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The New Benchmark in Hydrophilic Wires?

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Vascular interventional procedures are becoming ever increasingly complex. One of the primary tools for the interventionist is a high-performance hydrophilic guidewire. As the name implies, a hydrophilic wire must have excellent lubricity, accomplished with a durable hydrophilic coating. Additionally, torque control and radiopacity contribute to the overall performance of hydrophilic guidewires. For years, the hydrophilic wire of choice has been the Terumo Glidewire (Terumo Interventional Systems, Somerset, NJ). Many manufacturers have attempted to create a guidewire equivalent to or superior to this benchmark without success. The purpose of this study is to determine if the Aquatrack (Cordis Corporation, Warren, NJ) hydrophilic guidewire has the lubricity, hydrophilic-coating durability and adhesion, torque control, and radiopacity to become the wire of choice for the demanding interventionist.[1-3]

MATERIALS AND METHODS

The Aquatrack wire was evaluated in each of four categories: hydrophilic-coating lubricity and durability, torque response, radiopacity, and hydrophilic-coating jacket adhesion. For each category, the Terumo Glidewire and the Boston Scientific Zipwire (Boston Scientific Corporation, Natick, MA) were also evaluated under identical conditions as the Aquatrack. Both regular and stiff wire configurations were tested for each brand.

Hydrophilic-Coating Lubricity and Durability

The lubricity and durability test subjects the hydrophilic-coating surface of the guidewire to a rigorous series of wiping motions using hydrated gauze pads. The equipment (Figure 1A) is meant to simulate a worst-case wiping scenario seen in a clinical environment.

The wiping equipment wipes the wire 24 times with a high grip force, meant to stress the durability of the hydrophilic coating. After wiping, the wire is fed into a decreasing spiral (Figure 1B), intended to represent a worst-case tortuous path in anatomy.

The peak force seen during this test was recorded as the output for that particular sample. The maximum specification for insertion force for the lubricity tester was 100 grams. Any insertion force above 100 grams was considered too high for clinical use and a failure in the hydrophilic coating. Ten percent of this maximum specification was used as a population difference. This level was based upon input from many interventionists

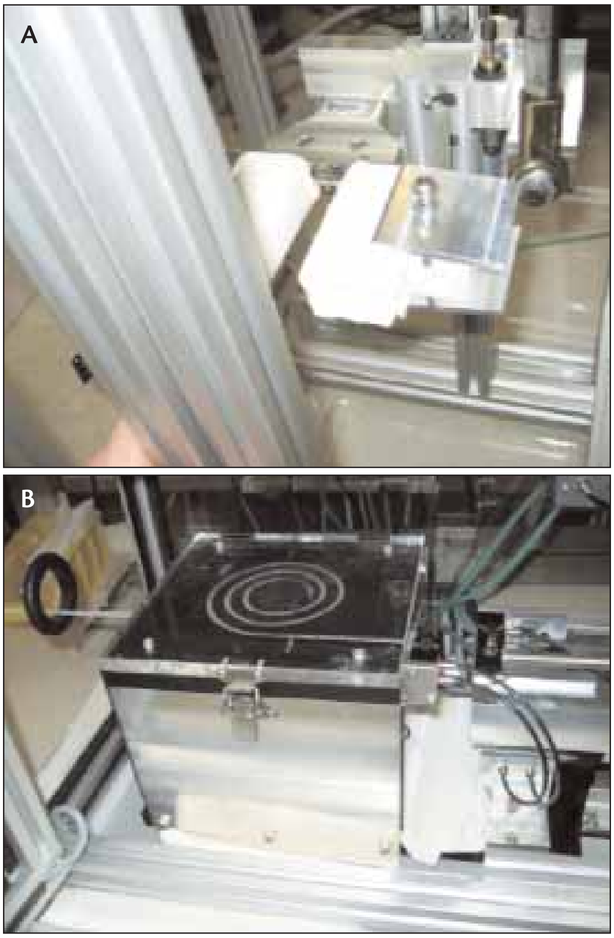

Figure 1. Guidewire wiping pads (A). Decreasing spiral test path (B).

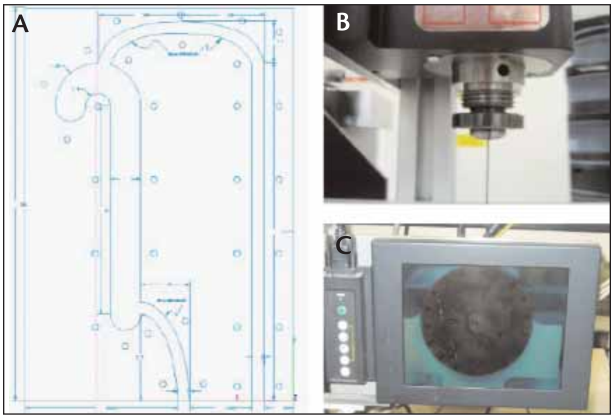

Figure 2. Anatomical model for torque testing (A). Collet to rotate the proximal end (B). Video display for angular output (C).

during development of this test. Maximum push-force values were recorded for each type of wire (stiff or regular) and each wire brand (Aquatrack, Zipwire, and Glidewire).

Torque Response

The test for torque response used an anatomical model simulating a left subclavian access procedure via a left femoral entry (Figure 2A). The test fixture was filled with 0.9% saline solution and heated to 37ºC. The proximal end of the wire was rotated in 20º increments by the torque tester collet (Figure 2B). Angular output of the distal end of the wire was read on the calibrated protractor as seen on the visual display screen (Figure 2C).

To quantify torque response, all wires were tested for the maximum whip of the distal end. Whip is defined as the uncontrolled movement of the tip of the wire caused by the sudden release of energy stored in the wire shaft. Maximum whip values are recorded for each type of wire (stiff or regular) and each wire brand (Aquatrack, Zipwire, and Glidewire). Any wire with a maximum whip value of >60º is considered a failure.

Radiopacity

Digital radiographic images were taken with nine samples spaced evenly over a 10-mm-thick aluminum plate as required per ASTM F640-79, Standard Test Methods for Radiopacity of Plastics for Medical Use. Of the nine samples, three were Aquatrack Hydrophilic Guidewires, three were Terumo Glidewires, and three were Boston Scientific Zipwires. Test groups were divided up into regular and

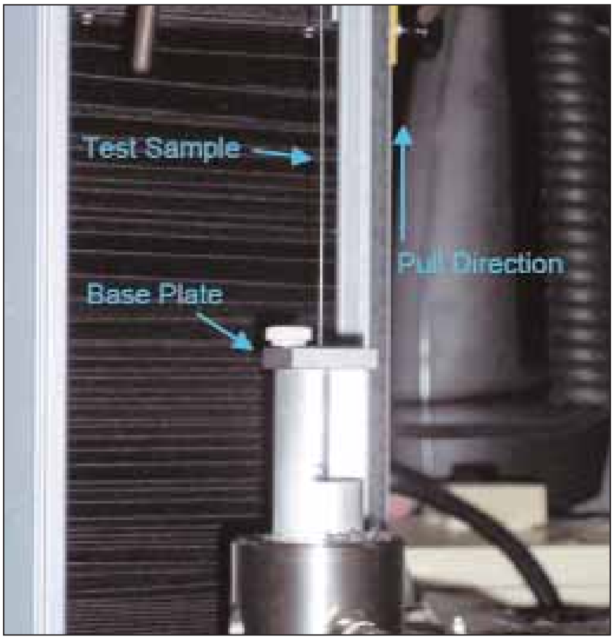

Figure 3. Jacket adhesion test setup.

stiff wire configurations. Within each test image, wires were randomly ordered next to one another. Image settings were set to automatic when obtaining samples. A total of 162 wires, 27 from each type of wire (regular and stiff) and wire manufacturer (Cordis, Terumo, and Boston Scientific), were imaged using this method.

Digital images were then analyzed using ImageJ software. First, images were calibrated from grayscale values to an optical density scale. Then, within each image, software tools were used to analyze the average optical density value for each wire sample. Twenty-seven average optical density values per group were recorded and used for statistical comparison.

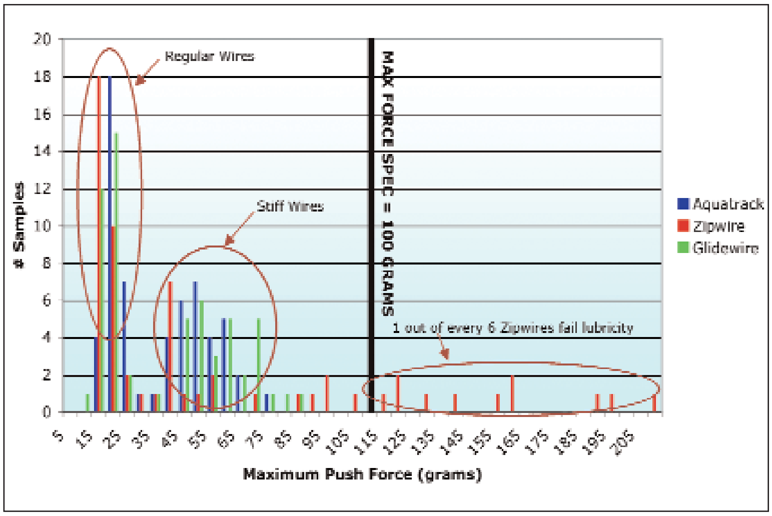

Figure 4. Histogram comparison of lubricity.

TABLE 1. LUBRICITY RESULTS

Test Group	Sample Size	Average Max Force (grams)	Comparison Results (Using T-Test)
Regular: Aquatrack	30	18.4	Aquatrack has similar lubricity as regular Glidewire and Zipwire
Regular: Zipwire	30	14.8	Zipwire has similar lubricity as regular Aquatrack and Zipwire
Regular: Glidewire	30	15.5	Glidewire has similar lubricity as regular Aquatrack and Zipwire
Stiff: Aquatrack	30	49	Aquatrack has similar lubricity as stiff Glidewire and better lubricity than stiff Zipwire
Stiff: Zipwire	30	90.6	Zipwire has worse lubricity than stiff Aquatrack and Glidewire
Stiff: Glidewire	30	55.6	Glidewire has similar lubricity as stiff Aquatrack and better lubricity than stiff Zipwire

TABLE 2. TORQUE RESPONSE RESULTS

Test Group	Sample Size	Average Max Whip (°)	Comparison Results (Using T-Test)
Regular: Aquatrack	30	42.93	Aquatrack has better torque response than Glidewire
Regular: Zipwire	30	37.7	Zipwire and Aquatrack have similar torque response
Regular: Glidewire	30	69	Glidewire has worse torque response than Aquatrack and Zipwire
Stiff: Aquatrack	30	36.13	Aquatrack has similar torque response to Glidewire and Zipwire
Stiff: Zipwire	30	37.4	Zipwire has similar torque response to Aquatrack and Glidewire
Stiff: Glidewire	30	44.07	Glidewire has similar torque response to Aquatrack and Zipwire

TABLE 3. SUMMARY OF RADIOPACITY COMPARISON

Test Group	Sample Size	Average Optical Density	Comparison Results (Using T-Test)
Regular: Aquatrack	27	0.364	Aquatrack is darker than Zipwire and Glidewire
Regular: Zipwire	27	0.351	Zipwire is darker than Glidewire
Regular: Glidewire	27	0.32	Glidewire is the lightest of the test group
Stiff: Aquatrack	27	0.364	Aquatrack is darker than Zipwire and Glidewire
Stiff: Zipwire	27	0.337	Zipwire is darker than Glidewire
Stiff: Glidewire	27	0.309	Glidewire is the lightest of the test group

TABLE 4. SUMMARY OF JACKET ADHESION TESTING			
Test Group	**Sample Size**	**Average Pull Force (lbf)**	**Comparison Results (Using T-test)**
Regular: Aquatrack	29	12.89	Aquatrack has higher jacket adhesion than Glidewire and Zipwire
Regular: Zipwire	29	5.31	
Regular: Glidewire	29	4.25	
Stiff: Aquatrack	27	27.32	Aquatrack has higher jacket adhesion than Glidewire and Zipwire
Stiff: Zipwire	27	4.75	
Stiff: Glidewire	27	2.41	

Hydrophilic-Coating Jacket Adhesion

The jacket-adhesion test measures the force to separate the hydrophilic-coating jacket from the core wire by pulling the core wire through a base-plate hole that is only large enough to allow the wire to pass through and not the jacket material. Because there are two wire types, both stiff and regular, two different base plates were used. The test setup and description can be seen in Figure 3.

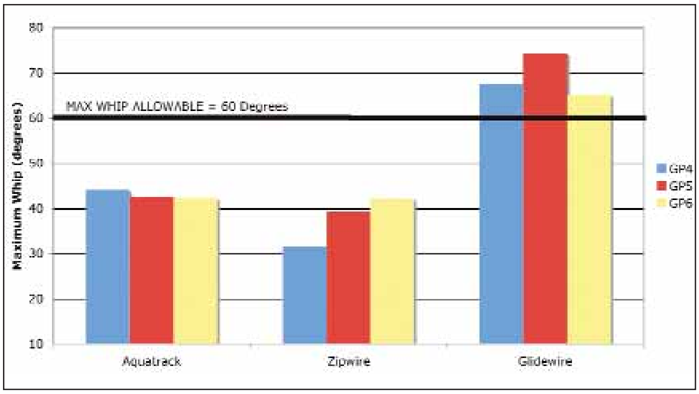

Figure 5. Bar chart comparison of regular wire torque.

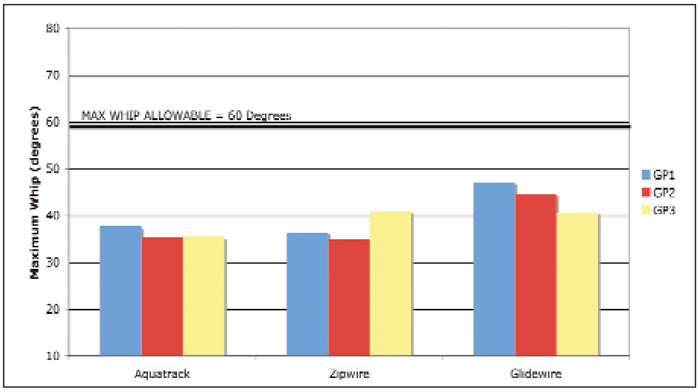

Figure 6. Bar chart comparison of stiff wire torque.

Wire samples were cut into 5-inch pieces. The jacket was removed from the top 4 inches, and the last 1 inch was the test area. Because the jacket edge that touches the base plate is a critical area, a scalpel was used to ensure the top surface of the jacket had a 90° cut. Average jacket adhesion force values were recorded for each type of wire (stiff and regular), each brand, and across three different lots for each brand.

Normality of the various test groups was checked using Minitab's Test for Normality (Minitab Inc., State College, PA). Aquatrack jacket adhesion forces were compared to Zipwire and Glidewire using the Student's t-test.

RESULTS

Hydrophilic-Coating Lubricity and Durability

Average lubricity values and statistical comparison results are summarized in Table 1.

Regular wires tend to have a lower push force than stiff wires. This is due to the fact that regular wires have less metal in the core wire and therefore less outward force when the wire is pushed into a spiral. One out of every six Zipwires had very high push forces, indicating a failure in the hydrophilic coating. Figure 4 shows a graphical comparison of the lubricity and durability results.

Torque Response

Average torque response and statistical comparison results are summarized in Table 2.

Stiff wires perform better than regular guidewires because there is more metal core of the wire resulting in more backbone to support the wire and to transmit the torque. Figure 5 shows a graphical comparison of the torque response results for regular wires. Figure 6 shows a graphical comparison of the torque response results for stiff wires.

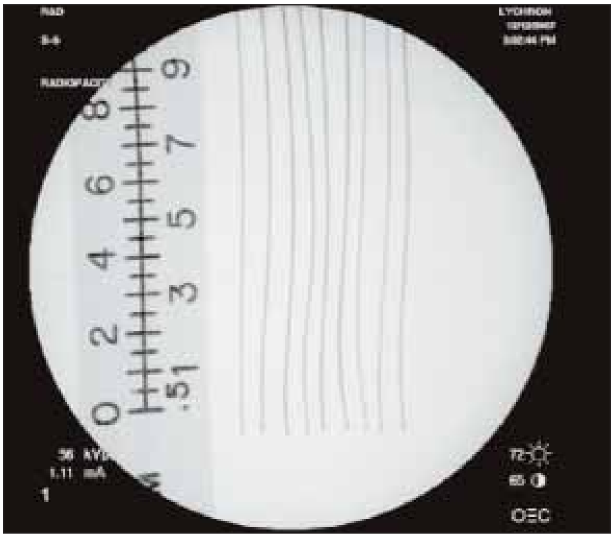

Figure 7. Typical digital radiographic image: nine samples, random order.

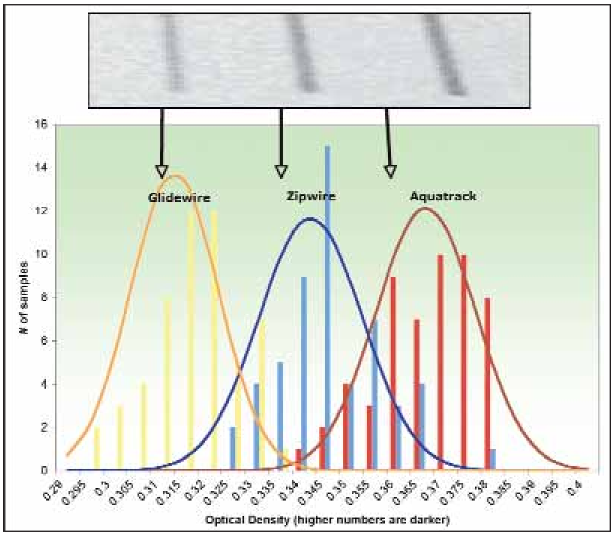

Figure 8. Visual and optical density comparison of guidewires.

Radiopacity

Average optical density values and statistical comparison results are summarized in Table 3. All data sets from the test groups had a *P*-value >.15, indicating that the sample distribution is normal.

As can be seen in Figures 7 and 8, there is a perceptible optical difference between the different brands of wires. Results are tabulated in Table 3. For a final comparison, data sets for each brand of wire were compared on a single graph in Figure 8. As can be seen by the superimposed image of the three wires, there is a clear visual and statistical difference between the various brands of wires.

Hydrophilic-Coating Jacket Adhesion

Average jacket adhesion forces and statistical comparison results are summarized in Table 4 and Figures 9 and 10. All data sets from the test groups had a *P*-value >.05, indicating that the sample distribution is normal.

During the testing it was noted that the Aquatrack wires required a much greater force to remove the jacket. When pulled through the base plate, adhesion between the jacket and the core wire was so strong that a thin film of jacket material remained on the wire; this did not occur with Glidewire or Zipwire (Figure 11).

DISCUSSION

One of the important tools for any interventionist performing a complex percutaneous intervention is a high-performance hydrophilic wire. Hydrophilic-coating lubricity and durability are fundamental characteristics that must be present. We have all come to rely on the outstanding lubricity of the Terumo Glidewire based on years of hands-on experience. The results of the current study demonstrate Aquatrack Hydrophilic Guidewire has equivalent lubricity compared to Terumo Glidewire both for regular and stiff configurations.

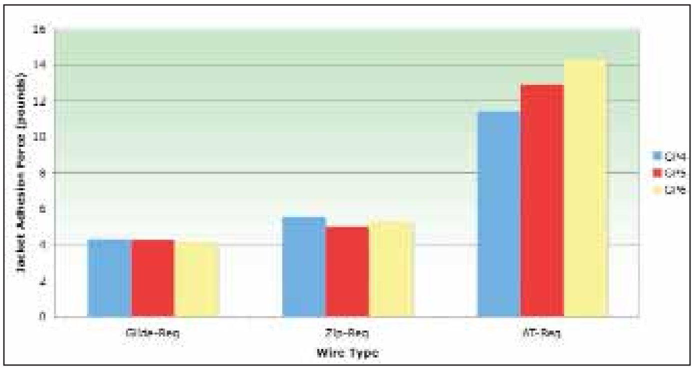

Figure 9. Regular wire jacket adhesion comparison.

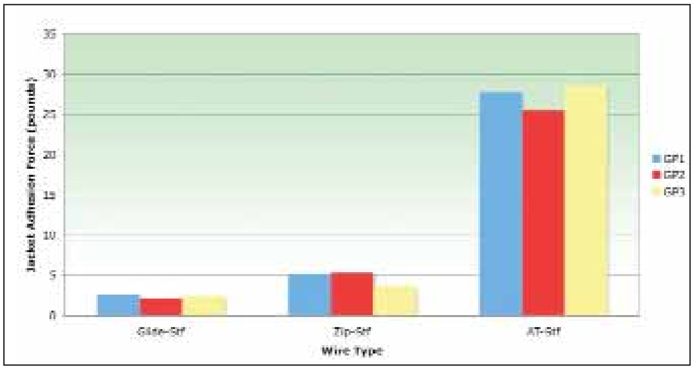

Figure 10. Stiff wire jacket adhesion comparison.

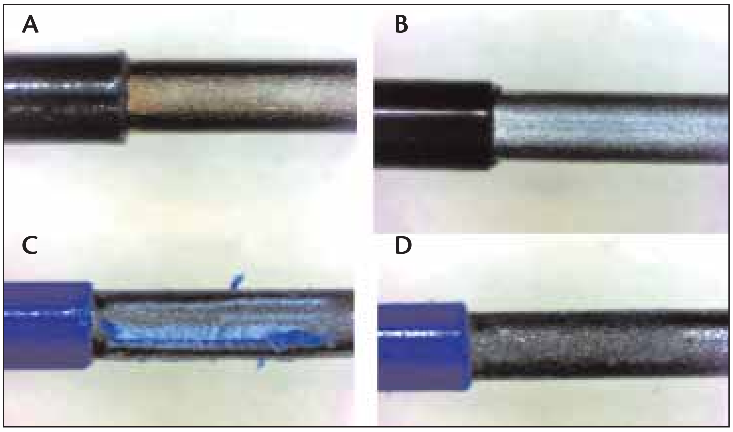

Figure 11. Glidewire test sample (A). Zipwire text sample (B). Aquatrack bonded wire surface (C). Aquatrack after scraping (D).

Although Boston Scientific Zipwire has similar lubricity to Aquatrack and Glidewire for regular shaft configuration, the stiff shaft Zipwire has inferior lubricity to Aquatrack and Glidewire. Of all the wires tested, one out of every six Zipwires had very high push forces, indicating a failure in the hydrophilic coating. The benchmarks for hydrophilic-coating lubricity and durability are Aquatrack and Glidewire.

Another important characteristic for high-performance hydrophilic wire is torque response. As can be seen from the average torque response data, stiff wires tended to perform better than regular wires. With regular wires, the amount of metal core is less, which makes the shaft less stiff. Because there is less metal, there is less backbone to support the wire and to transmit the torque. As a result, regular wires tend to have worse torque response compared to stiff wires.

For regular shaft wires, the results of this study show Aquatrack has better torque response than Glidewire. Zipwire showed similar torque response to Aquatrack. These differences may become important with respect to the successful completion of a complex intervention. Based on the results of this trial, Aquatrack and Zipwire are the benchmarks for torque response in regular shaft wires.

Radiopacity is also an important characteristic for a high-performance hydrophilic guidewire. This is particularly true if the wire is being used in a patient with a high body mass index or under less than optimal fluoroscopy conditions. In this study, Aquatrack Hydrophilic Guidewire showed better radiopacity compared to both Terumo Glidewire and Boston Scientific Zipwire. This superior radiopacity was clear visually and reached statistical significance.

For any hydrophilic wire to maintain its performance characteristics, the jacket of hydrophilic coating must remain firmly adherent to the core wire. If jacket adhesion is compromised, then the hydrophilic coating will peel off the wire, causing it to fail. Aquatrack Hydrophilic Guidewire has the highest jacket adhesion of all wires tested for both regular and stiff wire types. Four to ten times the pull force was required to remove the jacket from Aquatrack compared to Terumo Glidewire or Boston Scientific Zipwire.

According to the results of this study, Aquatrack Hydrophilic Guidewire is the benchmark for hydrophilic-jacket adhesion.

Each individual interventionist places differing levels of importance on the hydrophilic-wire characteristics discussed above. For the interventionist who wants equivalent hydrophilic-coating lubricity compared to the proven historical benchmark, Glidewire, as well as best-in-class torque response and radiopacity, Cordis Endovascular Aquatrack Hydrophilic Guidewire is the obvious choice. Additionally, with Aquatrack's superior hydrophilic-jacket adhesion, it can be used with confidence, even in the most challenging anatomy, such as extensive irregular calcific plaquing.

In conclusion, based on the results of this study, Aquatrack Hydrophilic Guidewire is the new benchmark hydrophilic guidewire in terms of coating lubricity and durability, torque response, radiopacity, and hydrophilic-jacket adhesion. This conclusion is supported by the authors' experience with Aquatrack in the animal lab setting. Further study in patients with advanced peripheral vascular disease is needed to corroborate these findings. All interventionists owe it to themselves and their patients to perform a side-by-side comparison of Cordis Aquatrack versus their hydrophilic guidewire of choice in their next five interventional cases. ■

The authors are consultants to Cordis Corporation and have prepared this paper at Cordis' request.

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