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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

# Rotational thrombectomy of acute peripheral vascular occlusions using the ThromCat XT device: techniques, indications and initial results

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PURPOSE
To gather initial procedural experiences with the ThromCat XT, a new rotational thrombectomy catheter primarily developed for coronary interventions.

MATERIALS AND METHODS
The ThromCat XT is a 150-cm rapid exchange thrombectomy device consisting of an atraumatic tip and a steel helix with a kink-resistant covering. It was employed in native arteries, veins, grafts and stents in ten patients presenting with acute and subacute thrombembolic occlusions.

RESULTS
Technical success with a restoration of flow was achieved in 70% of patients. The mean thrombectomy time was 8.0±2.33 min, and the aspirated blood volume ranged from 120 mL to 280 mL. Peripheral thrombembolism was detected in two cases, and embolic protection was applied in four cases. Vessel injuries and catheter failures were not observed in any of the cases.

CONCLUSION
The ThromCat XT is an easy-to-handle, reliable and atraumatic device for the removal of fresh thrombi in native and artificial vessels. In our series, the thrombus age—especially if greater than five days—had a major impact on technical success.

*Key words:* • *rotational thrombectomy* • *thrombosis* • *dialysis fistula*

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Mechanical thrombectomy and percutaneous catheter aspiration thrombectomy have become accepted alternative methods for the recanalization of acute and subacute vessel occlusions because of their distinct advantages as compared to conventional thrombolysis. Amongst other procedures, mechanical thrombectomy and percutaneous catheter aspiration thrombectomy are faster, safer, more efficient and more cost-effective. Therefore, the use of these procedures avoids expensive intensive therapy as well as complications. In the last decade, various mechanical thrombectomy devices have been introduced and established for clinical applications, and their use is relatively wide-spread. There are two categories of devices for mechanical thrombectomy: rotational and rheolytic recirculation devices (1, 2).

The ThromCat® XT catheter (Spectranetics International; Leusden, The Netherlands) is a new rotational thrombectomy device primarily developed for coronary intervention, but with CE mark approval for the mechanical removal of thrombi from native coronary arteries and infra-inguinal arteries. It has a construction similar to that of other well-known rotational catheters, but has a somewhat different design, which modifies its field of application and turns it into a suitable revascularization device for peripheral occlusions with special indications. The purpose of our pilot trial was to gather initial procedural as well as clinical experience and to identify possible indications by introducing it into peripheral intervention.

## Materials and methods

### *System design of the ThromCat XT device and its application*

The ThromCat XT is a rapid exchange thrombectomy device that was designed as a flexible and kink-resistant catheter with a working length of 150 cm. The catheter operates on a 0.014-inch guide wire via a 6 F sheath or a 7 F guiding catheter.

The ThromCat XT consists of a nylon blend containing a stainless steel helix and a so-called stainless steel catheter neck encasing the distal end of the helix, thus avoiding any direct contact with the vessel wall. The details of the overall system set-up are shown in Fig. 1. Because of the improved flexibility of the helix, the new system can be applied using both the prograde and cross-over techniques. The helix itself is connected to a control unit containing a motor that powers the extraction spiral. A 500-mL extraction bag and a power cord are connected to the control unit. The distal catheter end is covered by an asymmetric, slightly pointed and atraumatic tip made of rubber to prevent vessel injury. The operating principles of the ThromCat XT device are based on mechanical clot maceration and immediate removal of debris from the vessel lumen.

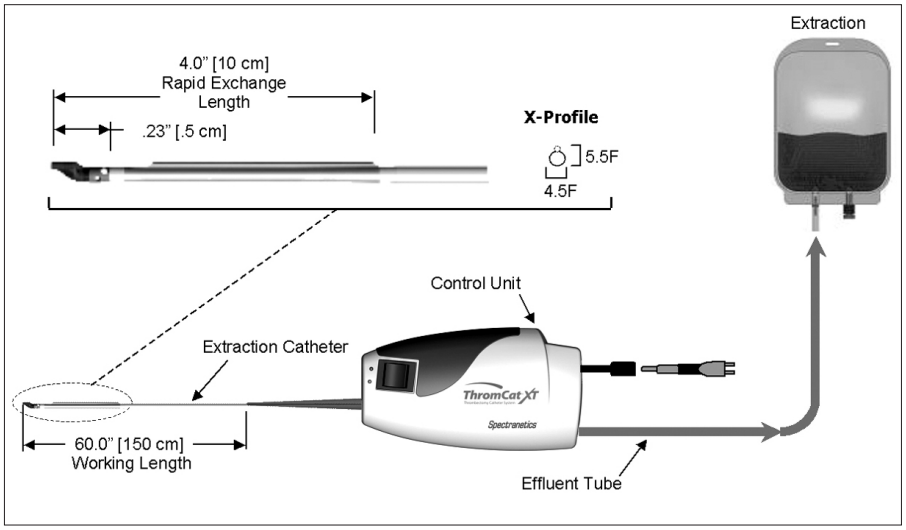


**Figure 1.** The ThromCat XT system components consist of the catheter itself, its distal end with the rapid exchange system, the control unit powering the extraction helix and the extraction bag (published with permission and courtesy of Spectranetics, Inc.).

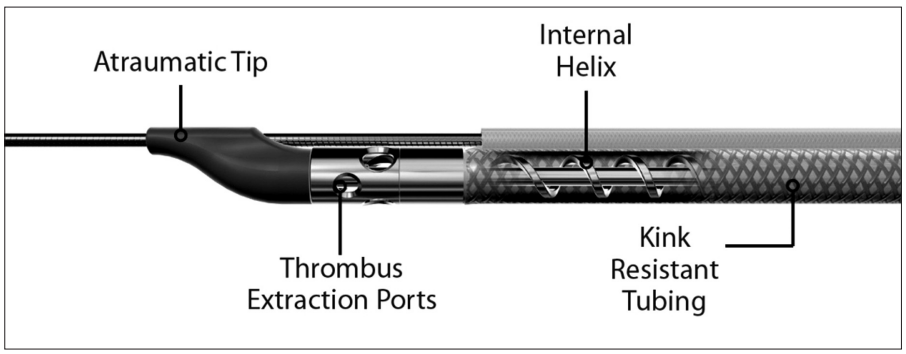


**Figure 2.** Design of the ThromCat XT catheter tip with eccentric wire guidance (published with permission and courtesy of Spectranetics, Inc.).

At the catheter tip, the rotating helix creates a negative pressure by using the principle of Archimedes' screw. The thrombotic material is eliminated through five small extraction ports (Fig. 2) in the catheter neck and transported through the catheter lumen, where it is macerated, to the collecting bag. The rotating spiral creates an extraction flow of approximately 38 mL/min. Because of its rapid exchange design and eccentric wire guidance, the catheter itself can be torqued 360° around the guide wire, thereby allowing for a flexible adaption of the thrombectomy radius. Application of the ThromCat XT system is limited to vessels with diameters ranging from 2.5 to 7 mm. This construction allows the operator to use a single catheter for vessels or grafts with varying diameters. The advantage of this design is that catheters do not need to be changed during the intervention, thus saving time and money. The small catheter diameter enables its use even in distal vessels, such as infrapopliteal arteries, in which commonly used thrombectomy devices are not suitable because of their inappropriate diameter (3).

Before beginning thrombus removal with the ThromCat XT device, the lesion must be crossed with a guide wire. Afterwards, the catheter is advanced and retracted in the vessel lumen as often as necessary to aspirate the thrombotic material. The time required for recanalization occlusion depends primarily on the vessel diameter and occlusion length.

*Patients*

From October 2009 to May 2010, ten patients (60% male; mean age, 72.70±14.64 years; range, 54–96 years) with acute and subacute vascular occlusions underwent rotational thrombectomy with the ThromCat XT device in our department for interventional radiology.

We treated two patients with thrombosis of dialysis shunts (one expanded polytetrafluoroethylene (ePTFE) loop shunt and one native venous shunt, Fig. 3), three patients with bypass graft thrombosis, one patient with peripheral thrombembolism after bypass revascularization (Fig. 4), three patients with stent thrombosis in a lower limb (Figs. 5, 6), one patient with popliteal artery occlusion and one patient with posterior tibial artery occlusion.

The application areas were one expanded polytetrafluoroethylene (ePTFE) loop shunt, one native venous shunt, three popliteal arteries, one peroneal trunk, one posterior and one anterior tibial artery, one femorocrural bypass graft and two superficial femoral artery stents.

The pre-interventional diagnosis of the vascular occlusions was based on color-coded duplex sonography in eight cases and angiography in two cases. The age of the vascular occlusions was evaluated according to the patients' history and varied between 1 and 14 days (mean, 5.5±4.93 days). The clinical diagnosis of peripheral artery disease was classified according to the Rutherford criteria. Shunt occlusion in dialysis patients was discovered through acute dialysis failure. The patient characteristics and clinical parameters are summarized in Table 1.

*Procedure*

In seven cases, the affected limb´s common femoral artery (CFA) was punctured with an 18-gauge Teflon puncture needle (Peter Pflugbeil; Zorneding, Germany), and a 7F sheath (Terumo Radifocus Introducer II, 10 cm; Terumo Europe; Leuven, Belgium) was inserted anterogradely over a 0.035-inch standard guide wire (150 cm Terumo Radiofocus Guide Wire M; Terumo; Leuven, Belgium). The cross-over technique was applied in one case: after placing a 0.035-inch standard guide wire in the contra-lateral external iliac artery under fluoroscopic control using a 5F Hook catheter (Cook RIM 65 cm; Cook, Bloomington, Indiana, USA), a 7F cross-over sheath (Terumo Destination 45 cm; Terumo Europe) was inserted into the contra-lateral CFA. In the case of dialysis fistula intervention, an arterial angiography was performed after the brachial artery was first punc-

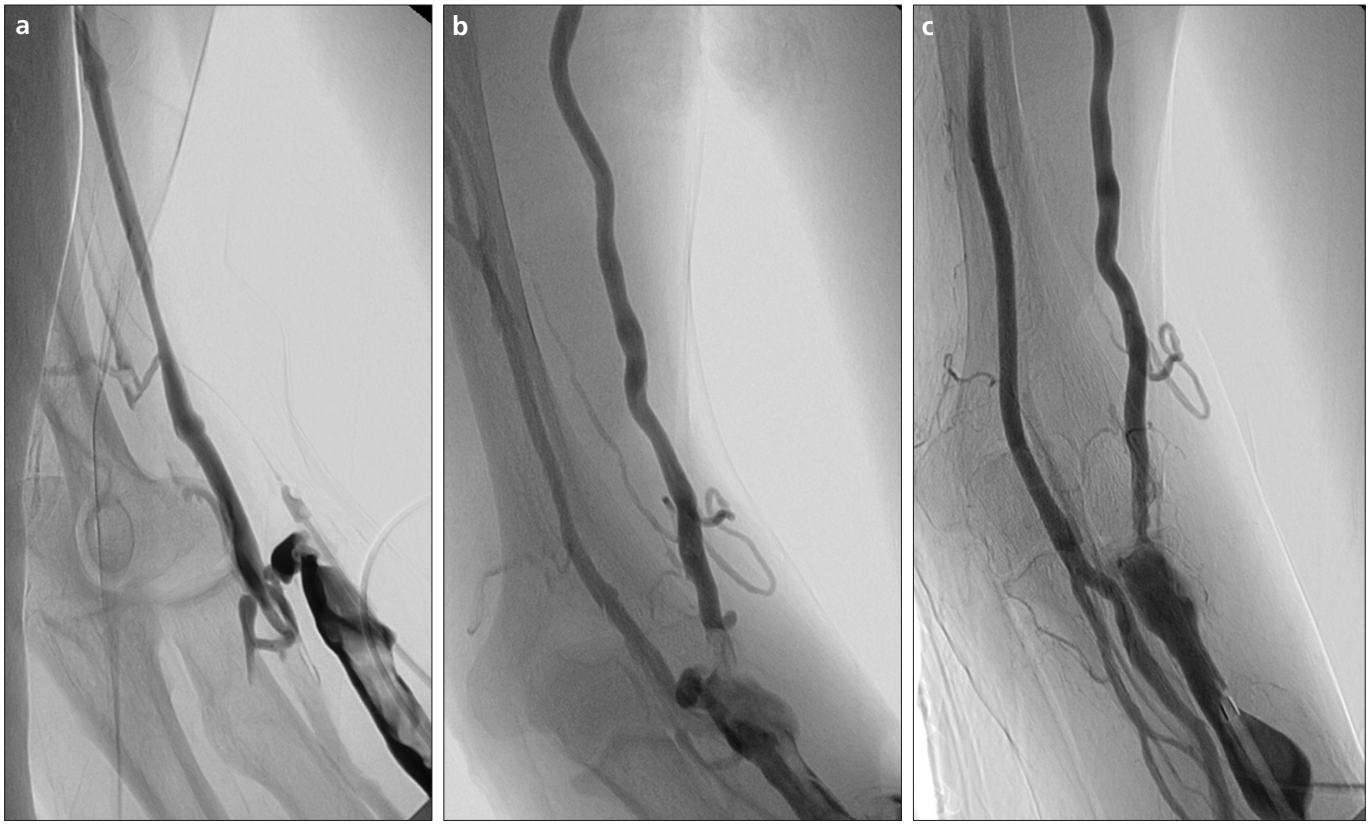


**Figure 3. a–c.** Thrombectomy of an acute occlusion in a native dialysis fistula on the left arm. Complete occlusion of the fistula with heavy thrombus burden **(a)**. A 0.014-inch guide wire had already been passed through the occlusion. Flow was partially restored after six passes with the ThromCat XT device, but a heavy thrombus burden was still visible **(b)**. Complete restoration of flow after additional balloon angioplasty of a higher degree stenosis **(c)**.

**Table 1.** Patient characteristics and clinical parameters

| | Age (years) | Sex | Duration of symptoms (days) | Vessel region | Clinical symptoms | Technical success | Residual thrombus (%) | Clinical success | Adjunctive therapy | Reason for failure |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 83 | F | 3 | Expanded polytet-rafluoroethylene loop shunt | Failure of dialysis | Yes | 20% | Yes | Heparin (therapeutic dosage) Urokinase | - |
| 2 | 69 | M | 5 | Vein shunt | Failure of dialysis | Yes | 10% | Yes | Heparin (therapeutic dosage) | - |
| 3 | 81 | F | 14 | Popliteal artery | Rutherford 4 | No | - | - | - | Organized thrombus |
| 4 | 57 | F | 2 | Superficial femoral artery stent | Rutherford 3 | Yes | No | Yes | Acetylsalicylic acid Clopidrogel | - |
| 5 | 57 | F | 3 | Superficial femoral artery stent | Rutherford 3 | Yes | 20% | Yes | Acetylsalicylic acid Clopidogrel | - |
| 6 | 91 | M | 2 | Popliteal artery | Rutherford 4 | Yes | No | Yes | Heparin (therapeutic dosage) Acetylsalicylic acid | - |
| 7 | 70 | M | 2 | Femorocrural bypass graft | Rutherford 3 | Yes | No | Yes | Heparin (therapeutic dosage) | - |
| 8 | 54 | M | 10 | Posterior tibial artery | Rutherford 4 | No | - | - | - | Organized thrombus |
| 9 | 69 | M | 13 | Anterior tibial artery | Rutherford 4 | No | - | - | - | Organized thrombus |
| 10 | 96 | M | 1 | Popliteal artery/ peroneal trunk | Rutherford 5 | Yes | 20% | Yes | Heparin (therapeutic dosage) Acetylsalicylic acid | - |

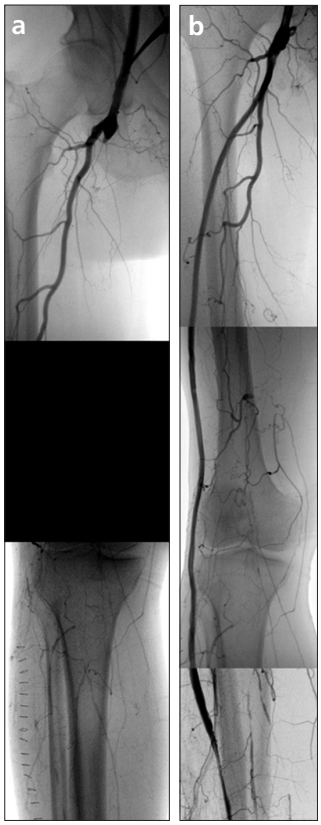


**Figure 4. a, b.** Complete thrombectomy of a femoro-crural expanded Polytetra-fluoroethylene (ePTFE) bypass graft with the ThromCat XT device. Incomplete angiography of the occluded bypass graft of the right leg **(a)**. Successful complete restoration of flow **(b)**.

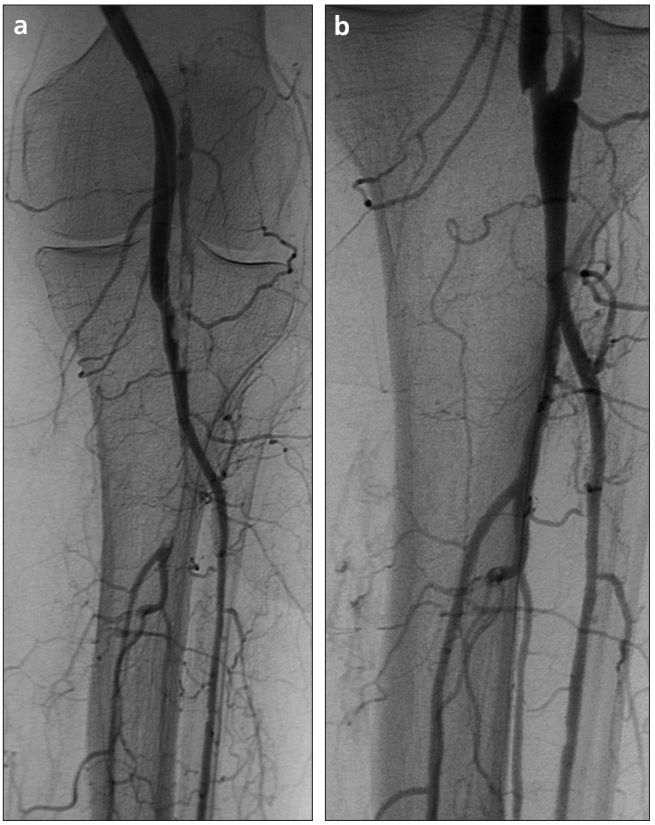


**Figure 5. a, b.** Thrombectomy of the peroneal trunk with the ThromCat XT device using the cross-over technique. Thrombotic occlusion of the left peroneal trunk **(a)** resulting from an embolism from a femoropopliteal bypass graft. The result after rotational thrombectomy with the ThromCat XT device **(b)** using a 7F cross-over sheath and contralateral access.

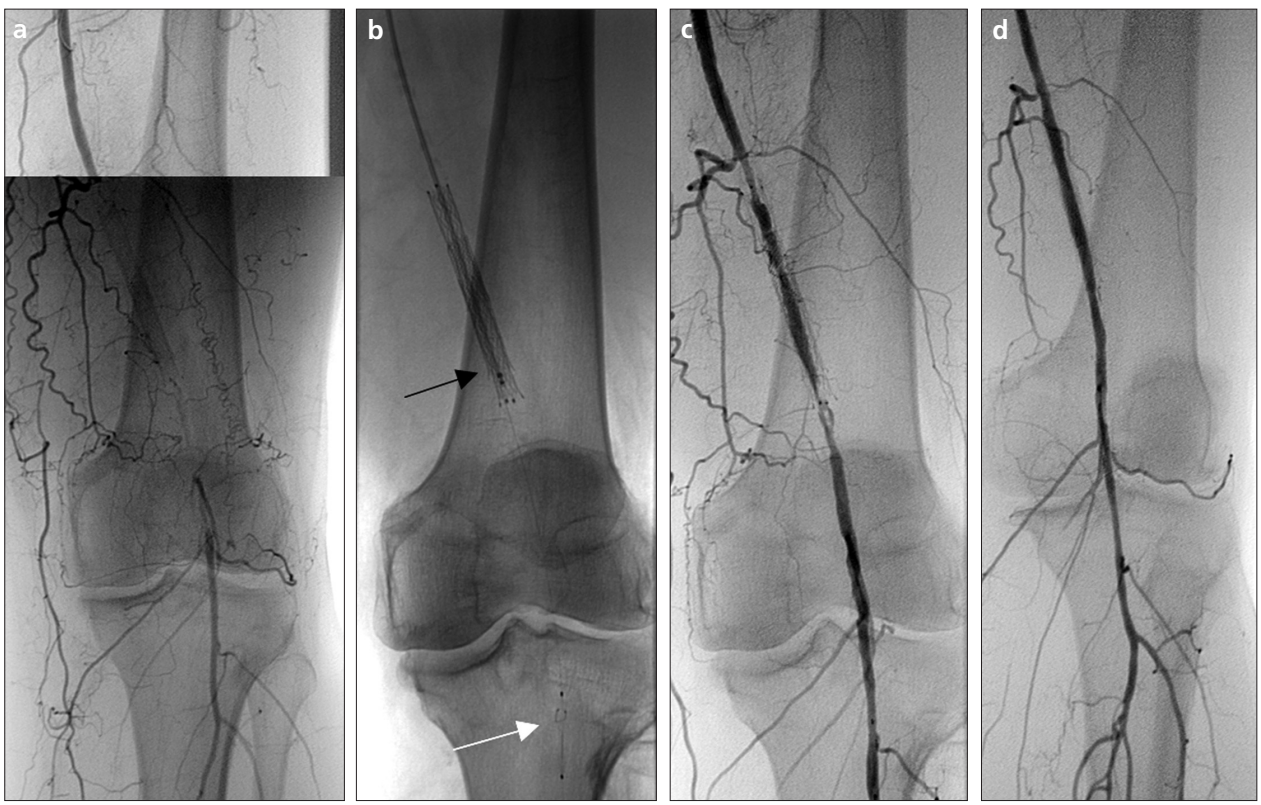


**Figure 6. a–d.** Recanalization of acute stent thrombosis with the ThromCat XT device under embolic protection. Acute stent thrombosis (two days after the onset of symptoms) in the distal part of the left superficial femoral and popliteal artery **(a)**. Thrombectomy **(b)** with the ThromCat XT device *(black arrow)*. A 5-mm Spider FX embolic protection device was placed in the distal part of the popliteal artery *(white arrow)*. Thrombectomy revealed a high-grade in-stent stenosis **(c)**, which was successfully treated by atherectomy with a Silverhawk LS-M device, leading to an excellent final result and complete flow restoration **(d)**.

tured. Then, an appropriate point of the fistula was punctured, and a short 7F sheath was introduced (Terumo Introducer II, 6 cm; Terumo Europe N.V., Leuven, Belgium) via a 0.035-inch standard guide wire.

In all cases, 5,000 IU of heparin was administered intra-arterially after the establishment of vascular access. The 0.035-inch standard guide wire was replaced with a 180-cm 0.014-inch guide wire (Cordis Stabilizer; Cordis Europe; Roden, The Netherlands) to cross the vessel occlusion. In four cases, an embolic protection device (SpiderFX 3 or 5 mm; ev3, Plymouth, Minnesota, USA) was employed, and the filter wire acted as a guide wire for the thrombectomy device. In all other cases, the device was guided solely by the 0.014-inch guide wire. If this guide wire failed to cross the lesion, it was replaced with a 180-cm 0.018-inch guide wire (V-18 Control Wire; Boston Scientific International, Nanterre Cedex, France) in combination with a 0.018-inch support catheter (Quick-Cross 90 cm; Spectranetics International). After positioning the catheter tip distal to the lesion, the 0.018-inch wire was exchanged for the 0.014-inch wire, and the support catheter was removed. In all cases, the occlusion was infiltrated with a bolus of 100,000 IU of Urokinase (Urokinase 100000 HS; medac Gesellschaft für klinische Spezialpraeparate mbH, Hamburg, Germany) by injecting the Urokinase directly into the occlusion through a 4F side-holed catheter (Altaflow Premium DSA-Catheter; Optimed Medizinische Instrumente, Ettlingen, Germany).

The ThromCat XT device was prepared according to the manufacturer's instructions for use. After removing the paper bands and connecting the device to the power cord, the attached extraction bag and the cord were handed to an assistant outside of the sterile field, who connected the cord to a nearby electrical outlet. A red diode indicated the catheter's off state. To prepare the device, its distal end was submerged 5 cm into a sterile saline solution before the catheter was switched on. The control switch was pressed until the red diode turned off, thus indicating that the device was successfully primed. Then, the control switch was adjusted to the "off" position, and the catheter was ready for use. Following these preparation steps, the catheter was inserted via the guide wire, moved through the thrombotic occlusion from the proximal to distal end and then retracted. This procedure was repeated as often as necessary (see Table 2 for procedure details). We defined technical success as the restoration of free blood flow in an occluded vessel using angiographic control after treatment with the ThromCat XT device. If patients suffering from peripheral arterial disease showed a corresponding relief of ischemic pain or if the shunt patients could immediately undergo dialysis after thrombectomy, we declared the thrombectomy to be clinically successful. After its use, the catheter was rinsed with sterile saline solution to completely remove all blood.

An underlying vascular stenosis was revealed by the thrombectomy in six cases. This was treated by balloon angioplasty in five cases or by additional directional atherectomy in one case (Silverhawk LS-M device; ev3 Endovascular). Additional endovascular stent placement was not necessary in any of the cases. Dialysis patients and bypass patients received therapeutic doses of post-interventional heparin for three days (prolongation of the partial thromboplastin time to 60–70 s). Two patients had an additional bolus of 200,000 IU urokinase administered because of peripheral thrombembolism (see Table 3 for all procedure-related complications). Patients with stent occlusions received 100 mg of acetylsalicylic acid and 75 mg of clopidogrel as long-term treatment. Adjunctive therapy is also listed in Table 1. Vessel patency after intervention—especially in patients with a wall-adherent residual thrombus—was monitored by color-coded duplex sonography on the following day and four days after intervention.

## Results

The recanalization was technically and clinically successful in seven of ten cases. The clinical parameters and residual occlusion rates because of a wall-adherent residual thrombus were registered and are shown in Table 1. Residual thrombotic material was dissolved as a consequence of additional heparinization or combined acetylsalicylic acid and clopidogrel therapy within four days in all cases. The ThromCat XT device was used to carry out mechanical thrombectomy in different vessel types with similar success rates in each region.

**Table 2.** Technical parameters of all ThromCat XT procedures

| | Native arteries with or without stent | Dialysis venous shunt | Bypass or dialysis graft | All vessels |
|---|---|---|---|---|
| Number of patients | 7 | 1 | 2 | 10 |
| Range of vessel diameter (mm) | 2.5–7 | 3–17 | 3–8 | 2.5–17 |
| Range of treated segment length (mm) | 30–100 | 40 | 40–120 | 40–120 |
| Range of blood loss volume (mL) | 120–240 | 280 | 230–260 | 120–280 |
| Maximum continuous run-time (min) | 2.8±0.84 (2–4) | 5 | 4±1.41 (3–5) | 3.4±1.19 (2–5) |
| Total duration of thrombectomy procedure (min) | 6.6±0.89 (6–8) | 12 | 9.5±2.83 (8–11) | 8.0±2.33 (6–12) |
| Catheter advancement and retraction (count) | 8±1.90 6–10 | 12 | 14±2.83 12–16 | 10±3.38 6–16 |
| Embolic protection system (number of patients) | 3 | 0 | 1 | 4 |

**Table 3.** Procedure-related complications

| | Native arteries with or without stent | Dialysis venous shunt | Bypass or dialysis graft | All vessels |
|---|---|---|---|---|
| Number of patients | 7 | 1 | 2 | 10 |
| Peripheral thrombembolism | 1 | 0 | 1 | 2 |
| Acute reocclusion during intervention | 0 | 0 | 0 | 0 |
| Vessel dissection, rupture, perforation | 0 | 0 | 0 | 0 |

Numbers indicate the count of patients.

The application time and blood loss were predominantly dependent on the vessel diameter and the occlusion length. The maximum blood loss was 280 mL. The device was advanced and retracted an average of ten times during the thrombus extraction. All technical parameters are detailed in Table 2. The maximum continuous run-time indicates the duration of the longest run-time without pause. The application time indicates the total duration of the thrombectomy procedure.

The device failed to restore vessel patency in three patients because of a denser thrombus consistency. The results are also listed in Table 1. In one of these cases, the patient developed an acute critical lower limb ischemia resulting from multiple peripheral thrombembolisms. The intervention was interrupted, and the clinical status of the patient required re-intervention. An aspiration thrombectomy combined with selective thrombolysis was carried out on the following day. In the other case, the thrombembolus dissolved within four days after administrating 200,000 IU of urokinase and therapeutic doses of heparin. We detected procedure related complications in two cases. The procedural complications are listed in Table 3.

## Discussion

The ThromCat XT catheter device was developed for coronary interventions but has been approved for peripheral use as well. Because of its interesting system design features, such as a changeable thrombectomy radius, an atraumatic flexible tip, and a flexible steel helix, we decided to first test its feasibility and performance in peripheral vessels and grafts. The improved flexible helix allows for crossover use, which is especially important in peripheral interventions. The set-up is fast and easy, and the catheter itself was found to be a safe and reliable mechanical thrombectomy device for the recanalization of acute thrombotic occlusions in native arteries and veins as well as grafts and stents.

We observed no catheter blockage or system failure. The fast thrombectomy procedure and the small catheter diameter allow for a smaller blood loss because of the shorter aspiration time. The rapid exchange system enables the use of short 180-cm guide wires as well as a simple combination with an optional embolic protection system. Therefore, the device can be easily applied by a single operator in contrast to most other devices, which require two operators in the majority of cases. The ThromCat XT device has a safe atraumatic catheter tip, and intra-operative vessel damage, such as dissection, rupture or perforation, is unlikely because of its flexibility (Fig. 2). No immediate vessel re-occlusion was observed, which is a considerable advantage in comparison to aspiration catheters whose stiff construction can lead to intimal injury in smaller or calcified vessels. Furthermore, there is no risk of adherence to wall plaques, calcifications or stent meshes, as the aspiration ports at the catheter tip are small (diameter <0.6 mm). This makes the ThromCat XT an ideal device for the treatment of severely diseased vessel segments or stent thrombosis. The variable thrombectomy radius and the small catheter diameter contribute to its ease of use and allow for the treatment of infrapopliteal vessels. However, despite its small diameter, the catheter provides an effective aspiration capacity at 38 mL/min, even in femoral and popliteal vessels or in dialysis shunts with relatively large diameters.

In our first experiences in peripheral vasculature, the ThromCat XT device adequately eliminated fresh thrombotic material to restore vessel patency, but it failed to aspirate and macerate organized thrombi with greater and denser consistency. We observed that only thrombotic material with an anamnestically assumed age of less than five days was adequately removed by the device. For cases in which the age of the thrombus was thought to be greater, wall-adherent residual material was always detected or the procedure failed. As a result of these observations, age appears to be an important factor in determining the effectiveness of thrombectomy with the ThromCat XT device. This fact is certainly due to the small aspiration ports, which make it difficult to aspirate partially organized thrombotic material.

Many percutaneous mechanical thrombectomy devices are currently being used to treat acute limb ischemia. However, the published literature may not reflect true clinical application rates. Among the mechanical thrombectomy devices, Rotarex and Aspirex (Straub Medical, Wangs, Switzerland), which are rotational thrombectomy systems, and AngioJet (Possis Medical, Minneapolis, Minnesota, USA), which is a rheolytic thrombectomy system, are dedicated to peripheral arterial intervention (4). The AngioJet thrombectomy device uses only the Bernoulli-Venturi effect to remove a thrombus, whereas the rotational thrombectomy devices combine an active negative pressure with an additional mechanical clot fragmentation. The most information—only preliminary data without randomized prospective studies—is available for the Rotarex device, but comparison studies have still not been

**Table 4.** Characteristics of mechanical thrombectomy devices for peripheral arterial application

| | ThromCat XT | AngioJet | Rotarex | Aspirex |
|---|---|---|---|---|
| Catheter design | Rapid exchange | Over the wire | Over the wire | Over the wire |
| Flexibility in case of cross-over in current literature | Good | Good | Catheter failure has occurred (6) | No available data |
| Catheter tip | Slightly pointed | Blunt | Blunt | Blunt |
| Catheter length (cm) | 150 | 135 | 80/110 | 80/110 |
| Catheter diameter (French) | 6 F | 4 F/5 F | 6 F | 6 F |
| Target vessel diameter (mm) | 2.5–7 (adjustable diameter) | 2–8 | 3–5 | 3–5 |
| Extraction flow (mL/min) | 38 | 50–60 | 45 | 45 |
| Peripheral application in current literature | Femoropopliteal-tibial arteries with or without stent; bypass and dialysis grafts and veins | Dialysis fistula (7); arteries and deep veins of the lower extremity (8, 9) | Femoropopliteal arteries with or without stent; bypass and dialysis grafts (10) | Mesenteric artery (11) (case report) |
| Complications in current literature | Distal embolization, 20% | Endothelial denudation, 12%±8%; distal embolization, up to 10% (9) | Vessel perforation, up to 8% (12); distal embolization, up to 24% (3) | No available data |

performed. In Table 4, we compare and list the technical data and clinical experiences of these devices based on the available literature.

There is always a considerable risk of thrombembolism during intervention with these catheters, especially in patients disposed to extensive thrombus formation or long-lasting thrombosis. Older thrombi have a higher propensity to become an embolism, as has been observed under *in vitro* circumstances. Therefore, the additional use of a protection system for the prevention of an embolism is reasonable in all patients, as the onset of symptoms is not always consistent with the age of the thrombus (5).

In conclusion, the ThromCat XT device is easy to set up and can be handled by a single operator. It proved to be a reliable and definitively atraumatic catheter for the percutaneous removal of fresh thrombi in native arteries and veins, as well as in grafts and stents including infrapopliteal vessels. Therefore, we regard this device as a reasonable and valuable completion of the endovascular arsenal for the treatment of peripheral arterial thrombembolism. According to our initial clinical experiences, the success of thrombectomy was unpredictable if the assumed age of the thrombus was greater than five days. The use of an additional thrombembolic protection system may be necessary in patients with excessive thrombus formation, but such systems can be easily and securely combined with this device.

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