Review

Catheter design primer for neurointerventionalists

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ABSTRACT

Neurovascular catheter technology has rapidly evolved over the past decade. While performance characteristics are well known to the practitioner, the design features of these new-generation catheters and their implications on performance metrics remain a mystery to most clinicians due to the limited number of available resources. This knowledge gap hampers informed device choices and also limits collaboration between clinicians and engineers. To aid fellow neurointerventionalists, in this primer we have summarized the basic concepts of catheter design and construction.

INTRODUCTION

Catheters and sheaths of many types represent the backbone of the interventionalist's trade, yet few if any resources are available to teach the community basic concepts in device construction. This deficiency in resources is compounded as specialty devices such as distal access catheters encompass more and more advanced design and construction features. While performance characteristics are well known to the practitioner, including essential features such as proximal support, distal trackability, and lumen size, exactly how the catheter engineer achieves stated performance goals remains a mystery to most clinicians. In this primer, we introduce the basic concepts of catheter design and construction to the practicing interventionalist.

HOW ARE CATHETERS BUILT?

The basic concepts of catheter construction are fairly well preserved across devices. In short, catheters must be large enough to accommodate interventional tools and/or contrast injections, small enough to fit into standard arterial access sheaths, stiff enough to provide support proximally but soft enough to track distally through tortuous anatomies, resistant to kink, and lubricious within the inner lumen to facilitate device insertion and along the outer lumen to enhance tracking. To achieve these myriad features, the basic mode of construction encompasses four elements, including an extremely thin lubricious liner, typically polytetrafluoroethylene (PTFE), a supportive skeleton usually constructed from metallic materials, a polymeric jacket, and finally a hydrophilic coating, the latter of which is generally limited to the distal segments of the device. The material of construction, thickness, pattern, and extent of each of these elements is customized to the given clinical indication to achieve requisite distal tracking and device passage.

The construction process begins with the placement of the inner lubricious liner, typically PTFE, over a very stiff mandril (if metal) or core (if non-metal). Non-metal cores are preferred for the construction of soft devices where stretching out of the core, rather than simply pulling from a metal mandril, might damage the device. The desired features of the lubricious core include high lubricity, super-thin construction, and durability to avoid damage during device passage. For this reason, PTFE is by far the most common liner used in catheter construction. Thicknesses range from 0.0004 inches to 0.001 inches based on the inner diameter of the catheter.

In contrast to liner choice, which is quite limited, there are myriad choices of backbone type, pattern, material, and processing. Metallic materials primarily include stainless steel, which is relatively inexpensive, and nitinol, which offers the benefit of shape memory. For either material, however, the pattern of construction is highly variable. In general, wires are applied over the liner in either a coil or braid pattern, or both. These wires can be round or flat and generally range in size from 0.001 inches−0.004 inches for most neurovascular applications. Figure 1 demonstrates a bare core and a core with stainless steel braid and PTFE liner.

Coils are favored for their excellent hoop strength, to avoid ovalization or kinking. Design features that drive coil performance include wire diameter/thickness, with larger diameters providing more stiffness and kink resistance but limiting distal softness.

Multiple different coils can be used along the length of a catheter, as it is easy to terminate one coil type and begin another along the device. Pitch, or the distance between coil winds, markedly affects stiffness, kink resistance, and pushability, with wider pitch allowing better softness but elevating kink risk and worsening pushability.

Braids may achieve excellent stiffness and compared with coils are highly pushable but may be prone to kinking. Braid designs encompass numerous features, including number of wires, single or double "start" braids, braid pattern (under-over, etc.), and use of multiple different wire types within a single braid. Unlike coils, braids are relatively difficult to terminate in the middle of a catheter build. The primary drivers of braid performance are metal density (pics-per-inch or PPI), with higher PPI, in general, leading to more kink resistant and softer features. However, relationships across the full range of PPI may be quite complex with higher PPI initially leading to improved softness but, at the extreme, becoming stiff. As with coils, the diameter

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Figure 1 Example of bare core (A) and core with a PTFE liner and braid (B).

of the wire is the prime determinant of stiffness. Braid angle can also determine a catheter's performance. As braid angle decreases, the direction of the braid wires becomes more parallel to the longitudinal axis, which significantly increases the catheter's pushability. On the other hand, a higher braid angle implies that the wires' direction is perpendicular to the longitudinal axis. Therefore, with increasing braid angle, the braid structure becomes more similar to coils.

After adding reinforcement (coil, braid, or both), a polymer jacketing material is placed over the catheter shaft. This polymer material also contains a metallic (generally, bismuth, tungsten, or barium) radiopaque filler to increase the radiopacity. Polyether block amide (PEBA) and nylon are the most commonly used polymers. Nylon is preferred for its stiffness. On the other hand, PEBA is a softer polymer and can be modified with nylons to combine the flexibility of polyurethanes and the strength of nylons. Manufacturers can determine the proportion of nylon in the PEBA mixture and thus can control the catheter's flexibility and stiffness. Therefore, PEBA is highly preferred in the design of neurovascular catheters.

At the final stage, the catheter is dipped into a polyurethane-based hydrophilic coating solution and withdrawn at a known speed. Next, the hydrophilic coating is cured with heat or ultraviolet light. Multiple dipping cycles might be required to achieve the desired coating thickness. The general structure of neurovascular catheters is summarized in figure 2.

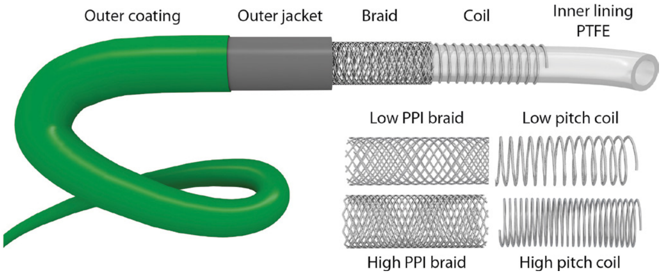

Figure 2 Structure of modern neurovascular catheters. In general, wires are applied over the core and inner liner (generally polytetrafluoroethylene) in either a coil or braid pattern, or both (hybrid design). The differences in coil and braid design features (braid angle and pics-per-inch for braids, and pitch for coils) can substantially affect the performance characteristics of neurovascular catheters. While it is not demonstrated in this figure, it is important to note that coil and braid structure can vary between different segments of the same catheter (e.g., different braid pics-per-inch values between proximal and distal segment). The outer jacket covers coil and braid wires and generally contains a radiopaque filler material. The outer hydrophilic coating is the outermost layer of catheters and reduces the friction during catheter navigation.

QUALITY CONTROL

A number of mechanisms are used to control the quality of a catheter's construction. The first of these is a manufacturing process document, which is used as the step-by-step guide to build each individual product. The document details the build steps, uses in-process inspection steps at key milestones to filter out faulty parts, and features a final inspection that measures key dimensions such as outer diameter using a triple-axis micrometer. Device features that are not inspected go through process validation to statistically verify the output to avoid inspection. A good example of this would be hydrophilic coating length. A regulatory-driven sample size of catheters will be built to validate that the coating process yields the proper coating length by applying a purple dye (Toluidine Blue) to the finished catheters that only bonds to the normally clear hydrophilic coating allowing it to be measured.

The Food and Drug Administration (FDA) and other regulatory authorities mandate the quality control of in-process and finished medical devices, and each catheter manufacturer employs different stringent quality control standards to limit device malfunction in the clinical setting. However, it is important to note that these quality control steps do not entirely prevent catheter malfunction and associated adverse events. For example, currently, there are more than 1000 reported reperfusion catheter malfunctions in the FDA's Manufacturer and User Facility Device Experience (MAUDE) database, and approximately 10% of these malfunctions are associated with clinical adverse events.[1] There are also published case studies showing that catheter tip ballooning and rupture during the procedure can result in permanent neurologic deficits and death.[2] Therefore, post-marketing surveillance is also one of the most important quality control steps.

MECHANICAL PROPERTIES OF CATHETERS

Durometer scale

Durometer scale is a measure of an elastomer's hardness and has been widely used by medical catheter engineers as a surrogate for comparing the flexibility of different polymers.[3] In this scale, higher values indicate stiffer materials and usually lower flexibility.[3] On the other hand, flexural modulus is the measure of a material's tendency to bend.[4] In general, there is a correlation between the material's hardness and flexural modulus. However, durometer scales are still an indirect measure of flexibility, and therefore, a softer durometer does not always mean better flexibility.[4 5] Additionally, the durometer scale does not correlate well with other catheter performance metrics such as kink resistance, torquability, and pushability.

Euler-Bernoulli's beam equations

Similar to cantilever beams, endovascular catheters are fixed and supported at only one end (proximal end; introducer sheath) and are free at the other end.[6] Therefore, Euler-Bernoulli's beam equations for isotropic materials can also be employed to compare the mechanical properties of catheters.[7 8] Contrary to durometer scales, these equations use material-specific modulus values and, therefore, provide more accurate estimates of the mechanical properties of catheters, including kink resistance and dimension-specific rigidity values (axial, flexural, and torsional rigidity).

Flexural rigidity

Flexural rigidity (or bending stiffness) of a catheter refers to the force couple required to bend the catheter. The vessel wall applies a perpendicular force to the long axis of the catheter at vascular curvatures. If this force overcomes the flexural rigidity of the catheter material, the catheter bends and adapts to vascular curvature. However, if the flexural rigidity is too high or, in other words, the catheter is resistant to bending, this force can cause significant stress to the vessel wall.[8] This can lead to dissection or vessel rupture. Therefore, low flexural rigidity is desired in neurovascular catheter design.

For a catheter consisting of a homogenous and isotropic material, flexural rigidity can be calculated with the following formula[8]

$$\textit{Flexural rigidity} = \frac{E\pi\left(D^4 - d^4\right)}{64}$$

E=modulus of elasticity of the catheter material
D=outer diameter of the catheter
d=inner diameter of the catheter

Axial rigidity and buckling force

Axial rigidity refers to the force required to produce axial deflection. In catheter design applications, axial rigidity is typically measured with Euler's Buckling formula.[8] In vascular curvatures such as iliac bifurcation or aortic arch, the vessel wall exerts an axial force on the catheter's distal tip and compresses the catheter along its long axis. If the force required to buckle the catheter (critical buckling force) is low, the catheter can easily adapt to vascular curvatures. However, if the critical buckling force is high, the vessel wall cannot deflect the distal tip, and subsequent pushing attempts can result in vessel rupture. Therefore, materials with low axial rigidity are preferred in catheter design.[8]

For a catheter consisting of a homogenous and isotropic material, the buckling force can be calculated with Euler's Buckling formula:[8]

$$\textit{Buckling force} = \frac{E\pi^3\left(D^4 - d^4\right)}{64\left(\beta l\right)^2}$$

E=modulus of elasticity of the catheter material
D=outer diameter of the catheter
d=inner diameter of the catheter
β=clamping factor
l=catheter length

Torsional rigidity

Torsional rigidity refers to the elastomer's resistance to the angular twisting motion along its rotational axis. There is a strong relationship between the catheter's torquability and elastomer's torsional rigidity. As the torsional rigidity increases, proximal manipulations transmit more easily to the distal tip. Additionally, applied force results in smaller distal tip movements with increasing torsional rigidity, and this provides more precise catheter control.

Torsional rigidity can be measured with two formulas based on distal tip moment or modulus and wall thickness:[8]

$$\textit{Torsional rigidity} = \frac{G\pi\left(D^4 - d^4\right)}{32} = \frac{l\,M_t}{\varnothing}$$

G=shear modulus of rigidity of the catheter material
D=outer diameter of the catheter
d=inner diameter of the catheter
l=length of the catheter
M_t=twisting moment
Ø= twisting angle

Table 1 Relationship between design features and performance metrics

Feature	Stiffer	Kink resistance	Torquability	Pushability
Outer Jacket				
Size	Thicker	Thicker	Thicker	
Material type	Higher durometer	Lower durometer	Higher durometer	
Dimensions				
Lumen size	Larger	Smaller	Larger	
Wall thickness	Thicker wall	Thicker wall	Thicker wall	
Coil construction				
Wire size	Thicker wires	Thicker wires	Thicker wires	
Wire material	Stainless-steel wires	Nitinol wires	Nitinol wires	
Pitch	Narrow pitch	Narrow pitch	Narrow pitch	Narrow pitch
Braid construction				
Wire size	Thicker wires	Thicker wires	Thicker wires	
Wire material	Stainless-steel wires	Nitinol wires	Stainless-steel wires	
PPI*	Lower PPI	Higher PPI	Lower PPI	Lower PPI

*Higher PPI initially increases the catheter's flexibility, however, at extreme PPI values the catheter becomes stiff.
PPI, pics per inch.

Kinking

Increasing bending movement decreases the curvature radius of the catheter. The catheter kinks after reaching the critical curvature radius, and its lumen gets occluded.

We can calculate the critical curvature radius with the following formula:[8]

$$\textit{Radius}_{\textit{critical}} = \frac{\left(1 - \upsilon^2\right) r^2}{Kt}$$

r=External radius of the catheter
t=wall thickness
υ=Poisson's ratio
K=kinking constant of the material

RELATIONSHIP BETWEEN DESIGN FEATURES AND PERFORMANCE

Based on the formulas listed above, relatively simple physical relationships can be gleaned before construction. Note that features such as bending stiffness and bucking force are related to the fourth power of the outer diameter, meaning that achieving the desired softness of a large-diameter device may be challenging, and high stiffness of a small-diameter device will similarly be difficult. Table 1 summarizes the relationship between design features and performance metrics.

In general, holding all other features constant, the following relationships are manifest:

Kink resistance

A lower durometer and thicker jacket, smaller inner diameter (ID), thicker catheter wall, and thicker coil/braid wires provide better kink resistance. Additionally, nitinol wires are more kink resistant than stainless steel wires.[9]

Stiffness and torquability

Stiffness and torquability increase as the fourth power of wall thickness. Also, smaller ID, thicker and higher durometer outer jacket are characteristics that increase the stiffness and torquability. Additionally, coil and braid design and wire features can affect the catheter's stiffness and torquability. Stainless steel wires are stiffer and provide better torquability than nitinol wires.[9] Also, the braided design provides better stiffness and torque control compared with coils.

There is a constant relationship between a polymer's stiffness and elasticity moduli (G/E: 0.4–0.5).[8 10] Therefore, it is not feasible to achieve low flexural rigidity and high torquability with conventional catheter design strategies. For this reason, we still do not have a single perfect catheter, and tradeoffs are required in how we design catheters depending on their specific performance requirements. For example, high torquability is imperative for diagnostic catheters to achieve selective vessel catheterization. However, torquability comes with high flexural rigidity, which explains why we can advance an 8F aspiration catheter to a middle cerebral artery but cannot advance a 4F diagnostic catheter to a distal extracranial internal carotid artery.

PERFORMANCE REQUIREMENTS AND DESIGN FEATURES OF DIFFERENT CATHETER TYPES

Guiding catheters

Guiding catheters are used to provide support for distal access. An ideal guiding catheter should not kick back into the aorta with pushing attempts and should offer a stable platform. For this reason, stiffness is crucial for guiding catheters. Stainless steel wires are five times stiffer than nitinol,[9] and a braided design provides significantly better stiffness than coils. Therefore, in design manufacturers usually prefer stainless-steel braids. Additionally, stiffer outer jackets such as nylon and high-durometer PEBA are commonly employed.

Microcatheters

Reaching distal small caliber vessels requires advanced engineering applications and complex design. Manufacturers usually employ a hybrid braid/coil design with varying pitch and PPI values along the microcatheters. In general, stainless-steel braids are employed proximally for support and torquability; and tight-pitched coils are preferred distally for better device trackability through tortuous anatomy. Also, softer polymers, such as low-durometer PEBA, are used as outer jackets to prevent vessel injury.

Diagnostic catheters

Diagnostic catheters are primarily used for selective proximal vessel catheterization. Therefore, torquability and precise control are imperative for diagnostic catheters. Since torquability and stiffness are closely related, manufacturers usually prefer stiffer materials in design, such as stainless-steel braids and nylon outer jackets. However, torquability comes with increased stiffness, which prevents the use of diagnostic catheters in distal tortuous vasculatures.[8]

Distal access and aspiration catheters

The aspiration flow increases as the fourth power of the inner diameter. Therefore, thin walls and larger inner diameters are desired in aspiration catheter design. However, advancing large-bore catheters through tortuous intracranial vessels is surely not without risks. Therefore, flexibility is essential in a large-bore distal access or aspiration catheter design. On the other hand, while offering a certain level of flexibility, the catheter's skeleton should also be strong enough to prevent catheter collapse under negative pressure. Additionally, maintaining pushability at the soft distal segments of these catheters is a major challenge. Therefore, aspiration catheter design is one of the most complicated fields in medical device engineering.

Manufacturers nearly always employ a hybrid braid and coil design for large-bore catheters. Like microcatheters, braids are used proximally for support, and coils are employed distally for better device trackability and hoop strength (resistance to collapse under negative pressure). However, in contrast to microcatheter design, stainless steel wires do not dominate the field. Nitinol wires offer better shape memory and kink resistance, potentially limiting kickback into the aorta and providing better pushability at vascular curvatures. Therefore, stainless steel and nitinol wires are equally popular in large-bore catheter designs. Additionally, softer outers are preferred for large-bore catheters, and nearly every manufacturer uses PEBA polymers due to their flexibility.

Future directions

Neurovascular catheter technology has been evolving at a rapid pace. Recently, a few super-large bore devices with inner diameters ranging between 0.088 and 0.096 inches have entered the market, and preliminary clinical studies support their safety and efficacy.[11–13] Additionally, there is growing interest in using steerable microcatheters, and recently, the FDA has for the first time approved the use of a steerable microcatheter in neuroendovascular procedures.[14] There are also exciting new technologies on the horizon, such as steerable magnetic catheters. With this technology, computer-generated magnetic fields can be used to navigate the catheter and control its tip. This could be an important milestone for teleoperated neurointerventional procedures.

CONCLUSION

Every catheter has a unique design and therefore has different merits and limitations. Generally, interventionalists develop their knowledge on the performance of catheters with clinical practice. Even though this will always be the most reliable method, it also has several limitations. There are various catheters available on the market, and it is not practical to gain comprehensive knowledge about all of them through clinical practice. However, obtaining at least a basic knowledge of catheter design can provide insights to the potential clinical performance characteristics of catheters. Therefore, we recommend fellow interventionalists to pay attention to catheter design features and reconcile clinical performance and catheter design features in their clinical practice. Thus, interventionalists can make better initial device choices and limit device-related complications and procedure time.

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