Removal of Peripheral Arterial Occlusive Material with the Rotarex® S Device: Mechanical Atherothrombectomy

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ABSTRACT

Mechanical atherothrombectomy (MATH) with the Rotarex® S (Straub Medical AG, Wangs, Switzerland) catheter is an endovascular therapeutic technique for removing fragmentable occlusive material from the lumen of peripheral vessels. It can be used as a rapid, safe and efficacious initial modality for the treatment of acute or subacute ischemia of the lower limbs, even in patients with an immediately threatened extremity and those with a contraindication for surgical and/or thrombolytic therapy. Patient placement in an intensive care unit and routine embolic prevention with a filter are not necessary. In the literature, the technical success of MATH has varied from 92% to 100%, with lower rates in subgroups with occluded bypass grafts (78%) and a crossover approach (56%). The number of secondary surgical revascularization procedures has ranged from 0% to 5.3% and the mortality rate at 30 days has varied between 0% and 1%. The 30-day clinical success has varied from 68% to 98%, secondary patency from 68% to 97.6%, amputation-free survival from 94.4% to 100%, frequency of major complications from 0% to 6.9%, major hemorrhage from 0% to 2.6% and frequency of major debulking device-related complications from 0% to 0.4%.

INTRODUCTION

Endovascular therapy of lower-limb chronic arterial occlusions is typically associated with balloon angioplasty, elastic recoil, local arterial dissection and stenting. During treatment, occlusive masses undergo remodeling, fractures, and separation from the vessel wall together with wall dissection and dilation.[1] Thus, arterial recanalization and extremity reperfusion are usually associated with pressure trauma and arterial wall stretch that can negatively influence arterial patency after treatment. Theoretically, the initial removal of occlusive material can limit or exclude vessel barotrauma, elastic recoil, wall stretch, and dissection, and reduce the frequency of stenting procedures after balloon angioplasty.

In acute or subacute arterial occlusions, rapid mechanical atherothrombectomy can be used as an initial therapy[2] even in immediately threatened extremities. Thus, the risks associated with open surgery and/or thrombolysis can be reduced and routine hospitalization in an intensive care unit is not necessary. Furthermore, a chance for successful treatment can be maintained for patients with contraindications for surgery or thrombolysis.

THE ROTAREX® S CATHETER: MODE OF ACTION

The Rotarex®S (Straub Medical AG, Wangs, Switzerland) is a single-lumen catheter equipped with a rotating head driven by a stainless-steel helix rotating at up to 60 000 rpm. There are no sharp blades on the head surface (Fig. 1). The device has two superimposed stainless steel cylinders, each with two lateral apertures; the outer cylinder is connected to the rotating helix, and the inner cylinder is connected to the catheter shaft. The shape of the head facilitates the detachment and fragmentation of occlusive material together with the creation of a strong vortex by rotation of the outer cylinder. The displaced occlusion fragments are aspirated through the head openings and shredded again into debris that is transported to an external collecting bag.[3] The catheter can be currently used in vessels with a diameter of 3 mm or more and its use is dependent on the ability to cross the lesion intraluminally with a guidewire. The efficacy of the Rotarex® S catheter depends on the presence of fragmentable occlusive material (atherosclerotic plaque, myointimal hyperplasia, fresh or old thrombus).

ENDOVASCULAR MECHANICAL ATHEROTHROMBECTOMY AS INITIAL THERAPY FOR ACUTE AND SUBACUTE LOWER-LIMB ISCHEMIA

Acute ischemia of the lower limbs (ALI) is a critical vascular emergency that not only endangers the affected extremity but also puts the patient‘s life at risk. Catheter-directed thrombolysis (CDT) and/or open surgery (OS) are common therapeutic modalities, but both are associated with significant mortality and morbidity rates. Serious comorbidities and cardiopulmonary complications influence postoperational outcomes in patients treated by surgery, and cardiopulmonary complications are responsible for 54-63% of the deaths at 30 days.[4,5] On the other hand, less-invasive thrombolytic treatment is more often complicated by major hemorrhage and stroke.[6-8] As a result, there is no overall difference in limb salvage or death at 30 days, six months or one year after initial surgery and/or thrombolysis.[9] A meta-analytic study[9] that evaluated data from five randomized trials and 1283 patients reported 30-day mortality of 4.6% (0-12.3%) and 30-day limb salvage of 88% (36-91%) in thrombolysis-treated participants. In open surgery patients, 30-day mortality was 8.2% (4.9-17.5%) and 30-day limb salvage was 87% (56-98%). Thrombolytic management was associated with major hemorrhage in 8.8% (0-11.8%) of patients at 30 days, and stroke occurred in 1.3% (0-1.8%) of patients in this group. In patients managed surgically, stroke was not observed and major hemorrhage occurred in only 3.3% (0-5.1%).

The guidelines[10-13] recommend surgical therapy when the extremity is immediately threatened and time to reperfusion is critical (category II B, early III[14]). In patients with milder symptoms (category I and II A[14]), thrombolysis is indicated. Due to the risk of stroke and major bleeding, certain guidelines[15] recommend surgery over thrombolysis.

The assumption that endovascular therapy without thrombolytics can reduce the number of serious bleeding complications has led to the development of mechanical techniques with the potential for prompt removal of occlusive masses. However, mechanical removal of arterial occlusive material has not yet replaced traditional treatments for various reasons, including limited experience with the techniques and the low efficacy of these approaches when used alone; they often must be combined with thrombolysis. Currently, technological progress has enabled rapid mechanical limb reperfusion in patients with embolic or thrombotic occlusions and an immediately threatened extremity. In primarily thrombotic occlusions, the Rotarex® S with its atherectomy potential can reduce not only the volume of the clot but also the fragmentable part of culprit and underlying lesions. Thus, the frequency of adjunctive balloon angioplasties and stenting procedures can be lowered. Soft occlusive material in acute or subacute occlusions allows safe guidewire penetration followed by mechanical atherothrombectomy in near-

Figure 1. Tip of the Rotarex® S catheter. The outer rotating cylinder is located between the black arrows. The white arrow shows the part shaped to produce a strong vortex.

ly all patients,[2] including those at high risk for surgery or thrombolysis. Prompt technical, hemodynamic and clinical effects can be reached in both aortoiliac (Figs. 2,3) and femoropopliteal segments, even in situations where it could be difficult to achieve good results with surgical or thrombolytic therapy (Fig. 4).

In patients with occlusions of the femoropopliteal arterial segment and crural arteries, the Rotarex® S can open the way to the tibial arteries, where percutaneous aspiration thromboembolectomy, PTA or stenting can be used to enhance the runoff (Fig. 4).

The technical success of MATH has varied from 92% to 100% in previous studies with target occlusions in infraaortic arteries,[16] femoropopliteal arterial segments[17-21] and femoropopliteal bypasses.[22,23] Lower technical success was reported in subgroups with occluded bypass grafts (78%) or a crossover approach (56%).[16] The frequency of concomitant thrombolytic therapy varied between 0%[21] and 21.8%.[24] The number of secondary surgical revascularization procedures ranged from 0%[16,18,20-23] to 5.3%[17] and the mortality rate varied between 0%[17,18,21] and 1%[16,20] at 30 days. The 30-day clinical success varied from 68% to 98%, secondary patency from 68% to 97.6%, amputation-free survival from 94.4% to 100%, frequency of major complications from 0% to 6.9%, major hemorrhage from 0% to 2.6% and frequency of major debulking device-related complications from 0% to 0.4%.

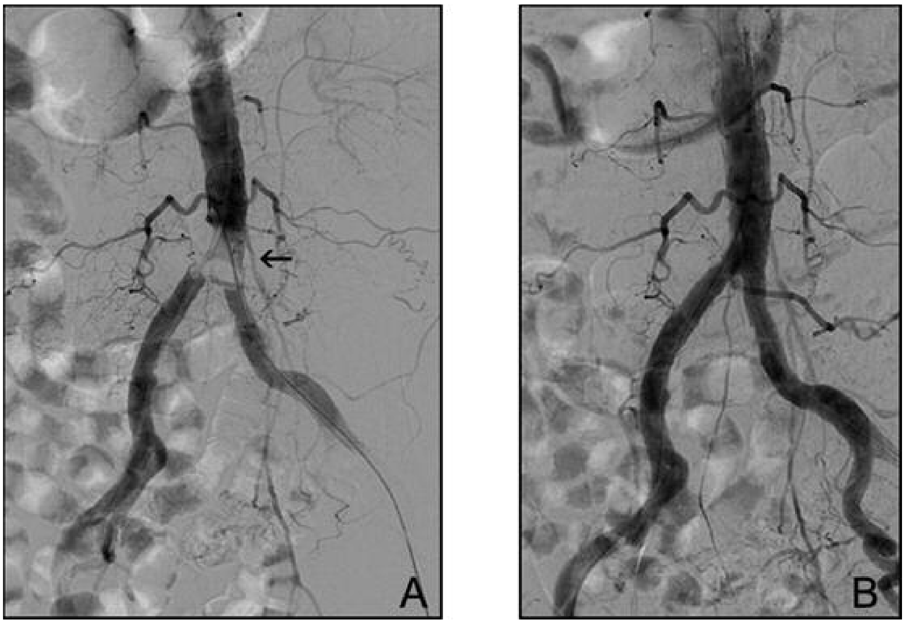

Figure 2. Female, 81 years old, ALI IIB - III, aortic bifurcation saddle embolism. (A) embolus in aortic bifurcation (arrow); (B) angiogram after embolus removal with the Rotarex® S introduced from the left groin. During Rotarex® S use, the balloon catheter stayed inflated in the right common iliac artery to protect the extremity from potential embolism.

After therapy, a significant elevation of mean ABI (ankle-brachial index) was regularly reported.

DEBULKING THERAPY IN OCCLUDED LOWER-LIMB BYPASS

The goal of surgical and/or endovascular therapy in patients with lower-limb ischemia is the elimination of return or progression of serious and threatening ischemic symptoms (resting pain, ischemic ulcers or gangrene).[11,25,26] Thus, bypass occlusion can be associated with renewed acute or critical ischemia and endangered lower extremity. The early (< 30 days) graft failure rate was 6.3% in a study that collected 9217 bypass procedures[27] and the frequency was higher in preceding emergency and reoperative procedures (8.2%). Typically, early bypass failure can be ascribed to technical factors (kinking or twisting of the graft, technical anastomotic problems, inadequate runoff, clamp injury, retained valves) and the prothrombotic

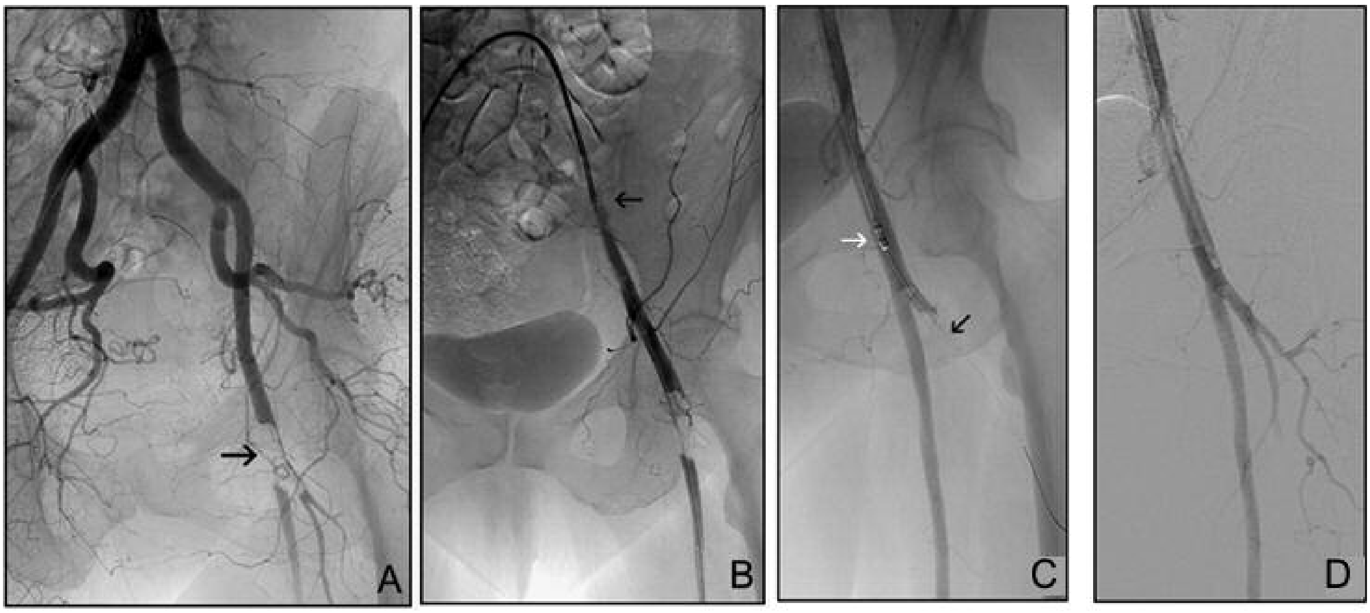

Figure 3. Female, 70 years old, ALI IIB, common femoral artery embolism. (A) left femoral bifurcation embolism (arrow); (B) percutaneous sheath (arrow) introduced from the contralateral approach; (C) superficial femoral artery was recanalized with the Rotarex® S (white arrow) and subsequently the deep femoral artery (DFA) was traversed with the guidewire (black arrow); (D) final angiogram after DFA recanalization.

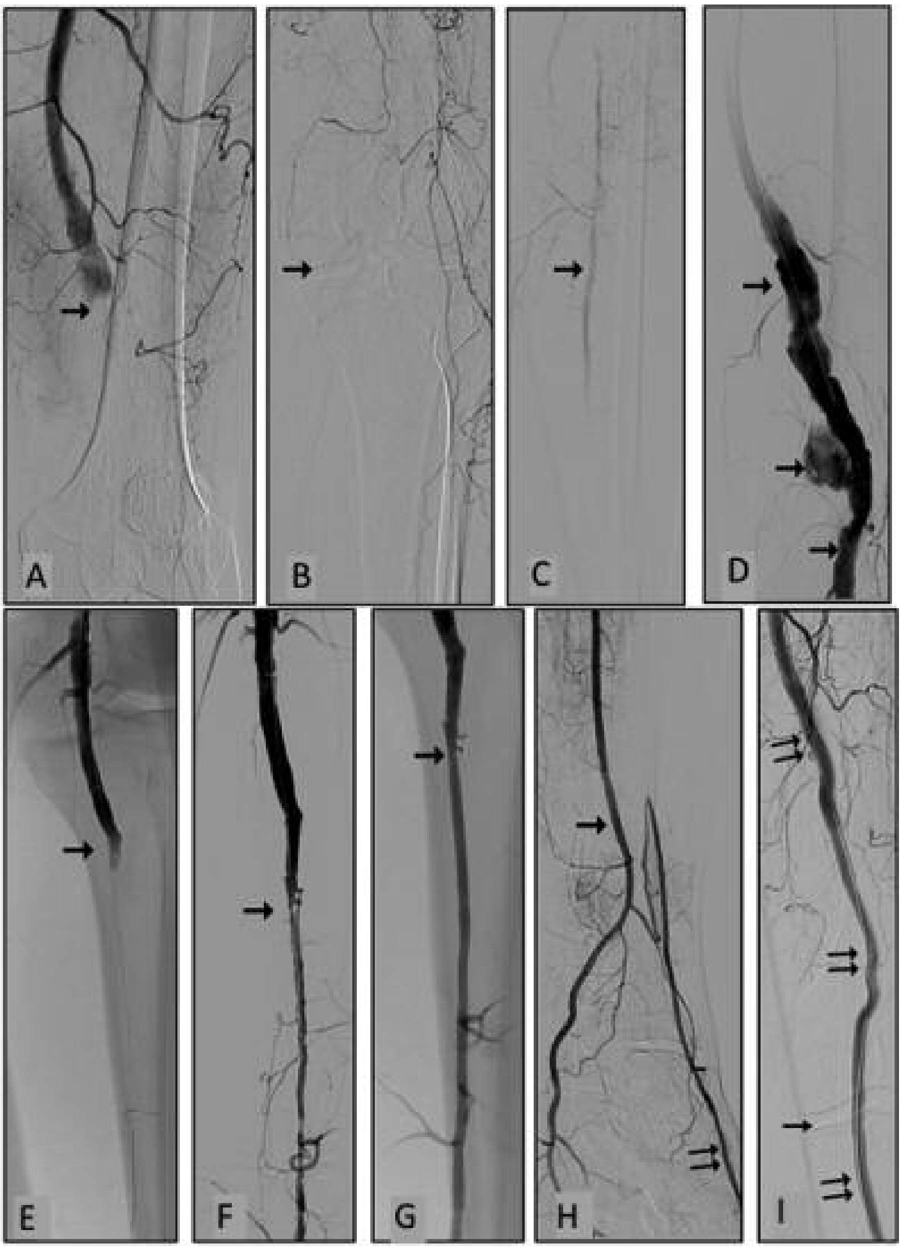

Figure 4. Male, 56 years old, ALI IIB, popliteal aneurysm thrombosis and calf vessel occlusion. (A) digital subtraction angiography (DSA), the arrow indicates the beginning of the popliteal artery (PA) occlusion; (B) knee joint aperture is depicted by the arrow; (C) only one fragment (arrow) of the calf vessel is filled with contrast material via collaterals; (D) after mechanical debulking of the PA with a recanalized lumen (arrows); (E) the PA was recanalized to its periphery (arrow) with the Rotarex® S catheter; (F) PA debulking opened the way for successful PAT of the peroneal artery with residual stenosis (arrow); (G) stenosed area after PTA and stenting (arrow); (H) the peroneal artery (arrow) supplies the plantar vessels directly and via collateral the dorsal pedis artery (double arrow); (I) finally, the popliteal aneurysm was eliminated by covered stents (Viabahn, W. L. Gore & Associates Inc, Flagstaff, AZ, USA) - double arrows, single arrow indicates the knee joint aperture.

state.[28] Intermediate graft failure (from 30 days to 18 months) is commonly associated with myointimal hyperplasia formation at the sites of anastomoses or valves (venous bypass grafts). Late graft failure is largely caused by the progression of atherosclerosis in the outflow or inflow vessels.

Excellent and long-lasting results (5-year primary patency rate 85-88%) can be expected with aortoiliac reconstruction in low-risk patients. Acute thrombosis of an aortofemoral graft limb occurs in about 2% of patients during the early perioperative period.[29] Primary patency rates of 87-100% (1 month), 69-86% (1 year) and 51-72% (5 years) have been reported[30] in femoropopliteal bypasses, with better results for suprageniculate and autovenous saphenous grafts. Patients who have undergone placement of lower-limb bypass grafts are followed-up with periodic evaluations that record the return or progression of ischemic symptoms. Therefore, hemodynamic deterioration caused by the progression of proximal or distal atherosclerosis and/or intimal hyperplasia can be detected before thrombosis and occlusion develop. In those cases, preventive balloon angioplasty, stenting or percutaneous atherectomy is used to assist the primary patency.

Surgical treatment of acutely thrombosed vein graft is usually associated with thrombectomy, thrombolysis and subsequent repair of the defects responsible for graft failure. Unfortunately, only 23% of vein grafts remained patent 3 years after successful thrombolysis and revision.[28,31] For intermediate-to-late vein graft failure, a new surgical reconstruction is recommended in patients with a threatened extremity. Nevertheless, advanced comorbidities and anatomy can preclude a major reoperation. Furthermore, it can be difficult to find sufficient vein for reoperation in patients with occluded prosthetic grafts. For secondary bypass grafts, primary patency rates of 25% (prosthetic) and 43% (autogenous vein) were reported five years after reoperation.[28]

Surgical and/or thrombolytic limitations are the reasons why endovascular, mechanical techniques are used in the management of occluded bypasses. Typically, femoropopliteal bypass occlusion is long and significant residual stenoses can be expected in proximal and/or distal anastomoses (Fig. 5) after MATH with the Rotarex® S. Thus, additional modalities (balloon angioplasty, stenting, percutaneous atherectomy) may be necessary. Furthermore, the clinical effect of successful bypass reflow may be insufficient in patients with poor runoff. Therefore, in such cases, the recanalization of natural vessels below peripheral anastomosis should be considered. Better results can be expected with an ipsilateral, antegrade approach because of better maneuverability with the catheters and a good chance for treatment of potential complications.

For the Rotarex® S catheter, technical success was reported in 98-100 % of a series with acute and subacute occlusions of femoropopliteal bypasses.[22,23] Lichtenberg et al.[22] managed 22 patients with venous (12) and prosthetic (10) occluded bypasses without major complication, death or reintervention during a 6-month follow-up. Wissgott et al. reported technical success in 42 patients (98%) with 81% venous bypasses, 4.8% complications (no amputation, no death) and 66% 12-month primary patency.[23] Zeller et al. reported lower primary success (78%) in 9 patients with occluded femoropopliteal bypasses compared to 91 cases of infraaortic occlusion.[16] A mixed series of 316 patients[2] with acute and subacute lower-limb ischemia (including 72 femoropopliteal bypass occlusions) reached 100% technical success at the level of target vessels with only minor complications (8%) associated with debulking therapy. The overall therapeutic success was negatively influenced by the infrapopliteal artery status and the low potential for effective endovascular and surgical treatment in this runoff area.

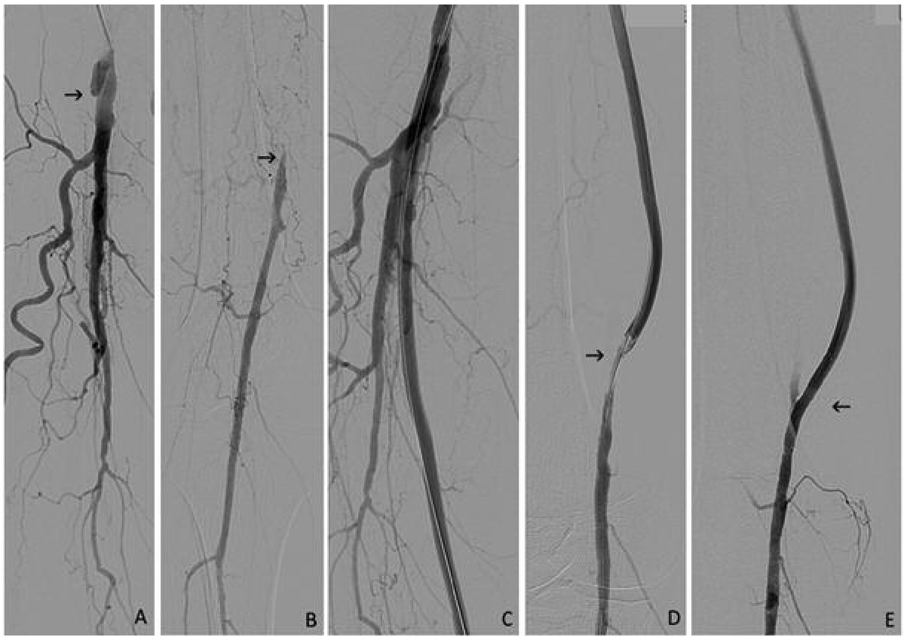

Figure 5. Male, 71 years old, subacute, right lower-limb ischemia, category Rutherford 3, prosthetic proximal femoropopliteal (FP) bypass thrombosis. (A) Occlusion of FP bypass at its origin (arrow). (B) The popliteal artery (PA) (arrow) is filled via collaterals. (C) Angiogram after bypass recanalization with the Rotarex® S. (D) Residual stenosis at the distal anastomosis (arrow). (E) Final angiogram after balloon angioplasty (PTA) and stenting (arrow).

MECHANICAL ATHEROTHROMBECTOMY AND ARTERIAL IN-STENT OCCLUSIONS

Bare metal, drug-eluting and covered stents are important tools for the endovascular treatment of lower-limb arterial disease to ensure vascular patency. In patients with lower-limb ischemia, these stents are beneficial for assuring a patent lumen following arterial elastic recoil and/or flow-limiting dissection. The majority of stents implanted are nitinol, self-expandable stents with closed-cell, open-cell or interwoven designs. The long-term patency of stented arterial segments is influenced by multiple factors (ischemic symptoms, lesion location and length, runoff, vessel diameter, stent fractures and length). Therefore, the primary patency rates at 12 months have been reported to range from 46% to 89%[32,33] in the femoropopliteal segment. Also, stent fractures were identified in 3%[34] to 36%[35] of treated limbs at 12 months. Higher primary patency rates at 12 months were reported for iliac stents (96%).[36,37] A recently published study that focused on Rotarex® S treatment of in-stent iliac and infrainguinal arterial occlusions reported procedural success in 98.6% of patients, with a restenosis rate of 20.5% at 12 months.[38]

The occlusion or stenosis of a stented artery usually causes the recurrence of ischemic symptoms, which can be even more serious than before stenting. Compared to surgery, mechanical atherothrombectomy is a less invasive procedure that avoids general anesthesia and offers the opportunity to immediately treat the underlying cause and concomitant lesions. A poor prognosis with a reocclusion rate of 64.6% (reocclusion/restenosis rate: 84.8%) at 24 months was reported for in-stent occlusions managed by balloon angioplasty (PTA) alone.[39] Without removal of occlusive material (debulking), PTA and stenting are associated with augmented arterial wall stretch and deep wall injury that can elevate the restenosis rate. Additionally, PTA and stenting are usually not applicable to fresh in-stent thrombosis where the risk of peripheral embolization is extreme.

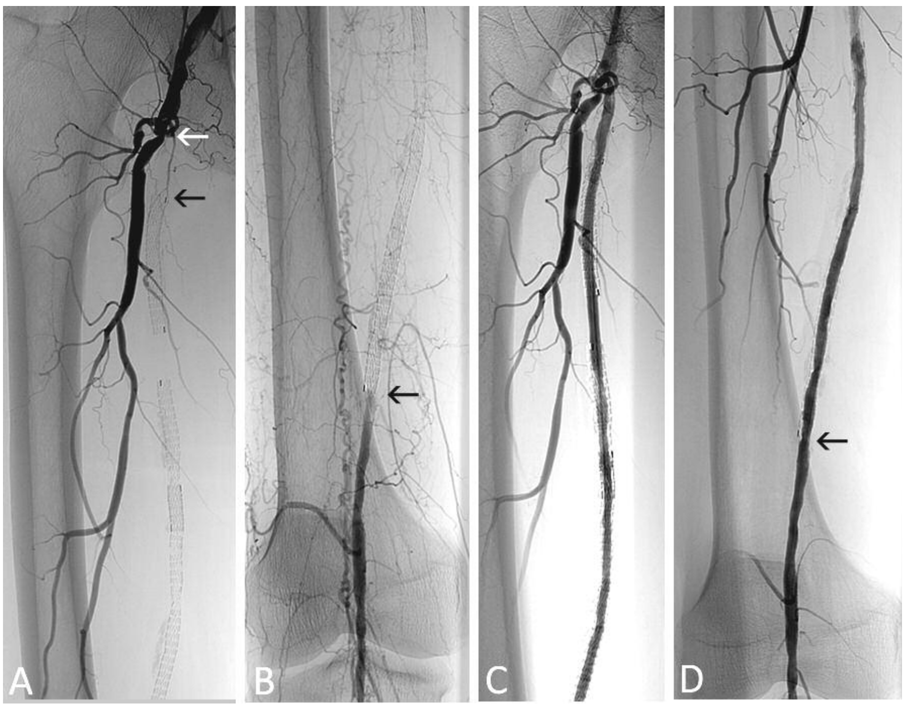

Figure 6. Male, 59 years old, acute ischemia of the right lower limb, category IIb. (A) The superficial femoral artery is occluded at its origin (white arrow), the proximal margin of the stented area is depicted by a black arrow. (B) The popliteal artery (arrow) is filled via collaterals. (C) Angiography after mechanical debulking with the Rotarex® S catheter and (D) following adjunctive balloon angioplasty. The distal margin of the stented area is depicted by an arrow.

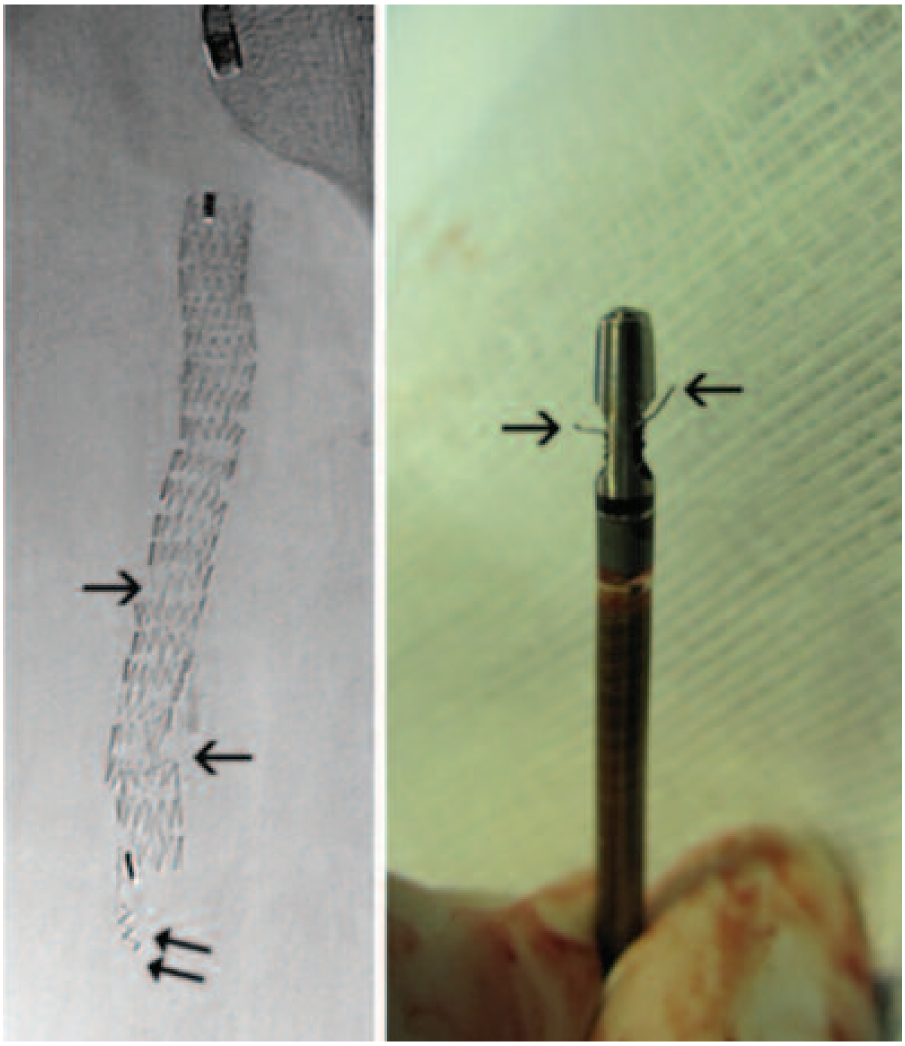

Figure 7. (Left) Careful examination of the stent before treatment can reveal strut fractures (arrows), deformations or sequestrated stent fragments (double arrow). If occluded, this stent would not be a good target for recanalization with the Rotarex® S. (Right) The catheter penetrating a multi-fractured, deformed and fragile stent can excise one of the struts which lodges within the helix and can jam the mechanism.

The Rotarex® S catheter has the potential for rapid removal (in a few minutes) of fragmentable atheroma, thrombus and myointimal hyperplasia even in long occlusive lesions (Fig. 6). As a result, the number of re-PTA and re-stenting procedures can be reduced. In acute and subacute in-stent occlusions, the risk of serious bleeding is reduced when mechanical removal of fresh occlusive material eliminates the need for thrombolysis.[2] Moreover, after successful Rotarex® S treatment, residual stenoses are shorter, less significant than the original occlusions[2] and require shorter stents, if any. Furthermore, removal of occlusive masses with uncovering of the endothelial layer can enable or facilitate drug uptake to the arterial wall from drug-coated balloons.

Rarely, problems with direct contact between the Rotarex® S rotating head and stent struts occur during mechanical debulking. Because such contact can damage the catheter, some caution and preventative measures are necessary. Before recanalization of an occluded, stented artery, it is important to carefully inspect the stent structure to assess its geometry, continuity, deformation, fractures, strut protrusion into the lumen and sequestration of metallic fragments (Figs. 7, 8).

In the presence of a significant proximal stenosis that does not allow sufficient blood flow to the rotating head, collapse of the arterial and stent walls may occur. Therefore, careful visual monitoring of the stent wall is important during Rotarex® S use and, if necessary, a proximal lesion should be treated before debulking continues.

In-stent occlusions of the proximal common iliac artery should not be managed from a contralateral approach. Due to the elasticity of the Rotarex® S catheter and its internal strain when bent over the aortic bifurcation, the rotating head may get in close contact with the outer (lateral) wall of the stent and safe catheter advancement may be impossible. In-stent occlusions of the common iliac arteries are better managed from ipsilateral retrograde puncture of the common femoral artery. In this case, additional saline injection through the side-port of the introducer sheath is necessary to prevent vessel collapse distal to the occlusion during Rotarex® S use. At the same time, the contralateral common iliac artery should be temporarily occluded by a balloon catheter to prevent embolism to the healthy limb. A crossover introducer sheath enables safe debulking of the contralateral external iliac artery. Ipsilateral, antegrade puncture is preferable whenever possible for infrainguinal in-stent stenoses and occlusions (Fig. 6). Stented infrapopliteal arteries can be managed when their diameter is 3 mm or more.

THE ROTAREX® S AND POPLITEAL ARTERY OCCLUSION IN PATIENTS WITH CHRONIC LOWER-LIMB ISCHEMIA

Elastic recoil, residual narrowing and dissections occurring after balloon angioplasty (PTA) significantly limit the immediate technical success of the technique. In such cases, stent implantation may be required to secure optimal blood flow through the treated segment. The popliteal artery is highly exposed to biomechanical stress resulting from repetitive vessel rotation, flexion, compression, torsion and extension occurring with knee flexion. Therefore, stents implanted into this challenging location can be prone to fracture, arterial wall damage and lumen-narrowing with subsequent loss of patency. Furthermore, the stent(s) located in the popliteal artery can restrict future surgical bypass options. These are the main reasons why the popliteal artery is often considered a “no-stenting zone” or a location where stent implantation should be highly restricted.

The advantage of mechanical atherothrombectomy can be seen in its potential to achieve a good technical success in patients with popliteal artery occlusion without the need for stent implantation (Fig. 9). This can be especially important in patients presenting

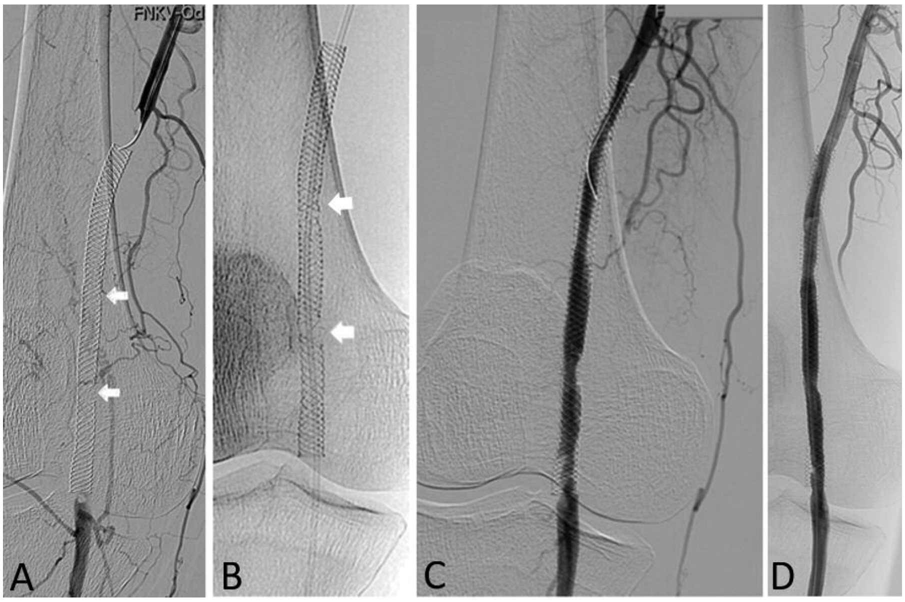

Figure 8. Female, 62 years old, subacute ischemia of the right lower limb, Rutherford category 4. (A) Instent occlusion of the popliteal artery with strut fractures depicted by arrows. (B) Interwoven stent design can be clearly seen with high-grade fractures - arrows. (C) Angiography after debulking alone. (D) Final result after low-pressure balloon angioplasty.

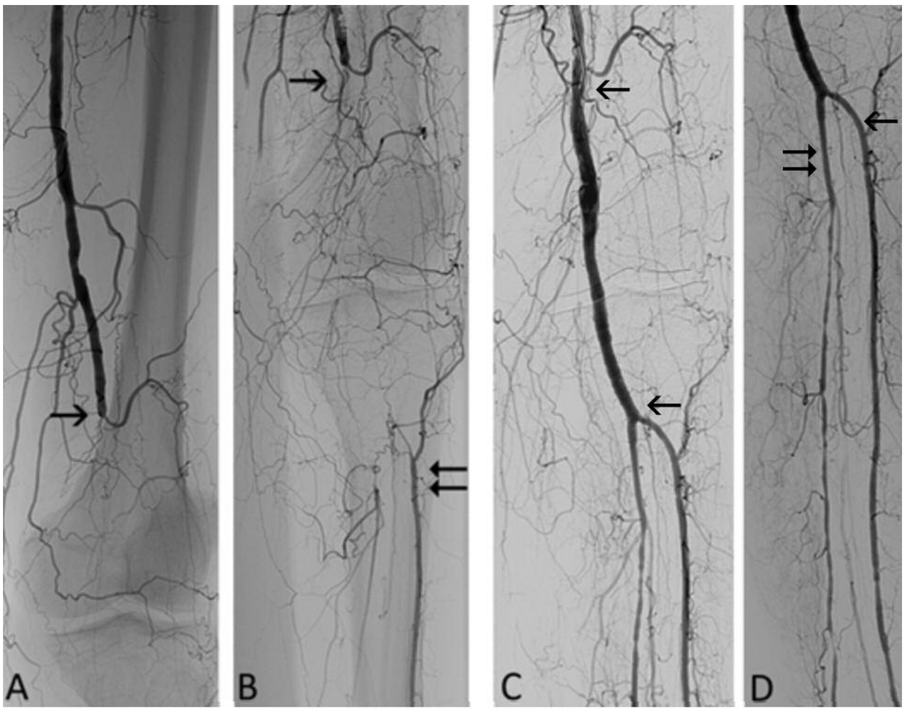

Figure 9. Male, 65 years old, chronic lower-limb ischemia, Rutherford category 4. (A) Popliteal artery occlusion at its origin (black arrow). (B) Anterior tibial artery (double arrow) is filled via collaterals. (C),(D) Angiography after debulking with the Rotarex®S catheter and balloon angioplasty (PTA) of the tibioperoneal trunk and anterior tibial artery.

with critical limb ischemia where surgical therapy is unfeasible or risky.

CONCLUSION

Mechanical atherothrombectomy with the Rotarex® S represents an initial therapeutic technique for patients with acute and subacute ischemia of the lower limbs. It allows effective and safe removal of occlusive material and prompt revascularization without major distant hemorrhage, without the need to place the patient in an intensive care unit. With low invasiveness, prompt reperfusion, a chance for immediate treatment of underlying and concomitant lesions, together with a low rate of bleeding complications, mechanical debulking offers advantages over catheter-directed thrombolysis and vascular surgery. Debulking with the Rotarex® S also opens access to infrapopliteal vessels and makes it possible to enhance runoff during the same procedure, if necessary.

In patients with ischemic symptoms for longer than three months (chronic ischemia), the technique can be considered when guidewire passage through the occlusion is intraluminal. Typically, in patients at high surgical risk, it may be useful in those with longer occlusions (bypasses) and a risk of stent fracture with reocclusion (popliteal artery). This technique can be efficacious even under difficult anatomic conditions and in extremities threatened with critical ischemia. STI

AUTHORS' DISCLOSURES

The author worked as a proctor for Straub Medical AG (Wangs, Switzerland).

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