# Ultrasound guided Thrombatherectomie with BYCROSS® in a complex case

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**Case:**

A 43-year-old, single-parent female patient with peripheral arterial occlusive disease (POD) clinical stage II b according to Fontaine classification with a symptom-free walking distance of only 150 m (Figure 1) on the basis of a renewed, but older, thrombotic occlusion of the left femoral fork; there was a desire for therapy.


← Image 1: 3D Reconstruction


Image 2: Occluded TEA zone

**General and vascular medical history :**

The patient's general medical history revealed a homozygous factor V Leiden mutation, persistent foramen ovale, and a moderately elevated cardiovascular risk profile (CVRP) with a nicotine consumption of 25 pack years, a body mass index (BMI) of 26.7, and dyslipidemia.

Specific vascular history revealed the following for the left leg: 08/2013 thrombectomy and biopatchplasty of the femoralis bifurcation for thrombotic occlusion, 10/2013 purple toe syndrome for recurrent peripheral microembolization, 02/2017 occlusion of the distal tibial artery (ATA). Oral anticoagulation (OAC) with Marcumar® and additive ASA was then established. However, this therapy was changed to heparin therapy in prophylactic dose during the course because of pregnancy. In the 28th week of pregnancy in 04/2020, a in clinical stage IIb according to Fontaine was again documented with a symptom-free walking distance of only 50 m. The patient was then treated with heparin. The pulsed wave (PW) Doppler flow signals in the superficial femoral artery (SFA) and the popliteal artery (A pop) were described as monophasic at this time, so that it can be assumed that there was already an occlusion or a high-grade stenosis within the TEA zone - probably caused by an anechoic and therefore not visible thrombus in B (brightness) image of the ultrasound device. In 09/2020, pregnancy progressed to further diagnosis and subsequent revision femoral bifurcation surgery with thrombectomy of an "older thrombotic" occlusion and suturing of a biopatch. A control in 02/2022 then documented an open TEA zone under therapy using Lixiana®, but also a stenosis of the SFA with V max 2.8 m/sec. In 12/2022, there was a PAD IIb stage on the floor of an intermediate-grade profunda femoris arteria (PFA) outflow stenosis (V max 200 cm/sec) and a higher-grade SFA outflow stenosis with V max 300 cm/sec. At this time, computed tomography (CT) imaging was arranged for January 2023 to supplement the diagnostic workup.

**Recent findings :**

The clinical condition worsened slightly again until 01/2023, so that the following findings were obtained at the end of January 2023: PAD IIb, occlusion pressures brachial bilaterally 130 mmHg, over the tibialis posterior (ATP) 120 mmHg and 0 mmHg over the known occluded ATA / dorsalis pedis (DPA), thus Ancle-brachial-Index (ABI) 0.92. However, the peculiarity of this complex case could be seen in the duplex sonography: The inflow to the inguinal region showed a normal, triphasic flow signal up to the distal external iliac artery (EIA), the PFA received inflow proximally via branches of the internal iliac artery and in turn fed the SFA, only the TEA zone in the area of the biopatch was completely occluded by a duplex sonographically inhomogeneous mass (Figure 2). The occlusion process could be confirmed morphologically by CT angiography (Figure 1).

Image 3: BYCROSS and 6F sheath

Image 4: BYCROSS tip and closed wing

Image 5: BYCROSS tip and extended wing

**Treatment planning :**
In particular, we felt that the circumstances of the thrombophilic tendency and the previous surgeries performed argued for interventional procedures rather than further surgery. Regarding an intervention to be performed, we set the following goals: If possible, no foreign body such as a (covered) stent should be implanted and as much as possible of the thrombotic/fibrotic/proliferative material of the occlusion should be removed. Antegrade inflow into the DFA and SFA should be restored. Towards the end of the intervention, a drug-eluting balloon (DEB) should be applied in the TEA zone, and finally, the intervention should be ultrasound-guided, both to save X-ray radiation and to assess the changing hemodynamics during the intervention.

In order to be able to achieve all these goals, our choice fell on the BYCROSS® system from the company plus medica. This is a system from the field of rotational atherectomy, which is applied in two stages: First without and then, if necessary, with an "activated wing" (Figs. 3-5).

**Intervention:**

The treatment was performed in the setting of a normal digital subtraction angiography (DSA) extended by the ultrasound device E10® of the company GE® prepared for sterile use. The intervention was performed in cross-over technique via an inserted 45 cm long 8 French sheath (Figure 6 shows the initial situation in DSA technique).

After successful intraluminal penetration of the occlusion with a Command 18® wire, atherectomy was performed with the BYCROSS® system (Figure 7) from the position of the distal EIA into the proximal SFA first with the slow rotation speed of the system (Stage 1) and then with the fast one (Stage 2). This was followed by the use of the wings of the BYCROSS® system (Figure 8), which resulted in further lumen gain.

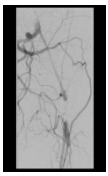

Image 6: pre- intervention


Image 7: BYCROSS first passage

Image 8: BYCROSS open wing

All passes were primarily performed under visualization by ultrasound, and in each case the lumen gain achieved was described by B-scan and color-coded duplex sonography (FKDS) (Figure 9) as well as hemodynamics by PW Doppler. Since the TEA zone in the occlusion portion had a height diameter of approximately 1 cm and thus could not be fully captured by the BYCROSS® system in terms of atherectomy without a temporary trick , we decided to narrow the TEA zone after the third pass of the system by applying external pressure with the transducer. Thus, having already ablated occlusive material, compression of the TEA zone (Figure 10) allowed further material to be brought into the effective range of the BYCROSS® system, thus achieving further lumen gain beyond the typical extent of the system.


Image 9: Improved hemodynamic

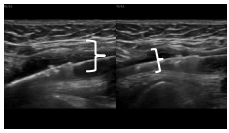

Image 10: left without, right with external compression

After reconstruction the junction into the SFA, the Command 18® wire was redirected into the DFA, thus treating the dorsal portion of the occlusion process in the same manner. After an overall successful atherectomy, the planned DEB application of the 10 mm Ranger® balloon in the TEA zone was performed over 3 min with, however, only 2 bars. The intervention was completed by applying a 6x100 mm DEB placed from the distal EIA to the proximal SFA and inflated with low pressure for 3 min. Radiographs using the DSA technique were used for documentation purposes only.

**Result:**
On the following day, we documented an occlusion pressure above the ATP of 110 mmHg with a brachially determined occlusion pressure of 100 mmHg, corresponding to an ABI of 1.1, in a patient without symptoms. Duplex sonography showed the TEA zone to be open with excellent lumen gain (Figure 11). The inflow to the SFA and DFA was undisturbed and the flow signal in the SFA was triphasic (Figure 12). The DFA maintained its typical antegrade inflow, but inflow from the branches of the internal iliac artery to the proximal DFA was also still present.

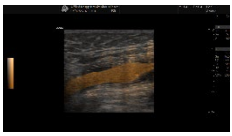

Bild 11: B-Flow-Image – TEA zone- following day

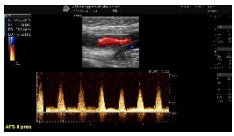

Bild 12: PW- Signal SFA- following day

Conclusion: The BYCROSS® system can be used safely and successfully at suitable intervention sites under visualization by ultrasound. The system can be clearly detected at rest and in action using ultrasound and its therapeutic performance is immediately visible. As this case demonstrates, the use of ultrasound with compression of the TEA zone by the ultrasound probe itself can quantitatively expand the power spectrum of the BYCROSS® system compared to a classic intervention using DSA technique, thus increasing the lumen gain (see above).

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