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# Metallic-Tip-Facilitated Recanalization Angioplasty-An Innovative, Easily Applicable, Effective and Safe Therapeutic Option for Balloon-Uncrossable Lesions

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## Abstract

**Background:** Despite advances in guide wire and catheter technology, the impossibility to insert a balloon for angioplasty after successful wire passage of the lesion is still an unsolved challenge in some percutaneous peripheral interventions. The purpose of this study was to investigate the feasibility, safety and efficacy of a metallic tip recanalization catheter in modifying the occluding atheroma to facilitate subsequent balloon placement.

**Patients and Methods:** Between 10/2010 and 06/2013, twenty-two patients with peripheral artery disease (PAD) and balloon-uncrossable lesions (24 separate lesions, 21 femoro-popliteal (87.5%), 2 below-the-knee (8.3%), 1 common iliac (4.3%), 13 total occlusions (54.2%), were enrolled into the study. The primary study endpoint was the rate of successful passage of the metallic tip support catheter (XableCath, XableCath Inc., Salt Lake City, Utah) and subsequent angioplasty without causing distal embolization as assessed by reduction of TIMI-flow grade.Secondary endpoints were the abscence of major adverse events (MAE) as defined as (1) vessel perforation, (2) dissections, (3) occurrence of a detectable embolism or vessel closure, (4) groin site complica-tions or (5) cardiovascular death during the follow-up period.
Results Primary success was achieved in 23 lesions (95.8 %), reaching 100% after a secondary Xable Cath attempt. By Quantitative Coronary Angiography (QCA) the Minimal Lumen Diameter (MLD) increased from 0.2 ± 0.1 mm (0,0-0.5) to 2.4 ± 1.0 mm (0.1-4.2) after Xable Cath passage ($p<0.001$), and to 4.1 ± 1.8 mm (0.1-7.4mm) after adjunctive angioplasty ($p<0.001$ vs. baseline). TIMI flow across the lesion increased from 0.7 ± 0.3 to 2.9 ± 0.7 after Xable Cath-modifying angioplasty ($p<0.001$). No vessel-perforations or ma-jor dissections nor distal embolizations of debris were documented. No procedure-related MAE's occurred during 6-months follow-up.

**Conclusion:** The metallic-tip XableCath support catheter is feasible, safe, easy to use and highly effective in modifying balloon-uncrossable PAD-lesions in order to make subsequent angioplasty possible without creating vessel perforations or major dissections nor detectable distal embolizations or no-reflow phenomena.

**Keywords:** Uncrossable stenosis; Recanalization; Metallic tip catheter; Xable Cath; Balloon-uncrossable failures.

## Text

There is growing interest in percutaneous peripheral intervention for complex peripheral lesion including Chronic Total Occlusions (CTOs), particularly in patients with critical limb ischemia.

Important technical and device advances including newer generation and novel guidewires, retrograde techniques, novel catheters, and lower profile balloons have positively impacted the uncrossable lesion but remain an unsolved challenge. Importantly, once the lesion has been successfully crossed with a wire, a key reason for procedural failure is the inability to deliver a balloon, microcatheter and/or stent to the target lesion. Interventionalists often colloquially refer to this situation as "the wire has crossed but nothing will go." Balloon failure-to-cross after successful guidewire crossing is the second most common cause for CTO failure in percutanous coronary interventions, occurring in up to 7% of cases [1].

Several options are available in this scenario of a balloon uncrossable complex lesion. Standard initial maneuvers are upsizing support, buddy wire, anchoring or subintimal techniques [2,3] respectively combinations of the aforementioned techniques and the "grenadoplasty", which consists of advancing small balloons into the proximal cap of the CTO and attempting to "rupture" them in order to modify plaque morphology [4]. In addition atherectomy-techniques can be considered (directional- or rotational atherectomy, or the Silver-Hawk™ Plaque Excision System (Medtronic, Minneapolis, MN, USA) but they include the possibility of vessel perforations, i.e. in non-subintimal recanalizations. Rotational atherectomy (Rotablator™, Boston Scientific Inc. Maple Grove, MN) can be very effective (i.e. calcified lesions) but technically and time demanding and is frequently not applicable due to non-successful wire passage in cases where only a hydrophilic-coated polymer guidewire permit passage of the complex atherosclerotic lesion [1]. Alternatively, the Tornus penetration catheter (Tornus™, Asahi-Intecc, Aichi, Japan) could be used in balloon-uncrossable lesions to create a channel, thus allowing balloon passage like Excimer Laser Coronary Angioplasty (ELCA) represent an interesting alternative to create a pilot hole [5,6]. Limitations and hazards of ELCA include the risk for dissections and perforations, which is especially relevant in subintimal dissection techniques. But laser techniques are complicated, need adequate training and are time- and money consuming [7].

The new metallic-tip support catheter (Xable Cath, Xable Cath Inc., Salt Lake City, Utah) has especially been designed as a support catheter for balloon-uncrossable lesions in order to modify the occluding atheroma with two versions of metallic tip to make subsequent balloon placement possible (Figure 1a and Figure 1b).

The purpose of this Xable Cath study is to report the feasibility, safety and efficacy of Xable Cath facilitated plaque modification in balloon-uncrossable lesions.

Figure 1a XableCath (blunt-type)

Figure 1b XableCath (abrasive-type)

## Patients and Methods

## Study Population

Patients with balloon-uncrossable lesions were eligible for enrollment. Patients with childbearing potential and with known contraindications to aspirin, heparin, or clopidogrel were excluded from the study.

Enrollment for the XableCath study took place between October of 2010 and June of 2013. All patients gave written informed consent, and the study was conducted according to the principles of the Declaration of Helsinki.

## Data Collection

Information concerning patients' demographics, clinical presentation, angiographic findings, procedural success, Xable Cath plaque-modifying procedure, adjunctive therapy, acute results, procedural complications, hospital course, and complications were recorded by the investigators and maintained in a central cohort database. Angiograms were initially evaluated by the investigators, using visual assessment at baseline, and immediately after Percutaneous Transluminal Angioplasty (PTA). The morphology of the target lesion, presence of calcium, lesion length, Minimum Lumen Diameter (MLD), and flow across the lesion were documented. Adverse events were registered at 4 weeks and 6 months, including death, cerebrovascular accident, amputation and myocardial infarction as abrupt or late target vessel closure, perforation, minor or major dissections, distal embolization, or no-reflow phenomena as encountered during the procedure and hospitalization.

## Study Endpoints and Definitions

The primary study endpoint was the rate of successful passage of the Xable Cath support catheter and subsequent balloon angioplasty and/or stent-implantation/Drug-Coated Balloon Application (DCB) without causing distal embolization as assessed by reduction of TIMI-flow grade. Procedural success was defined as: complete crossing of the entire lesion by the XableCath support catheter and successful placement of the angioplasty balloon in the target lesion and reestablishment of a normal flow (TIMI Grade 3) upon completion of the Xable Cath procedure. Procedural failure was defined as the inability to pass the lesion with the blunt or abrasive-type Xable Cath and/or inability to make balloon placement possible and/or reduction of blood flow across the target lesion.

Flow was graded as Grade 0 (= no flow), Grade 1 (= significantly impaired flow), Grade 2 (= slightly impaired flow), Grade 3 (= unimpaired flow) analogous to the TIMI Grade scale in coronary arteries (Thrombolysis in Myocardial Infarction) [8].

The secondary endpoint was the absence of Major Adverse Events (MAE) defined as (1) vessel perforation, (2) dissections, which were considered to be major if there were flow-limiting or associated with limb ischemia, or the need for vascular surgery and minor if it did not lead to clinical complication, (3) occurrence of a detectable embolism or vessel closure, (4) groin site complications or (5) cardiovascular death during the follow-up period.

Vessel perforation was defined as persistent extravascular collection of contrast medium beyond the vessel wall with or without associated clinical complications. Vessel dissections were defined according to the classification of Huber et al. [9].

Vessel closure was defined as reduced antegrade flow (TIMI < l) caused by acute occlusion of the target lesion. Groin site complications included need for blood transfusion or surgical intervention.

Percutaneous Xable Cath facilitated lesion modifying procedure. Written informed consent for the XableCath support catheter application was obtained. Access to the target lesion depended on the location of the lesion (cross-over, antegrade). After achieving arterial access, standard or hydrophilic recanalization guide wires (Terumo 0.035" (Terumo Medical, Somerset, NJ), connect 250T 0.018" (Abbott Vascular, Santa Clara, CA), Confianza 0.014" (Abbott Vascular, Santa Clara, CA) or ChoicePT 0.014" extra support (Boston Scientific/Scimed, Inc., Maple Grove, MN) were used for recanalization intraluminarily or subintimally in the complex lesion. Patients were eligible for applying the XableCath support catheter, if successful balloon placement failed. All patients received standard angioplasty anticoagulation including aspirin (250 mg/IV), clopidogrel (600 mg PO) and heparin (5000 IU).

In all procedures, a blunt-type XableCath was first used and inserted over-the-wire. After reaching the lesion, the XableCath support catheter was advanced through lesion through gently rotating (tracking and twisting) the entire body of the device, while the guide was fixed/anchored with the other hand.

In cases where the blunt-tip did not cross the lesion immediately (Figure 1a), the abrasive-type Xable Cath was used (Figure 1b).

Following Xable Cath passage of the entire lesion, adjunctive balloon angioplasty, drug coated balloon angioplasty and, if necessary, stent implantation (i.e., nitinolstents) was performed. Figure 2a,2b,2c,2d shows an example of a typical Xable Cath procedure.

## Angiographic analysis

We obtained angiograms in routine manner. Vessels and lesions were analyzed with a computerized quantitative analysis system (Siemens Axiom), according to established and validated edgedetection algorithms, with use of the catheter for calibration [10,11]. We obtained measurements of the interpolated reference diameter, stenosis parameters, MLD and lesion length from the angiograms, after Xable Cath passage and after adjunctive angioplasty of the target lesion.

## Statistical Analysis

Statistical analysis was performed at the Department of Biometrics, EMA University Greifswald, Germany. Categorical factors are described using percentages and frequency of characteristics or event. Continuous measures are described using means with standard deviations. The associations between the dichotomous outcomes and baseline factors were evaluated using logistic regression modeling techniques. The baseline factors considered were age, gender, diabetes, hypertension, Left Ventricular Function (LVEF), lesion morphology, calcifications, MLD and lesion length. A p-value of $<0.05$ was considered significant. Statistical analysis was performed using a standard statistical package.

Figure 2 (a-d) XableCath modifying lesion angioplasty of a balloon-uncrossable tibial artery in a 72y old male, PAD Rutherford 5/6

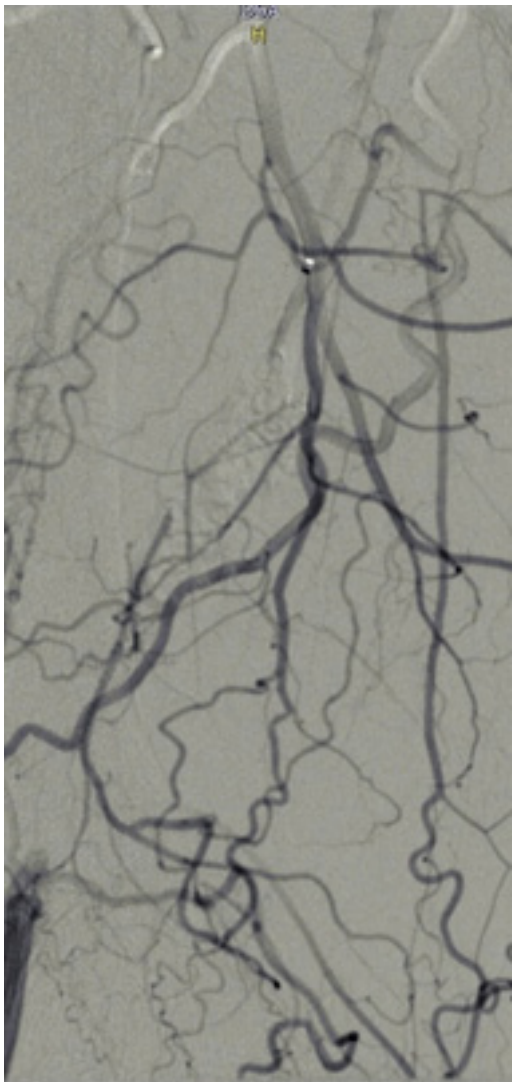

Figure.2a Calcified balloon-uncrossable lesion

Figure.2b XableCath 0.018”

## Results

## Clinical Characteristics

Xable Cath facilitated plaque modification was performed in 24 separate lesion in 22 patients with a mean age of 75 ± 17 years (range 54-93 years, 50.0% females). The baseline characteristics of patients and morphologic data of treated balloon-uncrossable lesions are shown in Table l. The baseline morphologic characteristics of the target vessels are expressed in Table 2.

## Procedural Results

Table 3 depicts related procedural information. Primary Xable Cath success was achieved in 23 patients (95.8 %). Secondary XableCath success was obtained in all patients after the primary crossing failure (cross-over access) was successfully crossed secondarily during a second Xable Cath 0.018” attempt in antegrade technique. Adjunctive balloon angioplasty was carried out in all lesions.

By QCA theMLD increased from 0.2 ± 0.1 mm (0.0-0.5) to 2.4 ±1.0 mm (0.1-4.2mm) after Xable Cath passage ($p<0.001$), and to 4.1±1.8 mm (0.1-7.4) ($p<0.001$ vs. baseline after adjunctive angioplasty (Table 3).

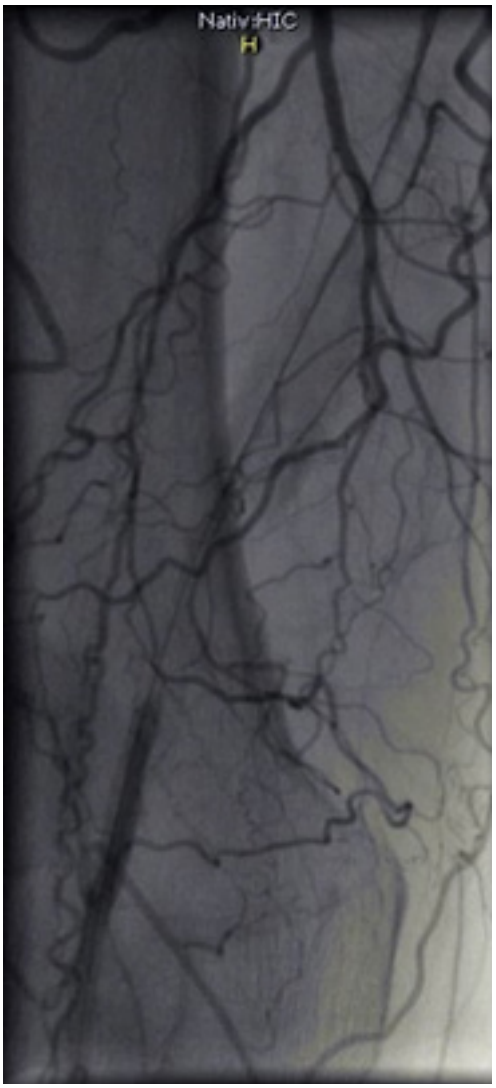


Figure.2c After XableCath recanalization

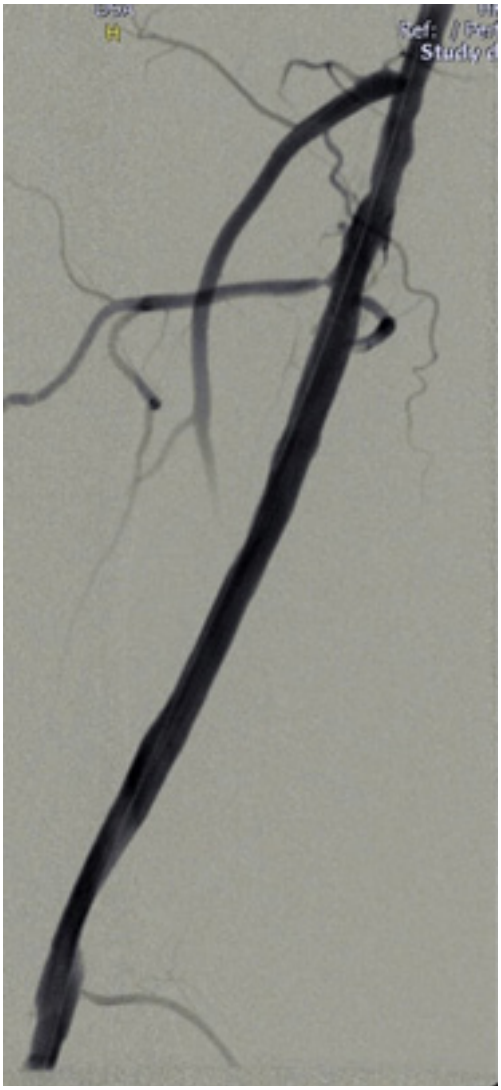

Figure.2d After DES-balloon angioplasty

The TIMI flow across the lesion increased from 0.7 ± 0.3 to 2.9 ± 0.7after Xable Cath-modifying angioplasty ($p<0.001$) (see Table 3). Table 4 delineates the procedure-related complications. No vessel-perforations or major dissections nor distal embolizations of debris could have been documented (Table 4).

Follow-up at 4 weeks and 6 months was obtained in all patients. No procedure-related Major Adverse Events (MAE) occurred in any patient.

## Discussion

In percutaneous peripheral intervention of complex peripheral lesion (including chronic total occlusions), the impossibility to insert a balloon for angioplasty after successful wire passage of the lesion, is a well-known challenge despite several important technical and device advances.

The main reason for the inability to let a balloon pass into the atheromateous lesion is prolapsing atheroma edges, which cannot be passed by the relatively soft plastic balloon tip. A metallic tip, which includes more tangential power to overcome the atheroma forces, or which can abrade the prolapsing atheroma edges, represents the basic idea of the Xable Cath support catheter with its metallic tip. In contrast to currently available interventional options, the Xable Cath support catheter is a support catheter which is easy to use (8.3 minutes procedure-time per balloon-uncrossable lesion) in order to modify the obstructing atheroma edges at the proximal cap of the lesion without cutting too deep into the vessel structures including potential disadvantages (i.e. perforations), which is frequently the case after using the competing atherectomy devices i.e. in subintimal recanalization.

| Table 1: Baseline characteristics and lesion data | | |
|---|---|---|
| Variables | n = 22 (24 lesions) | |
| Female | 11 | (50.0%) |
| Age (years) | 75.3 ± 16.7 | (54–93) |
| Diabetes Mellitus | 16 | (72.7%) |
| Hyperlipidemia | 17 | (77.3%) |
| Hypertension | 18 | (81.8%) |
| Glomerular filtration rate (GFR) ml | 51.0 ± 26.4 | (32–80) |
| Left ventricular ejection fraction (LVEF) | 51.3 ± 15.6 | (40–65) |
| PAD (Rutherford 3/4) | 14 | (63.6%) |
| (Rutherford 5/6) | 8 | (36.4%) |
| Lesion characteristics | | |
| Femoro-popliteal | 21 | (87.5%) |
| Common iliac | 1 | ( 4.3%) |
| Below the knee | 2 | ( 8.3%) |
| Lesion length (mm) | 56 ± 38 (12-250) | |
| calcification | 20 | (83.3%) |
| total occlusions | 13 | (54.2%) |
| balloon-access-failures | 24 | (100%) |

| Table 2: XableCath Procedure Data | | |
|---|---|---|
| Number of lesions | 24 | |
| XableCath application-technique | | |
| subintimal | 1 | |
| intraluminal | 23 | |
| XableCath catheter | | |
| 0.035” | 16 | |
| 0.018” | 8 | |
| Blunt-type | 24 | |
| Abrasive-type | 4 | |
| XableCath passes | 1.8 ± 0.8 | (1– 3) |
| XableCath procedure time (min) | 8.2 ± 4.1 | (3–14) |
| Adjunctive PTA | 23 | (95.8%) |

| Table 3: Results | | |
|---|---|---|
| Number lesions treated | 24 | |
| Primary Procedure success | 23 | (95.8%) |
| Secondary Procedure success | 24 | (100%) |
| Minimum lumen diameter (mm) | | |
| At baseline | 0.2 ± 0.1 | |
| After XableCath | 2.4± 1.0 | |
| After adjunctive POBA/Stent | 4.1 ± 1.8 | |
| Antegrade vessel flow (TIMI grade) | | |
| At baseline | 0.7 ± 0.3 | |
| After XableCath +adj. POBA | 2.9 ± 0.7 | |

| Table 4: Procedure-related Complications | | |
|---|---|---|
| Number occlusions treated | 24 | |
| Perforations | 0 | ( 0%) |
| Dissections | 4 | (16.7%) |
| Major (NHLBI type C or greater) | 0 | ( 0%) |
| Minor (NHLBI type A or B) | 4 | (16.7%) |
| Acute shunt re-closure | 0 | ( 0%) |
| Peripheral embolization | 0 | ( 0%) |
| Major access complications | 0 | ( 0%) |

Using the metallic tip Xable Cath support catheter vessel perforations or major dissections did not occur in any patient, while procedure primary success was 95.8% and secondary success rate was 100%. Moreover and representing theoretically as a potential risk of the XableCath (embolization of atheroma-debris due to its abrasive abilities), no reduction of vessel flow, detectable thromboembolizations or no-reflow phenomena was documented.

XableCath support catheter use and treatment is capable of modifying effectively the balloon-uncrossable lesion in order to make angioplasty possible. 23 balloon-uncrossable lesions could were crossed primarily, in one patient a second attempt had to be carried out without causing procedural related complications.

The choice of Xable Cath support catheter depends mainly on vessel size and the access route including the extent of force on the metallic tip (e.g. 0.035" Xable Cath in cross-over cases, 0.018" in antegrade and/or popliteal or below-the-knee cases).

In summary, we have demonstrated that Xable Cath-facilitated angioplasty represents a safe, effective, easily applicable and cost-effective new therapeutic option to make treatment of balloon-uncrossable lesion treatable. The encouraging data of these first patients awaits confirmation by subsequent multicenter registries or controlled prospective studies.

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