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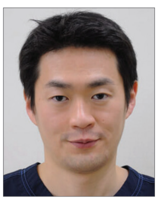
In vitro evaluation of the appropriate guidewire for performing the reversed guidewire technique to treat severely angulated bifurcated lesions



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KEYWORDS

- bifurcated lesion
- percutaneous coronary intervention
- PTCA guidewire
- reversed guidewire technique

Abstract

Aims: The aim of this study was to determine which guidewire is best for crossing through severely angulated bifurcation lesions.

Methods and results: Bench test 1 determined which wire could access the orifice of the side branch. A composite coil wire (SION blue), a polymer-coated wire (Fielder FC), a polymer-coated tapered wire (Fielder XT-R), and a polymer-coated composite core wire (SION black) were evaluated. We manipulated all the guidewires with 90° and 45° angles at 3 cm and 1 mm, respectively, from the guidewire tip. The tip of the SION blue and Fielder XT-R wires detached from the main branch and did not turn to the orifice of the side branch. The Fielder FC and SION black wires reached the ostium along the main branch. Bench test 2 measured the wires' crossability with pull force using a double lumen catheter. The Fielder FC and SION black were chosen based on the bench test 1 results. The pullback force was significantly smaller for the SION black than for the Fielder FC (8.14±0.90 cN vs. 12.00±1.29 cN, p=0.0016). The SION black's shape changed, whereas the composite core wire retained its original shape.

Conclusions: When treating severely angulated bifurcated lesions, a polymer-coated composite core guidewire is optimal.

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Introduction

Bifurcated lesions account for 15-20% of percutaneous coronary intervention (PCI) cases[1]. The complexity and wide anatomical spectrum of bifurcated lesions compared to non-bifurcated lesions make treatment difficult and uncertain[2]. In cases of bifurcated lesions, the risk of side branch (SB) occlusion should be considered[3]. The standard treatment of bifurcated lesions is provisional stenting[4], which involves implanting one stent in the main branch (MB) and then stenting the SB if dissection or flow disturbance occurs in the SB[5]. To prevent complications in the SB, guidewire placement in the MB and SB is required. The placement of a guidewire in the SB when a stent is implanted in the MB is the jailed guidewire technique, which has been shown to improve the outcome of bifurcated lesions[6]. However, the complexities of bifurcated coronary anatomy such as the SB take-off angle and different patterns of atherosclerotic lesion distribution make SB wiring challenging[7]. However, when initial wiring of the SB is impossible, plaque modification with a balloon or rotablation may facilitate wire passage[8]. To overcome complex SB wiring, new techniques and guidewires have been developed[8,9]. However, in the case of bifurcation with severe angulation of the SB, wiring is especially challenging.

The reversed guidewire technique was first described by Kawasaki et al in 2008 to cross through severely angulated SBs, and it is now performed with some modifications[10,11]. Although the technique has evolved, there are still some concerns. When performing the reversed guidewire technique, the use of polymer-coated guidewires is recommended. However, the reason why the coil guidewire is not recommended is unclear, so the different kinds of polymer-coated wires that can be selected should be assessed. Therefore, the present study was performed to 1) clarify the reasons why polymer-coated guidewires are recommended more than coil wires, and 2) compare the performance between different polymer-coated wires.

Methods

In vitro bench tests with coronary bifurcation models were used in this study. Bench test 1 was performed to evaluate the wire's accessibility. We selected coil or plastic polymer-coated guidewires to compare the behaviour of the tip of the guidewire and determine which guidewire is most suitable for approaching the orifice of the SB. The SION™ blue (SiBlue; Asahi Intecc, Tokyo, Japan) was used as a composite coil wire, and the Fielder™ FC (FFC; Asahi Intecc) was used as a polymer-coated plastic wire, as in previous reports[10,11]. We also selected the following new guidewires that have never been evaluated in previous reports. The Fielder™ XT-R (FXTR; Asahi Intecc) has a slender tip (0.010-inch) compared to conventional 0.014-inch guidewires, and the SION™ black (SiBlack; Asahi Intecc) has a new composite core structure compared to conventional polymer-coated wires.

We manipulated all the guidewires into the same shape: 90° angle 3 cm from the guidewire tip and 45° angle 1 mm from the guidewire tip **(Figure 1)**. We inserted the wires into an assumed coronary bifurcation model consisting of two different parts made of a transparent plastic tube: distal (diameter 2.0 mm, length 21 mm) and proximal (diameter 3.6 mm, length 29 mm) **(Figure 2)**. We recorded the behaviour of each guidewire.

Bench test 2 was performed to measure the pullback force of the guidewire when crossing through a severely angulated and stenotic lesion. We created a severely angulated MB and SB in

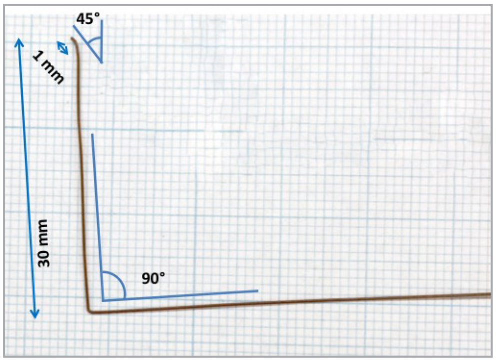

Figure 1. *Guidewire manipulation. All wires were manipulated into the same shapes: 90° angles were created 3 cm from the guidewire tip, and 45° angles were created 1 mm from the tip.*

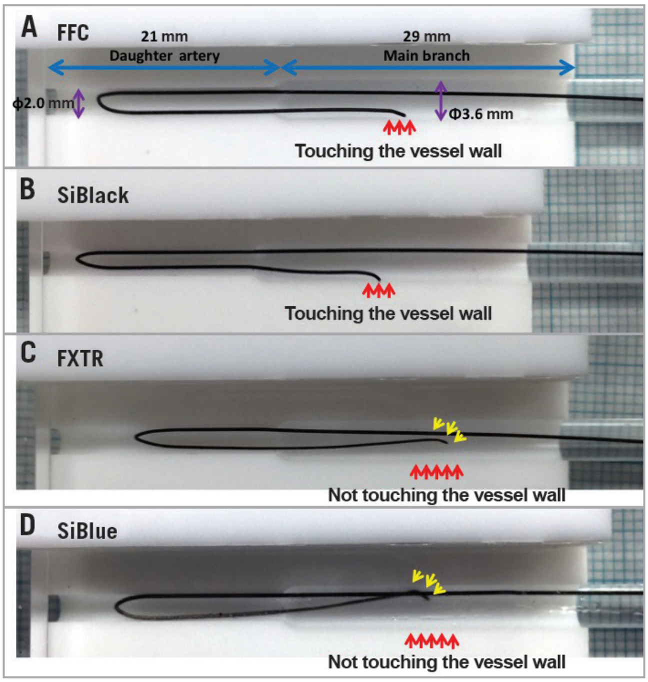

Figure 2. *Vascular bifurcation model. All wires were inserted into the same vascular bifurcation model that was made from a transparent plastic box with two parts: distal (diameter 2.0 mm, length 21 mm) and proximal (diameter 3.6 mm and length 29 mm). The tips of the Fielder FC (A) and SION black (B) faced the side branch along the trunk of the MB. Conversely, the tips of the Fielder XT-R (C) and SION blue (D) did not face the MB wall; instead, the wire tips turned inward towards the vessel wall. FFC: Fielder FC; FXTR: Fielder XT-R; MB: main branch; SiBlack: SION black; SiBlue: SION blue*

a 160° bifurcated coronary model using a plastic tube **(Figure 3A)**. The plastic tube was filled with 0.9% saline. Severe stenosis was simulated by bending the middle part of the plastic tube (i.e., the SB) **(Figure 3B)** to assess the crossability of the guidewires. A microcatheter (SASUKE®; Asahi Intecc) was used to perform the reversed guidewire technique[11] and cross the guidewire through the SB and stenotic lesion. The pull force (cN) was calculated by using a spring balance attached to the torquer of the SB wire **(Figure 4)**. The tests were repeated seven times. Then the shapes of the guidewires were assessed.

Statistical analysis

All data were analysed using the Mann-Whitney U test with SPSS, Version 21.0 statistical software (IBM Corp., Armonk, NY, USA). Data are presented as a mean±standard error of the mean. Values of $p<0.05$ were considered statistically significant.

Results

BENCH TEST 1

All wires were inserted into the same vascular bifurcation model. The tip of the FFC and SiBlack faced the SB along the trunk of the MB **(Figure 2)**. However, the tips of the FXTR and SiBlue did not touch the vessel wall of the MB; instead, the wire tips turned inward towards the vessel wall **(Figure 2)**.

BENCH TEST 2

On the basis of the results of bench test 1, we selected the FFC and SiBlack as the candidate guidewires to perform the reversed guidewire technique. The tips of these guidewires moved along the vessel wall of the MB, which was beneficial when approaching a severely angulated SB ostium. Although the FFC and SiBlack entered the SB ostium easily, the pullback force to cross through the SB ostium and stenotic lesion was significantly higher with the FFC than with the SiBlack (12.00±0.49 cN vs. 8.14±0.34 cN, p=0.0016) **(Figure 5)**. Regarding the shapes of the guidewires, the SiBlack was superior to the FFC, as it retained its original shape. The characteristics of each wire are summarised in **Table 1**.

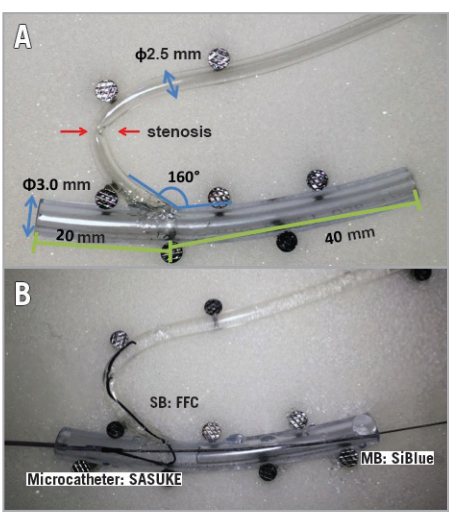

Figure 3. *Angulated bifurcation model. A) The severely angulated MB and SB of the 160° bifurcated coronary model was created using a plastic tube. The diameters of the MB and SB were 3.0 mm and 2.5 mm, respectively. The distal part of the MB from the SB orifice was 40 mm, and the proximal part was 20 mm long. B) The plastic tube was filled with 0.9% saline. Severe stenosis was simulated by bending the plastic tube (i.e., the SB). A SASUKE microcatheter was used to perform the reversed guidewire technique. FFC: Fielder FC; MB: main branch; SB: side branch; SiBlue: SION blue*

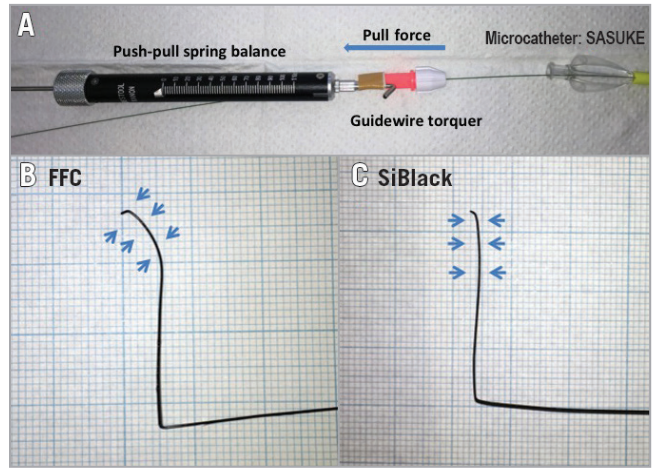

Figure 4. *Measurement of pull force by push-pull balance. A) The pull force required to cross the guidewire through the stenotic SB was calculated by using a push-pull spring balance attached to the wire torquer of the SB. The reversed guidewire technique was performed seven times, and the FFC (B) and SiBlack (C) were removed to assess their shapes. FFC: Fielder FC; SiBlue: SION blue*

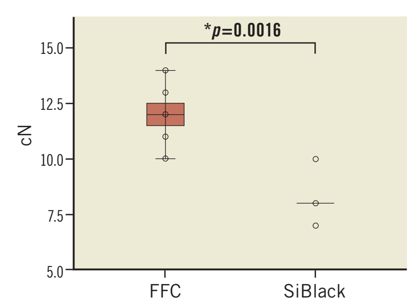

Figure 5. *Pull force of the Fielder FC and SION black wires. Box-and-whisker plot showing the results of the pull force. FFC: Fielder FC; SiBlack: SION black*

Table 1. Accessibility and pull force of the different guidewires.

	FFC	SiBlack	FXTR	SiBlue
Accessibility	yes	yes	no	no
Pull force	big	small	N/A	N/A

N/A: not applicable; FFC: Fielder FC; SiBlack: SION black; FXTR: Fielder XT-R; SiBlue: SION blue

Discussion

Compared to non-bifurcation lesions, PCI for coronary bifurcated lesions is challenging and associated with a higher complication rate[12]. As the placement of the SB wire in the jailed guidewire technique is significantly associated with angiographic success and target lesion revascularisation[6], physicians must consider crossing through the SB when treating bifurcated lesions. However, it is sometimes difficult to place the guidewire in the SB.

In the present study, the results of bench test 1 showed that, in terms of shaping the hairpin curve of the guidewire and performing the reversed guidewire technique[10], the FFC and SiBlack were most suitable. The main difference between the present study and a previous study[11] was the use of more human-like coronary artery bifurcation lesions that consisted of two different vessel diameters. The diameters of the SB and MB are not the same, thus the mother artery is larger than the daughter artery[13]. In the bifurcation vessel model, the FXTR and SiBlue did not move along the vessel wall of the MB. The following factors may have contributed to this result: the wire core of the FXTR is thinner, the SiBlue is not coated with a hydrophilic polymer, and the force of the guidewire to spread in the vessel and track the vessel wall is weaker than the FFC and SiBlack[14]. Therefore, the FFC and SiBlack are suitable for performing the reversed guidewire technique.

Results of bench test 2 showed a difference between the FFC and SiBlack in terms of the pullback force for crossing through the orifice and stenotic lesion before the entry of the SB. The conventional[10] or microcatheter-facilitated reversed guidewire technique[11] involves pulling the guidewires, so there is a risk of coronary dissection or subintimal wiring, which should be avoided when placing a wire into the SB[10]. Interestingly, the FFC required a significantly higher force than the SiBlack, although the diameter and load of their guidewire tips are the same. Moreover, in terms of the shaping memory, the SiBlack was superior to the FFC. Therefore, the shape retention of the guidewires may affect the pullback force, and the SiBlack may be safer than the FFC. Changes in the guidewire tip can lead to unintentional wire handling, which can cause coronary dissection or subintimal wiring. Compared to the FFC, the SiBlack has appropriate lubricity and vessel trackability, making it more durable for performing the reversed guidewire technique.

This is the first study to assess the crossability of the wire by using the handling force of the guidewire and a push-pull spring balance. We think that using the push-pull spring balance is suitable for objectively measuring the operator's handling of the guidewire during challenging manoeuvres.

Limitations

There are some limitations in this study. First, operators may change the bending angle or point to fit the coronary anatomy of each patient in the clinical setting. Although a different bending angle and point, such as a longer tip and acute angle, may solve the problem of lack of contact with the vessel wall noted with some guidewires, we fixed the bending angle and point to the same degree and position to evaluate each wire consistently. Second, this study only performed an *in vitro* evaluation; the behaviour of the guidewires in a human coronary artery may be different. The inner surface of the silicone tube used in this model is much smoother than real coronary arteries. Plaque distribution and calcification in the vessel may affect the behaviour of the guidewires. Third, we did not report the success rate and time taken crossing the SB. The bifurcated vessel model made with a plastic tube inner surface is different from a real coronary artery, and the ostium of the SB was difficult to recognise from the outer surface of the plastic tube, which is different from the contrast-enhanced angiography-guided wiring during real percutaneous coronary intervention (PCI). Lastly, we think the skills or experience of the operators did not affect the results of the experiments.

Conclusions

When treating severely angulated bifurcated lesions, wire selection is the key to successful treatment. Polymer-coated wires are better than composite coil wires for approaching the orifice of the SB and, among polymer-coated wires, a polymer-coated composite core wire has better accessibility, crossability, and shape retention. These factors should be considered when selecting an appropriate guidewire.

Impact on daily practice

Knowledge of the features of each guidewire is essential for every interventional cardiologist. When treating severely angulated bifurcated lesions, several factors should be considered when selecting the appropriate guidewire.

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Conflict of interest statement

The authors have no conflicts of interest to declare.

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