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Case Report

An Endovascular Strategy for Occlusion or Stenosis with Severe Calcification in the Non-Stenting Zone, creatinG Lumens And SlitS with Crosser in Unique Technique (GLASS CUT): A Case Report

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In treating non-stenting zones (NSZs), such as the common femoral artery (CFA) and popliteal artery (PA), the best method to treat severely calcified NSZ lesions remains controversial. Here we describe a new method for the treatment of severely calcified PA and CFA lesions using the Crosser® system (CS). After the first wire passed the lesion, the CS was passed through the other wire to create new cracks and lumens (NCAL) in both cases. After creating NCAL around the lumen of the first wire, a large scoring balloon was inflated to crush the severe calcification like a "GLASS CUT" with a glass knife.

Keywords: Crosser, non-stenting zone, common femoral artery

Introduction

The optimal endovascular or surgical therapy for non-stenting zones (NSZs), such as the common femoral artery (CFA) and popliteal artery (PA), is still unclear. For a cardiologist, opting for endovascular therapy entails the avoidance of stent deployment in NSZs owing to the flexibility of the hip or knee joint.[1,2] Moreover, puncture of the stented CFA or PA may result in complications due to stent malposition and fracture. In endovascular therapy, NSZ lesions are treated by percutaneous transluminal angioplasty (PTA) with a normal or scoring balloon and atherectomy devices. However, severe calcifications can make it difficult to cross the lumen using even mechanical crossing devices.[3] Simple ballooning, scoring, or atherectomy of the calcification, using only one wire, occasionally leads to a little improvement in blood flow at NSZs with severe calcification. Here we describe an original technique for the treatment of a severely calcified NSZ lesion using the Crosser® system (CS).

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Case Reports

Case 1

A 67-year-old woman was admitted to our hospital in August 2016 for the treatment of ischemic gangrene of the right foot, with a Rutherford classification of R5. She had a history of end-stage kidney disease, hyperlipidemia, and hypertension. The ankle–brachial index (ABI) of her right foot was 0, and echocardiography of the right lower extremity revealed a high peak systolic velocity ratio (PSVR) of 20.9 at the right PA. Her right foot was treated using a 6-Fr sheath (Radifocus introducer, Terumo Medical Corporation, Tokyo, Japan). Pre-procedural angiography revealed subtotal occlusion with hard calcification in the PA (**Fig. 1**). After the lesion was crossed with a 0.014-inch guidewire (Agosal XS, St. Jude Medical, Tokyo, Japan), a

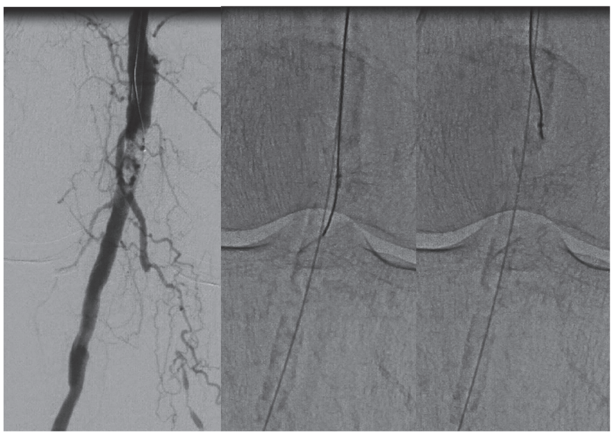

Fig. 1 (Left image) Pre-procedure angiography in Case 1. (Middle image) Direction 1. Crosser system (CS) over the second wire. (Right image) Direction 2. CS over the second wire.

second 0.014-inch guidewire (Treasure XS, St. Jude Medical) was placed in the CS (CROSSER, Medicon, Osaka, Japan) in an attempt to cross another lumen or create a crack (**Fig. 1**). When the second 0.014-inch guidewire (Treasure XS) had penetrated the calcification, the CS was used. The working time of CS was within 30 s. After repeatedly crossing a few lumens and creating cracks, a 5-mm balloon (Scoreflex PTA 5.0/40, Orbusneich Medical, Tokyo, Japan) was passed through the first 0.014-inch guidewire (Agosal XS), and it was inflated up to 10 atm for 60 s. After deflating the 5-mm balloon, the PA was checked via angiography and intravascular ultrasonography (IVUS)/catheterization (Eagle-Eye Platinum, Volcano, Tokyo, Japan), which revealed no major dissection or bleeding in the PA (**Fig. 2**) with an improved blood flow and pulsation. The ABI had also improved to 0.92.

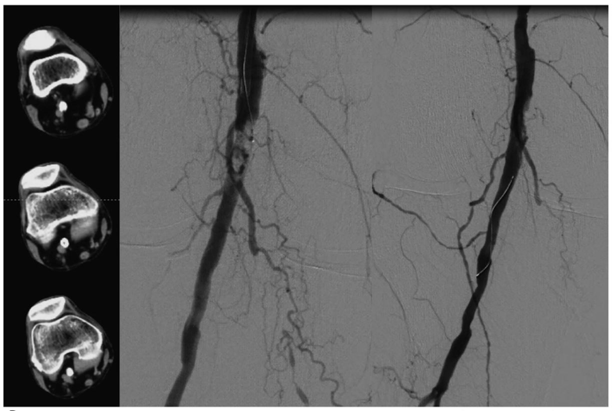

Fig. 2 (Left image) Pre-procedure computed tomography (CT) of the right popliteal artery for Case 1. (Middle image) Pre-procedure angiography for Case 1. (Right image) Final angiography for Case 1.

Case 2

A 73-year-old man was admitted to our hospital in October 2016 for the treatment of ischemic gangrene of the right foot with a Rutherford classification of R5. He had a history of end-stage kidney disease, coronary artery bypass grafting, type 2 diabetes, hyperlipidemia, and hypertension. ABI of the right foot was 0, and echocardiography of the right lower extremity revealed a high PSVR of 16 in the right CFA. The right foot was treated using a 6-Fr sheath (Destination 45 cm, Terumo Medical Corporation) via an ipsilateral approach. Pre-procedural angiography revealed subtotal occlusion with hard calcification in the CFA (**Fig. 3**). After the lesion was crossed with Agosal XS (St. Jude Medical) (**Fig. 3**), Treasure XS (St. Jude Medical) and CS (CROSSER, Medicon) were used in an attempt to cross the lumen or create a crack (**Fig. 3**). The direction of Treasure XS was repeatedly changed to create another lumen or crack with the CS. After employing the CS, as in Case 1, a 3.5-mm balloon (NSE PTA 3.5/20, Goodman, Nagoya, Japan) was advanced through the Agosal XS and inflated up to 10 atm for 60 s. Next, the 3.5-mm balloon was advanced through the Treasure XS and inflated up to 10 atm for 60 s. After deflating the 3.5-mm balloon, a 7-mm balloon (Sterling Monorail 7.0/20, Boston Scientific Japan, Tokyo, Japan) was advanced through the Agosal XS and inflated up to 14 atm for 120 s. CFA was evaluated via angiography and IVUS/catheterization, which revealed no major dissection or bleeding in the CFA (**Fig. 3**), with a significant improvement in blood flow and pulsation. The ABI had also improved to 1.07.

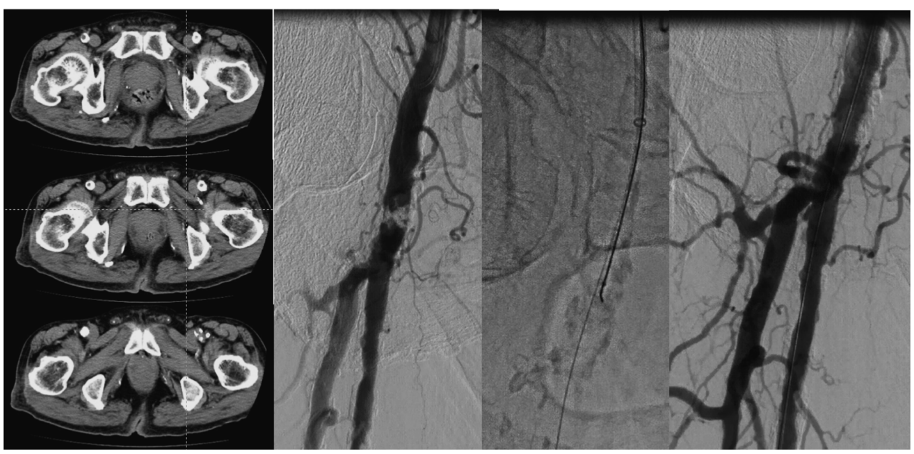

Fig. 3 (**A**) Pre-procedure computed tomography (CT) of the common femoral artery for Case 2. (**B**) Pre-procedure angiography for Case 2. (**C**) Crosser system over the second wire. (**D**) Final angiography for Case 2.

Discussion

Here, we described two cases in which we treated NSZs such as CFA and PA with an original technique using the CS. This technique was used to treat 18 cases (CFA, 7 cases; PA, 11) from April 2016 to March 2017. There was no procedure-related bleeding, hematoma, or death. Procedures for treating severe stenosis or occlusions in severely calcified NSZs include PTA, atherectomy; PTA; and provisional stenting for failed atherectomy, with or without PTA. However, both PTA and stent implantation in the CFA can result in recurring restenosis. A previous study reported that 12% of lesions resulted in restenosis with a median follow-up of 11 months.[1] However, a study by de Blic et al.[1] included only one patient with a severely calcified lesion in CFA. Thus, it is expected that PTA, or stent implantation, for a severely calcified lesion in CFA will result in a worsened patency.

A previous study reported an 88.8% primary patency rate of CFA at 16 months after endarterectomy,[4] whereas another study reported that atherectomy was not superior to angioplasty for blockage of the PA at approximately 12 months.[2] However, few reports have focused on severely calcified lesions in NSZs such as CFA and PA. Thus, it is unclear whether endarterectomy results in acceptable outcomes for severely calcified occlusive lesions of the CFA or PA.

In Japan, devices for endarterectomy, such as the Silver Hawk (Foxhollow Technologies, Inc., Redwood City, CA, USA), Turbo Hawk (Medtronic-Covidien, Dublin, Ireland), Jetstream PV (Boston Scientific, Marlborough, MA, USA), and Rotablator system (Boston Scientific), are unavailable. Consequently, peripheral artery lesions with severe calcification are treated with the CS at our institution. CS, a chronic total occlusion crossing device, is a unique system that was designed to achieve intraluminal penetration across long occlusions.[5] The CS creates high-frequency vibrations propagated by a stainless steel tip that facilitates the penetration of hard or calcified lesions. The PATRIOT study, in which the proportion of severely or moderately calcified lesions was 75%, showed a high probability of recanalization for guidewire-resistant chronic total occlusions (CTO) with the CS.[6] Crossing using the CS creates a 1.1-mm lumen in the severely calcified lesion. PTA of the lumen with a scoring or high-pressure balloon alone is inadequate to create a sufficient lumen in the calcified lesion. Therefore, another 0.014-inch wire, with a tip weight of 10 g or greater, is bent at an angle of 45° at 5 mm from the tip. The CS is then used via a second 0.014-inch wire to make some slits around the lumen of the first wire.

However, this technique for severely calcified lesions has some disadvantages and problems. First, the CS occasionally gets stuck in the severely calcified lesion because its tip may break. Consequently, the tip must be used gently and gradually advanced. Moreover, the CS is used for a maximum of 30 s at a time, as described above. Second, it is possible for the CS to penetrate the vascular wall. Thus, when advancing it, the distance between the tip and the target vessel wall in the 45° right and left anterior oblique views should be checked.

Third, this technique needs at least penetration of one 0.014-inch wire for use of a scoring balloon. Complete penetration is not always needed for the 2nd 0.014-inch guidewire because the minimum purpose of the 2nd wire with the CS is creating several cracks around the 1st wire that has passed lumen.

A scoring balloon is usually employed for PTA after making some slits around the lumen of the first wire. Because scoring balloons, such as NSE and Scoreflex, can produce a cleaner crack than that produced by compliant or non-compliant balloons, the diameter of the scoring balloon should be based on the vessel diameter, as assessed by pre-procedural ultrasonography. The availability of the scoring balloon to improve acute luminal gain in the calcified lesions has been reported.[7] However, the contribution of a simple scoring balloon to the patency rate for lesions in the NSZs with a high calcification burden still remains controversial. Schillinger et al. showed that treatment with a scoring balloon achieved a higher primary patency rate than that with a conventional balloon for superficial and popliteal arteries.[8] On the contrary, Canaud et al. reported the 1-year primary patency rate to be 64.4%.[9] Soga et al. showed that the scoring balloon effect was significantly higher than that of a conventional balloon in lesions with a calcification circumference severity of ≥360° and ≥180°. However, in lesions with a vessel diameter of >6.0 mm, as in the CFA, the scoring effect of NSE was not significantly superior to that of a conventional balloon.[7] In lesions with circumferential (360°) calcifications, as in the two cases reported here, treatment with only scoring balloon inflation can lead to minor improvement of the vessel lumen. Although a scoring balloon can achieve little improvement in blood flow, it may almost result in early recoil or restenosis.

If a severely calcified lesion is scored with a scoring balloon after making slits by "GLASS CUT" with a glass knife around the lumen of the first wire, the severe calcification could be crushed like breaking glass. To the best of our knowledge, this technique has not been previously reported.

Conclusion

Here, we report a new technique with the CS for highly calcified lesions in NSZs that does not employ PTA, atherectomy, or provisional stenting for failed atherectomy, either with or without PTA. This new technique has the potential to become a major modality for the treatment of severely calcified lesions in NSZs.

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Author Contributions

Study conception: TM
Writing of the initial draft of the manuscript: TM
Assistance in the preparation of the manuscript: AM
Data collection and interpretation and critical review: all authors
Final approval of the article: all authors

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