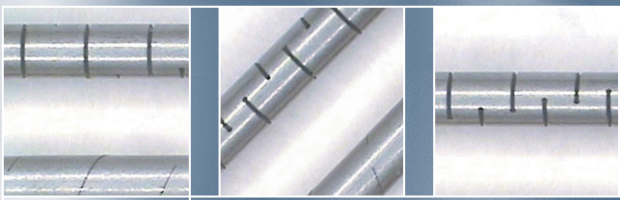
Metal Shafts:
Designs To Meet The Required Performance



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When designing shafts for minimally invasive devices such as catheters and guidewires, features that improve one area of performance may hinder performance in another area. This article describes how the traditional limits of metal shafts can be extended to enable their use in a variety of new applications.

The challenge to deliver

There has been a surge in growth in almost all sectors of the minimally invasive medical device industry in recent years. Cardiology devices, possibly the biggest market, is expected to experience growth of more than 12% in the next year, and the neurovascular markets and peripheral vascular markets are predicted to grow in excess of 30% and 9%, respectively, in the same period.[1] To a large extent this growth has been fuelled by developments in treatment options such as new drugs, procedures and device concepts, which are being developed on an increasingly regular basis. These new treatment options require physicians to reach new areas of the anatomy with an increasing emphasis on lower profile systems. As a consequence, delivery-system designs and materials are continually being challenged to keep up with these new treatments.

Many of the shaft performance characteristics of modern delivery systems are subjective. They are most commonly measured using comparative, company-specific tests that make absolute comparisons almost impossible. There also appears to be a variation between companies on the terminology used to describe many shaft performance requirements. For this reason, an explanation of the most common performance requirements are proposed below.

Definitions

Pushability. The ability of the shaft to transmit energy from one end of the catheter to the other, typically from the proximal to distal end as the shaft is advanced in the patient. A shaft's pushability can be improved by increasing its wall thickness, reducing its overall length, or increasing the stiffness of the material used to make the shaft. Pushability is often measured as a ratio of the force applied to the proximal end of the shaft *to* the corresponding force recorded at the distal end.

Torqueability. The ability of the shaft to transmit a rotational displacement along the length of the shaft. In applications where torque is important a 1:1 torque ratio is the desired result. With this torque response, a given angular rotation of one end of the shaft will directly relate to a similar rotation of the opposing end. Torque performance is most often expressed as the ratio of the angular rotation applied to the proximal end of the shaft *to* the corresponding rotation measured on the distal end. Torque performance can be improved by increasing the wall thickness of the shaft, increasing the shear stiffness of the material used to make the shaft, or decreasing the overall length of the shaft.

Kink. A measure of a shaft's ability to maintain its cross-sectional profile during deformation. The combination of forces required to kink a tube can occur in two situations. The first occurs when the shaft is being tracked around a tight bend. Once the bend reaches a certain radius, the compressive forces on the tube cause a collapse of the wall on the inside of the bend. The second occurs when the shaft is in the user's hands; it is possible to exert a compressive force on a section of the shaft, which will force the shaft to deform with a tight radius that can also result in kink failure.

Trackability. The ability of a shaft to travel or track through tortuous anatomy. This is often measured as the force required to push a shaft through a defined path. From the point of view of the shaft, trackability is influenced by the flexibility of the shaft and can be improved by reducing the shaft's outer diameter (o.d.) or decreasing the material's elastic modulus.

Optimising performance

From the definitions above, it is evident that not all of the desired performance requirements can be optimised at once. For example, design guidelines to maximise →

pushability are almost the direct opposite of those seeking to improve trackability. The challenge for the shaft designer is to find the optimum compromise for the particular application and anatomy in question.

Systems have been developed for the delivery of angioplasty balloons, stents, occlusion balloons, drugs, filters, light, cryogenic energy, aneurysm coils and pressure sensors to many different parts of the human anatomy. In all applications, product designers continually strive to increase the performance of the delivery system. Despite the diverse range of applications, the designers of these devices still struggle with the same performance characteristics. The primary function of a minimally invasive medical device shaft is to facilitate the delivery of a treatment from outside the body to the locally affected site. In most cases, the proximal end of the shaft must be relatively stiff to provide pushability to the device and allow pushing without risk of kinking. The distal end of the shaft should be flexible enough to traverse the tortuous anatomy to reach the treatment site. Throughout the length of the shaft the designer seeks to minimise the outer profile of the device to facilitate access through smaller openings and thus enable the use of smaller access sheaths or guide catheters. At the same time, consideration must be given to keeping the working inner lumen of the device as large as possible to facilitate more efficient treatments. In addition, the materials used for the shaft must be biocompatible[2] and chemically resistant. Finally, of course, cost will be a consideration in almost all designs.

Materials

Shaft materials can be divided into three general categories.

Metal shafts. The most common material in this category is stainless steel. Its high elastic modulus allows it to exhibit excellent pushability and torque, but at the expense of flexibility. Nitinol shafts can be included in this category, but their extremely high-cost, lower elastic modulus and processing difficulties make them a less attractive option for many applications.

Polymers. Although there is a vast range of compounds in this category, nylon polyurethane and polyethylene are some of the most commonly used materials for shafts. Polymer materials have a lower elastic modulus than is typical of metal shafts, but greater flexibility. In addition, they can have excellent biocompatability and lubricious properties.

Composite shafts. Typically, these consist of a woven metal mesh as the matrix in a polymer composite. These shafts display excellent torqueability and high burst pressures compared with pure polymer tubes.

Figure 1: Patterns that improve flexibility or torque transmission.

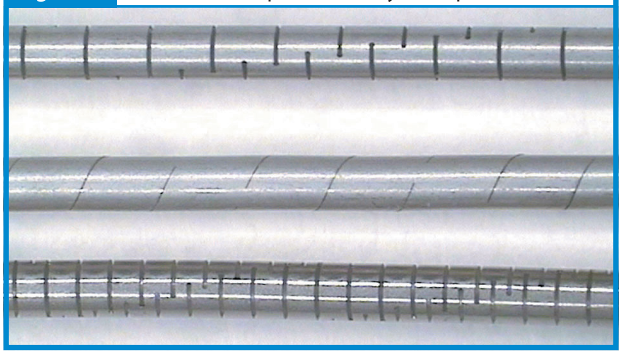
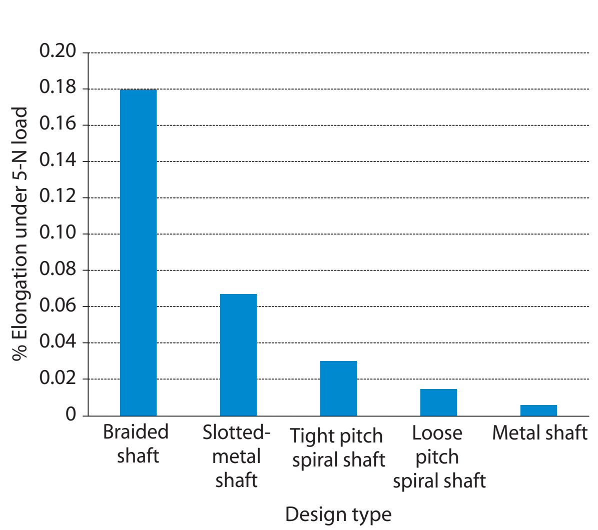


Figure 2: The percentage of elongation of each shaft under a 5-N tensile load.



Metal-shaft design

For all shafts, stiffness is dependent on the material's elastic modulus, its o.d. and inner diameter (i.d.). In this article, consideration is given to extending the traditional limits of metal shafts to enable their use in a variety of new applications. The designs can also allow seamless transitions between shaft sections with different performance characteristics.

A great amount of the design work in medical devices today is devoted to optimising the transitions between various sections of the device. With flexible, laser-profiled, stainless-steel shafts, stiffness transitions can be easily incorporated into the design. The stiffness of various shafts can be measured using a three-point bend test or other deflection-based methods. With this information, the stiffness of the adjoining shafts can be matched to give an almost flawless transition. In addition, the stiffness of various sections of the shaft can be accurately controlled and modified over a predefined distance. Design engineers have optimised a number of patterns that can improve flexibility or torque transmission (see Figure 1). Anisotropic designs (designs with different performance characteristics in varying directions) can also be cut where the tube displays various degrees of flexibility in more than one plane. When necessary, jackets can be applied to the shaft to seal it, to reduce the o.d. friction or to facilitate heat bonding of other components to the shaft.

Case study

The fabrication of laser-cut, flexible, stainless-steel shafts is described here. In this application, 304 stainless-steel hypotubes were processed and passivated in the normal way.[3]
A laser-cut pattern was cut in the tubes using a pulse Nd-YAG laser (Rofin-Baasel[4]). The kerf of the cutting width of the laser beam was less than 20 µm, which resulted in a minimal 5-µm heat-affected zone.
In this example, the laser-cutting system was originally designed to cut coronary stainless steel stents, but it had been customised to work with long tubes. In this design, the laser beam was held fixed while the tube was rotated and advanced under the laser beam. When correctly focussed, the laser cuts through the wall of the tube. With this technique, laser-cut profiles of almost any design can be processed relatively quickly.
Once the tube profile has been cut, cleaned and passivated, a jacket can be applied to the shaft. This jacket can be achieved in a number of different ways. With current technology, the most cost-effective option is for the jacket to be extruded directly over the stainless steel tube. Other methods include heat shrinking, where a polymer jacket contracts to a preset diameter on exposure to a certain temperature, typically in excess of 100 °C, and discrete bonding of extrusions to the shaft.

The following is an outline of two particular applications where profiled metal shaft designs have been able to offer a performance benefit in areas where metal shafts would traditionally not have been considered.

Figure 3: The minimum bending radius before the shaft kinks. In this example, flexibility is measured as the ability of the tube to resist kinking. It can be seen that the braided shaft and the slotted, profiled metal shaft have almost identical kink properties.

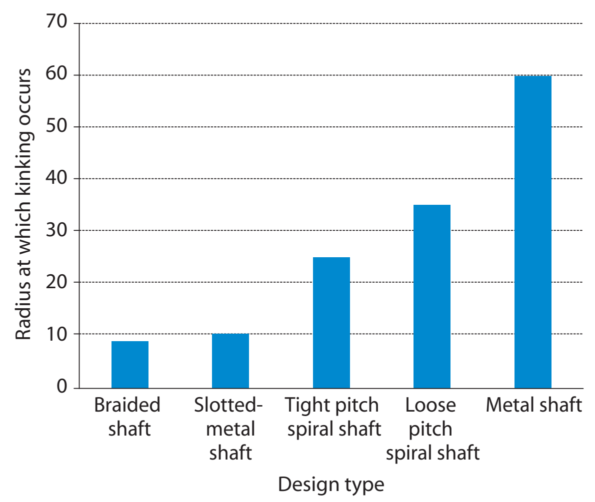
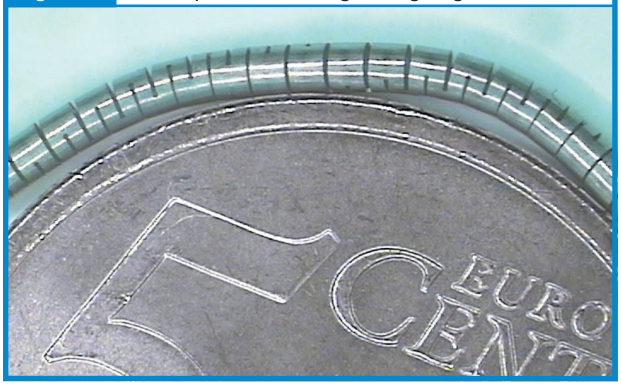


Figure 4: A laser profiled shaft negotiating a tight radius.



Application one: pushability

Delivery shafts for peripheral, self-expanding stents experience high tensile and compressive pull forces. This high force can be attributed to the high force required to deploy the self-expanding stent from its outer protective sheath. The outer sheath is often polymer lined and can result in the stent struts becoming embedded in the polymer liner. As the stent continues to exert an outward radial force, the force to move the stent from the outer liner can be high. In this case, extension of the outer or inner shafts under loading can result in a lack of accuracy during placement of the stent.

To optimise the accuracy of stent positioning, the shaft should be flexible enough to reach the carotid artery or the biliary duct, but should not extend or contract under the large forces required to deploy the stent. Until now, braided and polymer shafts have been the design of choice for this application. Pure polymer tubes have the flexibility, but cannot withstand the large deployment forces. Solid metal shafts can sustain the forces with minimal extension, but have not been flexible enough to negotiate the relevant anatomy. For this reason, braided shafts have been used in the vast majority of self-expanding, stent-delivery systems. The results presented in Figure 2 suggest that profiled metal shafts are an ideal solution to this design problem. It is no surprise that the solid metal shaft shows the least deformation and the braided shaft exhibits the most deformation under the applied load. For all options, the o.d. of the tubes remained the same. Figure 3 shows the tested flexibility of the profiled metal shafts and Figure 4 creates an impression of the real flexibility of these shafts.

Figure 5 shows the o.d. and i.d. profile of the different shaft options. For effective comparison, the o.d.s of all the selected tubes were as close as possible. The o.d. of the profiled designs was 0.001 in. (0.0254 mm) →

Figure 5: Shaft o.d. and i.d. and profiles.

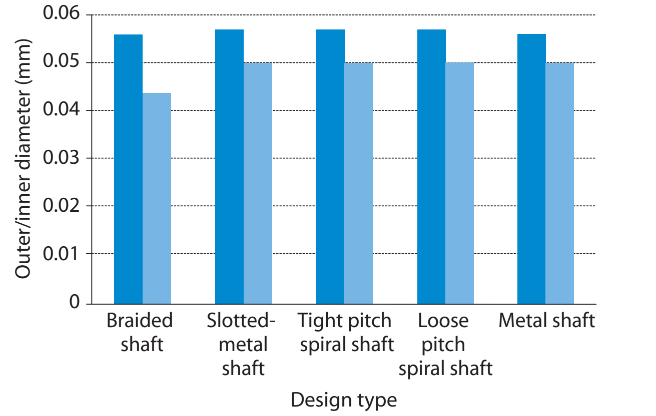
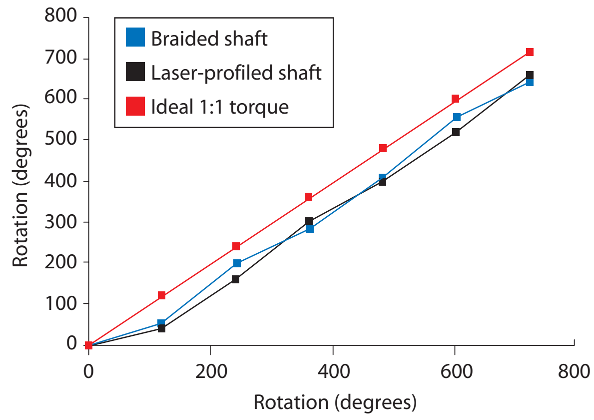


Figure 6: Torque response of a braided shaft and a laser-profiled tube. The shafts are compared with the ideal 1:1 torque response.



higher than the other designs because a 0.0005-in. (0.0127-mm) thick single-wall polyester heat-shrink layer was applied to the o.d..[5] The nature of the braiding process meant that the braided tube design had a significantly smaller i.d. and, therefore, a smaller working lumen.

Application two: torque performance

In many applications, torque response is essential for good product performance. Traditionally, polymer-braided shafts using high-tensile wire at a tight pitch have shown the best product performance. Figure 6 shows the torque response of a braided shaft and the comparative response of a profiled metal shaft. In addition to the superior torque performance, the profiled metal shaft has advantages in terms of profile and pushability, however, it does not have high burst pressure.

The torque-response test was performed using an 8Fr guide catheter that was immersed in water at 37 °C. The guide catheter was tracked through an anatomy model built to represent the human aortic arch. The results indicated that stainless steel shafts can be designed to give good torque response in an anatomy, where stainless steel tubing would previously not have been considered because of its high stiffness. In this instance, the stainless steel construction has the added benefit of offering a 30% reduction in the shaft wall thickness in typical applications.

Pushing performance boundaries

It is clear that there are many competing performance considerations to take into account when designing a medical device delivery shaft and individual performance features cannot be designed in isolation. With this in mind, the job of the designer is to obtain the best possible combination of features for the particular application. The applications considered here allow designers to develop the flexibility associated with a polymer shaft and the torque response associated with a braided shaft in a single product. In some cases, this allows the designer to facilitate shaft performance outside the traditional constraints imposed by material properties. It moves the industry closer to the possibility of designing a shaft that will "flex like a polymer and push like steel." mdt

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