Endovascular Mechanical Atherectomy with THrombectomy (MATH) using the Rotarex®S as initial therapy of acute lower limb ischemia

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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 postoperative outcome in patients treated by surgery with cardiopulmonary complications responsible for 54 %-63 % of the deaths at 30 days1,2. On the other hand, the less invasive, thrombolytic treatment is more often complicated by major haemorrhage and stroke. 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 initial thrombolysis6.
A meta-analytic study\(^6\) evaluating 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 surgery patients, the 30-day mortality was 8.2 % (4.9-17.5 %) and 30-day limb salvage 87 % (56-98 %). Thrombolytic management was associated with major haemorrhage in 8.8 % (0-11.8 %) of patients at 30 days and in the same group the stroke occured in 1.3 % (0-1.8 %). Major haemorrhage occured in 3.3 % (0-5.1 %), but stroke did not accompany surgical treatment.

The guidelines recommend surgical therapy\(^7\)-\(^10\) when the extremity is immediately threatened and time to reperfusion is critical (category IIb, early III)\(^11\). In patients with milder symptoms (category I and IIa)\(^11\), thrombolysis is indicated. Due to risk of stroke and major bleeding, certain guidelines\(^12\) 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 replaced the traditional treatments so far. The reasons have been mainly due to limited experience with the techniques and low efficacy of those approaches alone, which often required a combination with thrombolysis and its risk.

The **Figures 1-6** introduce different anatomic types of acute lower limb ischemia. Some of them are complex with only a low chance for successful treatment with surgery and/or thrombolysis. The main role of the Rotarex®S was to remove rapidly the fragmentable occlusive masses (thrombi, emboli, atheromas) and to re-establish the blood flow. The clot removal enabled further treatment of the residual stenoses by the balloon angioplasty (PTA) and/or stenting –stentgrafting (**Figures 3, 5, 7**). This way, the Rotarex®S also created the way towards the tibial arteries where the percutaneous aspiration thromboembolectomy, PTA and stenting could be used to enhance the runoff (**Figures 1, 3**).

The technical success varied from 92% to 100% in previous studies with target occlusions in infraaortic arteries\(^13\), femoropopliteal arterial segments\(^14-18\) and femoropopliteal bypasses\(^19,20\). Lower technical success was reported in subgroups with occluded bypass grafts (78%) and crossover approach (56%)\(^13\). Frequency of concomitant thrombolytic therapy varied between 0%\(^18\) and 14%\(^19\). The number of surgical revascularization procedures ranged from 0%\(^13,15,17-21\) to 5.3%\(^14\) and mortality rate varied between 0%\(^14,15,18\) and 1%\(^13,17\) at 30 days. Thirty days 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 haemorrhage from 0 % to 2.6 % and frequency of major debulking device-related complications from 0 % to 0.4 %. After the therapy, significant elevation of mean Ankle-Brachial Index was regularly reported.
73-year-old woman, ALI IIb. (A) Common femoral artery occlusion and no visible peripheral vessels on angiography. (B) Introduction of the angiographic catheter. (C) Selective angiography of thrombosed popliteal artery. (D) Patent segment of the tibial anterior artery (arrow). (E) Passage of the Rotarex®S. (F) Recanalized superficial femoral artery (SFA). (G) Patent popliteal artery. (H) Tibial anterior artery is patent to its periphery. (I) Peroneal artery and (J) deep femoral artery (DFA) were recanalized by adjunctive percutaneous aspiration thromboembolectomy (PAT).
70-year-old woman, ALI IIb. (A) Left common femoral artery embolism (arrow). (B) Percutaneous sheath (arrow) was introduced from contralateral approach. (C) First, MATH of SFA was performed with the Rotarex®S (arrow). (D) Subsequently, DFA occlusion (arrow) was traversed with guidewire. (E) Final result. (F) Runoff angiography.
56-year-old man, ALI IIb, popliteal aneurysm thrombosis and calf vessels occlusions. (A) Digital subtraction angiography (DSA), the arrow indicates beginning of popliteal artery occlusion. (B) Knee joint aperture is depicted by arrow. (C) Just one fragment (arrow) of the calf vessel is filled with contrast material via collaterals. (D) Situation after MATH of popliteal artery (arrows). (E) Popliteal artery was recanalized (arrow) with the Rotarex®S catheter. (F) Popliteal artery MATH opened the way for successful (PAT) of peroneal artery with residual stenosis (arrow). (G) Stenosis after PTA and stenting (arrow). (H) Peroneal artery (arrow) supplies plantar vessels directly and dorsal pedis artery (double arrow) via collaterals. (I) Finally, popliteal aneurysm was eliminated by covered stents (double arrows). Single arrow indicates the knee joint aperture.
**Figure 4**

81-year-old woman, ALI IIb - III. (A) Aortic bifurcation saddle embolism (arrow). (B) Angiography after embolus fragmentation and its aspiration with the Rotarex®S from the left groin. Balloon catheter stayed inflated in the right common iliac artery during the Rotarex®S run to protect the right extremity from potential embolism.

**Figure 5**

67-year-old man, ALI Ila. (A)+(B) In-stent occlusion of SFA. (C)+(D) Recanalized lumen after the Rotarex®S MATH. (C)+(E) Residual stenosis (arrow). (F) Stenosis correction (adjunctive PTA + stenting).
45-year-old man, ALI IIa, external iliac artery occlusion. (A) Acute thrombosis is located between arrows. (B) Residual stenosis after atherectomy with thrombectomy. (C) Angiogram after adjunctive PTA.

**Conclusion**

Mechanical atherectomy with thrombectomy with the Rotarex®S offers an eligible initial therapeutic technique for patients with acute and subacute ischemia of lower limbs. It allows safe removal of occlusive material, prompt revascularization without major distant hemorrhage and without the need to place the patient in an intensive care unit.

With low invasiveness, prompt reperfusion, chance for immediate treatment of underlying and concomitant lesions, together with a low rate of bleeding complications and no need to place the patient in an intensive care unit, MATH offers advantage over catheter-directed thrombolysis and vascular surgery. MATH with the Rotarex®S also opens an access to infrapopliteal vessels and enables to enhance the runoff during the same procedure.
References

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