Polymers Based Catheters Design

Karthik Reddy Bujuru (MS)[1], Rajesh Kandula (MTech)[2], Surya Kiran Aedma (MD)[3]

Abstract: ***Minimally invasive medical treatment using catheters is the path that the healthcare industry is being gradually coerced into for minimizing patient trauma, procedural time, infection rate and the recovery time. The design development of the catheters is an iterative process to accurately translate the physician user needs to mechanical performance. CathCAD® software helps the catheter designer to theoretically evaluate catheter design input parameters related to polymer jacket material, thickness, braid pattern type, braid configuration to mechanical performance outputs such as flexural, torsional, and tensile rigidities with minimal spending of time, human and capital resources.***

Keywords: Catheter design, CathCAD®, Flexural rigidity, Torsional rigidity, Braid, Kink radius

1. Introduction

Catheters are widely used in medical device applications that are minimally invasive. Clinicians from a vast number of medical disciplines utilize catheters to deliver diagnosis and/or therapy. Procedures that were previously required in - hospital stay for multiple days can now allow for outpatient services that do not require extended periods of stay in the hospital due to the use of minimally invasive catheters [Xiaohua Hu, Ang Chen, Yigang Luo, Chris Zhang & Edwin Zhang (2018) Steerable catheters for minimally invasive surgery: a review and future directions, Computer Assisted Surgery, 23:1, 21-41]. Catheters can have simple or complex design requirements based on the target treatment location/ physiology, disease condition and patient's anatomy. A combination of a complex few or all of these factors can require a catheter that may need a well evaluated recipe of the required specifications.

While there is literature on the indications, clinical procedural techniques, and the complications associated with the use of catheters, there is limited information on general methodology on the catheter design process for a given application. This article aims to guide the reader through a typical design development process for polymer - based catheters from translation of user needs to measurable outputs, along with various elements catheter design.

2. Catheter Product Development Cycle

2.1. Catheter - Product Development Cycle

Typical catheter design development will undergo a design control process per company's quality system built per industry regulations such as FDA Title 21 CFR 820.30 [https://www.fda.gov/media/116762/download] and ISO 13485. The catheter design development process is illustrated in the schematic laid out in Figure 1.

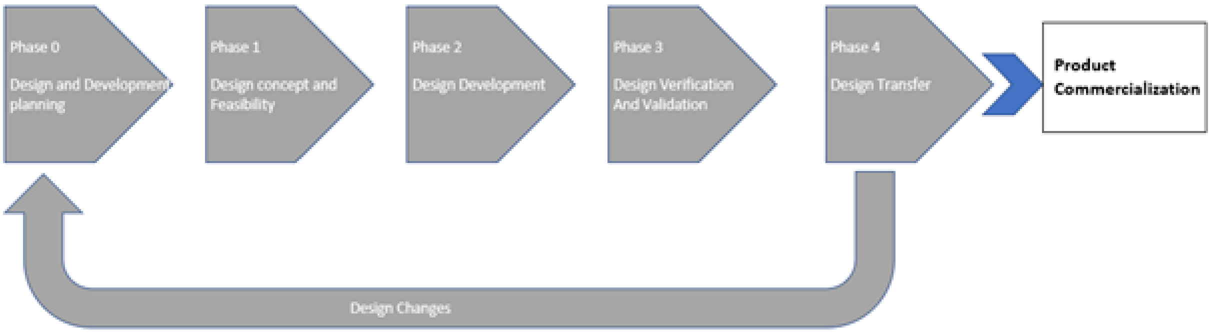


Figure 1: Product Development Process

Phases 0 is associated with collection of user/physician needs, while phases 1 and 2 are associated with developing design inputs and eventually design outputs of a catheter. The sources for development of user needs can be physician interviews, predicate device complaint data, cross functional interview of the cross functional teams regarding the areas of improvement for the predicate device etc. These user needs are translated into actionable product requirements which are otherwise referred to as design inputs. A single user need may lead to multiple design inputs, each of which may lead to the development of distinct design outputs of a catheter. The transformed design outputs/product specifications are used to verify and validate the user needs for that catheter.

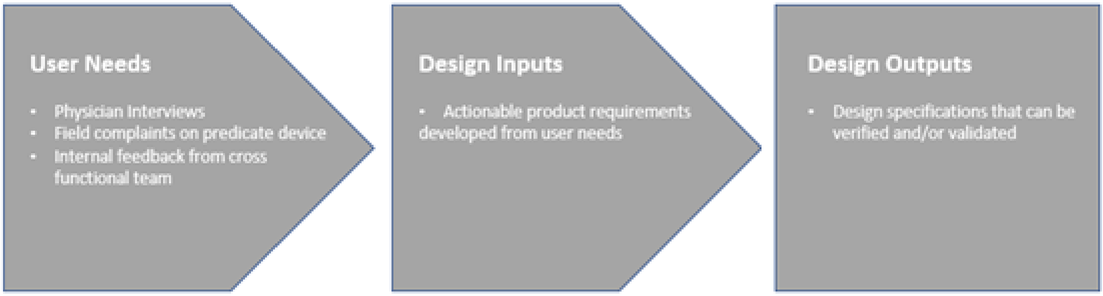


Figure 2: Design Requirements Traceability

2.2. Catheter Design Specifications/outputs

Generally, the user needs for the catheter are associated with the following elements.

- Overall working length and French size compatibility for patient population.
- Compatibility with other ancillary devices required for the procedure.
- Mechanical properties like tensile, bending and torque strengths [(1966). I. Mechanical Properties of Catheters. *Acta Radiologica, 5*, 11 - 21].
- Functional requirements specific to the application - ability to safely deliver the device through minimally invasive methods, ability to deploy a stent etc.
- Ability to flush, maintain hemostasis and overall safety to the patient (no unacceptable trauma to vessel

These user needs are translated into product requirements/design inputs by the cross - functional teams and then converted to design outputs by the product development team which are used as target specifications development. The following table provides a few examples of translation of stent delivery catheter user needs into quantifiable and verifiable design outputs.

Table 1: Illustrative Example: User Needs to Design Input Translation

Serial number	User Need	Design Input	Design Output
1	Catheter to have adequate working length to reach the target site for 95 percentile patient population.	Catheter must be long enough to reach tricuspid annulus	Catheter working length shall be 700 ± 10mm
2	Delivery conduit for the catheter (Sheath) to allow free passage of catheter during prosthetic valve delivery.	Catheter OD and sheath ID must be compatible with each other	• Catheter OD shall be 28F maximum. • Sheath ID shall be 30F maximum.
3	Catheter shall be able to rotate to align prosthetic valve with native valve commissures.	Catheter must have adequate torque response output in the target site for given input in the handle.	• Catheter distal section shall have torsional rigidity of 10 lbf - inch^2
4	Catheter needs to deliver the prosthetic valve at target site when intended	Catheter must deliver the prosthetic valve with button actuation in the handle	• Catheter shall have tensile/buckling strength of 5 - pound force.
5	Catheter needs to conform to patient anatomy and bend along vasculature	Catheter must bend around the inferior vena cava and reach the tricuspid annular plane.	• The catheter shall have flexural rigidity of 4 lbf - inch^2. OR • The catheter's kink/bend radius shall be minimum of 2 inches.

The catheter design development is centered around meeting the design outputs evaluated during design verification or validation of the catheter.

3. Catheter Construction

A typical polymer - based catheter shaft includes a low friction/high lubricity polymer (e. g., PTFE liner) on the inner diameter (ID), a braid enforcement over it, and a thermoplastic elastomer jacket on the outer diameter (OD).

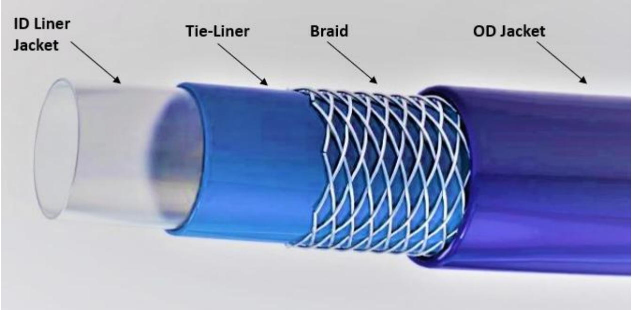


Figure 3: Catheter Construction (Image credits: Machine Solutions)

If the ID liner is made from PTFE which has low surface energy to bond with interfacing catheter components, it is chemically, or plasma etched on the OD to allow for better bonding characteristics with other catheter components that are reflowed over it [Kim, S.R. (2000), Surface modification of poly(tetrafluoroethylene) film by chemical etching, plasma, and ion beam treatments. J. Appl. Polym. Sci., 77: 1913-1920]. The catheters commonly also have mechanical enforcements such as braid, coil or a Laser cut Hypo - tube (LCH) laid on top of the ID liner. In some instances where the density of braid is high preventing acceptable bond of the ID liner with the outer jacket, a thin layer of thermoplastic elastomeric jacket like PEBAX - known as Tie Layer - is used as bridge bonding member between the ID liner and the OD jacket. The braid or the LCH are covered with another to provide atraumatic interface with the human anatomy. In certain instances where the tensile strength provided by the braid is not adequate, axial strengthening members made from round or flat stainless - steel wire or in some instances polymer fibers made from polyethylene (e. g., Dyneema) or Liquid crystal polymer (e. g., Vectran) are used.

4. Catheter Design Development

While there may be numerous specifications/design outputs that are developed from the user needs for a catheter, this paper focuses on discussing the following 2 aspects.

- Catheter Jacket Materials
- Catheter Mechanical properties (tension, torque and bending)

4.1 Catheter Jacket Materials:

4.1.1 ID Liner Jacket

The ID of the catheter is typically lined with polymer materials that have low coefficient of friction to allow for easy trackability of other ancillary devices that are used during the procedure. The ID jacket material options are currently limited to using PTFE or Propell™ loaded thermoplastic elastomer compounds such as PEBAX. Poly Tetra Fluro Ethylene (PTFE) is a synthetic fluoropolymer and is most commonly used catheter liner material on the ID to provide excellent lubricity, temperature stability and wear resistance [Blumm, J., Lindemann, A., Meyer, M. et al. Characterization of PTFE Using Advanced Thermal Analysis Techniques. Int J Thermophys 31, 1919–1927 (2010)]. The impact of the ID jacket on the overall mechanical properties of the catheter is generally limited due to the low thickness of the ID jacket used - typically not exceeding 0.005 inches. However, it plays agreater role if its thickness is comparable to that of the outer jacket.

4.1.2 OD Jacket:

The choices for the OD jacket generally range between soft amorphous copolymers to rigid semi - crystalline copolymers which have varying degree of flexibility, kink resistance, tensile and torque strengths. Most commonly used catheter OD jacket polymer materials are discussed below.

Thermoplastic Elastomers: These are hard polymer segments embedded in matrix of soft amorphous polymer segments, with physical bind between the segments giving the material the desired elastic properties. Unlike thermoset plastics, the physical binding between the copolymer segments is reversible by melting and cooling. The combinations of copolymer segments can be engineered to the desired strength, stiffness, and hardness of the polymer. The following are the most commonly used thermoplastic elastomers.

- PEBAX [Flesher, J.R. (1986). Pebax® Polyether Block Amide — A New Family of Engineering Thermoplastic Elastomers. In: Seymour, R.B., Kirshenbaum, G.S. (eds) High Performance Polymers: Their Origin and Development. Springer, Dordrecht]: Pebax is in a class of thermoplastic elastomer Amide (TPE - A) with flexiblepolyether block amides embedded in rigid polyamide. A varied combination of polyamide and polyether blocks yield different grades of pebax stiffnesses ranging from 75A to 75D shore hardness without the use of plasticizers. The lower the shore hardness number, greater the manufacturing process like lamination/reflow difficulties. Pebax has high abrasion resistance and good biocompatibility.
- Thermoplastic Elastomer Urethane (TPE - U): TPUs are either polyester or polyether - based copolymers which are generally more elastic with hardness ranging from 75A to 75D and with properties such as excellent abrasion resistance and biocompatibility. Other distinct characteristic of TPU is that it softens with temperature and moisture in the patient’s body which allow for unique applications that can utilize this material property [Zdrahala RJ, Spielvogel DE, Strand MA. Softening of Thermoplastic Polyurethanes: A Structure/Property Study. Journal of Biomaterials Applications. 1987;2(4):544-561].
- Polyamide (Nylon): Polyamide is categorized as semi - crystalline copolymer commonly referred to as Nylon. The mechanical properties of Nylon can be varied by changing the number of carbon atoms between the functional amide groups with PA6, PA11 and PA12 having the name indicated number of carbon atoms for each of the respective PA. Nylon has high strength, bend stiffness, hardness, and wear resistance.

4.1.3 Other Catheter components

Other most commonly used catheter materials for manufacturing are discussed below.

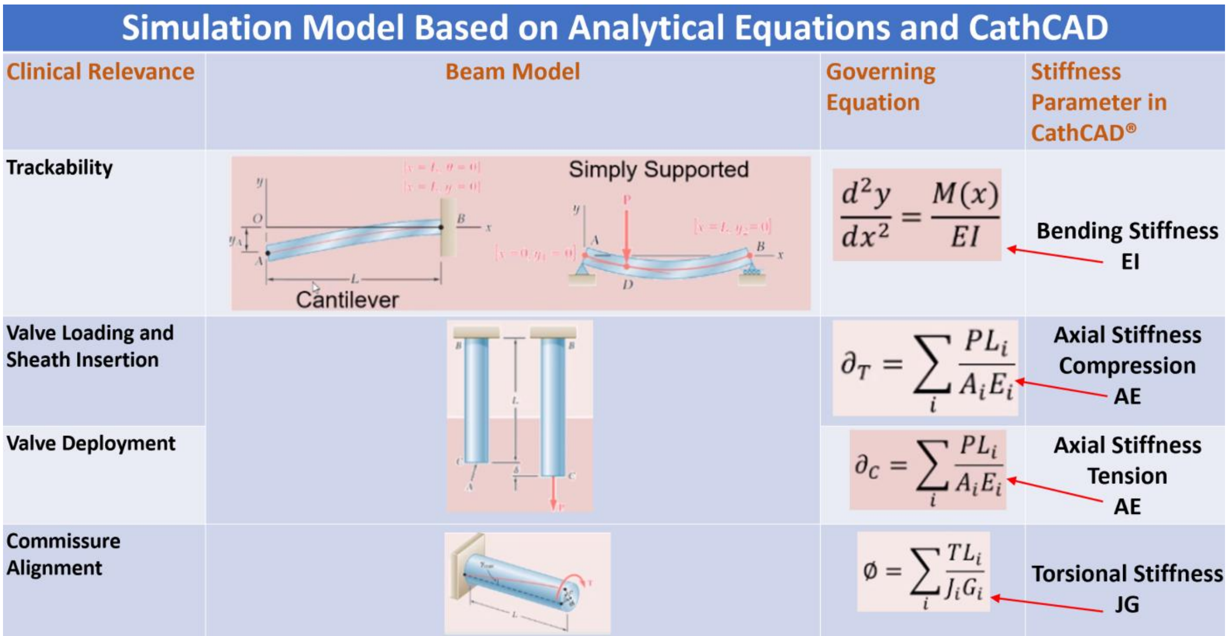
- Fluorinated Ethylene Propylene (FEP): Fluorinated Ethylene Propylene (FEP) is a copolymer of Tetra Fluoro Ethylene (TFE) and hexafluoropropylene (HFP) that has good lubricity, chemical inertness, and flexibility and processability [Teng, H. Overview of the Development of the Fluoropolymer Industry. Appl. Sci. 2012, 2, 496-512]. The FEP also has a distinct property of shrinking under application of heat which allows for catheter reflow operations and bonding joints.
- Polyethylene Terephthalate (PET): PET is another commonly used thermoplastic copolymer used as heat shrink on catheter shafts that may need to be insulated fromheat, current, moisture and other chemically active solvents.
- In addition to the above discussed materials, other thermoplastic polymers such as low - density polyethylene (LDPE), High Density Polyethylene (HDPE) are also known to be utilized for catheter shafts manufacturing.

4.2 Catheter Design for Mechanical Properties:

A catheter design is typically evaluated for bending (to able to track the patient’s anatomy), tensile strength (ability to translate linear displacement in the catheter’s handle to the catheter’s distal end), and torque strength (able to withstand torsional loads on the catheter without kinking). The overall catheter’s mechanical properties are dependent on those of the ID liner jacket, braid or LCH structural member, and the OD jacket. The ID liner jacket thickness is relatively small to impact the overall properties, while the OD jacket and the braid or LCH drive the overall mechanical properties of the catheter. In a typical catheter shaft design, its often a balancing act between bending, tensile and torsional properties to reach an optimized design [Carey, Jason, Atef Fahim, and Michael Munro. "Design of braided composite cardiovascular catheters based on required axial, flexural, and torsional rigidities." Journal of Biomedical Materials Research Part B: Applied Biomaterials: An Official Journal of The Society for Biomaterials, The Japanese Society for Biomaterials, and The Australian Society for Biomaterials and the Korean Society for Biomaterials 70.1 (2004): 73-81], as changing one design parameter brings the designer close to a target value for one property and an opposite effect on the other properties. In such situations, CathCAD® software may be used to guide the designer towards an ideal design without having to go through the costly iterative process of prototyping until an ideal design is achieved. The rest of this paper discusses how CathCAD® can be used to design catheter shafts, particularly the effect of braid design parameters on the performance of the catheter with respect to bending, torsion and tensile properties.

4.2.1 CathCAD® Software Overview

This predictive software model, an intellectual property of Roth Technologies LLC, is used to optimize the catheter design utilizing theoretical analytical equations governing the mechanics of bodies under load. The software model also utilizes the classical lamination theory, buckling theory governed by Brazier effect to determine some of the catheter properties.



Simulation Model Based on Analytical Equations and CathCAD

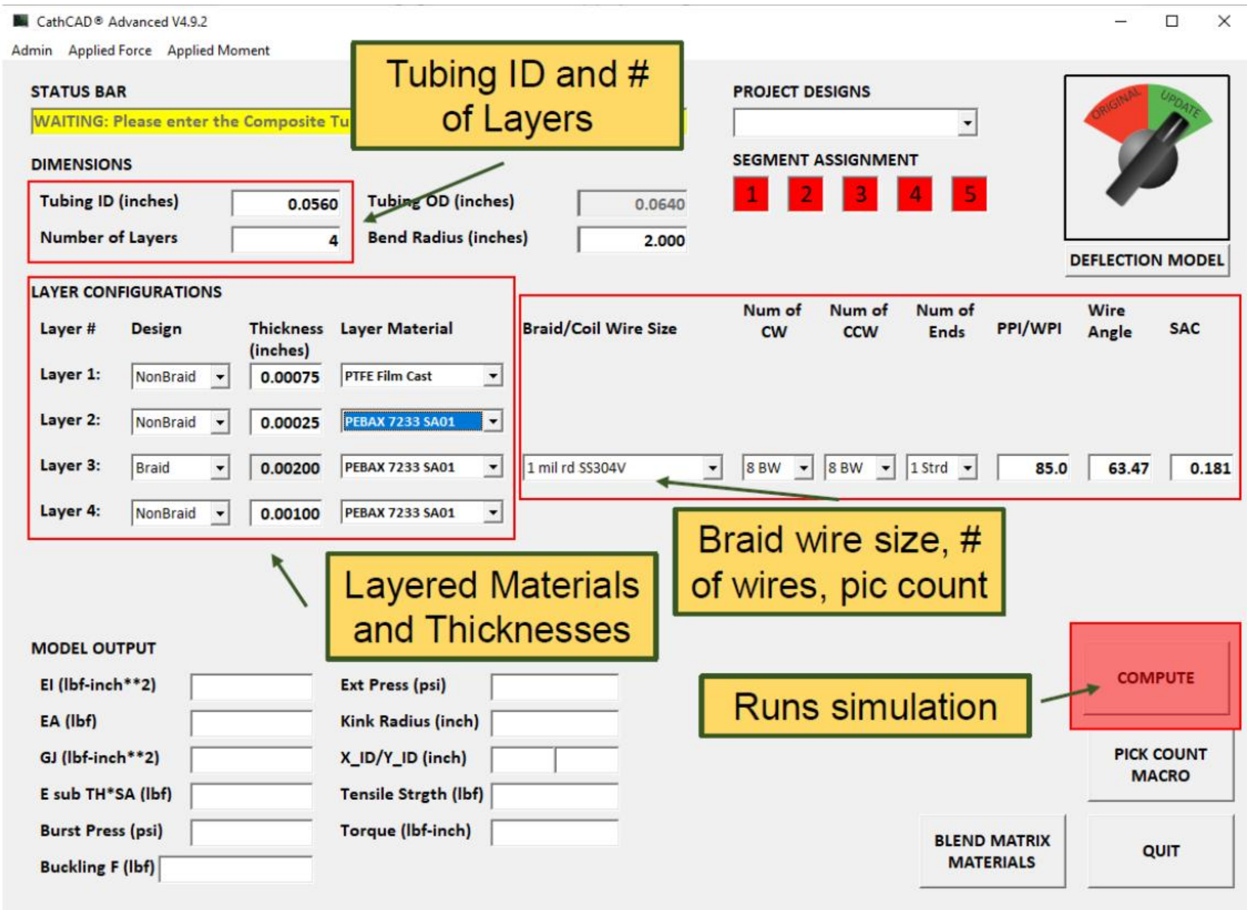
Clinical Relevance	Beam Model	Governing Equation	Stiffness Parameter in CathCAD®
Trackability	Cantilever Simply Supported	$\frac{d^2y}{dx^2} = \frac{M(x)}{EI}$	Bending Stiffness EI
Valve Loading and Sheath Insertion		$\partial_T = \sum_i \frac{PL_i}{A_iE_i}$	Axial Stiffness Compression AE
Valve Deployment		$\partial_C = \sum_i \frac{PL_i}{A_iE_i}$	Axial Stiffness Tension AE
Commissure Alignment		$\emptyset = \sum_i \frac{TL_i}{J_iG_i}$	Torsional Stiffness JG

Figure 4: CathCAD® Software governing Analytical Equations (Image credits: Roth Technologies, LLC)

The software uses stiffness parameters for bending, tension, and torsion derived from the analytical equations to theoretically predict the catheter product specifications such as pushability (ability to push the catheter without buckling), bending flexibility, torque transmissionetc. The user is allowed to provide inputs for multilayered catheter construction such as jackets material type and thickness, number of layers in the catheter and braid parameters to determine catheter design specific mechanical properties [Roberta Piazza, Sara Condino, Aldo Alberti, Raffaella Nice Berchiolli, Gioachino Coppi, Marco Gesi, Vincenzo Ferrari & Mauro Ferrari (2017) Design of a sensorized guiding catheter for in situ laser fenestration of endovascular stent, Computer Assisted Surgery, 22:1, 27-38].

4.2.2 Braid configuration Selection

The CathCAD® software allows the user to input braid parameters such as wire size, number of wires, number of strands in each wire and picks per inch (PPI) to compute braid wire angle and catheter mechanical properties for chosen jacket material type and thicknesses.



STATUS BAR

WAITING: Please enter the Composite Tu

DIMENSIONS

Tubing ID (inches) 0.0560

Number of Layers 4

Tubing OD (inches) 0.0640

Bend Radius (inches) 2.000

LAYER CONFIGURATIONS

Layer #	Design	Thickness (inches)	Layer Material	Braid/Coil Wire Size	Num of CW	Num of CCW	Num of Ends	PPI/WPI	Wire Angle	SAC
Layer 1:	NonBraid	0.00075	PTFE Film Cast							
Layer 2:	NonBraid	0.00025	PEBAX 7233 SA01							
Layer 3:	Braid	0.00200	PEBAX 7233 SA01	1 mil rd SS304V	8 BW	8 BW	1 Strd	85.0	63.47	0.181
Layer 4:	NonBraid	0.00100	PEBAX 7233 SA01							

MODEL OUTPUT

EI (lbf-inch**2)

EA (lbf)

GJ (lbf-inch**2)

E sub TH*SA (lbf)

Burst Press (psi)

Buckling F (lbf)

Ext Press (psi)

Kink Radius (inch)

X_ID/Y_ID (inch)

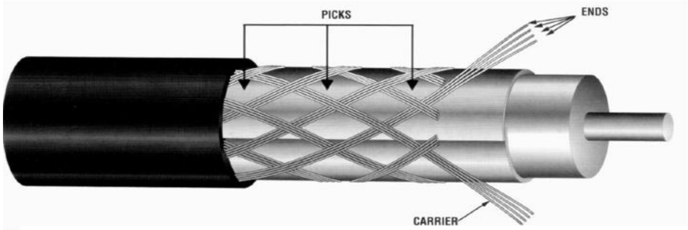
Tensile Strgth (lbf)

Torque (lbf-inch)

Figure 5: CathCAD® Software User Interface (Image credits: Roth Technologies, LLC)

For a chosen OD polymer jacket type and its thickness, the braid configuration plays a significant role in determining the mechanical properties of the catheter. The following section discuss therelationship between the braid density (PPI) and the catheter properties such as flexural rigidity, Torsional rigidity, longitudinal rigidity, kink radius, torsional and tensile strengths.

Per ANSI SCTE 51 Braid Standard, following is the illustration of braid and its design parameters.



α = Braid angle (radians) - the angle formed by the carriers with the longitudinal axis of the cable (refer to the illustration)

D = Diameter under the braid (inches)

C = Number of carriers - the number of groups of individual braid wires (ends), usually 16 for most cable telecommunications braided cables (refer to the illustration)

d = Braid strand diameter (inches)

P = Picks per inch – the number of carrier crossing points per longitudinal inch (refer to the illustration)

N = Number of individual wires (ends) in each carrier

Figure 6: Braid Design Parameters - ANSI/SCTE 51 2007 Standard

There are several patterns for the braid available for the designer to utilize and configure the desired catheter properties [Kyosev, Yordan. Braiding technology for textiles: Principles, design, and processes. Elsevier, 2014]. Some of the common catheter braid patterns are discussed in the table below and illustrated in figure 7.

Table 2: Common Braid Configurations

Serial number	Braid Pattern	Wires pattern	Pattern Characteristics
1	Full Load/Herringbone	1 over 2 under 2	• Maximizing pushability and flexibility • Runs at 100% carrier capacity • Maximum throughput
2	Diamond	2 over 2 under 2	• Maximizing torqueability, kink resistance and full coverage • Half as fast as full load pattern throughput
3	Half Load	1 over 1 over 1	• Runs at 50% carrier capacity • Easiest to remove from the core

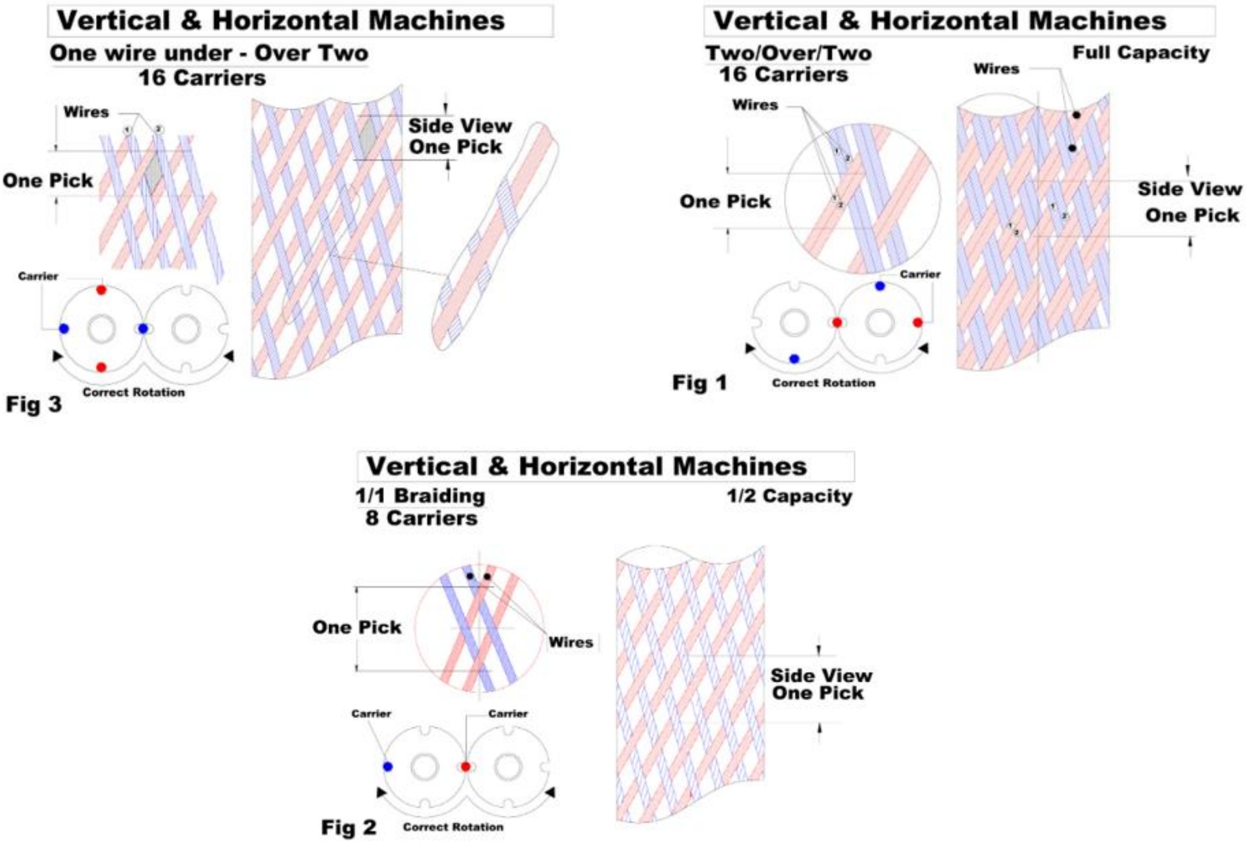
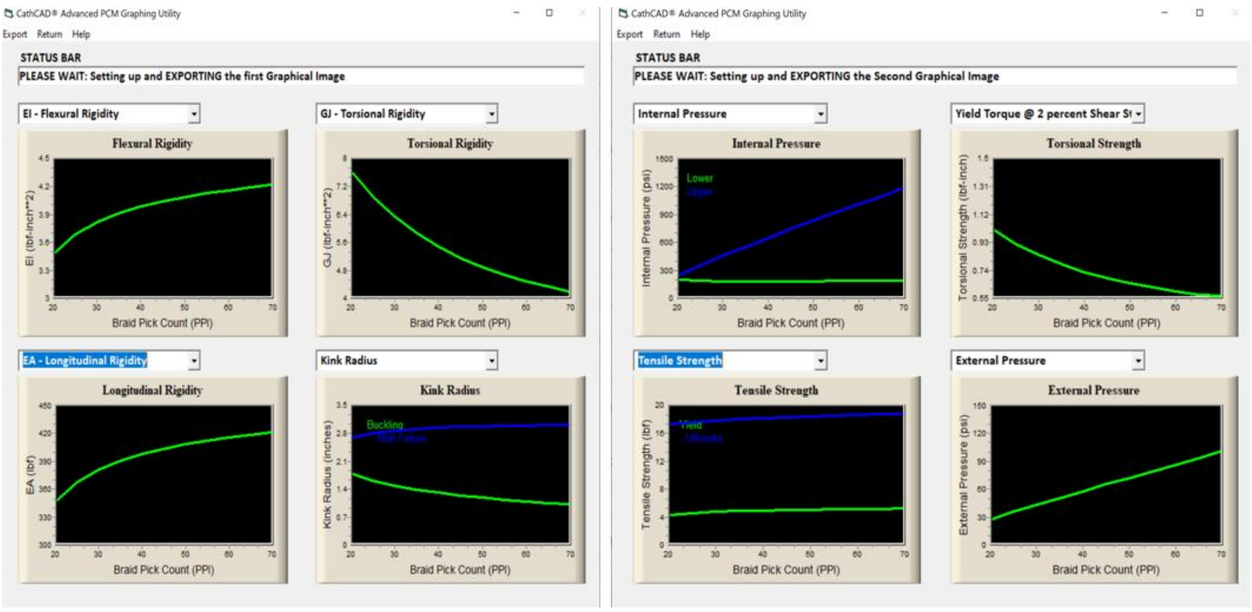


Figure 7: Common Braid Configurations (Image Credits - Steeger USA)

4.2.3 Braid Density vs Mechanical Properties: In this section, CathCAD® software is utilized to show the relationship between the braid density and the resultant mechanical properties of a catheter. Other catheter design parameters such as polymer jacket material, jacket thickness, braid design parameters (braid wire size, number of wires, braid pattern) are kept constant between different configurations of variable braid densities.



STATUS BAR
PLEASE WAIT: Setting up and EXPORTING the first Graphical Image

EI - Flexural Rigidity
GJ - Torsional Rigidity
EA - Longitudinal Rigidity
Kink Radius

STATUS BAR
PLEASE WAIT: Setting up and EXPORTING the Second Graphical Image

Internal Pressure
Yield Torque @ 2 percent Shear St
Tensile Strength
External Pressure

Figure 8: Braid Density vs Mechanical Properties (Courtesy: CathCAD® Software)

The following relationships are established between the braid density and the various mechanical properties of the catheter.

- Braid density vs Flexural rigidity: Linear relationship. As braid density increases flexural rigidity increases too. This implies that with increase in braid density (PPI), the catheter becomes increasingly difficult to bend.
- Kink/Bend Radius: Inverse relationship. As braid density increases the catheter's kink radius decreases. This is in line with the catheter's flexural rigidity performance with respect to increased bending stiffness with increasing braid density, as it become easier for an inflexible shaft to kink at a lower radius.
- Longitudinal rigidity: Direct relationship. As braid density increases the catheter's longitudinal rigidity increases too. With an increased braid density, it will be difficult to cause linear displacement in the catheter's material.
- Tensile Strength: Neutral relationship. No change in catheter's tensile strength (Yield and Ultimate) with increase in braid density.
- Torsional strength: Inverse relationship. The catheter's torsional strength decreases as the braid density increases, which implies that the catheter is easier to be subjected to lumen collapse under torsional load as the braid density increases.

Based on this understanding of the effect of braid density on the mechanical properties, appropriate braid density is chosen for a catheter based on the application needs of bending flexibility, tensile strength, bend radius and torsional strength. For maximum bending flexibility (low flexural rigidity) higher braid density is selected, however higher braid density selection has negative impact on longitudinal rigidity (column strength) which makes the catheter buckle easily under load. Also, higher braid density chosen for maximum bending flexibility has negative impact on torsional rigidity as it will be easier for the lumen to collapse under torsional load. Therefore, it is an act of balancing the required distinct mechanical properties with catheter design input factors such as jacket material, jacket thickness, number of jacket layers, braid configuration etc. The designer may also use multiple response optimization tools in Minitab using the inputs derived from CathCAD® software to determine the optimal level of each of the design input parameters for the desired catheter functional characteristics.

5. Conclusion

Catheter design methodology of developing verifiable design outputs, particularly catheter functionalities centered around its mechanical properties need to be agreed between product development stake holders at the beginning of design cycle to avoid cost prohibitive corrective actions in the later stages of development. Complex catheter design requirements can be translated into measurable mechanical properties of bending, tension and torque which can be optimized for a polymer - based catheter design using CathCAD® software without having to go through multiple prototype iterations during the early stages of design development.

References

[1] Xiaohua Hu, Ang Chen, Yigang Luo, Chris Zhang & Edwin Zhang (2018) Steerable catheters for minimally invasive surgery: a review and future directions, Computer Assisted Surgery, 23: 1, 21 - 41.
[2] https: //www.fda. gov/media/116762/download
[3] (1966). I. Mechanical Properties of Catheters. Acta Radiologica, 5, 11 - 21.
[4] Kim, S. R. (2000), Surface modification of poly (tetrafluoroethylene) film by chemical etching, plasma, and ion beam treatments. J. Appl. Polym. Sci., 77: 1913 - 1920
[5] Blumm, J., Lindemann, A., Meyer, M. et al. Characterization of PTFE Using Advanced Thermal Analysis Techniques. Int J Thermophys 31, 1919–1927 (2010)
[6] Flesher, J. R. (1986). Pebax® Polyether Block Amide — A New Family of Engineering Thermoplastic

Elastomers. In: Seymour, R. B., Kirshenbaum, G. S. (eds) High Performance Polymers: Their Origin and Development. Springer, Dordrecht

[7] Zdrahala RJ, Spielvogel DE, Strand MA. Softening of Thermoplastic Polyurethanes: A Structure/Property Study. Journal of Biomaterials Applications.1987; 2 (4): 544 - 561

[8] Teng, H. Overview of the Development of the Fluoropolymer Industry. Appl. Sci.2012, 2, 496 - 512

[9] Carey, Jason, Atef Fahim, and Michael Munro. "Design of braided composite cardiovascular catheters based on required axial, flexural, and torsional rigidities. " Journal of Biomedical Materials Research Part B: Applied Biomaterials: An Official Journal of The Society for Biomaterials, The Japanese Society for Biomaterials, and The Australian Society for Biomaterials and the Korean Society for Biomaterials 70.1 (2004): 73 - 81.

[10] Roberta Piazza, Sara Condino, Aldo Alberti, Raffaella Nice Berchiolli, Gioachino Coppi, Marco Gesi, Vincenzo Ferrari & Mauro Ferrari (2017) Design of a sensorized guiding catheter for in situ laser fenestration of endovascular stent, Computer Assisted Surgery, 22: 1, 27 - 38.

[11] Kyosev, Yordan. Braiding technology for textiles: Principles, design, and processes. Elsevier, 2014.