Home - > Medical Tubing Types - > Design Considerations in Small-Diameter Medical Tubing

Design Considerations in Small-Diameter Medical Tubing

Posted in Medical Tubing Types by mddiadmin on January 1, 2001

Share

Medical Device & Diagnostic Industry Magazine
MDDI Article Index

Originally Published January 2001

Cover Story

Ron Roth

With the development of new and revolutionary minimally invasive procedures, the corresponding requirements for small-diameter tubing have become more demanding and complex. Today's designers of medical devices are faced with demands for smaller, better, more-sophisticated, and more-cost-effective products. While the overall trend has been to minimize the cost of individual components, there still is a market for high-performance (and thus more-profitable) medical devices if either of two conditions can be met:

- A significant decrease in clinical procedure time can be demonstrated, with equivalent or improved results.
- The results from treatment using the device are new and are currently unattainable with any other method.

In many cases, achieving an efficient catheter-delivery system figures among the fundamental design requirements in developing a novel medical procedure. Examples of such device applications include angioplasty, stent-delivery, cryogenic, drug-delivery, and arthrectomy catheters, and various other retrievable catheter devices.

This article discusses a range of tubing design topics, including principles of geometric dimensioning and tolerancing, the use of Monte Carlo simulations, implementing the concept of design for manufacturability, modeling and optimization of catheter delivery systems, and future trends in the development of small-diameter tubing and catheter products.

GEOMETRIC DIMENSIONING AND TOLERANCING

Geometric dimensioning and tolerancing is a method for specifying design requirements with respect to the actual function and relationship of part features, and is a technique that can ensure their most economical and effective production. When developing small-diameter tubing, it is important for designers to specify the correct datums or features. Aids to successful design include making sure that:

- The features chosen are clearly identified or recognized.
- Corresponding features on mating parts are used to establish datums to ensure proper part assembly.
- The datums on an actual part are accessible during manufacturing so that measurements can be readily made.

Typically, the inner diameter (ID), outside diameter (OD), or both are selected as datums. Additional attributes, such as wall concentricity or eccentricity and part straightness along the length of the tube, may also be specified.

For ultra-thin-wall tubing, it is common for the designer to specify the ID and wall thickness as design features and the OD as a reference, as shown in Figure 1. For thicker-wall versions, it is better for the designer to specify the tube ID and OD; the ID, OD, and wall minimum; or the ID, OD, and wall eccentricity. The use of established drawing standards guarantees that the designer's intentions are accurately communicated to the tubing supplier.

Figure 1. Basic specifications drawing for small-diameter tubing.

MONTE CARLO SIMULATIONS

The use of a technique known as a Monte Carlo simulation can be very useful in determining correct part tolerances. A Monte Carlo–determined tolerance is roughly two to three times larger than a tolerance determined by a worst-case analysis. This is particularly true under the following circumstances:

- The required tolerance results obtained from a worst-case analysis are too tight.
- The fit and attribute performance from two or more mating parts is complicated and the results thereof cannot easily be determined analytically.
- A part attribute is critical and the designer wishes to understand the impact that tolerance variations will have on

Most Recent

Most Viewed | Top Rated | Most Emailed

Experts: FDA's Draft on Combo Products CGMP Helpful

Managing Risk When Using a New Medical Device Material

Edwards Goes From Strength to Strength in TAVR Market

Batteries for Wearables—Not Good Enough Yet

Top 10 Medical Device Deals of 2014 (Butterfly Network)

Top 10 Medical Device Deals of 2014 (MID Labs)

Top 10 Medical Device Deals of 2014 (AqueSys)

Top 10 Medical Device Deals of 2014 (Holaira)

Related articles

Producing Bubble/Taper Tubing for Medical Applications

by mddiadmin on January 1, 2000

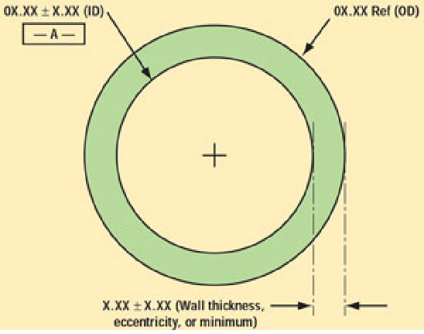
Low-Profile Balloon Catheters are Critical to TAVR's Success

by MDDI Staff on October 21, 2014

Parker Hannifin Opens Center To

that attribute.

The term *simulation* refers to any analytical method meant to imitate a real-life system, especially when other analyses are mathematically complex or difficult to reproduce. A Monte Carlo simulation is a method in which randomly produced numbers (typically from a computer) are generated for uncertain variables and analyzed to determine the model and/or assembly performance. As recently as 10 years ago, it was common for large companies to spend significant funds to purchase Monte Carlo simulation software; today, this function can be completed on a personal computer using common spreadsheet programs.



In some cases, it is permissible to specify tolerances for a part that may not be achievable all of the time. This situation is acceptable if a system is in place that eliminates the bad parts sometime during the manufacturing process. The process for eliminating "bad" parts is often as simple as adding an additional part requirement that is usually directly related to the actual part function. For example, suppose that the tubing designer has determined that a tight wall specification is necessary to meet a required pressure rating, and the tubing vendor has responded with a high quote, citing the tight tolerances. Working together with the tubing vendor, the designer could relax the tight wall tolerance and add a 100% pressure-testing inspection requirement.

The following example is provided to demonstrate actual results that can be obtained from using a Monte Carlo simulation in designing a catheter shaft. A designer wished to better understand the yield point of a 0.022-in.-ID x 0.028-in.-OD polyimide tube. (In this case, the term *yield point* is defined as the point at which the tube begins to elongate under a load, which generally is taken as an elongation of 2%.) For this example, both the ID and OD tolerances were ±0.00025 in. and the wall was assumed to be perfectly concentric. Based on pull-test data, the yield stress of polyimide was determined to be between 11,500 and 14,500 psi.

For purposes of the simulation, it was assumed that the minimum and maximum of the three variables (ID, OD, and yield stress) are three-sigma statistical limits. Using a Microsoft Excel spreadsheet, 10,000 tubes were modeled. For each tube, the computer randomly chose an ID, OD, and yield stress, with the variables following a standard Gaussian distribution. Based on each catheter design, the cross-sectional area of the tube was computed from the computer-generated ID and OD. This cross-sectional area was multiplied by the computer-generated yield stress, which resulted in the computed yield-point load.

A graph of frequency of occurrence versus predicted tubing yield load is shown in Figure 2. The distribution is Gaussian because the assumption was made that all of the variables involved in the computation were Gaussian distributed. For a Monte Carlo simulation model size of 10,000 samples, the predicted yield load varies from 2.50 to 3.60 lb. However, 98% of the time, the yield load varies from 2.75 to 3.40 lb. Thus, according to the Monte Carlo simulation, approximately 1% of the time the part had a yield load of 2.50 to 2.75 lb. A worst-case analysis might lead the designer to frequently expect low yield-load results. A Monte Carlo simulation states that the likelihood of such low yield loads is in fact very rare, and also guides the designer in focusing on identifying and minimizing variations in the overall assembly.

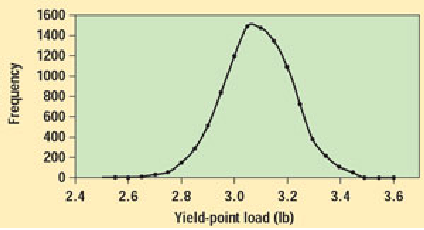


Figure 2. Predicted yield loads of 0.022 x 0.028-in. polyimide tube from Monte Carlo simulation.

A Monte Carlo simulation is typically not a tool used every day by catheter designers. However, it can play a useful role in determining part tolerances, forcing designers to analyze and determine which attributes are critical to the part specification. Such precision in the design process can often spell the difference between a successful product launch and one that is mired in manufacturing difficulties.

DESIGN FOR MANUFACTURABILITY

One of the pressing issues for any new product or process development project is the complexity of the required manufacturing process and its expected yields. Many manufacturers incorporate early manufacturing involvement teams into their design organization, with the objective of optimizing the manufacturability of the design from the beginning of the development process. The following sections summarize recent trends in catheter manufacturing, including assembly techniques, component outsourcing tactics, and sterilization methods.

Assembly Techniques. Until recently, epoxies were commonly used in catheter assemblies. These adhesives deliver very high performance but have the drawback of requiring long cure cycles or elevated cure temperatures. The use of epoxies thus requires additional manufacturing floor space for staging of subassemblies during the cure cycle, which results in higher overhead. As a result, the use of epoxies in catheter subassemblies has often been replaced by the following alternatives:

- Adhesives that can be cured on demand through exposure to ultraviolet light.
- Thermal welding of mating parts. This is accomplished via localized heating of certain materials (for example, Pebax and urethanes), which causes them to reflow and create a integral adhesive bond for the surrounding parts.
- Elimination, in some cases, of the use of adhesives altogether through innovative processes. For example, variable-stiffness catheter products can be manufactured as a continuous process.
- The alteration of certain plastics that require an adhesive bonding operation to produce more manufacturing-friendly materials. For example, a polyimide tube can be modified by overcoating the OD with a Tecoflex urethane layer in the region where a thermal welding operation (joining) is to occur.

Component Outsourcing. Many major medical device manufacturers are outsourcing more subassembly to component manufacturers. This trend requires the component manufacturers to assume more responsibility for delivering finished or nearly finished catheter components. Additional operations that are typically requested from component manufacturers include:

Research New Uses For Polymers in Medical Devices

by Arundhati Parmar on October 2, 2014

Rota-Trach Tracheostomy Tube

by Chris Wiltz on June 18, 2013

Webcast: How to Choose the Right Heat-Shrink Tubing for Your Application

by Jamie Hartford on October 10, 2012

New Age Industries Offering Customized Plastic Tubing

by Chris Wiltz on October 1, 2012

Pump Up Balloon Tubing Process

by mfontanazza on October 18, 2011

1 2 3 next › last »

- Cutting to exact length tolerances of nonbraided tubing products.
- Cutting to length of braided components in which the tip is nondeformed and the braid wires are imbedded in the tubing product (nonfrayed).
- Secondary operations such as flaring, tipping, hubbing, hole drilling/punching, curve forming, and ID/OD tube tapering.
- Surface preparation of fluoropolymer materials for bonding.

Problems with outsourcing subassembly operations can often be minimized by requiring that the component manufacturer have a good quality system in place. ISO certification of quality systems is fast becoming a requirement for medical component suppliers.

Sterilization Methods. Another important issue concerns the terminal sterilization method used for the finished catheter device. Many catheter manufacturers are tending to favor the use of E-beam or gamma irradiation over ethylene oxide gas. The preference for high-energy sterilization has the result of eliminating the use of some fluoropolymer materials, such as fluorinated ethylene propylene (FEP) or polytetrafluoroethylene (PTFE) in catheter assemblies. This can compromise the finished devices' performance, since equivalent substitutes have not been found that offer all of the performance attributes of these two materials.

MODELING AND OPTIMIZATION OF CATHETER DELIVERY SYSTEMS

In the design of any catheter delivery system, among the important design qualities that may come into play are the tubing's profile or form factor as well as its trackability, pushability, and torqueability. Trackability refers to the characteristic of a catheter that allows it to follow through tortuous paths to its ultimate destination. Trackability cannot be measured directly, but rather is a combination of factors such as:

- Shaft flexibility.
- The friction between a catheter and its surrounding environment.
- Column strength, which is the ability of the catheter to withstand axial forces without compression or stretch.

The requirements for any delivery system have to take into account specific but often contradictory design parameters. For example, a small profile and flexible tip may meet the requirement for a nontraumatic design but also result in lower pushability and torqueability of the catheter shaft.

In order to minimize the number of iterations required to arrive at an optimal catheter system design, it is useful to develop an analytical model of a tubing shaft. The simplest approach is to develop a linear, lumped parameter model to estimate product qualities. The following section summarizes the governing equations that a designer can use to estimate catheter pushability, torqueability, and flexibility.

Figure 3. Axial force (F), or pushability, applied to length of tube.

Catheter pushability refers to the response of a tube when a longitudinal force is placed along its axis, as shown in Figure 3. For small deflections, the tubing properties can be considered to approximate a spring system, in which the longitudinal stiffness of the spring is determined by the equation

$$k_{long} = \frac{EA}{L}$$

where k_{long} is the longitudinal spring constant, E is the modulus of elasticity, A is the cross-sectional area, and L is the length of the catheter shaft. In order to maximize pushability, the designer needs to maximize the quantity k_{long}. This can be achieved in various ways:

- By maximizing the cross-sectional area of the tubing.
- By maximizing the modulus of elasticity by using a stiffer material.
- By decreasing the overall part length.

Catheter torqueability describes the behavior of a tube when a moment of torque is placed about its longitudinal axis (Figure 4). Once again, for small deflections, the tube's mechanical properties approximate a spring system, in which torsional stiffness is determined such that

$$k_{torq} = \frac{GJ}{L}$$

where k_{torq} is the torsional spring constant, G is the shear modulus, J is the polar moment of inertia, and L is the length of the catheter shaft. Maximizing torqueability means maximizing the quantity k_{torq}, which can be accomplished:

- By maximizing the polar moment of inertia. For a simple tube profile, the governing equation for J is as follows:

$$J = \frac{\pi}{32}\left(d_o^4 - d_i^4\right)$$

where d_o is the tube OD and d_i is the tube ID. In order to maximize J, the designer needs to maximize the outside diameter and the wall thickness:

- By maximizing the shear modulus using a stiffer material.
- By decreasing the overall part length.

Tube flexibility can be modeled as a clamped beam system subject to a downward force at the beam, as shown in Figure 5. For small deflections, the tubing approximates a spring system, with the flexural stiffness determined by

$$k_{flexural} = \frac{3EI}{L^3}$$

where $k_{flexural}$ is the flexural spring constant, E is the modulus of elasticity, I is the moment of inertia, and L is the length of the catheter shaft. In many cases, it is desirable to minimize the flexural stiffness of the catheter, which the designer does by minimizing the quantity $k_{flexural}$ through actions that can include:

- Minimizing the moment of inertia. For a simple tube profile, the governing equation for I is as follows:

$$I = \frac{\pi}{64}\left(d_o^4 - d_i^4\right)$$

where d_o is the tube OD and d_i is the tube ID. In order to minimize I, the designer needs to minimize the OD and the wall thickness:

- By minimizing the modulus of elasticity by using a soft material.
- By increasing the overall part length.

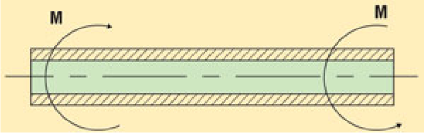
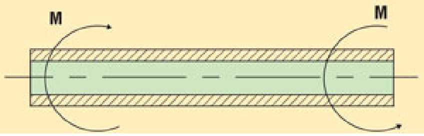


Figure 4. Torque or moment (M) applied to a tube.

Figure 5. Flexibility (F) or bending force applied to end of tube.

Commonly, composite tubing designs are used for catheter delivery systems. These include designs consisting of one or more plastic materials as well as wire-reinforced (braid or coil) designs. The modeling concepts described previously can also be used to analyze and compare composite tubing designs. The stiffness properties of each separate and distinct layer can be computed and combined using principles of classical lamination theory.



To illustrate the effectiveness of the lumped parameter model previously described, six different small-diameter tubing designs were evaluated in terms of flexibility, pushability, and torqueability. A different material was used for each of the six tubes: Tecoflex 60D, PTFE, PeBax 72D, Hytrel 8238, polyimide, and braided polyimide.

For this example, it was assumed that the tubing featured an ID of 0.032 in., an OD of 0.040 in., and thus a wall thickness of 0.004 in. Results from this analysis are summarized in Table I. For simplicity, the catheter shaft length was considered to be the same for all six designs. To illustrate the range of tubing properties that can be obtained, the most flexible (the Tecoflex 60D tube) and the stiffest (the braided polyimide tube) can be compared in terms of push, torque, and flexural stiffness:

- The braided polyimide tube has a longitudinal stiffness (EA) of 817, whereas the Tecoflex 60D tube has an EA of only 6. The braided polyimide tubing thus provides approximately 135 times more push than the Tecoflex 60D tubing.
- Similarly, the braided polyimide tubing offers 281 times more torque than the Tecoflex 60D tubing.
- Finally, the flexural stiffness of the braided polyimide tubing is approximately 133 times higher than the Tecoflex 60D tubing.

Given these results, it is obvious that the braided polyimide tubing design should be used on the proximal end of a delivery catheter system, where pushability is a requirement. The Tecoflex 60D design—because of its flexibility—should be used on the distal end of the catheter shaft.

Tubing Characteristics	**Tubing Material**					
	Teco 60D	**PTFE**	**PeBax 72D**	**Hytrel 8238**	**Polyimide**	**Braided Polyimide**
ID (in.)	0.032	0.032	0.032	0.032	0.032	0.032
OD (in.)	0.040	0.040	0.040	0.040	0.040	0.040
Modulus of elasticity (psi)	13,200	50,000	63,000	135,000	500,000	1,800,000 (computed)
Wall thickness (mil)	4	4	4	4	4	Inner layer: 1.5 mil PI Int. braid layer: 0.7x5-mil SS 304V, 16 wires, pick count = 60 Outer layer: 1.0-mil PI
Flexural stiffness (lb/in.^{2})	0.001	0.0037	0.0046	0.01	0.037	0.134
Longitudinal stiffness (lb)	6	22	29	61	226	817
Torsional stiffness (lb/in.^{2})	0.00075	0.0029	0.0036	0.008	0.028	0.212

Table I. Results of a lumped parameter modeling example.

The format shown in Table I allows the designer to make quick and simple comparisons between different tubing designs. This format is particularly useful in comparing composite tubing designs in which the number of variables—including materials, layer thicknesses, and reinforcement construction (wire material, number of braid wires, and braid angle)—increase significantly.

DEVELOPMENT TRENDS

Composite Tubing. Composite tubing (tubing with two or more materials) is increasingly being used in medical devices. The reason is that composite tubing often offers significant product enhancement compared with a single-material tube design. For example, braided polyimide tubing with a PTFE inner liner is replacing plain polyimide tubing in many medical devices. The composite tubing design offers increased pushability and torqueability and improved lubricity on the ID compared with the unlined polyimide tube.

Safety Factors. Driven by the competition, manufacturers are striving to achieve further reductions in the wall thicknesses of small-diameter tubing products. However, designs offering the smallest profile sometimes result in a lowering of safety factors. For example, reducing the wall thickness of a tube that is pressurized during product use induces higher component stress levels. The techniques discussed in this article can assist the designer in better understanding the trade-offs involved.

Sensor Development. A prominent trend in catheter design is the development of systems that provide diagnostic as well as therapeutic capabilities. One method of approaching this objective is through the integration of sensors into the catheter shaft or tip.

In the case of tissue ablation, for example, the physician observes sensor-derived feedback and increases or decreases a control variable (typically, the voltage applied) to effect the degree of ablation required. For improved results, one or more thermocouples can be incorporated into the catheter shaft to provide useful information to the physician. For example, if it is known that the best tissue ablation occurs at a temperature of 42° to 47°C, either the physician can adjust the voltage required to obtain the correct set point or a microprocessor can be integrated into the supporting electronics to adjust the voltage using a PID or fuzzy-logic control system.

CONCLUSION

According to industry reports, the world market for minimally invasive medical devices was approximately $13 billion in 1999, and is growing at 15 to 20% annually. Based on these projections, the future for novel catheter-based product development appears to be bright.

Given the pressure to reduce device size and cost and improve performance, it is important for the product designer to completely understand the overall tubing system being developed. As part of this process, choices must be made that achieve optimization of materials, device geometry, and cost, while at the same time resulting in a simple product that is easy to manufacture. When finalized, these design choices must be documented in engineering drawings that communicate the requirements in a concise manner to the manufacturing department.

The models described in this article allow the designer to determine the proper part tolerances and catheter performance attributes. These models can be helpful in reducing the development cycle and producing a robust product design. When successful, the new catheter-based products can contribute to lower overall medical-systems cost, improved procedure outcomes, and enhanced quality of life for the patient.

BIBLIOGRAPHY

Jones, Robert. *Mechanics of Composite Materials*. Washington, DC, Scripta Book Co., 1975.

Shigley, Joseph Edward, and Mitchell, Larry D. *Mechanical Engineering Design,* 4th ed. New York: McGraw-Hill, 1983.

Ron Roth, PhD, is vice president of engineering at HV Technologies Inc. (Trenton, GA). The company manufactures polyimide tubing, high-performance composite tubing, and catheter subassemblies for the minimally invasive medical device market.

Return to the MDDI January 2001 table of contents | Return to the MDDI home page

---

Tags: Design, Feature, Manufacturing, Medical Tubing Types

Printer-friendly version