang down from the operating table. It may occur that the thrombotic material is very organized, occluding the spiral and catheter at some point. Occasionally, a second interventionalist should press on the tube connecting the device to the debris bag while the first operator continues to activate the device. This allows for an easy check as to whether blood and debris is being transported out of the artery into the bag. If no filling of the tube during pressing can be observed, the catheter should be taken out and saline should be aspirated to flush the catheter.

The Rotarex™ Atherectomy Device has a broad indication, mainly because it works well in acute, subacute, and also some chronic lesions, across a large variety of lesion types, and in arterial segments like iliac, femoral and popliteal, and proximal tibials.

If there is no filling of the bag during activation within the artery but the stent struts are pulled towards the Rotarex™ Atherectomy Device tip, the reason is probably a hyperplastic stenosis at the origin of the stent that is not allowing any blood flow to follow into the occluded stent during the Rotarex™ Atherectomy Device passage. Predilatation of the stent entrance can solve this problem before resuming with the Rotarex™ Atherectomy Device treatment.

Embolization when treating these kinds of lesions can always occur. However, in the time I have used Rotarex™ Atherectomy Device, I have witnessed low embolization rates compared to other devices, because of its high aspiration force. We only use embolic protection in cases with absolute contraindication for thrombolysis and poor run-off, approximately 5% of our cases.

What do you see regarding use of the Rotarex™ Atherectomy Device in the future?

Of course, there is a place for other thrombectomy or atherectomy devices, and the choice of the optimal device for a specific lesion depends on many factors. The Rotarex™ Atherectomy Device has a broad indication, mainly because it works well in acute, subacute, and also some chronic lesions, across a large variety of lesion types, and in arterial segments like iliac, femoral and popliteal, and proximal tibials. ■

This article is sponsored by Becton, Dickinson and Company (BD). Dr. Schmidt is a paid consultant of BD. See important Safety and Risk Information below.

Rotarex™ Atherectomy System Safety and Risk Information: The Rotarex™ Atherectomy System is intended for use as an atherectomy device and to break up and remove thrombus from native peripheral arteries or peripheral arteries fitted with stents, stent grafts or native or artificial bypasses. Contraindications: In patients not suitable for atherectomy/thrombectomy • In the cardiopulmonary, coronary, carotid, cerebral and renal vasculature • In vessels that are undersized for the particular device used • In the venous vasculature. Potential Adverse Events: Embolization, especially distal embolization • Pulmonary embolisms of all degrees of severity • Re-occlusion • Vessel wall injury Please consult package insert for more detailed safety information and instructions for use.

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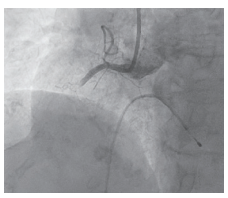
In the Literature: *CLD* Editor's Picks

JOURNAL OF Invasive Cardiology

Manual Coronary Thrombectomy in Primary PCI: What a Satisfaction it is Sometimes to Look Into the Catheter

Alessio Arrivi, MD, PhD; Nicola Bier, MD; Andrea Ascione, MD; Marcello Dominici, MD



ABSTRACT: An 89-year-old woman was referred to our cath lab for a primary percutaneous coronary intervention (pPCI) following electrocardiographic evidence of inferior ST-segment elevation myocardial infarction. A coronary angiography revealed single-vessel disease with complete occlusion of the right coronary artery (Figure 1). After crossing the occlusion with a guidewire, we proceeded with manual thrombectomy using the Eliminate Aspiration Catheter (Terumo Europe).

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VDM Vascular Disease Management

Long-term Outcomes for Resorbable DES for BTK Applications and LIFE-BTK Trial Update

iSET

Written by Debra L. Beck, MSc;
Presented by Ramon L. Varcoe, MBBS, MS, PhD, Mmed (ClinEpi)

Evidence continues to accrue for the use of bioresorbable vascular stents (BVS), with the first-generation Absorb device (Abbott) showing excellent long-term patency and freedom from target lesion revascularization in the tibial arteries. Ramon L. Varcoe, MBBS, MS, PhD, Mmed (ClinEpi), presented the ISET 2022 audience the 5-year findings for the Absorb device and an update on resorbable drug-eluting scaffolds for below-the-knee (BTK) applications.

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