The Rotarex®S catheter in the treatment of peripheral arterial in-stent occlusions

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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, they are beneficial to ensure 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. 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 in a wide range 46%-89%¹² in the femoropopliteal segment. Also, the frequency rate of the stent fractures was identified in range of 3%-36%³⁴ of treated limbs at 12 months. Higher primary patency rates at 12 months were reported for iliac stents (96%)⁵⁶.
A recently published study that focused on the Rotarex®S treatment of in-stent iliac and infrainguinal arterial occlusions, reported the procedure success in 98.6% of patients with restenosis rate 20.5% at 12 months. The occlusion or stenosis of a stented artery usually causes the recurrence of ischemic symptoms, that can be even more serious than before stenting. Compared to endovascular treatment, surgery is associated with higher mortality and morbidity rates and is not always feasible. Poor prognosis with 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. Without removal of occlusive material (debulking), PTA or stenting are associated with augmented arterial wall strain and the deep wall trauma that elevate the restenosis rate. Furthermore, PTA and stenting are usually not applicable to fresh thrombosis where the risk of peripheral embolization is enormous. The Rotarex®S catheter (Straub Medical AG, Wangs, Switzerland) has the potential for rapid removal (in a few minutes) of fragmentable atheroma, thrombus and myointimal hyperplasia even in long occluded lesions.

Figure 1

(A) Non-active Rotarex®S catheter located inside the stent. Diameter of the stent (arrow) is appropriate. (B) The Rotarex®S activation can lead to stent (vessel) wall collapse (arrow) when blood flow to the rotating head is low or absent. Thus, the struts can get into the close contact with rotating head and its windows. A significant proximal lesion is usually the cause and vessel collapse disappear after catheter is deactivated or the lesion successfully managed. (C) Careful examination of the occluded stent before treatment can reveal strut fractures (arrows), deformations or sequestrated stent fragments (double arrow). (D) The Rotarex®S 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. Care must be taken when approaching strut fractures, deactivating the catheter, passing the fractured segment and reactivating of the catheter.
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 with debulking as it eliminates the need for thrombolysis. Additionally, post-Rotarex®S use, any significant residual lesions will require lower inflation pressures and much shorter adjunctive stents. After removal of occlusive material, there is the potential for a higher-drug uptake to the arterial wall where drug eluting balloons are utilized. Thus, their anti-proliferative ability can achieve a greater effect.

Rarely, problems with direct contact between the Rotarex®S rotating head and stent occur during debulking. Nevertheless, because such a contact can damage the catheter some caution and preventive measures are necessary. The operator has to exercise caution at the moment the rotating head is introduced into the proximal end of the stent and an increase in sound frequency is noted. A very slow catheter advancement can be recommended at this moment or alternatively introducing the catheter about 1cm within the stent without device activation. On withdrawing the catheter to the original position, the Rotarex®S can be activated again and its introduction repeated.

Where a significant proximal stenosis is present that doesn´t allow sufficient blood flow to the rotating head, collapse of the stent walls may occur (Figure 1 A, B). Subsequently, catheter damage can occur when the stent structure is irregular, deformed or interrupted. Careful visual monitoring of the stent anatomy is important before and during catheter introduction and if necessary, a proximal lesion should be treated e.g. with PTA before debulking continues.

Figure 2
56-year-old woman, acute right lower limb ischemia, category IIb. (A) In-stent occlusion of the right common iliac artery (arrow). (B) Angiography after Rotarex®S catheter debulking and (C) balloon angioplasty. (H) PA (arrow) and tibial vessels.
77-year-old man, bilateral chronic limb ischemia, Rutherford category 4. (A) Occlusion of aortic bifurcation (arrow) and common iliac arteries. The external iliac arteries are filled via collaterals (double arrows). (B) Margins of the stents are depicted by arrows. (C) Angiography after bilateral debulking with the Rotarex®S catheter and balloon angioplasty.

59-year-old man, acute ischemia of the right lower limb, category IIb. (A) The superficial femoral artery is occluded at its origin (white arrow), proximal margin of stented area is depicted by 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. Distal margin of stented area is depicted by arrow.
Before mechanical debulking of an occluded, stented artery it is necessary to carefully inspect the stent structure to assess its geometry, continuity, deformation, fractures, strut protrusion into the lumen and sequestration of metallic fragments (Figure 1 C, D; Figure 5B).

In-stent occlusions of iliac arteries are usually managed from ipsilateral retrograde puncture of the common femoral artery (Figure 2, 3). Additional saline injection through the side-port of the introducer sheath is necessary to prevent vessel collapse distal to the occlusion. In-stent occlusions of the proximal common iliac artery should not be managed from a contralateral approach. It is recommended to dilate a balloon catheter in the contralateral common iliac artery during mechanical debulking of proximal common iliac in-stent occlusion to prevent embolism to the healthy limb. Due to the elasticity of the Rotarex®S catheter when positioned over the aortic bifurcation, the rotating head may be in close contact with the outer (lateral) wall of the stent and catheter advancement can be impossible. An up-and-over introducer sheath, over the aortic bifurcation, enables safe mechanical debulking of the contralateral iliac external artery.

Ipsilateral, antegrade puncture is preferable whenever possible for infrainguinal in-stent stenoses and occlusions (Figure 4-8). Infraopliteal arteries can be managed when their diameter is 3 mm or more (Figure 9).
Figure 5

77-year-old man, bilateral chronic limb ischemia, Rutherford category 4. (A) Occlusion of aortic bifurcation (arrow) and common iliac arteries. The external iliac arteries are filled via collaterals (double arrows). (B) Margins of the stents are depicted by arrows. (C) Angiography after bilateral debulking with the Rotarex® catheter and balloon angioplasty.

Figure 6

63-year-old woman, chronic ischemia, Rutherford category 3. (A) In-stent occlusion of the popliteal artery (marked with arrows). (B) Stent distal margin (arrow). (C) Angiography after mechanical debulking and (D) after adjunctive balloon angioplasty.
67-year-old man with subacute ischemia of the left lower limb, Rutherford category 3 (A) Occluded left superficial femoral artery with stents marked by double arrows. (B) Popliteal artery is filled via collaterals. (C) Angiography after mechanical debulking with the Rotarex®S catheter. (D) Residual stenosis (arrow). (E) Final result after adjunctive stenting.

71-year-old man, chronic ischemia, Rutherford category 3. (A) Diffuse in-stent stenosis of left femoropopliteal arterial segment. (B) Distal end of stented area is depicted by arrow. (C+D) Angiography after mechanical debulking with the Rotarex®S catheter and gentle balloon angioplasty.
Conclusion
Mechanical debulking with the Rotarex®S catheter can be safely and efficiently used as an initial treatment of in-stent acute, subacute and chronic occlusions in patients with lower limb ischemia. Typical cases with angiograms documenting the technical effect are presented.
References


