Introduction

Acute leg ischemia either due to emboli or local thrombosis remains a severe clinical problem endangering limb prevention and may also become life-threatening. It might also be a part of an interventional procedure.

As an alternative to surgical thrombectomy, local thrombolysis has been introduced decades ago, but it suffers from several limitations. It is time-consuming, has a significant bleeding risk especially in the elderly, and does not have striking advantages over surgical embolectomy. In severe ischemia, allotted treatment time is too long to become an alternative to surgery and there is a risk of developing compartment syndrome.

Starck and Sniderman \(^1,2\) independently developed aspiration embolectomy as a mechanical thrombectomy approach. Aspiration embolectomy is a reliable low-budget approach, especially below the knee joint and in smaller arteries. However, aspiration embolectomy of larger thrombi from larger arteries frequently results in failure or the need for large access diameters to remove thrombus material effectively. Subacute occlusion is difficult both to be operated on or to be treated percutaneously due to increased organization and wall adherence of the occluding material.

To improve this situation, several mechanical thrombectomy systems have been described with the last three decades, but only few are still available.

We describe here a standardized concept of combining aspiration embolectomy preferably with one rotational thrombectomy device (Rotarex, Straub Medical Inc., Wangs, Switzerland) and also different additional tools in a consecutive cohort of patients over the last decade.

Classification of Acute Ischemia

Acute limb ischemia is classified by the Rutherford classification for acute ischemia,\(^3\) which should not be confused with the other Rutherford classification for chronic limb ischemia.

In stage I, the limb is not immediately threatened. There are no sensory losses or muscular weakness. These are usually patients with partly compensated ischemic events, sometimes older for some weeks and unfortunately overseen as an ischemic event.

In stage IIa, the limb is marginally threatened but may be saved by immediate revascularization. Symptoms include minimal sensory losses and no muscular weakness with still audible arterial signals and audible venous flow.

In stage IIb, the limb is immediately threatened and revascularization is urgently and rapidly required. Sensory
loss is above the toe level, rest pain is present, and muscular weakness is mild to moderate.

In stage III, the limb is irreversibly lost. It is profoundly anesthetic, paralyzed, and no arterial or venous flow can be detected.

Treatment is possible in stage I to IIb, but urgent revascularization is a must. After successful recanalization, rapid inflow is often accompanied by tissue swelling and edema leading to compartment syndrome. This may cause ancillary surgical decompression.

### Methods of Mechanical Recanalization

The basic technique of mechanical thrombectomy is aspiration. While this was a highly effective but low-budget technique for decades using simple end hole catheters, stroke management has fostered development of high-end aspiration catheters with low-profile surface coating and high flexibility that can be equally used in extremity arteries. These also allow safe embolectomy from pedal arteries.

As an adjunct, retriever systems for neurointervention can be considered in particular cases.

Motor-driven mechanical thrombectomy includes use of waterjet catheters (AngioJet BSIC, Boston, MA, United States), cutting and suction devices such as Rotarex (Bard Medical, Covington, GA, United States), and directional (HawkOne, Medtronic) and rotational atherectomy devices (Jetstream, BSIC). Usage of the latter devices should be limited to spot treatment of wall-adherent clots (HawkOne) or mixed occlusions with thrombi and calcified lesion (Jetstream).

Stents can be used in clot treatment by fixing and displacing a thrombus to the arterial wall, for example, in the iliac arteries or the middle and proximal femoral arteries. In smaller arteries, this is a bailout approach in very rigid and wall-adherent thrombi; in the iliac arteries, it is a quick, easy, and feasible approach with low risk of distal embolization.

### General Remarks

With the exception of iliac and common femoral occlusions, we prefer an antegrade ipsilateral approach. This allows use of relatively short instruments. Even the deep femoral artery is usually reachable by this approach.

In mechanical thrombectomy, attention to the simple principle of “bigger is better” is often helpful especially for arteries above the knee joint. We usually start with a 6-Fr access for planning the procedure but quickly switch to an 8-Fr sheath in particular if the level of occlusion goes above the P3 segment of the popliteal artery.

The intervention should be terminated by use of a closure system (8-Fr Angio-Seal or 7-Fr FemoSeal).

### Type of Occlusion

The pattern of thromboembolic occlusions varies widely and influences the way the lesion is approached. Embolic lesions can be with or without additional apposition thrombosis, which determines the lengths of the occluded segment.

There are recent on-top thromboses attached to atherosclerotic obstructions, spontaneous thromboses within aneurysms or entrapment lesions, and—rarely but problematic—paraneoplastic thromboses.

Occlusion length may include only few centimeters, and may or may not involve the flexion segments.

But it may be extended to involve the adjacent segments. Each setting requires a careful and well-planned approach.

### Location of the Occluded Segment

The location of an occlusion influences the methods of treatment. Of course, many occlusions involve several segments. So, in embolic occlusions, a careful check of the profound femoral artery is mandatory and it is recommendable to declot the profound artery also as it is the main hub for important collaterals.

Also, the outflow situation should be checked meticulously by selective angiography even after passage of the occlusion in order to identify outflow vessels. Overview angiography frequently misses a true imaging of the distal circulation.

### Lower Limb Arteries

The arteries of the lower limb are the most frequent targets for percutaneous thrombectomy. The reasons are manifold. Small emboli travel all the way down to the lower limb and iatrogenic embolization leads to distal embolization. The lower limb arteries offer a number of technical advantages for mechanical thrombectomy as they are usually small, ≤3 mm. Small-diameter end hole catheters of 4 to 6 Fr are mostly enough to fulfill the request for a match between the diameter of the artery and the catheter to allow successful aspiration of an embolus or thrombus (~Fig. 1).

Usually the aspiration catheter can be guided by a coated guidewire or a microguidewire (0.014–0.018 in) into the target vessel. The catheter should then be slightly advanced with or without the guidewire but there should be no attached syringe or stopcock at its distal end—in order to allow the thrombus material to easily enter into the lumen—until blood flow stops from the inner lumen. Then suction should be applied by use of a special vacuum syringe. The catheter is then retrieved slowly upward together with the syringe maintaining vacuum until brisk blood flow into the syringe occurs or the catheter has been removed from the sheath. Therefore, sheaths with a removable hub should be preferred. If not available a regular valve sheath has to be cleared by sucking at the side port and opening the valve by use of a simple syringe. If the sheath remains blocked, it needs to be exchanged over a guidewire and cleared outside the body.

Final angiography is needed to prove successful declotting. If not, the procedure needs to be repeated eventually by use of a different-sized catheter. Recently, high-quality coated catheters have been introduced—mainly as an off-spring from mechanical stroke management, which allows distal travels even down into the pedal segments.
Challenging Settings

Although the small arterial diameters favor use of aspiration, there are not too many mechanical alternatives available for lower limb arteries. Challenging situations are long-segment downward thrombosis with inclusion of all lower limb arteries and no remaining patent distal segment. In these cases, at least an artery should be tried to be reopened with a distal runoff. In these desperate cases, additional use of local application of thrombolytics and overnight intra-arterial thrombolysis may become necessary.

Other challenging setups are very small distal emboli that cannot be reached by aspiration due to the size or status of the carrier artery. In these cases, use of microcatheters, retrieving systems from stroke management, or microcatheter advancement with local thrombolysis are valid options.

The most challenging are iatrogenic calcified emboli after atherectomy procedures and should be avoided in any case. Also, late thromboembolectomy offers a different level of technical challenge (see later).

As a minimal goal, at least one patent artery with sufficient distal collateralization should be achieved.

Popliteal Artery

Thrombectomy of the popliteal artery depends on the original size of the artery and the level of occlusion. In small arteries a 6-Fr approach is sometimes feasible, but usually a 7-Fr or better still 8-Fr access is helpful. In the P3 segment of the popliteal artery, usually aspiration works well when a sufficiently large catheter is applied (►Fig. 1). This can become more challenging in the P1 and 2 segments. As a rule, start using a mechanical device when the level of occlusion is above the knee joint and few runs of aspiration were not convincing in removing the clot material.

Size matters for both aspiration catheters and mechanical devices (►Fig. 2). In large popliteal arteries, 8-Fr devices are recommended, while in small arteries, a 6-Fr device can be enough. As mechanical devices are expensive, a prudent selection of size is recommended.

Fig. 1 (A) Embolic occlusion of the distal popliteal artery below the knee. (B) After aspiration by use of a 7-Fr aspiration catheter recanalization of the popliteal artery and the trifurcation. Remaining embolus in the fibular artery. (C) Additional thrombectomy by use of a 4-Fr aspiration catheter with complete recanalization of all three lower limb arteries. No further downward embolization. Total treatment time was 26 minutes.

Fig. 2 (A) Occlusion of the popliteal artery in the P2 segment. (B) After aspiration, only incomplete recanalization with remaining clots was achieved. (C) Use of a 6-Fr Rotarex catheter and balloon angioplasty was applied. Remaining thrombus in the proximal anterior tibial artery (ATA) and in posterior tibial artery (ATP). (D) After additional aspiration and careful use of the Rotarex in the ATA, recanalization was completed without downward embolization.
Major focus should be on how to avoid downward embolization into patent distal lower tibiofibular arteries when thrombectomy is performed.

There are a couple of patterns that allow a different approach:

- The tibiofibular trifurcation is involved: In this case, mechanical thrombectomy can be performed within the popliteal artery without any further precautions.
- The thrombus ends within the lumen of the popliteal artery: Again, the very distal portion may be spared from using the mechanical device but should undergo aspiration embolectomy instead. Alternatively, a protection device may be placed in case enough length remains below the distal thrombus. You may also place an inflatable tourniquet around the calf and inflate it above the systolic blood pressure while mechanical thrombectomy is performed.

**Superficial Femoral Artery**

The problems of declotting the superficial femoral artery (SFA) are similar to the proximal popliteal artery. As the artery is usually bigger, a primary 8-Fr approach is recommended. Aspiration embolectomy is only successful in smaller artery diameters, so early use of mechanical devices is recommended.

There is one exception. Short or midsize occlusions—mainly on top thromboses—may be treated by primary stent implantation and subsequent balloon dilatation. This offers a good protection against downward embolization and definitive treatment of the underlying atherosclerotic lesion.

Mechanical declotting frequently leaves wall-adherent thrombus on the wall, especially at the very proximal segment of an occlusion. Then, three options exist. Predilation with a suiting balloon may help disrupt this part of the thrombus, which may be loosened, eventually embolizing distally and may be removed from there by aspiration or mechanical thrombectomy.

Alternatively, rigid clot may be removed by use of directional or hybrid atherectomy.

Finally, a rigid adherent clot may be fixed to the wall using a self-expanding stent and subsequent balloon dilatation.

**Femoral Junction**

Frequently there is a coexistent thromboembolic occlusion of the profunda femoral artery. This can be reached by an antegrade access (→ Fig. 3). A small guidewire (0.014–0.018 in) is parked within the SPA and parallely, an angulated catheter is advanced into the sheath through which a coated guidewire is brought forward into the profunda femoral artery. After removal of the SPA wire, the sheath is advanced into the profunda femoral artery and aspiration is performed. Usually, a 6- to 8-Fr system is used.

Involvement of the common femoral artery usually requires a surgical approach. In rare instances, declotting of the common femoral artery may be attempted via a crossover approach.

**Iliac Arteries**

Mechanical thrombectomy of the iliac arteries is rarely performed. Due to the discrepancy in arterial diameter and diameter efficacy of mechanical devices, mechanical thrombectomy is usually difficult. As an alternative to surgical thromboembolectomy, stent placement with clot displacement offers a percutaneous way to restore iliac artery patency (→Fig. 4).

**Bypasses, Stents, and Stent Grafts**

Declotting of artificial bypasses is possible by use of mechanical thrombectomy. Usually, these are long occlusions and aspiration alone is usually insufficient due to the lengths and size of the occluded segment. We prefer rotational thrombectomy in these cases by use of the Rotarex catheter. An 8-Fr device is recommended for femorofemoro- or femopopliteal bypasses, while in smaller grafts a 6-Fr device may be sufficient. Utmost care should be taken to distal anastomosis especially in small access arteries, and the device should not enter the native artery. A selective aspiration using 4- to 6-mm device is therefore recommended.

Also, proximal anastomosis requires particular care as a rigid clot is frequently found at this location, which might be resistant to mechanical thrombectomy alone. Additional use of angioplasty, directional atherectomy, or stenting may
become necessary (Fig. 5). These areas should always be cleared completely; otherwise, re-thrombosis is likely.

Also, in stented and stent grafted segments, rotational thrombectomy or atherothrombectomy is recommended as neointimal tissue and thrombus are removed. During the procedure, you may experience a collapse of the stent lumen due to vacuum. This is not worrisome but allows a very effective thrombectomy result with significant luminal gain. You must, however, be careful not to entangle with the stent struts. If this happens, stop rotation immediately and move the tip of the device away from the spot.

Again, a special focus should the very proximal and distal end of the occluded segment requiring particular care.

Venous bypasses are not a good target for mechanical thrombectomy as wall damage may appear and thrombus material is usually wall adherent. In short occlusions, aspiration may be an option. Alternatively, venous bypasses may by endoluminally recanalized by endoluminal implantation of a long stent graft.

**Clinical Experience**

We retrospectively analyzed our results from 156 treatments for lower limb ischemia by mechanical thrombectomy within a 10-year period. Only stage I to IIB patients were included. The analysis did not include patients with an
embolic event during PTA for peripheral atherosclerotic disease and patients with thrombectomy for the treatment of thrombosed stents, stent grafts, and bypasses.

Patients presented with limb ischemia Rutherford category I (viable limb) in 68 cases (44%), Rutherford category IIa (partial sensory loss but no muscle paralysis) in 64 instances (41%), and Rutherford IIb (muscle paralysis and partial sensory loss) in 24 instances (15%).

In 62 cases (39.7%), the occlusion site was below the knee joint level, while in 94 (60.3%) cases, the occlusion site started at or above this level.

Treatment included aspiration thrombectomy by appropriate end hole catheters (Bard Medical) of 5 to 8 Fr as the basic technique.

Usually, an intervention was started by aspiration. If aspiration failed to remove significant amounts of clot, an additional device was added. Most frequently, a rotational thrombectomy device (Rotarex 6 or 8 Fr, Straub Medical Inc.) was used. In rare instances, other devices were added.

**Technical Success**

In 145 cases, technically the procedure was successful with at least one patient lower limb artery.

Aspiration was used in 153 incidents (98%). A combination of different catheters was used in 81 cases. Rotational thrombectomy was applied in only three patients.

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Rotational thrombectomy by use of the Rotarex catheter was added in 60 cases (38%).

Directional atherectomy was rarely applied (Fig. 5), and so were retriever systems (n = 7).

Additional PTA was performed in 74 patients (47%) either to flatten residual clot to the wall or to treat underlying stenoses. For the same purpose, self-expanding stents or stent grafts were implanted in 18 patients (11.5%).

In seven patients, an embolus was found in the deep femoral artery and was treated in six by aspiration.

**Acute Complications**

There were a number of acute complications. Most frequently, a downward embolization occurred (n = 11) but was usually solved by further aspiration. In two incidents, severe arterial spams of the lower leg arteries occurred but had no clinical sequelae (Fig. 6). Local application of spasmylic medication is recommended.

Arterial perforation occurred in two cases, in one due to rotational thrombectomy. Prolonged balloon dilatation was sufficient to seal the vessel in both cases.

Five patients suffered from severe hypotension, and termination of the procedure was required in three cases. In one patient, the intervention had to be terminated due to severe pain.

In one patient, the closure system could not be delivered properly, leading to development of a severe groin hematoma that required immediate surgical revision.

**Clinical Success**

Clinically, 135 patients (86.5%) showed an improvement of their clinical situation. In 21 patients, the clinical results remained insufficient (13.5%). Early re-occlusion despite primary technical success occurred in four cases (2.7%).

There were three surgical groin revisions due to access hemorrhage (1.9%). Three patients developed lower leg compartment syndrome despite successful thrombectomy.

**Discussion**

Acute lower leg ischemia is a relatively frequent problem in current practice and may be caused by either embolic events preferentially from the heart or local thrombosis based on severe atherosclerosis or paraneoplastic thrombosis in patients with advanced tumors.

Unfortunately, acute limb ischemia is frequently overseen or underscored by patients and doctors, which results in delayed admittance to hospitals. Delayed thrombectomy is not a preferred setting by surgeons as partial organization of the occluding material may compromise surgical embolectomy. It is also a problem in percutaneous embolectomy, as aspiration frequently fails to remove already wall-adherent clot material and makes use of additional instruments necessary.

Thrombolysis has been developed early as an alternative to reopen subacute or chronic occlusions in peripheral arteries. It has also been tested to treat acute limb ischemia and may have a role in Rutherford I cases. But in patients with threatened limbs, time to reestablish perfusion is usually regarded as too long for these cases. Furthermore, a bleeding rate up to 20%, and rate of 2.5% for intracranial hemorrhage, and development of compartment syndrome in up to 10% were reported with thrombolysis in acute limb ischemia.

Kashyap et al reported on 129 limbs treated with thrombolysis and partly additional pharmacomechanical means such as hydrodynamic thrombectomy (AngioJet, BSIC) and spray lysis. Thrombolysis was performed over 0 to 1 day in 49% and 1 to 2 days in 39%. Ninety-one percent had adjunctive procedures with 38% surgical or combined treatments. Technical success was 82%. Amputation rate varied from 40% (Rutherford IIb) to 14% (Rutherford I) and increased by days of thrombolysis. Early amputation rate was 15%. Compartment syndrome was seen in 4% and local hematoma (11%).

In our view, reported results of thrombolysis in acute limb ischemia in the literature are not encouraging, and from personal practice, long application times and incomplete results make thrombolysis less attractive in this group of patients.

Starck et al and Sniderman et al independently developed aspiration embolectomy, which quickly got accepted as a rapid low-budget method offering quick recanalization especially for below-the-knee arteries. Recently, it has become quite popular for the treatment of intracerebral stroke management. New atraumatic and flexible aspiration catheters as derivatives from stroke approach are now available that allow thrombosityction even from very small pedal arteries.
Surprisingly, there have not been too many publications about aspiration embolectomy over the years. Despite that, in many interventional institutions, thrombosuction is the working horse for managing acute limb ischemia. Nevertheless, there are several drawbacks. Suction will fail in large arteries; also, complete removal from the wall may fail with simple aspiration and wall-adherent material will be resistant to aspiration. Wagner and Starck\(^9\) therefore developed additional tools to face these problems such as rotational nitinol baskets (PAT-RAT, formerly Angiomed Inc., Karlsruhe, Germany). This system, however, is no longer available. In 1992, Wagner and Starck\(^9\) published their results of this approach in 102 cases. They achieved technical success in 93% with an additional use of rotational devices in 12%.

Success of thrombosuction depends on the relation of the diameter of the catheter used and the diameter of the artery treated. At least in our experience, 8-Fr catheters are a suitable size for the P3 segment as below the P3 level 6-Fr catheters will usually work in proximal calf arteries. Above this level, aspiration may fail even with 8-Fr catheters. This is illustrated by our findings. Below the knee joint level, rotational thrombectomy was utilized in a maximum of 20%, but above the knee joint it was used in more than the half the cases, up to 75% in emboli/thrombi starting at the SFA or P1 level.

The Rotarex rotational catheter was introduced in interventional radiology around 20 years ago. There are several publications of its usefulness and efficacy.\(^10,11\) Recently, Heller et al\(^12\) reported on their results with the Rotarex device in acute limb ischemia in 147 patients. They used the Rotarex device as a primary tool in 120 cases and as a bailout tool in 27 cases. They reported on technical success with Rotarex alone combined with aspiration in 68.7%, but with additional thrombolysis in 90.5%. They had a rate of compartment syndrome of 4% and access site hematoma of 4%. The overall success rate was similar to ours although their approach was different with the first rotational thrombectomy in the majority of cases.

One of the potential drawbacks of aspiration embolectomy and large rotational catheters is its frequent need for large access sheaths. Although larger access diameters were applied in the majority of patients, the rate of access bleeding and pseudoaneurysm formation remained low in our cohort. We assume that routine use of large closure devices seems to contribute to keep the access complication rate rather low.

Also, delayed treatment leads to technical problems as wall-adherent material is difficult to be removed by thrombosuction alone. Maceration by PTA followed by repeated thrombosuction or shaving by additional directional atherectomy may be alternatively applied. In the approach described herein, delayed treatment onset did not result in a significant decay in treatment success and may be attractive as an alternative to late surgical embolectomy.

Kwok et al\(^13\) compared thrombolysis with primary aspiration embolectomy and found a primary technical success rate...
of roughly 50% in their cohort of patients. This is quite consistent with our findings that in a nonselected setting of patients with acute leg ischemia, more than half of the patients are expected to show thrombosis above the knee joint level, in which case aspiration alone will have limited success.

For these patients, additional instruments will be needed to achieve a successful result. Although stents have proven to be excellent tools to locally fix fresh thrombus to the arterial wall, it is not a preferred option in the popliteal artery; it should be limited to the SFA alone.

For popliteal thrombosis, rotational thrombectomy using the Rotarex device has proven to be a reliable, safe, and effective tool to remove clot from the SFA and the popliteal segments.

Rotational thrombectomy, however, is not an option in very distal lower leg arteries. The development of very flexible and atraumatic aspiration catheters certainly offers more options, but stent retrievers—originally developed for stroke treatment—may be applied in selected cases.

During embolectomy, there is always a certain risk of further downward embolization due to the manipulations performed. This can become a challenging task but in larger arteries, 4-Fr diagnostic catheters and new very flexible aspiration catheters adopted from cerebral stroke treatment are usually effective to remove thrombus even from the pedal arteries. If this fails, alternatively retriever devices might be used to remove thrombus from smaller arteries. The risk in general seems low compared to the chances of limb salvage by rapid recanalization.

In conclusion, mechanical thrombectomy without thrombolysis combining thrombosuction and rotational thrombectomy—if needed—seems to be a technically successful and cost-effective approach in patients with acute leg ischemia.

Conflict of Interest
None declared.

References