Insights for More Efficient Braided Catheter Development

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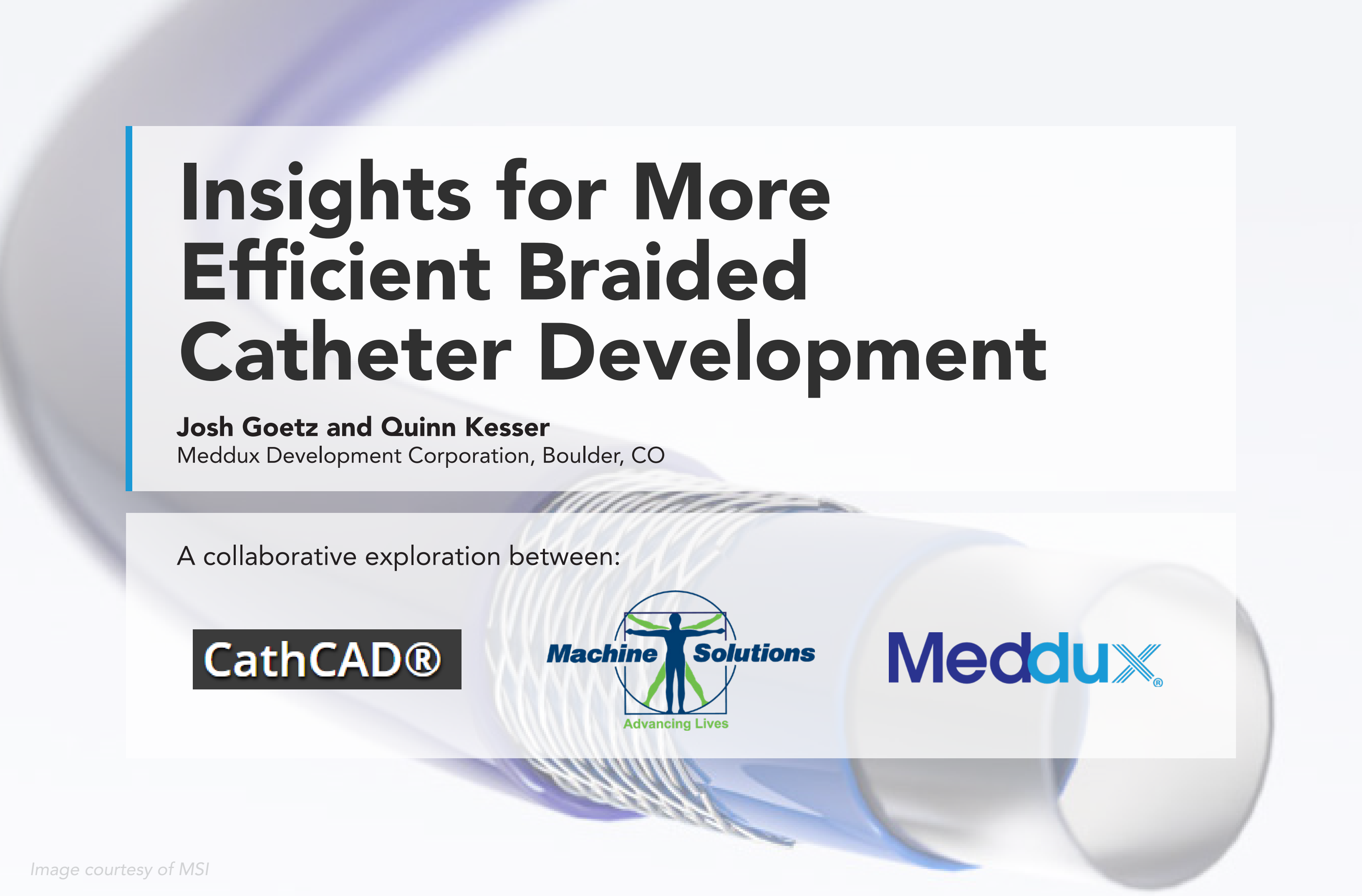
A collaborative exploration between:

CathCAD® Machine Solutions Advancing Lives Meddux®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> Do more expensive braid patterns deliver performance gains that are worth the added cost in a typical interventional application?

Abstract

Catheter reinforcement using braid or coil is often utilized by medical device developers to optimize functional performance including kink resistance, flexibility, and torque. Traditionally, developers have had to rely on experience and several iterations of design, prototyping, and testing to optimize catheter functionality and meet the clinical performance requirements. The development of CathCAD® analytical software has streamlined catheter development by allowing users to perform iterative analysis in software to accurately predict catheter functional characteristics before spending valuable resources on fabricating prototypes. While CathCAD® allows the user to configure reinforcement material, profile, number of strands, and density, the software does not differentiate between braid patterns in its algorithm. Common opinion is that more expensive braid patterns significantly improve catheter performance, but do more expensive braid patterns deliver performance gains that are worth the added cost in a typical interventional application?

This paper explores the correlation of CathCAD® predicted and empirical catheter performance data and the impact of braid pattern on catheter performance and manufacturing cost.

Background

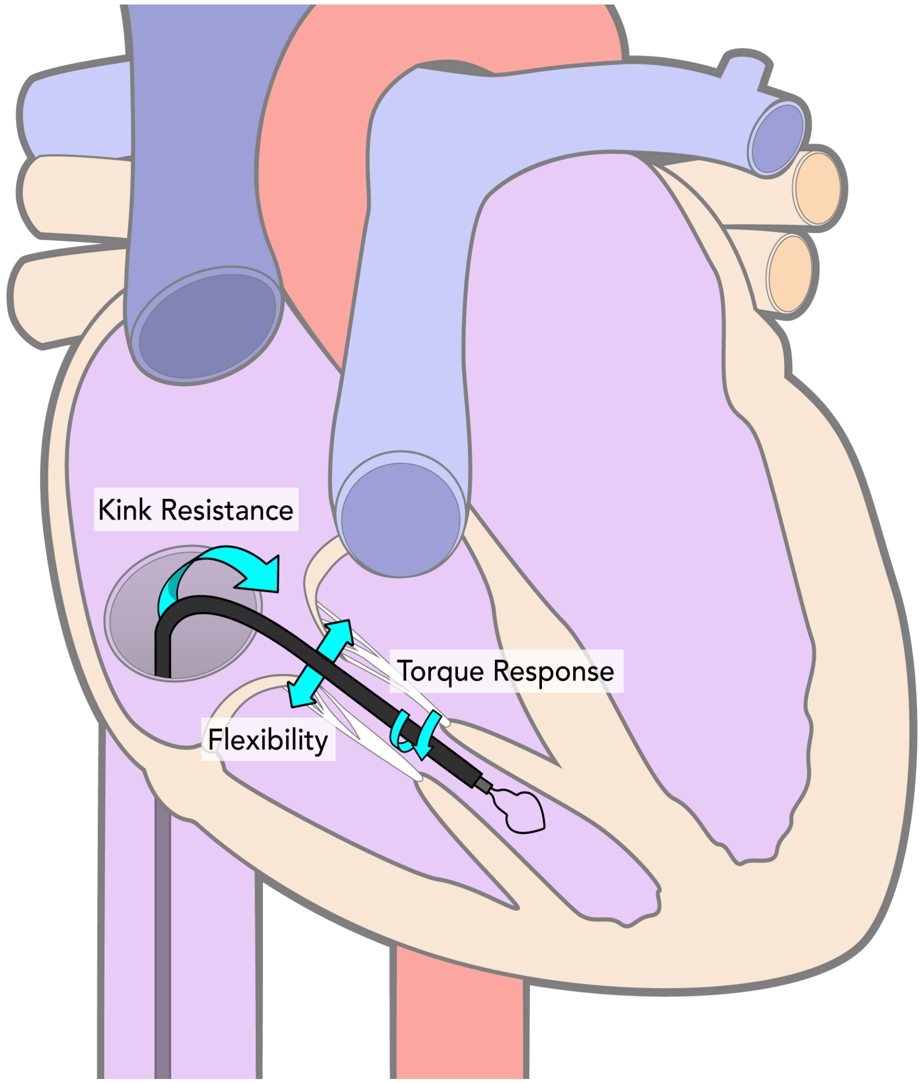


Figure 1. *Three important catheter performance characteristics in an interventional procedure.*

Advancement of Interventional Therapeutics and Minimally Invasive Surgery
Over the last 40 years, interventional and minimally invasive surgical procedures have revolutionized nearly every surgical specialty to improve patient standard of care. The shift to less invasive treatments has required the development of devices capable of navigating torturous anatomy from a variety of clinical approaches, whether intravascularly, endoscopically, or laparoscopically. In particular, the innovations in interventional cardiology and radiology have been driven by advances in manufacturing technologies leading to more specialized and miniaturized catheter-based devices. Medical device engineers have an ever-expanding array of options for developing catheters for the next frontier of clinical treatments.

Braid Reinforcement and Performance Characteristics
Catheter engineers often utilize braid, coil, and sometimes combination reinforcement to optimize catheter functionality. Figure 1 depicts the importance of three catheter performance characteristics, kink resistance, flexibility, and torque response in an interventional procedure. In this application, the catheter is introduced percutaneously through the right femoral vein and advanced into the right atrium of the heart. To gain access to the right ventricle, the device must be deflected and torqued without kinking into an orientation allowing passage through the tricuspid valve. Catheter reinforcement allows the designer to optimize these performance characteristics while maintaining a low profile, which allows for less invasive access to the treatment site and reduced patient recovery time.

Catheter Design Approach
Medical device developers have traditionally relied on an iterative approach to catheter design. While this method can lead to design optimization, the approach is inherently inefficient and often costly. The development of CathCAD® in the early 2000s has modernized the catheter design approach by allowing users to analyze and predict the mechanical characteristics of catheters in a virtual environment, and thereby reduce design iteration that contributes to increased time to market and device cost. While CathCAD® allows users to easily configure reinforcement material, profile, number of strands, and density, the software does not differentiate braid pattern in its algorithm.

Purpose

Cost and Benefit of Common Braid Patterns

Figure 2 illustrates the most common braid patterns utilized in catheter design: regular, half-load diamond, and diamond, each with 16 strands. Regular braid pattern produces one wire under two and then over two ("1u2o2") and is the least expensive braid pattern to manufacture because this pattern runs twice as fast as the diamond patterns. Faster processing speed is a result of the horn gear on the braider needing to rotate only once per braid pick versus two gear rotations for the diamond patterns. A single wire alternately passes under then over another single wire ("1u1o1") in the half-load diamond pattern. To produce this pattern, the braiding machine must run at half load or 50% capacity (32 carrier machine for 16 wire pattern), which results in higher manufacturing cost. In the full-load diamond braid pattern, two wires side by side alternately pass under two wires and then over two wires ("2u2o2"). This pattern is cited to yield better kink resistance and higher torque response but is the most expensive braid pattern because it uses twice as much material as the regular and half-load diamond patterns at equivalent pick count.

Objectives

The lack of published cost-benefit data on catheter braid patterns makes design decisions difficult for catheter developers. The objectives of this paper are (1) to correlate CathCAD® predicted and empirical catheter performance data in a common shaft size, and (2) to quantitatively assess the value of braid pattern on catheter performance and manufacturing cost.

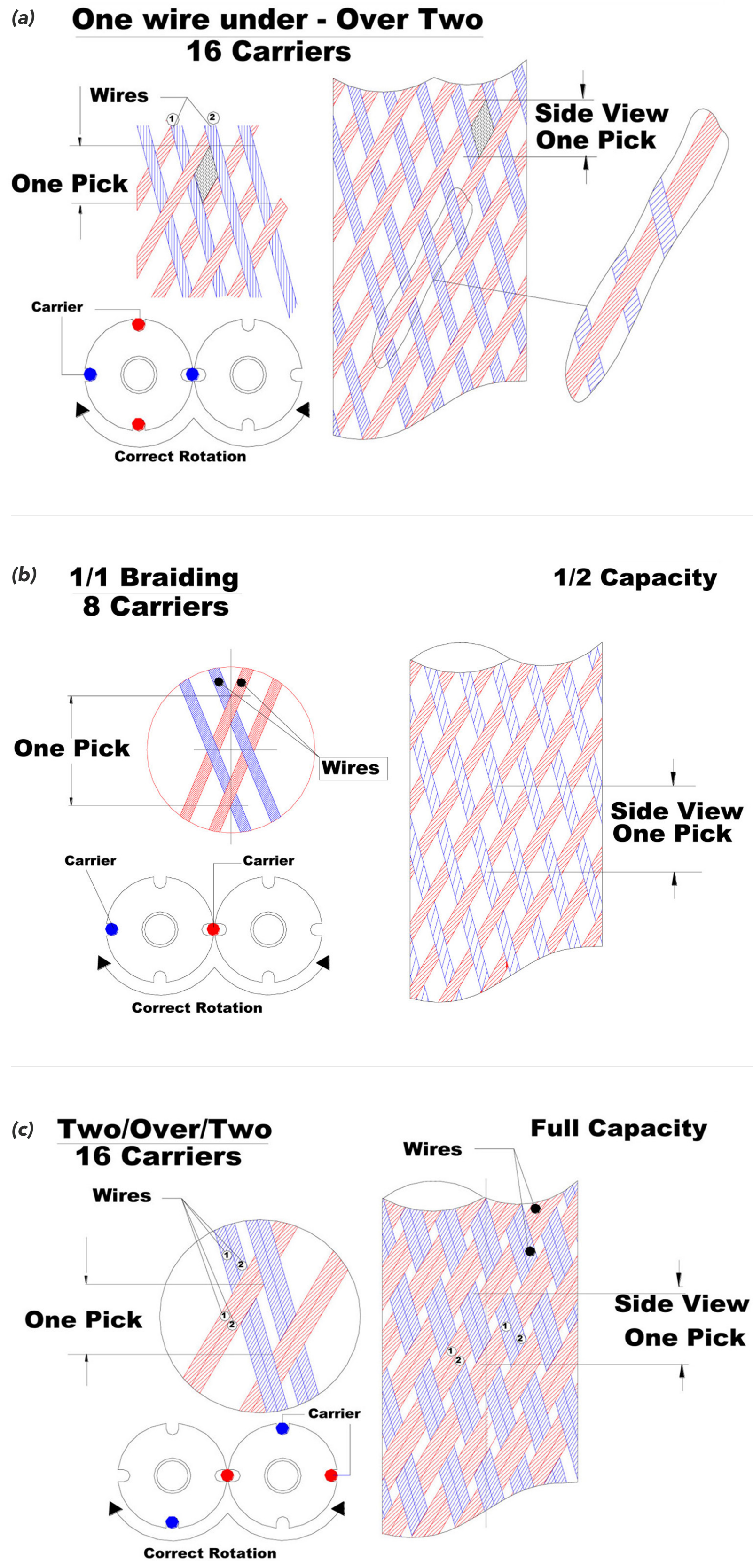


Figure 2. *Catheter braid patterns:* ***(a)*** *regular;* ***(b)*** *half-load diamond;* ***(c)*** *diamond.*
Images courtesy of MSI

Test Sample Design & Predictive Modeling

Table 1. *Braided catheter test sample designs.*

DESIGN CONSTANTS				
Description	**Imperial (in)**	**Metric (mm)**	**French (Fr)**	**Manufacturing Method and Material(s)**
Inner Diameter (ID)	0.075	1.91	5.7	N/A
Wall Thickness (WT)	0.007	0.18	0.5	N/A
Outer Diameter (OD)	0.089	2.26	6.8	N/A
Layer 1 (inside) WT	0.00100	0.0254	N/A	Film Cast PTFE
Layer 2 WT	0.00025	0.0064	N/A	Film Cast Pebax® 72D
Layer 3 WT	0.00200	0.0508	N/A	Extruded Pebax® 55D with 304V SS Braid
Layer 4 WT	0.00390	0.0991	N/A	Extruded Pebax® 55D
Braid Profile Thickness	0.001	N/A	N/A	N/A
Braid Profile Width	0.003	N/A	N/A	N/A
# of Braid Wires	16			N/A
Braid Picks per Inch (PPI)	38			N/A

DESIGN VARIABLES		
Configuration 1	**Configuration 2**	**Configuration 3**
Regular Braid Pattern	Half-load Diamond Braid Pattern	Diamond Braid Pattern

Test Sample Design

The test samples were designed with typical construction (laminated liner, braid, and jacket layers), materials (PTFE liner, stainless steel braid, and Pebax® jacket), and profile (7 French outer diameter) relevant to many minimally invasive procedures. A thin-wall design was utilized to highlight the effects of the regular, diamond, and half-load diamond braid patterns on catheter performance. The three test sample designs were identical except for braid pattern. All test samples were manufactured with flat, stainless steel braid wire. Table 1 contains detailed information on catheter test sample construction.

Predictive Modeling

CathCAD® was utilized to predict performance of the catheter design. Figure 3 illustrates the CathCAD® user interface with model inputs and outputs.

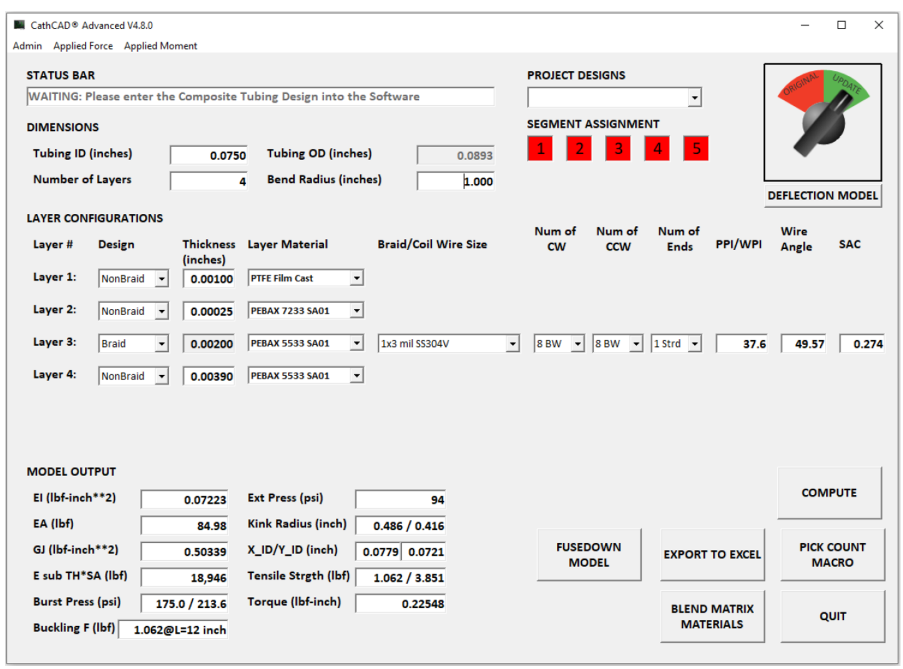


Figure 3. *CathCAD model for test catheter design. Image courtesy of Roth Technologies LLC*

Test Methods & Results

Three-point Bend Test

The three-point bend test illustrated in Table 2 is performed on a universal testing machine with a three-point bend fixture comprised of two test sample supports and a "nose" to apply a downward force on the middle of the test sample. The universal testing machine measures applied force and displacement which can be used to calculate flexural modulus of the test sample.

Kink Test

The test sample is positioned in an arch between two plates in the kink test per Table 3. A universal testing machine is used to capture a force versus displacement curve from which the kink radius of the test sample can be calculated.

Torque Test

A torque test is used to measure the applied torque to rotate a test sample. A torque versus angular displacement curve is captured with a universal test machine or custom fixture per Table 4 and can be used to determine the shear modulus of the test sample. Torque data was captured with the MSI Interventional Device Testing Equipment (IDTE) for this study.

The average measured value was compared to the CathCAD® predicted value for each test. The results are summarized below.

Table 2. *Three-point bend (flexural modulus) test results and percent error (predicted vs. measured).*

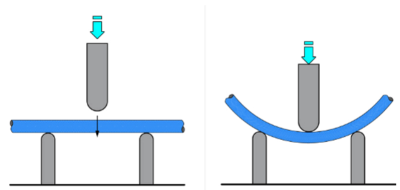
Diagram	Braid Pattern	Predicted Flexural Modulus (ksi)	Measured Flexural Modulus (ksi)	Percent Error (%)
	Regular (1u2o2)		46.61	2%
	Half-load Diamond (1u1o1)	46.05	44.71	3%
	Diamond (2u2o2)		46.36	2%

Table 3. *Kink radius test results and percent error (predicted vs. measured).*

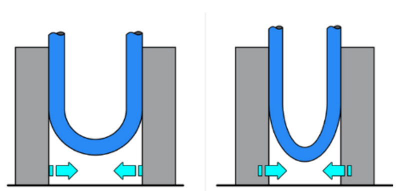
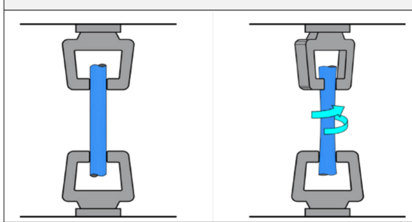
Diagram	Braid Pattern	Predicted Kink Radius (in)	Measured Kink Radius (in)	Percent Error (%)
	Regular (1u2o2)		0.470	4%
	Half-load Diamond (1u1o1)	0.451	0.460	2%
	Diamond (2u2o2)		0.440	2%

Table 4. *Torque (shear modulus) test results and percent error (predicted vs. measured).*

Diagram	Braid Pattern	Predicted Shear Modulus (ksi)	Measured Shear Modulus (ksi)	Percent Error (%)
	Regular (1u2o2)		163.90	2%
	Half-load Diamond (1u1o1)	160.48	157.80	2%
	Diamond (2u2o2)		100.30	37%

Conclusion

The data in Tables 2, 3, and 4 indicates a strong correlation (<5% error) between the CathCAD® predicated and measured values for flexural modulus, kink radius, and shear modulus. Poor correlation between the predicted and measured shear modulus values for the diamond braid pattern likely resulted from the software's braid pattern neutrality: the diamond braid wire angle differs from the regular and half-load diamond braid wire angles at equivalent braid picks per inch as illustrated in Figure 5. The test samples were fabricated with 38 PPI braid, which is approximately 50° braid wire angle for the regular and half-load diamond patterns versus 67° braid wire angle for the diamond pattern, and torque response is optimized at angles approaching 45°.

Table 5 compares the performance characteristics and manufacturing costs of the half-load diamond and diamond patterns to the regular pattern. Except for the diamond pattern shear modulus (noted above), minimal differences (<5%) in flexibility, kink resistance, and torque response were observed between the three braid patterns at equivalent density. Considering that the diamond patterns are more expensive than the regular braid pattern, a catheter engineer should only consider the more costly braid patterns for specialized applications where the modest performance improvement justifies the added cost.

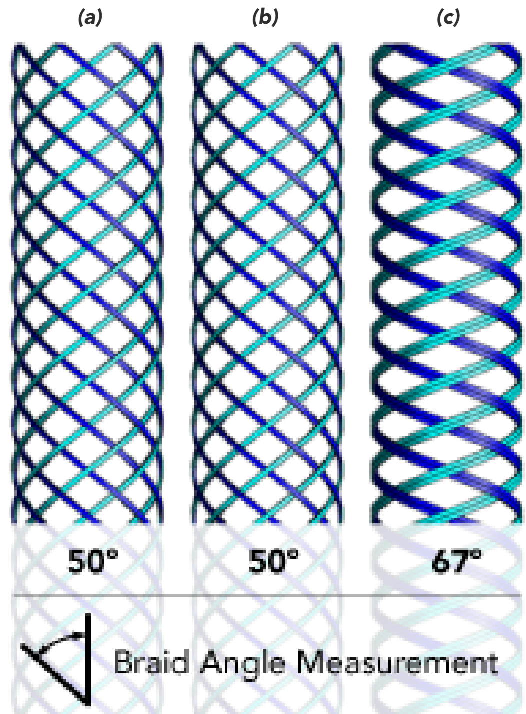


Figure 5. *Comparison of catheter braid patterns at equivalent PPI:* ***(a)*** *regular;* ***(b)*** *half-load diamond;* ***(c)*** *diamond.*

Table 5. *Performance and cost comparison of 16 wire regular, half-load diamond, and diamond braid patterns.*

DESIGN	PERFORMANCE CHARACTERISTICS			MANUFACTURING COST	
Braid Pattern	**Flexural Modulus**	**Kink Radius**	**Shear Modulus**	**Run Speed**	**Material Usage**
Regular (1u2o2)	N/A	N/A	N/A	N/A	N/A
Half-load Diamond (1u1o1)	-4%	+2%	-4%	-100%	0%
Diamond (2u2o2)	-1%	+6%	-39%	-100%	+100%

Designing and manufacturing the optimal catheter for a medical device requires balancing interrelated and often complex performance requirements with development timeline and cost. Medical device developers facing market pressure to make smaller, better, and lower cost products can accelerate time to market and reduce timelines for achieving an optimal clinical solution by making use of modern design tools. Analytical modeling allows a developer to predict and compare performance attributes of catheters in software and make informed design and manufacturing decisions faster in the design process. Successful collaboration between design engineers using modern design tools and the latest advances in manufacturing technologies continues to push the innovation edge towards better and more cost-effective solutions for clinicians and their patients who benefit from new therapies.