Technical aspects of the new BYCROSS TM atherectomy device - preliminary results after 28 patients

Dominik Liebetrau, Jörg Teßarek, Florian Elger, Viktoria Peters, Christian Scheurig-Münkler, Alexander Hyhlik-Dürr

Angaben zur Veröffentlichung / Publication details:

Liebetrau, Dominik, Jörg Teßarek, Florian Elger, Viktoria Peters, Christian Scheurig-Münkler, and Alexander Hyhlik-Dürr. 2024. "Technical aspects of the new BYCROSS TM atherectomy device - preliminary results after 28 patients." *Vasa* 53 (6): 388–96.
https://doi.org/10.1024/0301-1526/a001151.

Technical aspects of the new BYCROSS™ atherectomy device – preliminary results after 28 patients

Dominik Liebetrau[1], Jörg Teßarek[2], Florian Elger[3], Viktoria Peters[1], Christian Scheurig-Münkler[4], and Alexander Hyhlik-Dürr[1]

[1] Vascular Surgery, Medical Faculty, University of Augsburg, Germany
[2] Vascular Surgery, Bonifatius Hospital Lingen, Lingen (Ems), Germany
[3] Cardiac, Thoracic and Vascular Surgery, Medical Faculty, University Medical Center Göttingen, Germany
[4] Department of Diagnostic and Interventional Radiology, University Hospital of Augsburg, Germany

Summary: Purpose: Technical aspects are crucial for the planning and performing of the atherectomy to treat peripheral arterial disease. This report illustrates the use of a novel atherectomy device and investigates the feasibility, efficacy, and safety procedures involved in performing the atherectomy on 28 patients. Materials and methods: We performed a prospective analysis of patients who underwent an atherectomy with the BYCROSS™ Atherectomy device between August 2022 and September 2023 at a tertiary referral centre. Patients with a lesion below the aortic bifurcation (vessel diameter ≥ 3mm) having a de novo or restenotic (stent-included) present were recruited. Major adverse events (MAE) are defined as amputation, death, myocardial infarction, or angiographic distal embolization that require a separate intervention. Results: Of the 28 patients treated with the BYCROSS device, 23 were men with a mean age of 65.6 ± 9,6 years and a mean BMI of 24,6 ± 3.9 kg/m^2. Most patients had a typical atherogenic risk profile as well as multiple preexisting comorbidities. In all patients, a symptomatic peripheral arterial disease (PAD) was the main reason for an intervention. The most common Rutherford category was 5 (12/28). The most common lesion region was the femoropopliteal segment (25/28) with 23 de novo stenosis. Mean lesion length was 218,0 ± 93,7 mm. The mean PACCS Score was 3,0 ± 1,0. Stenosis grade was by mean 99,3 ± 3,7%. Ankle Brachial Index (ABI) increased significantly after BYCROSS atherectomy (pre- 0,44 ± 0,43 vs. post-procedure 0,84 ± 0,30 P<0,001. Target lesion/vessel revascularization (TLR/TVR) within the first 30 days was 3,6% (1/28). 30-day MAE rate was 14,3% (vessel perforation in 3/28 patients, embolism in 1/28). There were no deaths, index limb amputations, or myocardial infarctions. Conclusion: The BYCROSS™ atherectomy system is a new device with numerous advantages in treating high-grade, calcifying stenosis and occlusion processes in PAD. Based on the above findings, the BYCROSS™ Atherectomy device represents a feasible, safe, and effective method for endovascular treatment of peripheral arterial disease.

Keywords: Critical limb ischemia, endovascular revascularization, mechanical thrombectomy, limb salvage, Crossing the occlusion device, rotational atherectomy

What is already known about this subject

- Atherectomy systems play an essential role in the treatment of peripheral arterial disease (PAD).
- Each atherectomy system has its limitations (e.g., very long-calcified lesions, complete occlusions, diameter of the created channel).
- In addition, atherectomy is associated with certain risks such as perforation, vascular injuries, and distal embolism.

What this report adds

- Initial preliminary results of a new atherectomy system with potential advantages over other systems due to its new technical innovation.
- Demonstrates technical conditions and the usage of the novel atherectomy device in treating peripheral arterial disease.
- Depicts how the BYCROSS™ atherectomy system is used to treat severely calcified lesions in a minimally invasive manner, which previously was reserved for bypass surgery only.

What impact this may have on practice or policy

- Familiarization with the new BYCROSS™ atherectomy system as an easy-to-use device.
- Knowledge on how the BYCROSS™ atherectomy device has numerous advantages in treating high-grade stenosis and occlusion processes.
- Evidence that an additional innovative tool for the treatment of long-calcified lesions/occlusions is available.

Introduction

There are several treatment strategies for peripheral arterial disease (PAD) with a focus on minimally invasive options which have been developed as "first-line treatment" options in recent years. As a result, open surgical interventions and their stress on the patient can thus be avoided [1]. Furthermore, the duration of hospital stay can be significantly reduced, and patients can benefit from a rapid recovery [1, 2]. Atherectomy systems play an essential role in achieving such benefits. Furthermore, any complex lesions below the aortic bifurcation zone, as well as long calcified or in-stent occlusions, can be removed in a minimally invasive way. A canal can be "milled" into the occlusive material using dedicated systems which are then followed by the evacuation of debris or plaque material instead of the use of a high-pressure balloon angioplasty/additional stent implantation.

The Atherectomy technique is a technique that has been in use since the late 1990s to achieve optimal lumen gain in various lesion morphologies [3, 4]. So far, the most established catheter systems operate optimally in their respective application areas. Nevertheless, each atherectomy system does pose limitations (affected arterial segment, lesion morphology and degree of calcification, effective lumen gain) [5]. In addition, atherectomy as a robust "cutting" treatment modality is associated with certain risks such as perforation, vascular injuries and distal embolism [6, 7, 8, 9]. Despite the long history of technical developments and widespread use of this form of therapy, there is still considerable potential for improvement.

The novel BYCROSS™ atherectomy system (TARYAG-MEDICAL GmbH, 14 Ha'Ilan st Or-Akiva, 3065101, Israel) represents a further development of the already available atherectomy systems, thus eliminating known limitations of the technique and thereby providing new therapeutic options.

Objective of the study

To report preliminary short-term (30-day) results as well as proving the feasibility, efficacy, and safety of a new atherectomy device conducted on 28 patients presenting with PAD (Rutherford 2–5, [10])

Material and methods

All patients who underwent the atherectomy with the BYCROSS™ Atherectomy device between August 2022 and September 2023 at a tertiary referral center were investigated. Patients with de novo or re-stenotic (also in-stent) lesions below the aortic bifurcation (vessel diameter $\geq$ 3mm) present were recruited.

The Ludwig-Maximilians-University Munich (LMU) ethics committee gave its approval (project number: 22-0047). Informed consent was obtained from all patients.

The results were prospectively recorded in a database (Microsoft Excel® version 2019) and analyzed. Twenty-eight patients (23 male, 5 female) with PAD were included. PAD was classified according to the Rutherford classification [10]. The primary endpoint was technical success defined as the passage of the occlusion with the BYCROSS® device and post-atherectomy residual stenosis $\leq$ 50% relative to reference diameter to allow for angioplasty and/or stenting if the required and complete procedural success of residual stenosis $\leq$30%. Procedural success was defined as restoring the blood flow of the lesion in the case of a failed atherectomy via the well-known balloon angioplasty (POBA), Drug-Coated Balloon (DCB), or Stent placement. In all cases, after the atherectomy was performed, the lesions were treated with additional angioplasty using a DCB (MagicTouch, Concept Medical, Tampa, USA) for 180 seconds. The device was used without any embolic protection systems in place. Hybrid procedures such as the well-known femoral artery patch plasty have been performed to increase inflow or outflow from the revascularized lesion.

Major adverse events (MAE) were defined as major amputation, death, myocardial infarction or angiographically visible distal embolization that require a separate intervention.

Statistics

Data analysis was conducted on SPSS 28.0 (IBM Corp, Armonk, NY). Data cleaning, recoding and organization was performed to facilitate statistical analysis. We chose an α-level to be equal to .05 such that a P-value<.05 denoted a statistical significance for all our tests. According to their retention rate and the level of measurement undergone, the data is represented as absolute values and percentages. The mean value is represented with its corresponding standard deviation value. To evaluate the level of significance for continuous variables, a t-test was conducted.

Description of the BYCROSS atherectomy device

The BYCROSS™ device is a minimally invasive, single-use crossing, atherectomy, and thrombectomy device

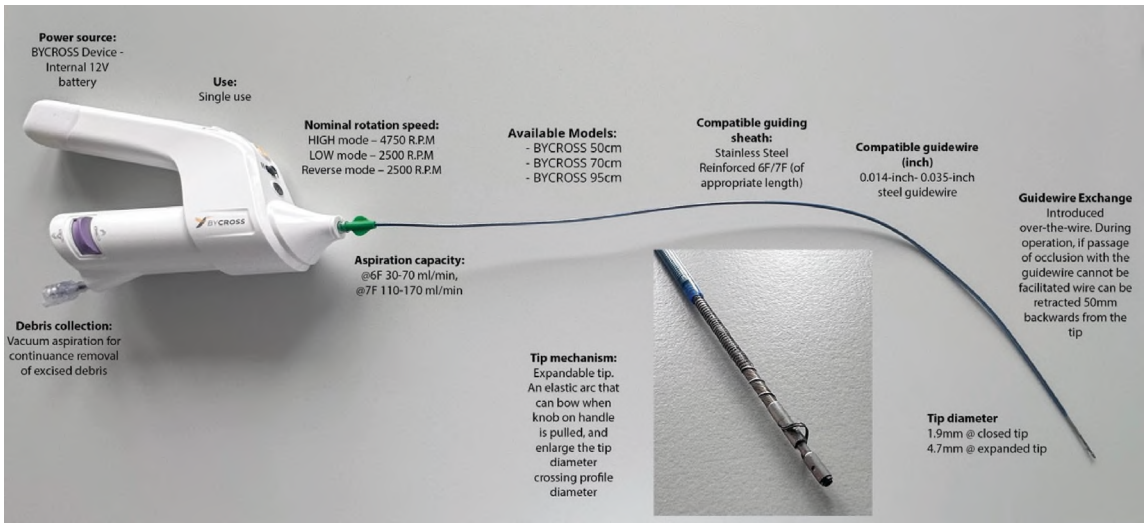

Figure 1. Device properties.

commonly introduced through a guide wire for the revascularization of acute or chronic occluded peripheral vessels (Figure 2a–d). Patients with de novo or re-stenotic lesions below the aortic bifurcation with a vessel diameter up to $\geq$ 3mm can be treated in an antegrade and retrograde approach [11].

The device's properties are shown in Figure 1. The Animation explains the basic features of the system. The BYCROSS^{TM} device has a coaxial flexible rotating shaft with an expandable tip that integrates an aspiration system for suctioning plaque debris and broken-down thrombotic material. The expandable tip carries an elastic arc (Nitinol) that can bend and enlarge the tip diameter from the external tip diameter of 1.9mm at closed conditions to 4.7mm at open conditions (Figure 1). The device is available in various working lengths (50cm, 70cm, or 95cm). As the shaft rotates (Low-Mode: 2500rpm, High Mode: 4750rpm), the tip breaks the calcified atheroma/thrombus into small particles, which are simultaneously suctioned into the guiding sheath and removed into the attached collection bag.

The BYCROSS^{TM} device allows the injection of contrast and thrombolytic agents through the rotating tip during the procedure as a means of providing continuous imaging as well as the prevention of appositional thrombus formation. Due to its non-symmetrical spiral design, the tip rotation is an eccentric feature. While the BYCROSS^{TM} is introduced through a steel guidewire (between 0.014-inch–0.035-inch platform), it does not require the passage of occlusion with guide wire at first. To cross the occlusion, the BYCROSS^{TM} operates in an advanced back and forth motion in a closed condition. Once the occluded segment is crossed, the procedure is repeated with an open tip in larger diameter vessels to further remove any remaining atheroma or thrombus.

The device operates without capital equipment, pedals, or non-sterile equipment and is battery powered. The stainless-steel design provides complete hub-to-tip radiopacity.

The BYCROSS^{TM} is powered by 12V lithium batteries that can be disposed of separately from the device as non-bio-hazard waste. The BYCROSS^{TM} motor has a reverse function and an electronic chip which controls all parameters such as: rotational speed, tension of the shaft, and resistance at the tip, which function as inherent safety features to prevent malfunction or vessel injury.

Technique

All procedures were performed following standard procedures. To avoid thrombosis and early failure, intraoperative anticoagulation is necessary. After the introduction of the sheath, a single dose of 70 international units of heparin/kg bodyweight is administered. A dose adjustment can be made as well as the ability to perform an intraoperative monitoring (e.g., ACT "activated clotting time" determination). Recanalization of the lesion can be performed in different ways, either using intraluminal wire passage first or immediate passage with the Bycross system without wire guidance.

The maximum lumen gain of 4.7mm is achievable only in vessel segments with a reference diameter of 5mm. Otherwise, the Bycross must be explicitly used with a closed tip only.

The combination of a maximum aspiration capacity of 65–200ml/min (depending on the sheath diameter 6–8F) and the Archimedes screw function of the rotating shaft allows for maximization of the inherent embolic protection function.

Subsequently, the angiographic verification of the stenosis/occlusion is performed, as well as the passage using guidewire. Thereafter the BYCROSS^{TM} is placed in front of the stenosis/ occlusion under fluoroscopy. Once the BYCROSS^{TM} is activated, the stenosis/occlusion is passed at a speed of 0,5-1 mm per 1 second. Firstly, 2/3 of the stenosis/occlusion is passed, leaving a distal cap to minimize embolization risk. Secondly, In a vessel diameter of at least 5 mm the atherectomy can be performed with an open catheter tip (diameter of the tip 4,7mm. The procedure is then repeated for the remaining one-third of the stenosis/occlusion.

An angiography needs to be performed in order to verify the results. A supplementary angioplasty is usually required

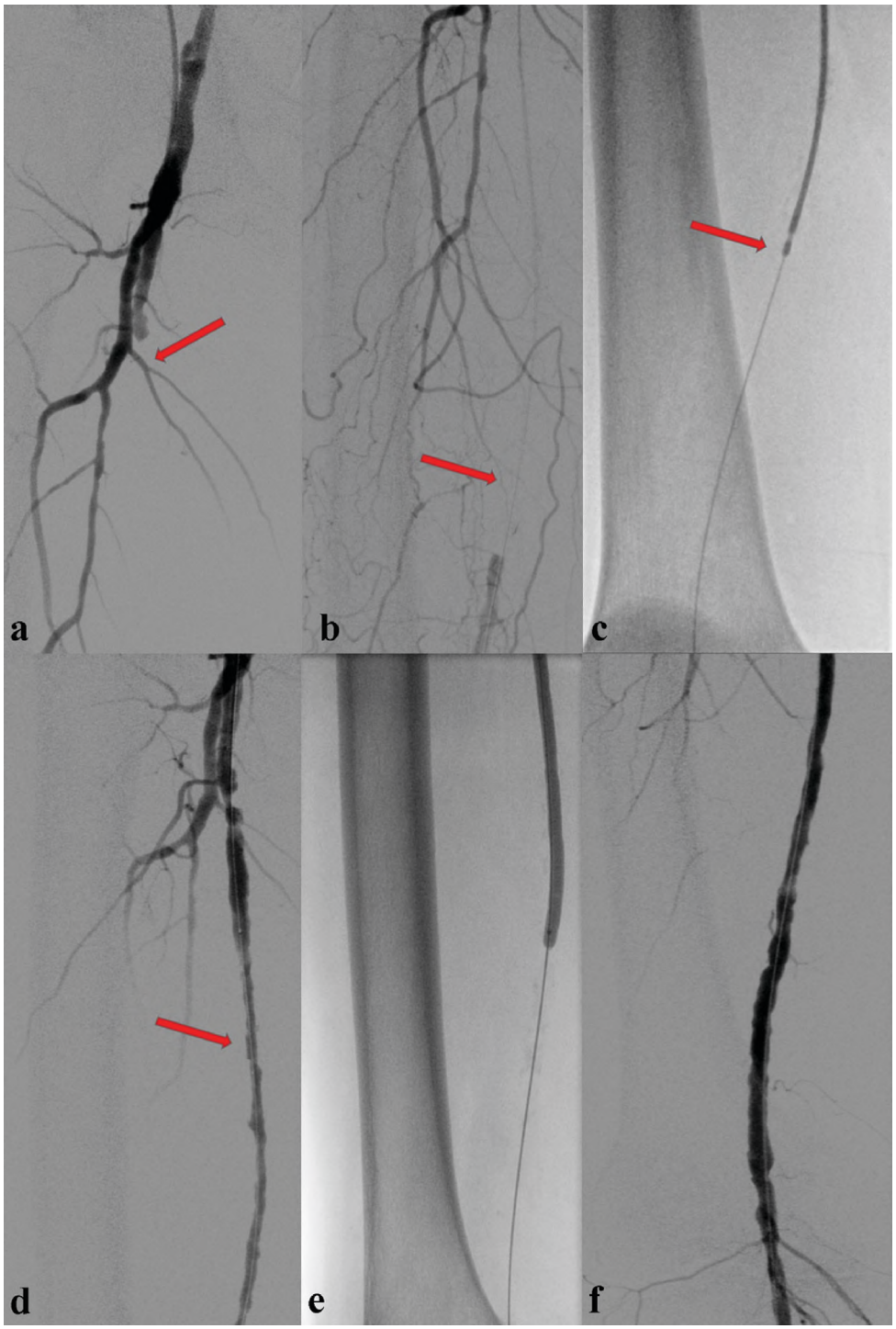

Figure 2. Patient Nr. 1 Table II, a) Identification of the occlusion (red arrow), b) intraluminal passage of the occlusion with guide wire, c) application of the Bycross atherectomy device d) angiographic control after Bycross application, recanalized vessel (red arrow) e) additional angioplasty f) final angiography.

as well. The aim is to achieve an angioplasty with comparatively low atmospheres (1–3 atm) and a duration of at least 180 seconds. To confirm the local findings, an additional angioplasty will be performed using a drug-eluting balloon (Figure 2e). The application of the BYCROSS^{TM} atherectomy system without the use of guide wire to break the cap is a novel system in dealing with the frustration brought on by luminal guidewire passage. The BYCROSS^{TM} catheter can be advanced through the occlusion without an existing wire passage. The system can center itself and pass through calcified lesions due to its flexible tip configuration. Once the occlusion has been passed and a guide wire has been advanced, the system can be used in the standard manner displayed in the IFU [11] (Figure 3).

Results

Of the 28 patients treated with BYCROSS, 23 were men with a mean age of 65.6 ± 9,6 years and a mean BMI of 24,6 ± 3.9 kg/m^2. Most patients had a typical atherogenic

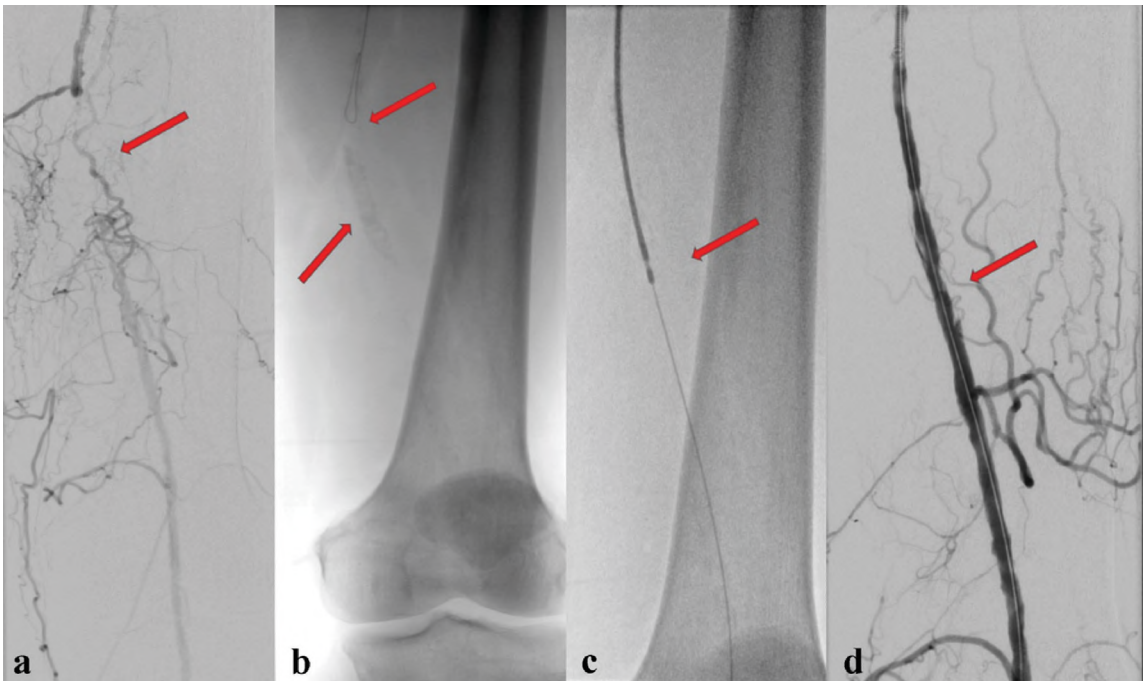

Figure 3. Patient Nr. 2 Table II, a) identification of the occlusion (red arrow), b) unsuccessful intraluminal guide wire passage, c) Application of the ByCross® atherectomy device initially without guide wire, after successful intraluminal passage application of the ByCross® system wire guided d) angiographic control after angioplasty.

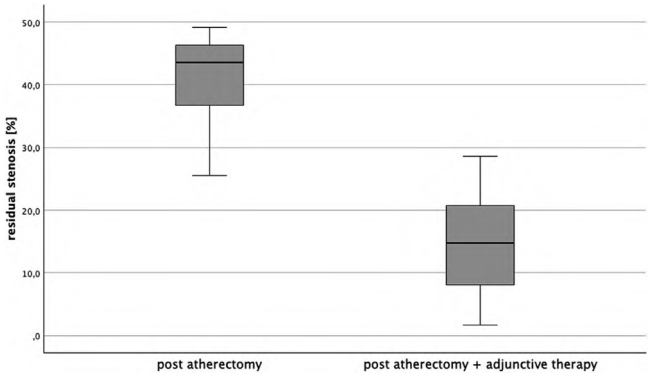

Figure 4. Overview of the residual stenosis after atherectomy and atherectomy + adjunctive therapy. Adjunctive therapy was defined as Plain old balloon angioplasty (POBA), Drug-Coated Balloon (DCB), or Stent placement. In 27/28 cases the target lesion was occluded.

risk profile and multiple preexisting comorbidities. In all patient's asymptomatic peripheral arterial disease (PAD) was the reason for intervention. The most common Rutherford category was 5 (12/28) (Table I). The most common lesion region was the femoropopliteal segment (25/28) with 23 de novo stenosis. The mortality rate was zero and amputation-free survival by day 30 was 100%. The mean lesion length was 218,0 ± 93,7 mm. The mean PACCS Score was 3,0 ± 1,0. The mean stenosis grade was 99,3 ± 3,7% (Table III). The BYCROSS atherectomy was performed in 15/28 cases on the left leg. The antegrade recanalization approach was successful in 22/28 patients. A hybrid procedure was accomplished in 13/28 patients. The median residual stenosis after atherectomy was 43,5% and after atherectomy + adjunctive therapy 14,8% (Fig. 4). Primary technical success was achieved in 92,9% (Table II). Mean procedure time was 148,7 ± 72,5 min, and the median (IQR) BYCROSS atherectomy run-time was 373 [138,3–658,5] sec. The mean aspiration volume was 89,1 ± 64,7 ml. An additional stent placement was necessary in 13/28 patients. The most common reason for stenting was dissection (Table V). The ABI increased significantly after the BYCROSS atherectomy (pre-:0,44 ± 0,43 vs. post-procedure 0,84 ± 0,30 P<0,001, Table II). Target lesion/vessel revascularization (TLR/TVR) within the first 30 days was 3,6% (1/28). The 30-day MAE rate was 14,3% (vessel perforation in 3/28 patients, Embolism in 1/28). There were no deaths, index limb amputations or myocardial infarctions (Table IV).

Discussion

Atherectomy for treating complex and advanced PAD has developed as a viable alternative to POBA, stenting [12] or bypass surgery.

Table I. Baseline clinical characteristics

Included patients (n)	28
Age (y)	65,6 ± 9,6
Sex (m/f)	23/5
BMI[4] (kg/m)	24,6 ± 3,9
Hospital stay in d[1] (mean)	10,9 ± 15,2
Comorbidities	
Hypertension	23/28 (82,1%)
Hyperlipoproteinemia	21/28 (75,0%)
Current smoking	17/28 (60,7%)
Diabetes	15/28 (53,6%)
Coronary heart disease	9/28 (32,1%)
Chronic kidney disease	2/28 (7,1%)
COPD[2]	2/28 (7,1%)
Peripheral arterial disease	28
Rutherford catefory[3]	
2	1/28 (3,6%)
3	5/28 (17,8%)
4	10/28 (35,7%)
5	12/28 (42,9%)
Mean clinical stage (Rutherford)	4,2 ± 0,8

Notes. [1]d, days; [2]COPD, chronic obstructive pulmonary disease; [3]Rutherford [10], 4 BMI; [4]Body-Mass-Index.

Table II. Procedural data

Included patients (n)	28
technical success (%)	92,9
procedural success (%)	100
ABI[1] preoperative	0,44 ± 0,43
ABI[1] postoperative	0,84 ± 0,30
Duration in min	148,7 ± 72,5
Side (l/r)	15/28 (53,6%)
Percutaneous procedure	15/28 (53,6%)
Hybrid procedure	13/28 (46,4%)
Approach	
antegrade	22/28 (78,6%)
retrograde	5/28 (17,8%)
cross-over	1/28 (3,6%)
Median [IQR] Atherectomy run-time (sec)	373 [138,3-658,5]
aspiration volume in ml	89,1 ± 64,7

Notes. [1]ABI; Ankle-Brachial-Index.

Table III. Lesion characteristics

Included patients (n)	28
Region	
Iliac	2/28
Femoropopliteal	24/28
Below the knee	2/28
De novo lesion	23/28 (82,1%)
Re-stenosis[2]	5/28 (17,9%)
Stenosis grade in %	99,3 ± 3,7
Occlusions	27/28 (96,4%)
Lesion length (mm)	218,0 ± 93,7
PACCS Score[1]	
1	2/28 (7,1%)
2	8/28 (28,6%)
3	5/28 (17,9%)
4	13/28 (46,4%)
PACCS[1] score mean	3,0 ± 1,0

Notes. [1]PACCS Score; peripheral artery calcification scoring system. [2]Stent occlusion included.

Table IV. Complications

Included patients (n)	28
Vessel perforation	3 (10,7%)
Embolism	1 (3,6%)
Need for major amputation	0
Myocardial infarction	0
TVR/TLR[1]	1/28 (3,6%)
30-day mortality in %	0

Note. [1] TVR/TLR, target vessel/ lesion revascularization within the first 30 days.

Table V. Reasons for stenting

Included patients (n)	28
Stent implantation performed	13/28 (46,4%)
dissection	7
perforation	3
stenosis >30%[1]	3
Type of stent	
Stent graft (self-expanding)	5
Self-expanding Nitinol Stent	8
median stent length in mm	80 mm

Note. [1]remain stenosis after atherectomy and adjunctive angioplasty.

Its use in long and severely calcified lesions is currently well accepted, and many studies prove the effectiveness of various devices suited for this purpose [9, 13].

With the availability of more data, the clinical and technical limitations of each of the devices became more apparent, such limitations include but are not limited to> the severity of calcium deposits, the lesion morphology and position, the risk of embolization [6] or device overheating (run time limit) [14] requiring run time limits. Furthermore, there is a need for distal embolic protection devices to prevent complications as well as intricate rescue procedures. Such additional features increase the costs of the procedure.

The BYCROSS™ Atherectomy device received the CE mark in 2019 and represents a further development of pre-existing atherectomy systems and combines a variety of essential characteristics from each system in one single device (e.g., simultaneous aspiration and mechanical debris transportation following the principle of the Archimedes Screw, no capital equipment needed, compatibility with a wide guidewire portfolio, wire independent passage of occlusions) [5].

The device has a wide range of indications for de-novo and recurrent occlusive lesions (>70% degrees) in native vessels but also in stents or grafts independent from the PACC score of the lesion. The IFU covers all vessel segments below the aortic bifurcation down to vessels with a minimum diameter of 3mm [11]. Additionally, the

Bycross™ is compatible with guidewires <= 0.035", which allows its use with the local wire portfolio.

The published data so far proves its effectiveness in complex, long and severely calcified lesions, which have been seen as contraindications for other atherectomy systems [15].

In our study, the BYCROSS Atherectomy device represents a safe and effective (technical success 92,9%) means of recanalizing long calcified lesions (mean lesion length 218,0 ± 93,7 mm, mean PACCS Score 3,0 ± 1,0).

In general, treating critical limb ischemia requires the safe use of endovascular techniques and a multidisciplinary treatment approach [16]. In the present study, 22/28 patients (78.6%) had critical limb ischemia. Compared to the EASE study (33% with Rutherford category 4–5; [7]), the JETSTREAM post-market study (0, 8% with Rutherford category 4; (9)) or the TALON Registry (31.2% [3]), the proportion of patients with critical limb ischemia was significantly higher. In addition, the mean lesion length of 218.0 ± 93.7 mm was again considerably longer than in the EASE study (34.03 ± 29.88 mm; [7]), the JETSTREAM post Market study (16.4 ± 13.6 cm; [9]) and the TALON register (62.5 ± 68.5 mm, [3]). Tessarek et al. reported similarly long treated lesion lengths (229.2mm) by utilizing the BYCROSS device [15]. Recent publications on the atherectomy, as mentioned above systems, show an increasing tendency to use them even for longer lesions [8, 13].

The BYCROSS™ atherectomy device can be used for thrombotic occlusions and calcifying lesions/occlusions. In this study the main focus of the device is on calcifying lesions. The PACCS score (peripheral artery calcification scoring system [17]) can be used to determine the degree of calcification of the lesions treated [17]. The score was 3.0 ± 1.0 in the present group and is thus comparable to currently published studies [8, 13, 15]. In summary, the majority of the patients in this study were treated with CLI and long calcifying lesions.

The procedure for revascularization was performed analogously to the published CTO crossing algorithm by Korosoglou et al. [18] proved successful in all patients. Defined technical success was achieved only in 92.9% (26/28) of the patients. In 2 cases (both PACCS score 4), a passage of the BYCROSS was prevented by massive calcifications. The success was not limited by the catheter but by the attached sheath. A pre-dilatation of the lesion was not performed, but it could be a possible approach in facilitating the passage of the BYCROSS in future treatments. Finally, the blood flow was restored in all patients with POBA, DCB or stent placement, therefore procedural success was 100%. Nevertheless, the 92.9% technical success rate of the BYCROSS atherectomy combined with the significant increase in the ABI (pre-procedure: 0.44 ± 0.43 vs. post-procedure 0.84 ± 0.30 P<0.001) shows the great potential of the device. Thus, the result is comparable with the available literature [19].

The run-time limitation is important in treating long lesions when using atherectomy systems. The BYCROSS™ Atherectomy device rotates with a maximum velocity of 4750rpm and has no run-time limitations (11). Blood or fluid cooling is not needed to prevent carbonization or clotting of debris. The maximum tip temperature after continuous drilling in dry bone or equivalent does not exceed 47.1°C (data from lab testings at TARYAG-MEDICAL GmbH, 14 Ha'Ilanst, Or-Akiva, 3065101, Israel). Other atherectomy systems such as the Rotablator™ system (Boston Scientific, Marlborough, MA 01752 (USA) [20] or the Phoenix™ atherectomy system from (Philips Medical Systems, Veenpluis 6, 5684 PC Best, Netherlands) [21] have runtime limitations to prevent system blockage or heating [19]. In this study, the mean run-time was 485,5 ± 420,8 sec (max. 1824 sec = 30,4 min), which is longer than the pivotal study [15]. However, comparable data is available in the literature [9]). It is shown that there is no risk overheating present even with a runtime longer than 30 minutes.

Furthermore, a special guidewire is not recommended for the use of BYCROSS such as the one used in the Rotarex® atherectomy system (BD- Becton, Dickinson, and Company, 1 Becton Drive Franklin Lakes, 07417–1880 NJ) [22] or Jetstream™ (Boston Scientific, Marlborough, MA 01752 (USA)) [23]. Moreover, the atherectomy systems mentioned above, such as Phoenix™, Rotarex®, or Jetstream™, require a guide wire that has previously passed through the lesion. If no or only subintimal passage is possible, applying these atherectomy systems is outside the instructions for use (IFU). Wireless passage of lesions was not necessary in our cohort, but this modality is widely used and was part of the CE mark study which proved to be effective [15].

The potential of atherectomy on patients has already been established in various studies [3, 7, 9, 15].

The patient has to be informed about potential major procedural complications including embolism, vascular perforation and follow-up complications such as major amputation, myocardial infarction and death. The complication rate in the first 30 days of atherectomy is reported in the literature between 2–11.6% [3, 9, 24]. The complication rate in the present group was 14.3% (4/28), which is relatively high (Table IV) and requires further investigation. There were three vessel perforations and one embolism. The three vessel perforations occurred in patients with a PACCS score of 4 and a mean occlusion length of 278.7 ± 48.0 mm.

The catheter tip of the BYCROSS atherectomy device is designed in a way that the non-symmetrical helical rotating tip reduces the risk of damaging the vessel wall when crossing the occlusion. Nevertheless, perforations occurred for which there can be various reasons. One possible explanation is that the established guidewire was subintimal for a short distance, therefore a passage with the BYCROSS device would thus injure the vascular wall and cause a rupture. The consequences of subintimal atherectomy have already been described in the available literature [25, 26]. Despite the proof of correct intraluminal wire position distal to the lesion, long occlusions bear the risk of a segmental subintimal run of the wire, resulting in vessel injury.

Nevertheless, in the three cases, a subintimal wire passage is possible with an average lesion length of 278.7 ± 48.0 mm. An intravascular ultrasound (IVUS) to verify the wire position was not available. The potential benefit of IVUS during endovascular surgery has already been described in several studies [27, 28].

Luckily, in the above-mentioned cases, the perforation could be treated using a stent graft (VIABAHN, Gore, Flagstaff, USA). In all 3 cases, critical limb ischemia was present, and recanalization of the long occlusive section was successfully performed. As a result, it was possible to prevent a major amputation.

The removal of debris is based on the principle of the Archimedean screw (shaft configuration) and an active suction through a pump is installed in the handpiece (Figure 1). Active aspiration at the tip of the catheter takes place via a sheath attached to the handpiece, which minimizes the risk of embolization, which distinguishes it from the Phoenix® atherectomy system. The Phoenix® atherectomy system (Philips Medical Systems, Veenpluis 6, 5684 PC Best, Netherlands) is also based on the principle of Archimedean screw, but it has no active aspiration [7]. Nevertheless, present studies on the Phoenix system are promising and show low embolization rates [29, 30].

The additional active aspiration function of the BYCROSS™ aims to minimize the embolization rate further. Moreover, selecting the sheath size (6 Fr or 7 Fr) and the change in aspiration capacity (6 Fr = 30–70 ml/min vs. 7 Fr = 110–170 ml/min) is possible. In the present study, embolism was detected in 1 patient. The occlusion length was 195mm, and the PACCS score was 1. With a vessel diameter of 7 mm, the present occlusion was thromboembolic.

Measures to minimize the risk of embolism in atherectomy have been described [31] and should be established as part of a daily routine.

In the case of thrombotic occlusions specifically, an increase in aspiration and minimization of the embolization risk can be achieved by applying a 7 Fr. sheath. In this case, an increase in the aspiration capacity using a 7 Fr. sheath was omitted. In retrospect, the use of a 7 Fr. Sheath, with the associated increased aspiration capacity might have avoided the embolism. However, using an embolism protection system would have also been possible. The experiences published so far (embolism rate 0% [15]) as well as our observations of embolisms prove that embolism protection systems are not required; the standard use of embolic protection systems are not recommended by IFU [11]. In the context of the observed embolism (thromboembolic occlusion) it shows that it should be closely monitored in future use and the procedure should be reconsidered in the event of increased occurrence of complications. In the end, the embolism was successfully treated, and blood flow was restored. There were no further device-associated complications observed.

One patient underwent re-intervention within the first 30 days. The TVR/TVL rate is 3.6% and is comparable to data from the literature [15]. The reason for the re-intervention was recoiling within the lesion. Initially, the stent implantation was not performed because the angiographic result was good, however, the postoperative ultrasound control showed restenosis (>50%) which required a new angiography to be performed. An additional stent implantation was performed without a new atherectomy which could be executed without complications.

Limitations

This study is a monocentric investigation and presents preliminary results. The investigated population is small, and no long-term Follow-up period is available. The treated lesions were heterogeneous (de-novo and restenosis), and the indication for performing atherectomy and stenting was operator-dependent.

Conclusion

The advantages of the BYCROSS™ atherectomy system highlight the wide range of possible applications as well as the potential of an integration into daily routine.

Based on the published data available so far, the BYCROSS™ atherectomy shows the effectiveness in treating complex occlusive lesions and highlights its potential as a viable alternative to bypass surgery for patients presenting with advanced PAD and Critical limb ischemia. Nonetheless, complex endovascular procedures bear the risk of complications regardless and therefore a bail-out solution for device and procedure-related complications should be at hand when starting the operation.

Further investigations such as the post-market surveillance study (ClinicalTrials.gov identifier: NCT051100799 and multicenter studies (DRKS00029947), as well as the need for long-term follow-up data and comparative studies are mandatory for further evaluation.

References

1. Lee LK, Kent KC. Infrainguinal occlusive disease: endovascular intervention is the first line therapy. Adv Surg. 2008;42:193–204.
2. Adam DJ, Beard JD, Cleveland T, Bell J, Bradbury AW, Forbes JF, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. Lancet. 2005;366(9501):1925–34.
3. Ramaiah V, Gammon R, Kiesz S, Cardenas J, Runyon JP, Fail P, et al. Midterm outcomes from the TALON Registry: treating peripherals with SilverHawk: outcomes collection. J Endovasc Ther. 2006;13(5):592–602.
4. Garcia LA, Lyden SP. Atherectomy for infrainguinal peripheral artery disease. J Endovasc Ther. 2009;16(2 Suppl 2):II105–15.
5. Tessarek J, Oberhuber A. Innovations in the endovascular treatment of peripheral arterial disease. Gefasschirurgie. 2021;1–12.
6. Stahlberg E, Anton S, Sieren M, Wegner F, Barkhausen J, Goltz JP. Mechanical rotational thrombectomy in long femoropopliteal artery and bypass occlusions: risk factors for periprocedural peripheral embolization. Diagn Interv Radiol. 2021;27(2):249–56.

7. Davis T, Ramaiah V, Niazi K, Martin Gissler H, Crabtree T. Safety and effectiveness of the Phoenix Atherectomy System in lower extremity arteries: Early and midterm outcomes from the prospective multicenter EASE study. Vascular. 2017; 25(6):563–75.
8. Dukic D, Martin K, Lichtenberg M, Brodmann M, Andrassy J, Korosoglou G, et al. Novel Therapeutic Concepts for Complex Femoropopliteal Lesions Using the Jetstream Atherectomy System. J Endovasc Ther. 2023;15266028231161246.
9. Gray WA, Garcia LA, Amin A, Shammas NW, Investigators JETR. Jetstream Atherectomy System treatment of femoropopliteal arteries: Results of the post-market JET Registry. Cardiovasc Revasc Med. 2018;19(5 Pt A):506–11.
10. Rutherford RB, Baker JD, Ernst C, Johnston KW, Porter JM, Ahn S, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg. 1997;26(3):517–38.
11. GmbH T-M.IFU, Instructions for use, BYCROSS™ Atherectomy System https://wwwplusmedicade/fileadmin/user_upload/Taryag_IFU_EN_001-18pdf.viewed on 08.11.2022.
12. Dias-Neto M, Matschuck M, Bausback Y, Banning-Eichenseher U, Steiner S, Branzan D, et al. Endovascular Treatment of Severely Calcified Femoropopliteal Lesions Using the "Pave-and-Crack" Technique: Technical Description and 12-Month Results. J Endovasc Ther. 2018;25(3):334–42.
13. Giusca S, Hagstotz S, Lichtenberg M, Heinrich U, Eisenbach C, Andrassy M, et al. Phoenix atherectomy for patients with peripheral artery disease. EuroIntervention. 2022;18(5):e432–e42.
14. Gehani AA, Rees MR. Can rotational atherectomy cause thermal tissue damage? A study of the potential heating and thermal tissue effects of a rotational atherectomy device. Cardiovasc Intervent Radiol. 1998;21(6):481–6.
15. Tessarek J, Kolvenbach R. Safety and effectiveness of bycross rotational atherectomy and aspiration device: a prospective, multi-center pre-market approval study. CVIR Endovasc. 2023;6(1):19.
16. Frank U, Nikol S, Belch J, Boc V, Brodmann M, Carpentier PH, et al. ESVM Guideline on peripheral arterial disease. Vasa. 2019;48(Suppl 102):1–79.
17. Rocha-Singh KJ, Zeller T, Jaff MR. Peripheral arterial calcification: prevalence, mechanism, detection, and clinical implications. Catheter Cardiovasc Interv. 2014;83(6):E212–20.
18. Korosoglou G, Blessing E, Grozinger G, Teichgraber U, Schmidt A, Zeller T. Endovascular therapy or surgery for chronic limb threatening ischemia? Vasa 2023;52(4):214–7.
19. BostonScientific: IFU, Instructions for use, Rotablator Atherectomy System. 2024. https://www.bostonscientific.com/content/dam/bostonscientific/Interventional%20Cardiology/portfolio-group/Plaque-Modification/Rotablator-System-Reference-Guide_IC-193906-AA.pdf viewed on 09.09.2024
20. https://www.bostonscientific.com/content/dam/bostonscientific/Interventional%20Cardiology/portfolio-group/Plaque-Modification/Rotablator-System-Reference-Guide_IC-193906-AA.pdf
21. Philips.Instructions for use, Phoenix™ Atherectomy System https://wwwusaphilipscom/c-dam/b2bhc/master/peripheral-resource-portal/atherectomy-product-procedural-education/phoenix-in-service-guidepdf.viewed on 02.10.2022.
22. BD.IFU Insctructions for Use, Rotarex™ Rotational Excisional Atherectomy System. https://wwwbdcom/content/dam/bd-com-assets/en/en-us/documents/products/brochures/surgical/BDPI_Rotarex_PF10791_BD-16836_Brochurepdf. 16.09.2022;viewed on 17.09.2022.
23. BostonScientific.IFU, Instructions for use, JETSTREAM Atherectomy System. https://wwwbostonscientificcom/en-US/products/atherectomy-systems/jetstream-atherectomy-system/jetstream-systems-safety-informationhtml.viewed on 17.09.2022.
24. Su Z, Li Y, Yang S, Guo J, Guo L, Gu Y. Excimer laser atherectomy combined with drug-coated balloon angioplasty for the treatment of femoropopliteal arteriosclerosis obliterans. Ann R Coll Surg Engl. 2022;104(9):667–72.
25. Ho PC. Rotational atherectomy in coronary dissection. J Invasive Cardiol. 2010;22(10):E204–7.
26. Capretti G, Carlino M, Colombo A, Azzalini L. Rotational atherectomy in the subadventitial space to allow safe and successful chronic total occlusion recanalization: Pushing the limit further. Catheter Cardiovasc Interv. 2018;91(1):47–52.
27. Maehara A, Mintz GS, Shimshak TM, Ricotta JJ 2nd, Ramaiah V, Foster MT 3rd, et al. Intravascular ultrasound evaluation of JETSTREAM atherectomy removal of superficial calcium in peripheral arteries. EuroIntervention. 2015;11(1):96–103.
28. Hu G, Qi X, Li B, Ge T, Li X, Liu Z, et al. A Single-Center Study Using IVUS to Guide Rotational Atherectomy for Chronic Renal Disease's Calcified Coronary Artery. J Multidiscip Healthc. 2023;16:1085–93.
29. Giusca S, Lichtenberg M, Schueler M, Heinrich U, Eisenbach C, Andrassy M, et al. Publisher Correction to: Safety, effectiveness and mid-term follow-up in 136 consecutive patients with moderate to severely calcified lesions undergoing phoenix atherectomy. Heart Vessels. 2022;37(4):711.
30. Kronlage M, Erbel C, Lichtenberg M, Heinrich U, Katus HA, Frey N, et al. Safety and effectiveness of Phoenix atherectomy for endovascular treatment in calcified common femoral artery lesions. Vasa. 2021;50(5):378–86.
31. Shammas NW. JETSTREAM Atherectomy: A Review of Technique, Tips, and Tricks in Treating the Femoropopliteal Lesions. Int J Angiol. 2015;24(2):81–6.

Conflicts of interests

The author declares a potential conflict of interest.
Dominik Liebetrau is a consultant for Medtronic GmbH, Earl-Bakken-Platz 1 40670 Meerbusch, Germany.
Dominik Liebetrau declares to have received speaker honorary fees from plus medica GmbH & Co, Willstätterstraße 13, 40549 Düsseldorf for professional presentations.
Jörg Teßarek declares to have received speaker honorary fees from plus medica GmbH & Co, Willstätterstraße 13, 40549 Düsseldorf for professional presentations.
All other authors have declared no potential conflicts of interest with respect to this research, authorship, and/or publication of this article.

Publication ethics

The Ludwig-Maximilians-University Munich (LMU) ethics committee peer-reviewed the project (Projekt Nr: 22-0047).
Informed consent was obtained from all individual participants included in this study.

ORCID

Dominik Liebetrau
https://orcid.org/0000-0003-1050-6470
Jörg Tessarek
https://orcid.org/0000-0001-6827-8584
Christian Scheurig-Münkler
https://orcid.org/0000-0003-0702-7460
Alexander Hyhlik-Duerr
https://orcid.org/0000-0002-4217-7758

Correspondence address

Dr. med. Dominik Liebetrau
Vascular Surgery, Medical faculty
University of Augsburg
Stenglinstrasse 2
86156 Augsburg
Germany

dominik.liebetrau@uk-augsburg.de