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AJNR Am J Neuroradiol 1996, 17 (1) 29-34
http://www.ajnr.org/content/17/1/29

This information is current as of June 8, 2023.

In Vitro Evaluation of Coils for Endovascular Therapy

Michael P. Marks, Carol Tsai, and Hiram Chee

PURPOSE: To evaluate the physical characteristics and behavior of coils for endovascular therapy. **METHODS:** Mechanically detachable coils were constructed with simple helical (4 mm × 10 cm and 8 mm × 30 cm) and pretzel shapes (4 mm × 5 cm) made from three metals using 0.003- and 0.004-in wire. Stiffness or pliability, frictional resistance, shape memory, and coil stability were evaluated in vitro. **RESULTS:** The 0.004-in wire stock coils proved significantly stiffer when compared with the 0.003-in coils. Tungsten coils proved least pliable; platinum coils were intermediate in stiffness; and nitinol coils were softest. Frictional resistance in the catheter was greatest for stiffer coils. The 5-cm pretzel coil consistently created more frictional force than the 10- or 30-cm simple helical coils. Despite a shorter length, the 4-mm simple helical coil exerted more frictional force than the 8-mm coil. Stiffer metal coils constructed of larger-diameter wire (0.004 in) were more stable than softer coils. **CONCLUSION:** Stiffer coils exert greater frictional forces within the catheter and a greater resistive force during bending but are more stable after placement. Frictional forces also depended on the complex three-dimensional shape of the coil and the diameter of the turns in that shape rather than coil length. These data suggest that a family of coils of different metals is optimal for varied intravascular needs.

Index term: Interventional instruments, coils

AJNR Am J Neuroradiol 17:29–34, January 1996

Microcoils are now widely used for endovascular procedures including aneurysm thrombosis and occlusion of arteriovenous fistulas (1–4). Microcoils currently in clinical use are constructed with platinum. This in vitro study considered three biocompatible metals of varying sizes and shapes and was designed to provide a framework for evaluating physical characteristics of coil skeletons that are important for clinical performance.

Materials and Methods

Four physical properties of coil behavior were assessed in this study: (*a*) relative pliability or stiffness of the primary coil; (*b*) shape memory of the coil design; (*c*) friction generated in a microcatheter system; and (*d*) stability after placement in a pulsatile flow system. Coils of platinum, tungsten, and nitinol were constructed using different diameter wire stock and varying coil shapes and sizes. Stock wires of two diameters (0.003 and 0.004 in) were used for the experiments. The wires were wound into primary coils measuring 0.015 in in diameter. These primary coils were then shaped into two designs: two simple helical shapes of 4 mm × 10 cm and 8 mm × 30 cm (diameter of one coil turn × total length of the coil) and a complex pretzel shape of 4 mm × 5 cm (diameter of one loop × total length of the coil). All coils were constructed with the same type of detachment system as previously described using an interlocking mechanism (5). Figure 1 shows the detachment mechanism and the simple helical coil. Figure 2 shows the pretzel-shape coil and the measurements of coils that were used.

The relative stiffness of the primary coils of varying wire diameter and metal types was determined on a Tinius-Olsen Stiffness Tester (model 1000, Tinius-Olsen, Willow Grove, Pa). This device determined the load measured in inch-pounds generated by a coil after bending of that primary coil to preset angulations. Coils were bent in 5° increments from 0° to 45°. Five samples of the 0.003-in and five of the 0.004-in primary wires for each of the three coil types were tested.

Two groups of experiments were conducted to assess the ability of the coils to maintain their shapes. Coils were tested after aging studies and after being sent through a

Received November 9, 1994; accepted after revision June 20, 1995.

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Supported by a grant from the Whitaker Foundation, Washington, DC.

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AJNR 17:29–34, Jan 1996 0195-6108/96/1701–0029

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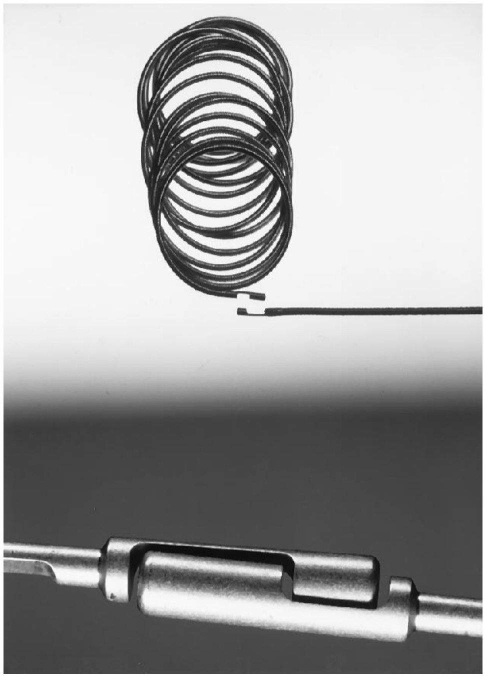


Fig 1. Composite photograph shows a simple helical coil and coil pusher with an interlocking detachment mechanism. The bottom portion of the photograph is a magnified view of the interlocking detachment mechanism. This design was used in all of the experiments.

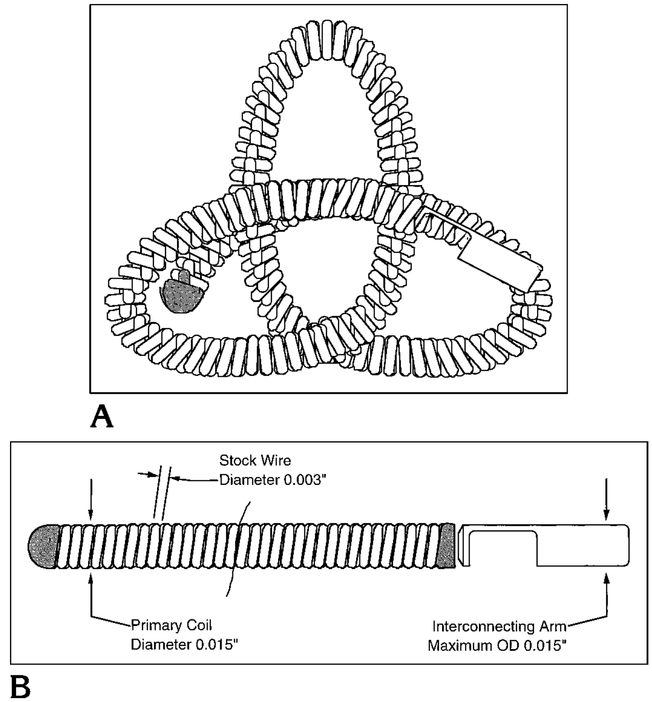


Fig 2. Schematic drawings of coil design.

A, A complete complex pretzel-shape coil.

B, An unwound primary coil before being configured into a 3-D shape. The primary coil has a diameter of 0.015-in as shown. This is made from a 0.003- or 0.004-in-diameter stock wire as shown.

catheter system. Sets of five samples of each coil's shape, wire diameter, and metal type were subjected to an accelerated aging process by being stored in an extended strained configuration inside a catheter for 2 weeks at 70°C. Storing coils at a higher temperature accelerates aging, because the time for a chemical reaction causing deformation to occur is inversely proportional to the temperature. Another group of sets of five coils representing each coil type was assessed before and after traveling through a 0.18-in microcatheter (Tracker, Target Therapeutics, Fremont, Calif). The distal portion of the microcatheter was fixed into a rigid figure eight. Coils were pushed and pulled through the catheter system 10 times. To assess any change in shape, the dimensions of all the coils used in the two experiments were measured with an optical comparator before and after storage or deformation. The optical comparator magnified the coil on a grid background onto a screen allowing for accurate measurement of the coil. For the simple helices the diameter of the coil was measured. For the complex-shape pretzels both the greatest width and length of the complete pretzel shape and the largest dimensions of one of its loops were measured.

Frictional force of the coil sliding through the catheter was recorded by an Instron tensile tester (model 4201, Instron, Boston, Mass). The catheter was set into the same rigid figure-eight pattern used for deformation testing. The tensile tester was set to generate one push and one pull 10 times. The coil was moved 5 in with each push or pull. The tensile tester then measured the amount of force (pounds) required to push or pull the coils through the assembly. The two helical and single pretzel coils were tested in both the 0.003- and 0.004-in sizes. Each of these shapes and sizes was fabricated from the three metals. Five coil samples were tested for each type of coil. Each of these samples was then subjected to 10 push and pull measurements. The push and pull forces were measured separately.

The fourth property, stability, was assessed by positioning a coil of the same type in each of four identical 1-cm-diameter glass aneurysms with a neck size of 5 mm connected in parallel via a branching series of Nalgene tubing to a pulsatile pump (model 1421, Harvard Apparatus, South Natick, Mass). Four measurements were evaluated to maintain an even branching system that allowed for pressure and flow to be evenly distributed to each of the aneurysms. The pump was set to approximate values previously measured for carotid blood flow (6) at 70 beats per minute delivering 350 mL/min to each aneurysm. An aqueous solution of 0.04% (wt/vol) xanthan gum (Merck & Co, Kelco Division, San Diego, Calif) and 40% glycerine was used to simulate blood at 46% hematocrit. This has been shown to be a good blood analog in flow conditions characteristic of large arteries (7). Coil motion and migration were noted at time intervals of 0, 30, and 60 minutes after coil placement. After 60 minutes, the pump was turned off, and tubes containing prolapsed coils were dismantled from their respective glass aneurysms. The tubes were clamped with a hemostat to prevent the coils from

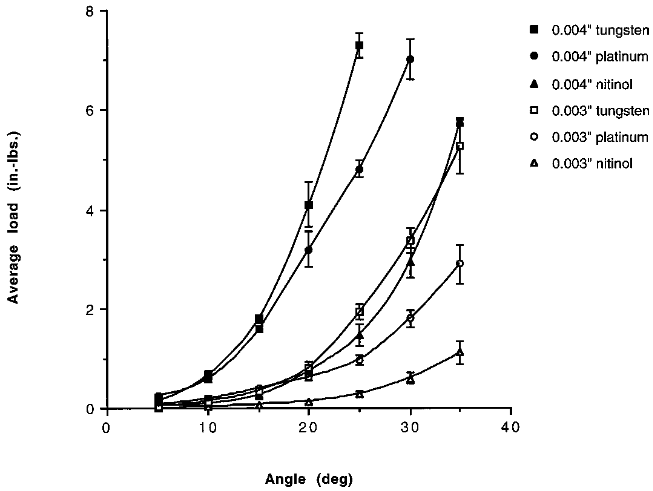


Fig 3. Comparative stiffness of primary coils. Load generated (inch-pounds) versus increasing angle of deflection (degree) for each metal type constructed of 0.003- and 0.004-in wires. Note that at greater degrees of deflection (>20°), stiffer coils (0.004 in) tend to generate much greater changes in load with small increase in deflection.

moving during dismantling. The segment of prolapsed coil was then measured.

Statistical analysis was conducted using one-way analysis of variance, followed by Tukey's test for pairwise comparisons.

Results

Primary Coil Stiffness

Figure 3 shows the force (average load) required to deflect the three metal types in each of the two primary wire sizes (0.003 and 0.004 in).

The 0.004-in primary coils were significantly stiffer than the 0.003-in primary coils for each of the metal types ($P < .01$). Of the three metals, the tungsten coil generated the greatest resistive force to bending, followed by platinum and then by nitinol. The differences between the various metals were statistically significant ($P < .01$).

Shape Memory

Only minimal changes in coil shape were observed during the accelerated aging studies and after coil deformation from use in a microcatheter, with coils maintaining a stable configuration. These changes were expressed as the mean percent changes of the five coil samples. Percent change is the difference in measurements before and after deformation divided by the measurements before deformation. The mean percent changes for platinum, tungsten, and nitinol were 2.5%, 0.8%, and 1.1%, respectively, for the 0.003-in coils. These changes were 0.6%, 0.3%, and 0.6% for the 0.004-in coils in platinum, tungsten, and nitinol, respectively. The accelerated aging mean percent changes for platinum, tungsten, and nitinol were 0.9%, 0.9%, and 0.7%, respectively, for the 0.003-in coils. These changes were 1.0%, 1.1%, and 0.5% for the 0.004-in coils in platinum, tungsten, and nitinol, respectively. No significant differences were seen between any of the metal types of any of the coil sizes.

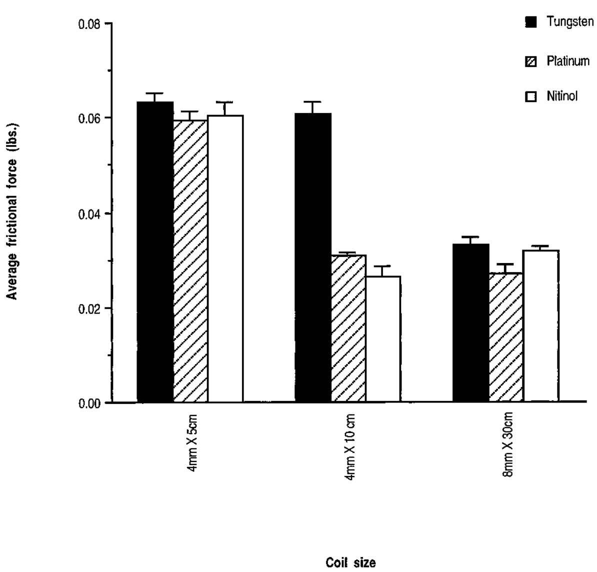
Frictional Force in a Microcatheter

Figures 4 through 7 show the frictional forces required to push and pull coils of the various sizes, shapes, and metal types through a 0.18-in microcatheter. Three variables, metal type, wire diameter, and coil shape, were found to affect the magnitude of the frictional force inside a catheter significantly. Tungsten required the highest force to push inside a catheter, followed by platinum and then nitinol. Between the two wire diameters, the 0.004-in coils proved more difficult to push and pull ($P < .01$). The shape of the coil also had a significant effect on friction. The 4-mm × 5-cm coils exerted the largest force, followed by the 4-mm × 10-cm coils and then the 8-mm × 30-cm coils. The differences were significant between the three coil shapes ($P < .01$). Frictional forces depended less on coil length than coil shape and the acuteness of coil turns. The 5-cm-long pretzel coils created more frictional force than the 10- or 30-cm simple helical coils with all metals tested ($P < .0002$).

Stability in a Pulsatile Flow System

None of the coils remained motionless in the glass aneurysms, because their sizes and lengths did not permit complete filling of the aneurysm lumen. Coils exhibited either a pulsing or whirling motion.

The Table shows the stability results for the 0.003- and 0.004-in coils. The coils that prolapsed from the aneurysm did so within the first 10 minutes after placement; usually this was an immediate response. Stiffer 0.004-in coils were generally more stable than their 0.003-in counterparts. The 0.004-in coils did not prolapse at all, with the exception of the 8-mm × 30-cm



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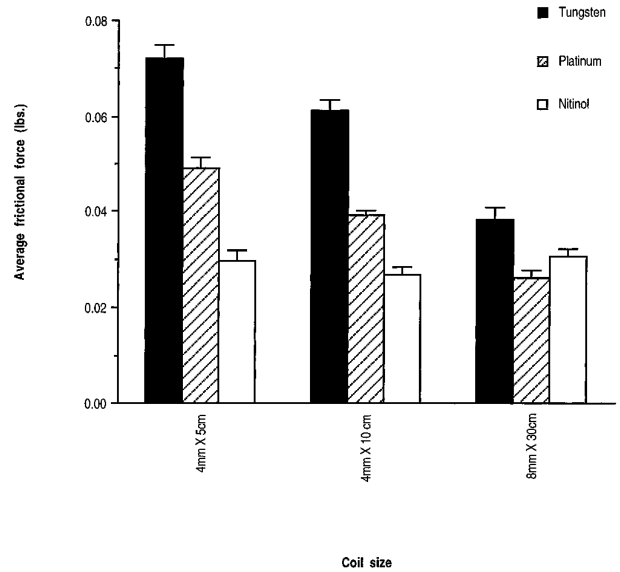

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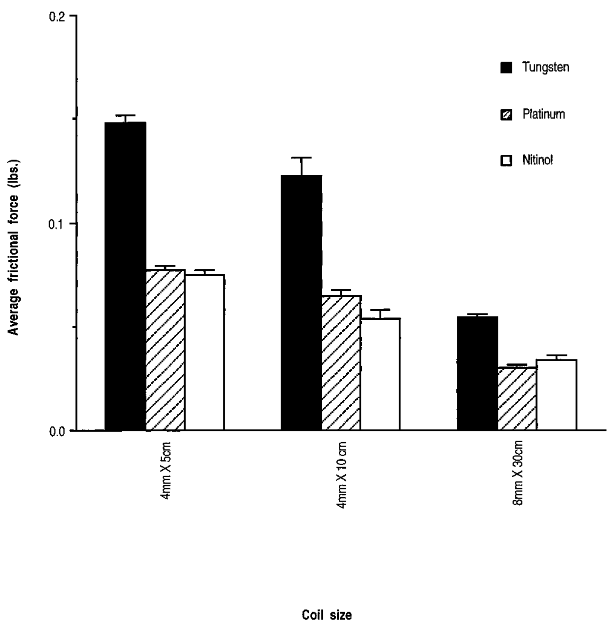

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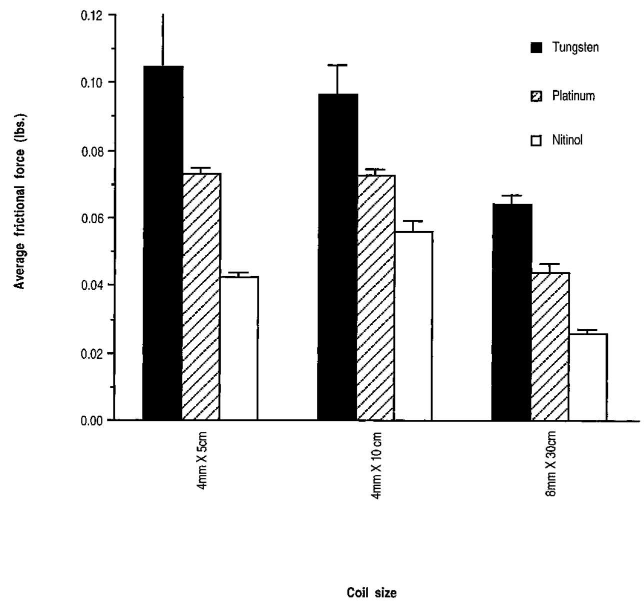

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Fig 4. Push forces with 0.003-in coils.
Fig 5. Pull forces with 0.003-in coils.
Fig 6. Push forces with 0.004-in coils.
Fig 7. Pull forces with 0.004-in coils.

nitinol coil, which moved into the bifurcation branches. In the 0.003-in coil group, the least stable coils were the 8-mm × 30-cm helical coils and those coils constructed of nitinol.

Discussion

Microcoils are being used more extensively to treat vascular lesions of the central nervous system, including arteriovenous fistulas, arteriovenous malformations, and aneurysms. For a coil to fill a three-dimensional space such as a blood vessel or aneurysm, it should ideally have certain characteristics. The coil must be straight while passing through a catheter; however, it must be able to maintain a complex 3-D shape after placement. The inherent shape memory of the coil should not appreciably contribute to the

Stability of coils in a pulsatile flow system*

	Tungsten	Platinum	Nitinol
0.003-in coils			
4 mm × 5 cm	None	30% and 15%	80% and 80%
4 mm × 10 cm	None	None	45%, 10%, 7.5%, 65%
8 mm × 30 cm	10% and 47%	17% and 20%	23%, 6.7%, 10%, 23%
0.004-in coils			
4 mm × 5 cm	None	None	None
4 mm × 10 cm	None	None	None
8 mm × 30 cm	None	None	60% and 50%

* Data are expressed as percent of coil that prolapsed. Four coils were evaluated in each group. When only two percentages are shown, the other two coils did not prolapse.

frictional force developed as the coil passes through the catheter. In addition, the coil must be soft enough not to perforate vascular structures such as aneurysms, which can be quite thin walled. On the other hand, it should not be so soft that it is easily deformed by pulsatile flow. For example, a platinum microcoil currently used at many centers to treat aneurysms has been designed to be very soft within the aneurysm and to adapt to the size and shape of the aneurysm (8). Preliminary clinical experience suggests that microcoils of this softer design are capable of successfully treating smaller narrow-necked aneurysms; however, the softer design has proved to create a compactible coil mass in larger, wide-necked aneurysms. This results in remodeling of the coil mass in response to pulsatile flow into the aneurysm (1).

This study assessed the relative stiffness or pliability of coils by measuring the load generated by a coil with varying degrees of bending. The results obtained show that significant differences in pliability or stiffness can be obtained with change in the primary stock of a coil or change in the coil material. Varying the coil wire stock from 0.003 to 0.004 in (without altering the diameter of the primary coils, 0.015 in) seemed to have a more profound effect on the relative stiffness of the coils than varying the type of metal. For instance, the 0.004-in nitinol coil (the softest metal evaluated) had similar stiffness characteristics across all angles of bending as the 0.003-in tungsten coil (the stiffest metal evaluated) as shown in Figure 1. The stiffness data also showed that pliability of coils constructed of 0.004-in wire stock had very steep increases in the average load exerted by the coil, particularly at a greater angle of bending (>20°). Data such as these have practical applications for the manufacture and use of such coils. This information suggests that coils of the same material and size can be controlled by varying the diameter of wire stock. The microcoil user is advised that packing of the coils at the time of placement can lead to significant distortion of the 3-D coil and can result in significant forces on the wall of the vascular structure. This force could result in perforation, particularly in thin-walled vascular structures such as aneurysms.

The frictional force required to advance and retract coils through a microcatheter is another important physical characteristic to the user. Often, vascular access requires the catheter to be placed along a very circuitous path; most users of conventional and detachable coil systems have experienced instances in which coils could not be placed, or coils became distorted and unraveled at the time of retraction because of these frictional forces. The data available from this study show that coil stiffness exerts a significant effect on frictional force, as does the shape of the coil, but that the overall length of the coil is relatively unimportant in determining the amount of frictional force from pushing and pulling. Stiffer coils exerted more frictional force, so that a stiffer metal such as tungsten exerted more frictional force when compared with coils of the same shape constructed of softer metal. In a similar fashion, coils constructed of the 0.004-in wire stock exerted more frictional force than coils constructed of the 0.003-in wire stock. The shape of the coil, rather than the length of the coil, significantly influenced frictional force within the catheter as well. The frictional force required to push or pull a microcoil varies with the diameter of the turns in the 3-D shape and the complexity of these turns. For example, when the two helical coils were compared, the helical coil with the 4-mm-diameter turns exerted far more frictional force than the helical coil with the 8-mm-diameter turns, despite the shorter length of the 4-mm-diameter coil. However, when comparing the complex pretzel shape with the simple helical shape, the complex pretzel shape with a 4-mm-diameter turn exerted far more force than the simple helical shape with a 4-mm-diameter turn. This difference was seen despite the fact that the complex pretzel-shape coil was significantly shorter than the helical-shape coil.

Coil stability after placement in a pulsatile flow system is certainly an important characteristic, particularly when evaluating coils for use in high-flow regions. One report has shown in an aneurysm model used in dogs that simple helical or flower petal designs are more stable within an aneurysm than simpler linear or circular coils (9). Another report has tested platinum coil stability in an in vitro system using plastic tubes that mimic straight blood vessels (10). These data showed that coils that maintained their circular geometric shape and were closely matched to the diameter of the plastic tube were more stable within the tube. The results obtained in this article show that softer coils are more likely to prolapse from a glass aneurysm model. This prolapse is caused by the deformation that occurs in the 3-D shape of the coil after placement in a pulsatile system. Factors that then contribute to stability include those factors that contribute to coils stiffness. The 0.004-in coils were more stable than the 0.003-in coils, and coils constructed of the stiffer metal (tungsten) were more stable than coils constructed of the softer metal (nitinol). In the 0.003-in category the data also suggest that the larger-diameter helical coils are less stable than smaller-diameter helical coils or complex pretzel-shape coils, although the number of experiments performed is too small to establish statistical significance. In areas of particularly high flow where coil stability may be troublesome, a stiffer coil may have an advantage, other factors being equal.

Data such as these suggest that a family of coils with variable physical characteristics may be optimal for treating different intravascular lesions. When one is treating a lesion that is difficult to access with a catheter because of tortuous route, and flows are relatively slow or there is a geometry to the vascular structure that suggests the coil will be in a stable position, a softer coil may be more optimal. On the other hand, when one is treating a lesion that has a more direct route to catheterization, and stability of coil placement may be affected by high flow or the geometry of the local environment, a stiffer coil such as tungsten or the 0.004-in coils may be optimal. Certainly other factors will influence the decision about the use of various coil materials. These include the short- and long-term changes that occur with coil placement in an intravascular environment such as thrombogenicity, inflammatory action, healing, and endothelial overgrowth. Further in vivo testing will be necessary to evaluate different coil materials more fully.

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