

Composite Tubing Fundamentals

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I. PURPOSE

The purpose of this document is to provide fundamentals for developing and modeling composite tubing using the CathCAD® software.

A standard nomenclature is provided for detailing a composite tube design. This guide also provides examples of different, common layer configurations.

Finally, this guide presents some simple composite tubing modeling approximations. In this section, basic rules of thumbs are provided to help the reader understand qualitative results expected with respect to geometry and as material property fundamentals.

II. COMPOSITE TUBING MANUFACTURING PROCESSES

Extrusion Process

The extrusion process involves the use of polymers (plastics) that when heated change from a solid to a viscous liquid. Once the polymer is in its liquid state it is extruded (pushed) out a die that provides a specific shape. The process is contained in an extruder that consists of a round barrel with a screw inside. The polymer is placed into a hopper throat. As the screw rotates, the polymer moves from the feed section up and through the die and takes shape of the orifice in the die.

Once the part is extruded out of the die in the molten state it passes through a sizer to control the shape of the part as it cools. This can be done in many methods depending upon the material and line rate in the process. Typically with tubing products a vacuum tank is used. The tank creates a vacuum chamber in which the part is passed thru. This forces the tube to push out against a sizer that is shaped and controls the size of the polymer until it is cooled below its melting point. Similar methods to sizing are vacuum calibration, air racks and open water tanks.

The polymer is cooled and then pulled using a take off puller. The take off puller is a key component to maintaining and controlling the size of the extrusion. The puller must take the material being exited from the die thru the sizer at the same continuous rate. The puller is set to a constant speed that is relational to the extruder output. The feed rate is key to determining the amount of sizer required to control the polymer and manufacture the correct end product.

Once the polymer is cooled and through the take off puller, it can be cut to length. Flexible products can be wound on spools.

A process referred to as coextrusion is also available. Coextrusion is the simultaneous extrusion of two (or more) compatible materials at the same time. Coextrusion can result in simplifying the manufacturing of composite tubing since it is one "process" step. Coextrusion also provides some opportunities in developing composite tubing that cannot be obtained in any other fashion.

Film Cast Process

In film cast tube fabrication method, tubing is manufactured by applying layers of polymers over a mandrel or wire. The polymer is in a liquid state and can range from very low viscosity (e.g. PTFE particles in a water like suspension) to a very viscous material such as polyimide enamel which has a nominal viscosity of 5,000 centipoise.

The wire is passed through the enamel bath followed by a sizing die which controls the amount of wire placed on the mandrel. The enameled wire is then passed through a cure oven which evaporates the solvent and then cures the enamel. This process is repeated multiple times until the required outside diameter (or wall thickness) of the enamel is achieved.

Proprietary methods are utilized to remove the base mandrel from the enamel. When the mandrel is removed, the result is a basic tube.

Braiding Process

A braid is a complex pattern formed by intertwining strands of materials such as textile fibers or wires. Many of the micro catheters on the market today are braided composites. These items are constructed as follows:

Continuous Manufacturing

- First, the base polymer layer is manufactured on a mandrel and spooled. The mandrel provides support during the braiding process.
- Second, the polymer on the mandrel is over braided continuously using the braider
- Third, the braided polymer on the mandrel is overjacketed continuously or on a piece part basis with an outer polymer material.
- The support mandrel is removed.

Piece Part Manufacturing

- First, the base material is manufactured. The base material is cut to length and sleeved onto a support mandrel
- Second, a braid layer is manufactured using a braider on a separate support mandrel.
- Individual braid pieces are removed from the support mandrel. They are sleeved over the base polymer layer/support mandrel combination.
- An outer polymer jacket is manufactured. It is sleeved over the polymer base/sleeved braid. A process referred to as "fuse down" process laminates the outer polymer jacket into the polymer base/sleeved braid.
- The support mandrel is removed

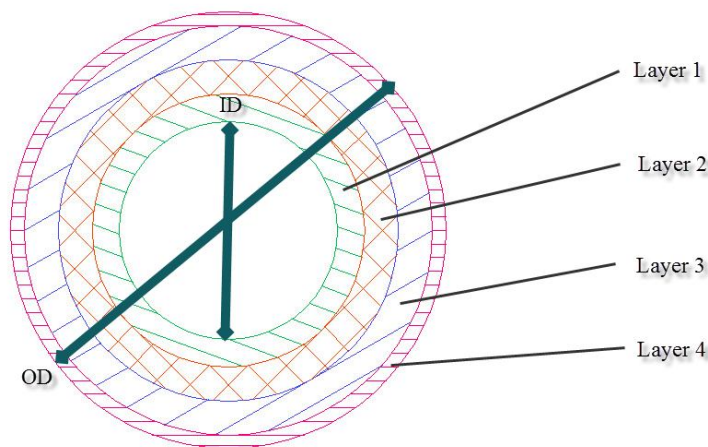
III. NOMENCLATURE

A standard nomenclature has been developed for detailing composite tubing designs. This nomenclature is fully described in this section. The nomenclature requires the following terms to be defined.

- The Inner Diameter is referred to as the ID
- The Outside Diameter is referred to as the OD
- The composite tubing design is segmented into individual layers. For a N layer design, the inner most layer is Layer 1, the next layer is Layer 2, ..., and the outer most layer is Layer N. Each layer has a thickness associated with it. Since layer thicknesses are typically very small and for English units, the units used for layer thicknesses is typically mils. The conversion from inches to mils is 1 mils = 0.001 inches.
- If a composite tubing design has N layers AND the thickness of Layer i is defined as t_i , then the following algebraic equation is applicable:

$$OD = ID + \sum_{i=1}^N (2 * t_i)$$

The following figure illustrates a four (4) layer construction. Layer 1 is the inner most layer. Layer 4 is the outer most layer.



A descriptive nomenclature is developed for describing a composite tubing design. This nomenclature allows the composite tubing design to be described at its nominal conditions. This nomenclature is used by the CathCAD® software when exporting modeling results to Microsoft Excel.

- The tubing ID is provided
- The tubing OD is provided

- The construction of each layer is provided beginning with Layer 1 and ending with Layer N. The delimiter "/" (forward slash) is used to separate each Layer's description
- A NonBraid Layer is fully described by providing (a) the thickness of the layer (in units of mils) AND (b) the Material in the Layer
- A Braid Layer is fully described by providing (a) The braid wire size, (b) Number of Braid Wires, (c) the Pick Count in units of Picks per inch, (d) The total number of braid wires. To determine the number of braid wires going clockwise and counterclockwise, the total number of braid wires is divided by two (2), AND (e) The Braid Matrix (BM) Material encapsulating the Braid Wires. The Braid Layer thickness is NOT required as it is defined by the braid wire (thickness) dimensions. The CathCAD® software provides (as reference only) the additional information of the equivalent Braid Angle (BA) as well as the Surface Area Coverage (SAC).

The following summary is provided as an example. The design can be detailed as follows:

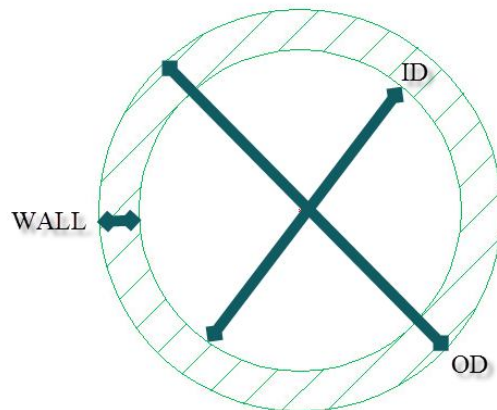
- The inner diameter or ID is 0.0298 inches
- The outer diameter or OD is 0.0380 inches
- The design is a three layer composite design
- Layer 1 is a 0.5 mil wall (0.0005 inches) of polyimide
- Layer 2 is a braid layer. The braid wire is 1.5 mil (0.0015 inches) round SS 304V Spring Temper. The number of braid wires is sixteen (16). The pick count is 36 picks per inch (PPI). The resultant braid angle is 23.5 degrees. The surface area coverage of the braid layer is 13.5 percent. The braid matrix is FEP.
- Layer 3 is 0.6 mil wall (0.0006 inches) of FEP

ID	(inches)	0.0298
OD	(inches)	0.0380
COMPOSITE LAYERED DESIGN	N/A	0.5 mils Polyimide / 1.5 mil rd SS 304V ST, 16 BW, 36.0 PPI, BA=23.5 DEG, SAC=13.5%, BM = FEP / 0.6 mils FEP

IV. ONE LAYER CONFIGURATION

A one layer tube design is the simplest and the most economical in terms of developing and producing in a manufacturing environment. The following figure illustrates a one layer design. The following geometric items are redefined:

- ID = Inner Diameter
- Wall = Wall Thickness
- OD = Outside Diameter. Note that $OD = ID + (2 * Wall)$



In order to model a one layer design in CathCAD®, the following procedure is provided:

- Enter the **ID** (Inner Diameter) of the tubing in units of inches
- Enter the **Number of Layers** as one (1). The system will update the screen to show a single layer design configuration
- Enter the **Config** as NonBraid
- Enter the Layer Thickness (**Thick**) in units of inches. The CathCAD® software will automatically compute the **OD** (Outside Diameter)
- Select the Layer Material

At this point, the configuration is complete. The Compute button may be selected and CathCAD® will compute and display EA, EI, GJ, and the Kink radius of the design¹.

- EI is an estimate of the catheter flexural stiffness normalized with respect to the length of the catheter
- EA is an estimate of the catheter longitudinal stiffness normalized with respect to the length of the catheter.
- GJ is an estimate of the catheter torsional stiffness normalized with respect to the length of the catheter

¹ The terms EA, EI, GJ and Kink Radius are fully defined and illustrated in the document, **CathCAD® Fundamentals Presentation**, Roth Technologies, LLC, 2012.

- The Kink radius is a buckling estimate of the smallest radius the catheter will make in an UNLOADED (no axial force applied) condition.

The CathCAD® model created is based on nominal conditions. In real life, the actual product manufactured may depart from the modeled conditions as follows:

- ID variations
- Wall thickness variations
- Wall Concentricity. This refers to the fact the tubing ID may be shifted and the wall be thinner on one side and thicker on the other side.

The CathCAD® software can be used to better understand the effects of variations in the tubing ID and Wall thickness by modeling the worse case expected conditions.

There are also materials that are considered composite in the classic sense in that they consist of two or more materials. Examples of these "classic" composite materials are the following:

- PeBax that is loaded with a radiopaque fillers such as BaSO₄
- Polyimide that is doped with PTFE powder or Tungsten

These examples are modeled within the CathCAD® software as uniform material and NOT as a composite material.

V. MULTILAYER DESIGNS

For the purposes of the following multilayer designs, we provide an illustration of the design AND some typical examples. Multilayer designs are either manufactured in one process step (coextrusion) and/or a layer by layer approach which is accomplished by a reel to reel process.

A reel to reel process is defined as follows:

- First, a base continuous mandrel or wire of the proper size is obtained and spooled on a properly sized reel.
- Second, the first Layer is manufactured on the Base Mandrel and then spooled onto a properly sized reel.
- Third, the second composite layer is manufactured on the Base Mandrel/First Layer and then spooled onto a properly sized reel.
- The process is repeated until all layers are completed.

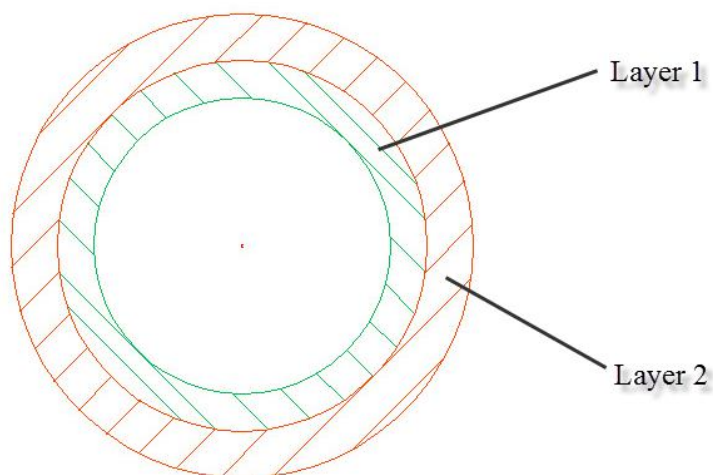
In order to model a multilayer design in CathCAD®, the following procedure is provided:

- Enter the **ID** (Inner Diameter) of the tubing which has units of inches
- Enter the **Number of Layers**. The system will update the screen to show the applicable number of layers as configured
- If a Layer Configuration is NonBraid
 - Enter the Layer **Config** as NonBraid.
 - Enter the Layer Thickness (**Thick**) which has units of inches.
 - Select the **Layer Material**
- If a Layer Configuration is a Braid Layer
 - Enter the Layer **Config** as Braid.
 - The Layer Thickness (**Thick**) will NOT be accessible. It is automatically computed by the CathCAD® software based on the Braid Wire Size
 - Select **the Layer Material**. This material is the Braid Matrix material (i.e. the material that encapsulates the braid layer)
 - Select the **Braid Wire Size**
 - Select the Number of Braid Wires (**# of Wires**) in the design
 - Enter the **Pick Count** (picks per inch) of the design. The braid angle and surface area coverage are automatically computed by the CathCAD® software.
- Repeat for all Layers until the design is completed

At this point, the configuration is complete. The Compute button may be selected and CathCAD® will compute and display EA, EI, GJ, and the Kink radius of the design.

Two Layer Configurations

The following figure illustrates a two (2) layer design.

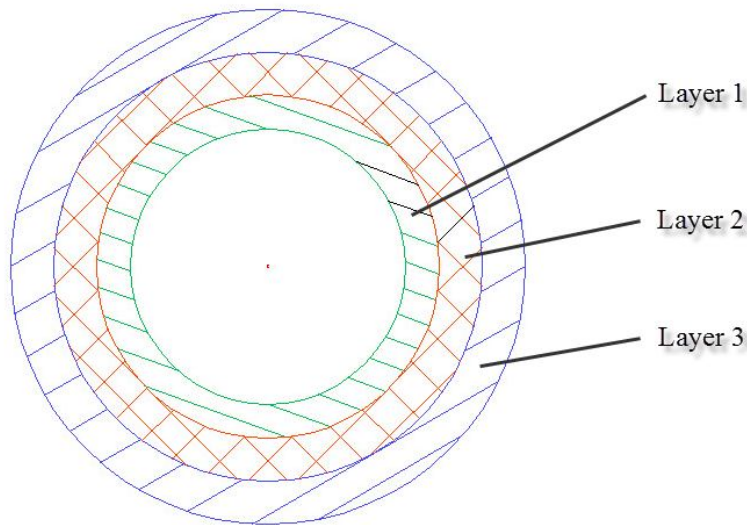


Common two layer designs used in the medical device industry are the following:

- Coextrusion designs (PE/Polyurethane)
- Lubricious Liner designs
 - Layer 1 = PTFE, Layer 2 = any other material
 - Layer 1 = FEP, Layer 2 = any other material
- Film Cast Products such as Polyimide/PeBax or Polyimide/Polyurethane. The purpose of the outer PeBax or Polyurethane layer is for bonding purposes.
- Braid with a Polyimide matrix/Polyimide outer. This design is very uncommon as this may result in exposed braid wires on the tubing ID.

Three Layer Configurations

The following figure illustrates a three (3) layer configuration. With the availability of three layers, many more potential designs become available to the designer.

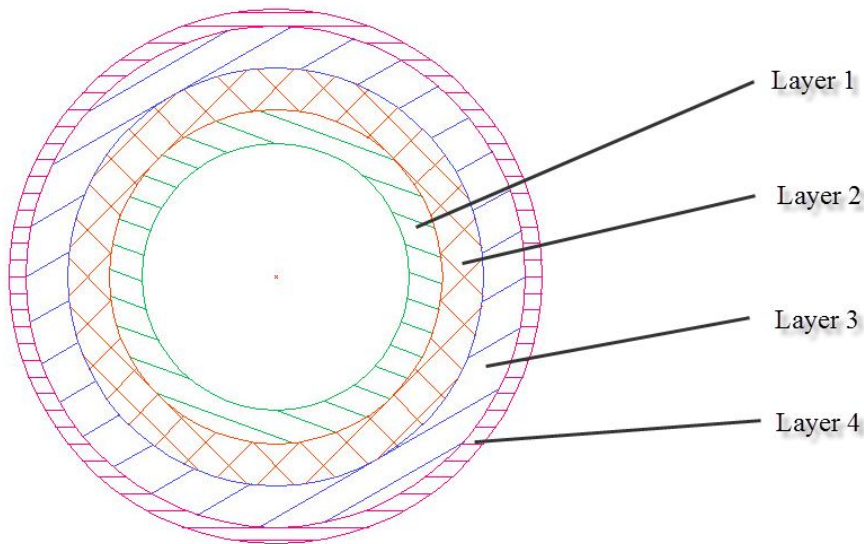


Common three layer designs are summarized as follows:

- Braided Designs
 - PTFE / Braid w PeBax Matrix / PeBax
 - Polyimide / Braid w Polyimide Matrix / Polyimide
 - PTFE / Braid w Polyimide Matrix / Polyimide
- NonBraid Designs
 - PE / Tie Layer Material / Low durometer PeBax or Nylon. The Tie Layer Material increases the bond strength between the inner PE layer and outer Layer material to prevent delamination of the inner and outer layers.
 - PTFE / Polyimide / PeBax
 - PTFE / Polyimide / FEP

Four Layer Configurations

The following figure illustrates a four (4) layer configuration.



Common four (or more) layer designs are summarized as follows:

- Braided Designs
 - PTFE / PeBax (tie layer) / Braid w PeBax Matrix / PeBax. The purpose of the PeBax (strike) tie layer improves the overall pressure rating of the tubing if the inner PTFE liner is manufactured via the film cast process.
 - PTFE / Braid w Polyimide Matrix / Polyimide / Layer 4 where Layer 4 = PeBax or Polyurethane, or FEP
 - PTFE / Braid w/ Polyimide Matrix / Polyimide / Braid w/ Polyimide / Polyimide which is a double braid, five layer design
- NonBraid Designs
 - Coextrusion tubing

VI. MODELING RULES OF THUMB

The CathCAD® software has been developed for ease of use. All individuals can be trained to enter composite layered designs into the software and obtain the estimated EA, EI, and GJ rigidities. However, it can be helpful to understand the weighting individual layers have on the design. Understanding these concepts may help you optimize your design more effectively. The following guidelines are provided to give you a better qualitative understanding of composite tubing designs.

- **Stiff Materials dominate the Design:** If the composite design has a layer with a very stiff material (e.g. a braid layer and/or a Polyimide or PEEK layer) and a layer with a relatively flexible material, the flexible material layer has minimal influence.
- The relative **Wall thickness of the layer** may allow you to ignore it when modeling the design. If the overall thickness of the design is large and the applicable layer is thin - then the model results with/without the thin layer will be nearly the same.

Example: A composite tube design has a 5 mil wall. This inner layer is 0.2 mils of PTFE. The remaining wall thickness is Nylon 6/6. Modeling approximation: The 0.2 mil PTFE wall could be neglected since it is a thin layer and more flexible as compared to the Nylon 6/6 layer.

- **The outer most layers (those close to the Tubing OD) may and can dominate the design** when computing tubing flexibility and torque.
 - Both the Area Moment of Inertia (I) and Polar Moment of Inertia (J) are proportional to the diameter raised to the fourth power.
 - The cross-sectional area (A) is proportional to the diameter raised to the second power.
- **For a given ID, as the wall thickness of the design increases,** the kink radius will decrease.
- For a given design, **as the pick count increases, typically the kink radius will decrease.** The higher pick count (and thus braid angle) provides more hoop support to the design.
- **A shorter (length wise) catheter will typically have better pushability** than a longer catheter. Comment: The CathCAD® software normalizes the results with respect to the length dimension. However, the overall length of the catheter is very important. As a design of the catheter system, do not forget to optimize the catheter length.