

Produced under an unrestricted educational grant from Terumo Medical Corporation.

Comparing Interventional Guidewires in an *Ex Vivo* Model

A multiple-endpoint performance evaluation of three currently available hydrophilic guidewires.

BY TAKAO OHKI, MD, PhD, AND JOE HUANG, MD

For any endovascular procedure, the first condition for success depends upon the operator's ability to introduce the guidewire to the target lesion. This is true for any disease, whether it is arterial-occlusive or aneurysmal in nature. The guidewire used to achieve initial access is called the access wire. Since the first generation of interventional guidewires was developed for coronary angioplasty,¹⁻⁴ numerous guidewires have been developed and are now available to peripheral interventionists and surgeons. Although the literature describes the development of individual guidewires over time, the comparative performance of each access wire has not been critically evaluated previously.⁴⁻⁹ Therefore, we created a bench model to assess the performance and capabilities of three major access guidewires currently used worldwide.

MATERIALS AND METHODS

Description of the *Ex Vivo* Model

A plastic model was constructed to mimic several vascular anatomies encountered in the clinical setting (Figures 1 and 2). Human arterial vessels were simulated using 2-mm, 3-mm, 5-mm, 10-mm, and 20-mm-diameter tubing filled with normal saline. This model possessed the ability to vary branch vessels, angles of bifurcation, vessel lengths, and the degrees of tortuosity. To standardize the amount of force

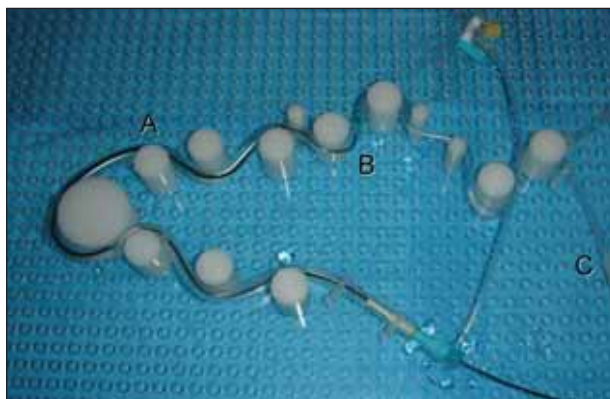


Figure 1. Model A. Points A, B, and C denote the points at which the torqueability test was performed.

used to advance the tested guidewires, we inserted a Glidecath catheter (Terumo Medical Corporation, Somerset, NJ) inside the 5-F sheath that was attached to the proximal end of the tubing.

Wires Tested

The three access wires tested in this study were the .035-inch angled Glidewire (Terumo Medical Corporation), the .035-inch angled Zipwire (Boston Scientific Corporation, Natick, MA), and the .035-inch angled HiWire (Cook Incorporated, Bloomington, IN).

ENDPOINTS

Visual and Manual Inspection

An experienced vascular surgeon was blinded to each guidewire and asked to identify the specific guidewire through visual and manual inspection. Three tests for each guidewire (totaling nine) were done.

Torqueability

Each guidewire was inserted into model A (Figure 1), passed through one 180° turn and seven 90° turns, and the tip of the guidewire was placed at 70 cm (point A), 84 cm (point B), and 107 cm (point C) from the insertion site. Using a torque device, the operator then rotated the



Figure 2. Model B. Point C is where the catheter was placed inside the 5-F sheath. Point L represents the left renal artery, and R denotes the right renal artery containing a tight stenosis.

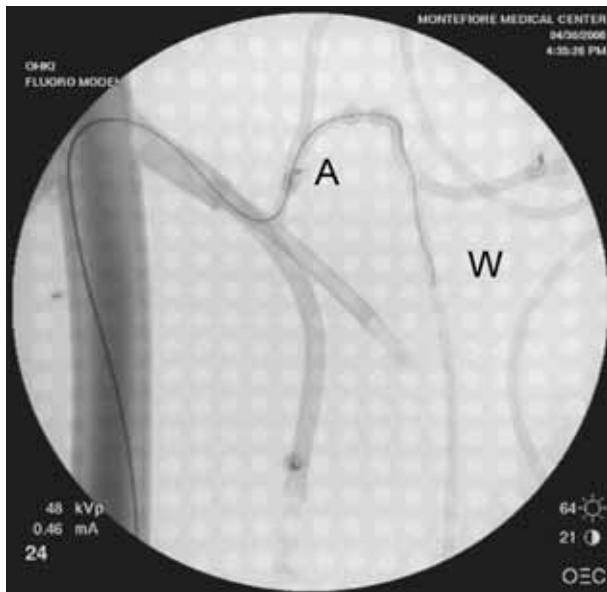


Figure 3. Model used to test trackability of the wire. Selective cannulation of the left renal artery and a simulated adrenal/gonadal (A) artery was accessed. Each wire was advanced through this tortuous tube with the endpoint being the maximal distance traversed by the wire (W).

guidewire until one complete rotation of the wire tip was achieved. The degree of rotation on the torque device required to achieve this rotation was recorded.

Trackability

Vessel trackability was assessed through the creation of a long, tortuous vessel using 2-mm, 3-mm, 5-mm, 10-mm, and 20-mm-diameter tubing (model B, Figure 2). Selective cannulation of the left renal artery and a mock adrenal/gonadal artery was accessed (Figures 2 and 3). Each wire was advanced through this tortuous tube, with the endpoint being the maximal distance traversed by the wire. The Glidewire was introduced into the tube through the 5-F sheath and was left protruding 20 cm from the sheath. The endpoint was determined to be the point the Glidewire buckled due to the excessive force from pushing the wire. The distance was then measured from the catheter entry site to the tip of the wire.

Ability to Cross a Lesion

In this experiment, a simulation of a renal artery stenosis model was created (model B, Figure 2). A Cobra catheter (Terumo Medical Corporation) was selectively cannulated into the ostium of the right renal artery, which contained a severe stenosis distally (Figure 4). This 15-mm-long lesion was created with ethyl-2-cyanoacrylate and represented a 95% stenosis of the renal artery. Under fluoroscopic control, five attempts were then made to cross the lesion with each

wire. The endpoint was the time needed to cross the lesion and the success rate within 5 minutes.

Shape Memory Capability

Shape memory capability (resistance to bending) refers to the ability of the wire to maintain its original straight configuration after passing through tortuous anatomy. Each wire was wrapped tightly around a plastic mandrel with a diameter of 5 mm. The wire was held in position for 15 seconds. After this period, the degree of bending of the wire was measured. This was quantified by measuring the angle between the tip of the wire and the line extending from the body of the wire.

RESULTS

Visual and Manual Inspection

Despite the fact that the operator was a very experienced interventionist, it was not possible to distinguish one wire from the other based on visual and manual inspection. This underscores the similarity in all three wires and the fact that it is impossible to tell them apart without the utilization of sophisticated testing.

Torqueability

At the shortest distance (point A), the average number of rotations needed to rotate the tip of the guidewire was 0.56 ± 0.05 for the Glidewire, 0.58 ± 0.08 for the Zipwire, and 0.33 ± 0.07 for the HiWire. At point B, the results were 0.68 ± 0.08 for the Glidewire, 0.75 ± 0.00 for the Zipwire, and 0.6 ± 0.07 for the HiWire. The number of rotations needed to rotate the tip at point C are shown in Figure 5.



Figure 4. Simulated high-grade renal artery stenosis (S) used to test lesion crossability.

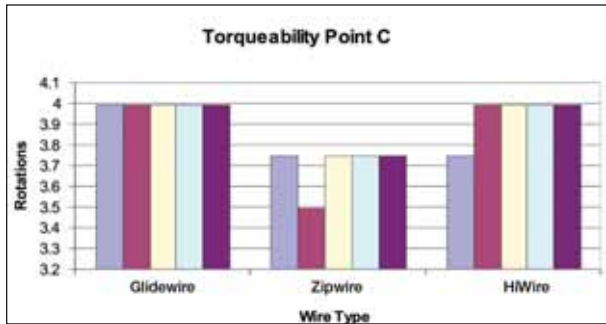


Figure 5. Torqueability data recorded at point C of Figure 1.

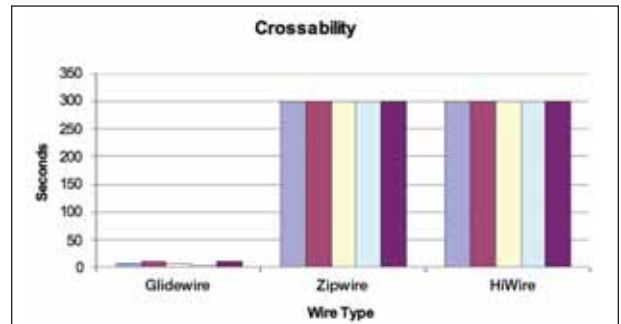


Figure 7. Time for each guidewire to cross the lesion.

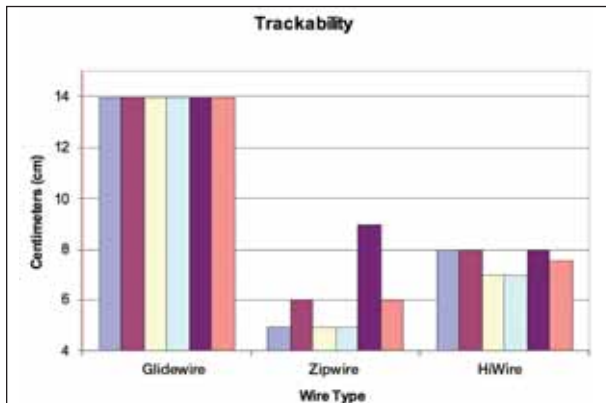


Figure 6. Guidewire trackability testing data.

Trackability

The Glidewire consistently tracked to a maximal distance of 14 cm through the tortuous model. The average maximal distance advanced for the Zipwire was 6 cm, and 8 cm was the average for the HiWire (Figure 6).

Ability to Cross a Lesion

Under fluoroscopic control, the Glidewire averaged 10 seconds to cross the stenotic lesion. Both the Zipwire and the HiWire were unsuccessful in all trials to cross the lesion. Attempts to cross the lesion took place for a maximum of 5 minutes, and if the lesion was not navigated, the trial was recorded as a failure (Figure 7).

Shape Memory Capability

After coiling the guidewires, the tips of the Glidewires maintained their original shape, while the tips of the Zipwires revealed an average curvature of 7.1° and the HiWires an average of 5.2° (Figures 8 and 9).

DISCUSSION

When the operator was blinded to the identity of the wires, each wire had a very similar visual and tactile feel and therefore the operator was not able to distinguish one wire from the other. This underscores the subtle differences in the performance of each wire and the difficulty in noticing

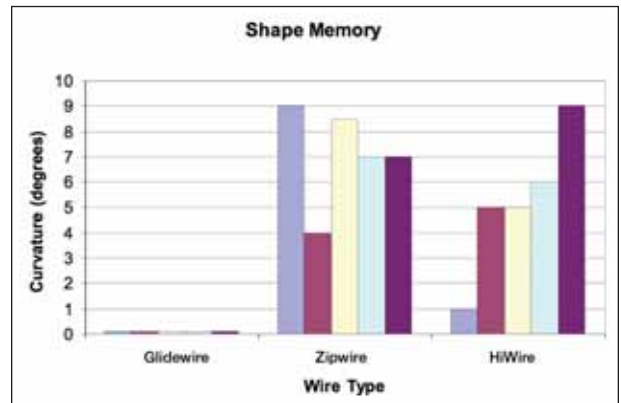


Figure 8. Shape memory capability data.

any difference in performance simply through manipulation. Based on this similarity, the remainder of the study effectively remained blinded to the operator.

The ability to cross a lesion is a very important function of an access wire. For example, if one is attempting to reach a tibial lesion and is approaching from the contralateral femoral artery, this accessibility comes into play. No matter how torqueable the wire is, if it cannot reach the target site through a torturous vascular pathway and then cross the lesion, it is of little value. Factors that affect the outcome of accessibility include the lubricity of the hydrophilic coating and the smoothness of the transition from the wire's floppy tip to the more stiff proximal shaft; this transition is a critical factor that affects the accessibility. It is critical that these attributes remain balanced. Based on this test, the Glidewire performed the best. Although the difference may seem subtle, this difference, in select cases, may mean the difference between success and failure.

As far as torqueability is concerned, it can be very frustrating for the operator when the wire flips or spins as he or she is attempting to maneuver the wire in a certain direction. Therefore, torqueability is another important aspect of an access wire. In our tests, there were no differences in torqueability when the guidewire tip was placed closer to the insertion site (points A and B in Figure 1). Subtle differences were noted only when the guidewire was introduced

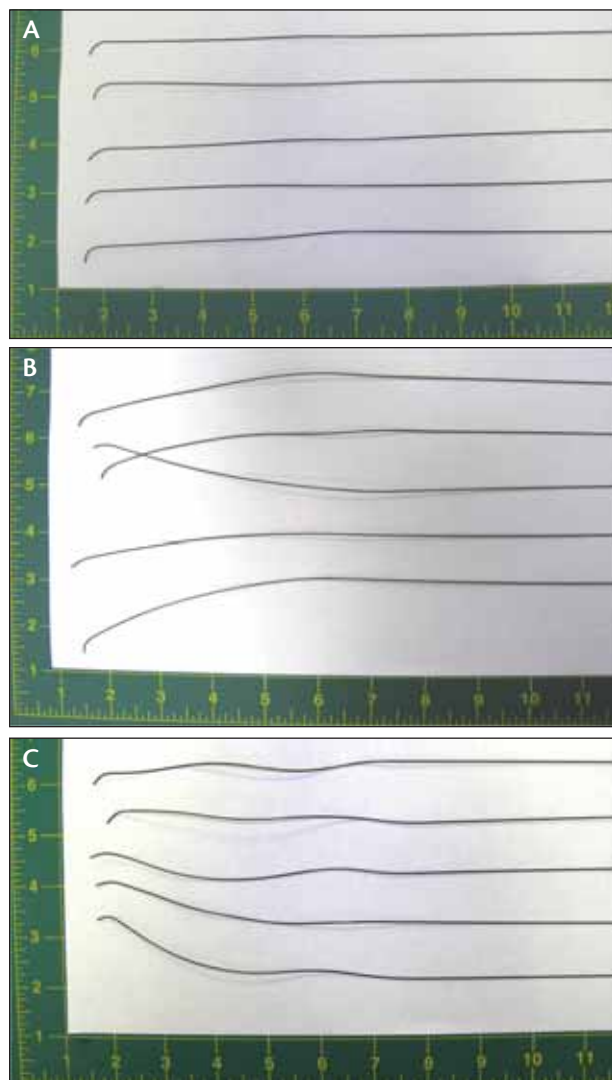


Figure 9. Photographs of the Glidewire (A), Zipwire (B), and HiWire (C) after the shape memory capability test. Note the difference in the ability to maintain a straight configuration.

deeper (point C in Figure 1). In this test, the Zipwire performed the best, followed by the HiWire, and then the Glidewire. One of the factors that affects torqueability is the stiffness of the core wire; however, stiffness/abruptness can also work against you, as demonstrated in the accessibility/crossability tests performed.

The most striking difference was observed in terms of the guidewires' abilities to cross the stenotic renal artery lesion. The Glidewire was consistently able to cross the lesion each time, within an average of 10 seconds. However, with regard to the Zipwire and HiWire, despite the fact that the operator spent up to 5 minutes attempting to cross the lesion, it was not possible. The reason the Glidewire was able to cross the lesion while the other wires failed is likely because the Glidewire has a more

gradual transition in stiffness, from a floppy tip to a stiffer body. The HiWire and the Zipwire have a long, floppy tip that abruptly changes to a stiffer body, and the subtle difference in this transition zone probably accounted for the difference in crossability.

As far as shape memory is concerned, the Glidewire was most successful in maintaining its original straight configuration. The clinical significance of this property becomes apparent when an operator attempts to manipulate the wire to access a lesion around the aortic arch or steer through torturous carotid or subclavian arteries. If the wire becomes bent, it will lose its torqueability and minimize the operator's ability to control the wire. Therefore, the ability of the wire to maintain its shape, even after going through torturous vascular anatomy, is another important characteristic that must be kept in mind when selecting an access wire.

CONCLUSION

Each access wire available to the interventionist has its own set of unique strengths and weaknesses. The differences are subtle in some areas and quite significant in others. Although no wire beat another in every test that was performed, based on the significant differences in crossability, accessibility, and excellent shape retention, we believe the Terumo Glidewire should be the access wire of choice. ■

Takao Ohki, MD, PhD, is Professor and Chief of Vascular and Endovascular Surgery, Albert Einstein College of Medicine, New York. He has disclosed that he is a consultant for Cordis, Gore & Associates, Medtronic, Aptus, NovoStent, SquareOne, CardioMEMS, GE, Morgan Stanley, Mitsui & Co., and Founder of Vascular Innovation. Dr. Ohki may be reached at (718) 920-4550 or +81 33433 1111 ext. 3400; takohki@msn.com.

Joe Huang, MD, is a Resident in Surgery, Montefiore Medical Center, Bronx, New York. He has disclosed that he has no financial interest in any product or company mentioned herein. Dr. Huang may be reached at (718) 920-4108; jhuang@montefiore.org.

1. McAuley BJ, Oesterle S, Simpson JB. Advances in guidewire technology. *Am J Cardiol.* 1984;53:94C-96C.
2. McDermott EA. Coronary angioplasty guidewire technology. *Z Kardiol.* 1987;76(Suppl):29-32.
3. Levin DC, Ganz P, Friedman P, et al. Percutaneous transluminal coronary angioplasty with an over-the-wire system. *Radiology.* 1985;155:323-326.
4. Wholey MH. A newly designed directionally controlled guidewire. *Cathet Cardiovasc Diagn.* 1986;12:66-70.
5. Butto F, Robinson JD, Hunter DW, et al. New heavy-duty exchange guide wire. *Radiology.* 1987;163:276-278.
6. Mooney MR, Mooney JF, Pedersen WR. The Ultra-Select guidewire: a new nitinol guidewire for coronary angioplasty. *J Invasive Cardiol.* 1991;3:242-245.
7. Corcos T, Favereau X, Guerin Y, et al. Recanalization of chronic coronary occlusions using a new hydrophilic guidewire. *Cathet Cardiovasc Diagn.* 1998;44:83-90.
8. Hartnell GG, Jones AM, Murphy P. Do hydrophilic guidewires affect the technical success rates of percutaneous angioplasty? *Angiology.* 1995;46:229-234.
9. Poncyliusz W, Falkowski A, Walecka A. Does use of hydrophilic guidewires significantly improve technical success rates of peripheral PTA? *Med Sci Monit.* 2004;10(Suppl):55-57.