

Extruded Medical Tubing: Process Parameters and Equipment Play Critical Role in Performance Characteristics

EXTRUDED MEDICAL TUBING: PROCESS PARAMETERS AND EQUIPMENT PLAY CRITICAL ROLE IN PERFORMANCE CHARACTERISTICS

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INTRODUCTION

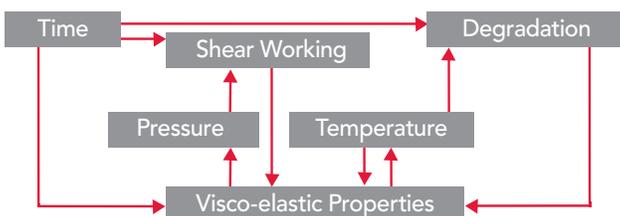
Most medical tubing specifications comprise a drawing of a tube with the material, dimensions, and tolerances. Rarely do the specs include other tubing attributes or process parameters associated with the production of the tubing. It is a common misconception that as long as a lot of tubing is made from the right material and meets the dimensional requirements, it will be the same as or equivalent to another lot of tubing made by the same supplier or a different supplier. While this may be true, there is a good chance that the 2 lots of tubing may be different. These differences are not always obvious or easily recognizable, even when inspected by incoming QC. The process parameters and the equipment used to extrude the tubing often are as important—or even more important—than the actual dimensions of the tube.

EXTRUSION PROCESS AND DEGRADATION

The process used to produce medical tubing can be extremely important in high-end diagnostic and therapeutic catheters. Market pressures have driven catheter manufacturers to design increasingly smaller devices with increasingly thinner walls. Examples of such applications include high-pressure catheter tubing; tubing used to make angioplasty and stent delivery catheters; balloon tubing used to fabricate medical balloons, especially high-pressure angioplasty and stent delivery balloons; tubing to be implanted or inserted in the body for long periods of time; and other applications in which the mechanical, physical, chemical, electrical, or thermal properties are critical to the function of the finished medical device.

Degradation during the extrusion process can greatly affect the properties of the end-use medical tube. Polymers are very large molecules that derive their unique and useful properties from their size (molecular weight). Degradation is a breakdown of these large molecules, which results in a change of properties such as tensile strength, brittleness, flexibility, discoloration, etc. To understand degradation, it is important to understand the various interactions that take place during the extrusion process. The following figure provides an overview:

FIGURE 1.



Various interactions take place during the extrusion process. A combination of these interactions can result in material degradation. *Courtesy of Chris Rauwendaal and Rauwendaal Extrusion Engineering.*

Degradation during extrusion is typically the result of:

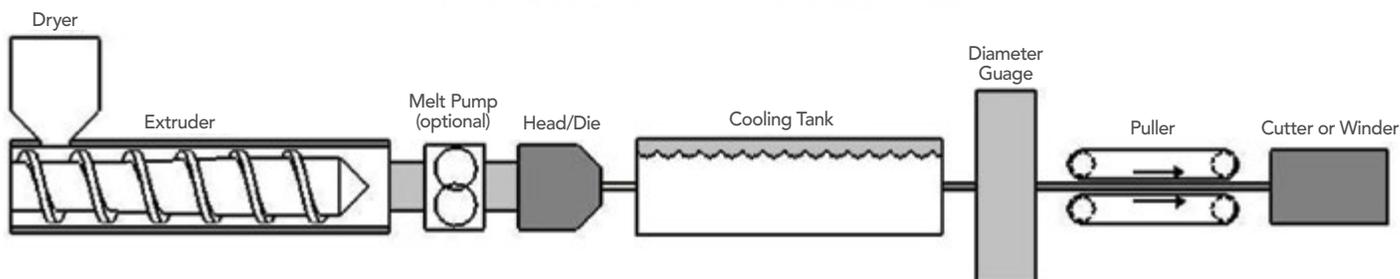
- Improper drying
- Overheating the material (running the polymer at too high a temperature)
- Overshearing the material (running the polymer at too high a screw speed or using the wrong screw design)
- Keeping the polymer in the molten state too long (long residence time)

Such changes occur primarily because of the effect of these factors on the chemical composition of the polymers. Some polymers, such as PET, are very sensitive to process parameters and can degrade easily. Other polymers, such as polyethylene, are very forgiving.

Another cause of degradation in extrusion is multiple melting process steps. For example, some materials used to make medical tubing must be precompounded, where the base material is melted and mixed with other materials such as colorants, radiopaque fillers, stabilizers, processing aids, etc. This often takes place in a separate extrusion operation to ensure that the components are properly dispersed and distributed. Compounding is often done in a twin-screw or single-screw extrusion process. This process step results in a heat history and shear history in addition to those that result from the tube extrusion process. The combination or sum of these processes results in overall loss of molecular weight and polymer degradation. If either one of these steps is carried out incorrectly, results can be compromised.

EXTRUSION OVERVIEW

FIGURE 2. TYPICAL MEDICAL TUBING EXTRUSION LINE



An extrusion line combines several pieces of equipment, including a resin drying system, the extruder, the die, the cooling tank, a take-up device (puller), and a cutter or winder.

DRYING

Often, the first step in the process is drying the polymer, a critical process in extrusion. Many polymers used in the medical device industry are hygroscopic, meaning they readily absorb moisture from the environment. Hygroscopic polymers must be carefully dried before being melt extruded or compounded.

All materials are not dried under the same parameters. Some materials require high temperatures for long periods of time, while others require low temperatures for shorter periods of time. Some materials are extremely sensitive to moisture content and must be very carefully dried, while others are easier to dry and much less critical. For example, drying PET is absolutely critical to the extrusion process. Even a very small amount of moisture can degrade PET beyond use.

Drying a material for too short a time and/or at too low a temperature can result in under-drying. This can leave residual moisture in the polymer, which results in hydrolysis during extrusion. Hydrolysis is a degradation process that results in significantly lower molecular weight. Under-drying of polymers often occurs in medical extrusions because run times can be very

short, with lots of material change-overs. Customers often request the same size tube in multiple grades of materials—for example, 3 different durometers of the same material—to optimize flexibility for a particular application. If the processor does not have 3 dryers available to predry all 3 materials, the second and third materials may not be properly dried before extrusion. The result could be that the engineer evaluates partially degraded material and makes the wrong choice for the application.

Over-drying can also occur because many medical extrusion lines run at very low throughputs (at low pounds per hour). Most commercial resin dryers are oversized for medical extruders. Therefore, the residence time in the dryer can be extremely long. If not properly monitored, this can result in over-drying, which can cause thermal degradation in some materials. Many polymers, such as nylon and polycarbonate, can be sensitive to over-drying.

Most resin manufacturers specify minimum drying times and temperatures for their materials. These recommendations must be followed very carefully to ensure that the materials are properly dried before extrusion. Normally, desiccant-type dryers are used in the medical extrusion industry to ensure proper drying. These dryers must be well maintained, and periodically cleaned, tested, and calibrated to ensure that they are functioning properly.

THE EXTRUDER

The extruder is a melting and pumping machine. It converts solid pellets into a uniform, molten state and forces the material through the die, ideally at a constant rate. Melting is accomplished through frictional heat generated from the mechanical work of the screw and heat conduction from the heated barrel of the extruder. The design of the extrusion screw is critical to achieve uniform melting and pumping of the polymer without overworking (overshearing) the material. Different materials require different screw designs to optimize the extrusion process. Many tube manufacturers use general-purpose screw designs and try to run all their materials using the same screw. This can result in overshearing and degradation in some materials, and improper melting and gels in others.

EXTRUSION DIE

The extrusion die sits at the end of the extruder and is the point where the polymer exits into a cooling tank. The die forms the initial shape of the tube. A tubing die typically comprises 2 major components: a mandrel or tip that forms the tube ID; and a die, or ring, that forms the tube OD. The die and mandrel are typically contained inside the extrusion “head.” Dozens of manufacturers of extrusion heads and tooling and many extrusion companies have developed proprietary head, die, and mandrel designs. The design of these components plays a critical role in the extrusion process and the ability of the extruder to produce precise dimensions and maintain proper physical properties of the material. The relationship between the die and mandrel dimensions and the finished tube dimensions is called the “draw-down ratio.”

Very small-diameter medical tubing with very thin walls can be difficult to extrude through a standard extrusion head/die. Often, the viscosity of these materials in the die is so high and the die gap is so small that the extrusion operator must increase the temperature of the polymer in order to reduce the viscosity of the material to get sufficient flow through the die. This practice can dramatically alter material properties. When extruding thin-wall tubing, specially

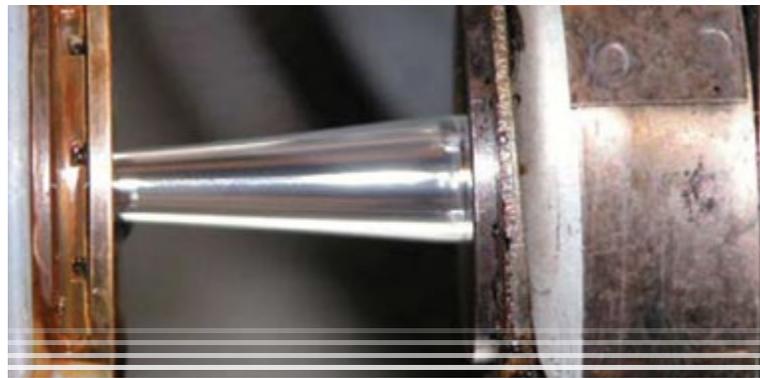


Figure 3. The extrusion process that creates the draw-down ratio.

designed heads are often required to produce high-quality tubing without degradation, gels, black specs, or undesirable residual stress.

Many custom extruders overcome these problems, producing tight-tolerance, small-diameter, thin-wall tubing using high draw-down ratios. This significantly improves dimensional tolerances, increases line speed, and makes tooling (dies and mandrels) much easier to fabricate. Unfortunately, running high draw-down ratios also results in significant orientation and residual stress/strain in the finished tubing. This orientation can significantly increase the tensile strength and reduce the elongation of the tubing in the machine direction. It can also reduce the tubing burst pressure due to the loss in hoop strength. The residual stresses from high draw-down ratios can wreak havoc during subsequent thermal processing, sterilization, or aging (natural or accelerated). These thermal processes can release the stresses built in during extrusion, causing the tubing to shrink significantly in length and increase in diameter and wall thickness.

COOLING

The extrusion cooling process is the next critical step. Cooling for many polymers is critical, and significant changes in physical properties and morphological structure can result from different cooling conditions. For example, many polymers are semicrystalline, meaning they contain amorphous regions and crystalline regions. When the polymer exits the die

and is cooled, rapid cooling/quenching tends to retard crystallization or completely eliminate it, while slow cooling can result in a higher degree of crystallinity and/or very large crystal formation.

In some medical applications, such as balloon manufacturing, it is critical that the extruded tubing be amorphous before the balloon-forming process. Therefore, cooling parameters are critical to ensure that crystallization does not occur in the tubing during the extrusion process. In other applications, such as the extrusion of PEEK tubing, it is critical that the tubing achieve a relatively high level of crystallinity when extruded to ensure that the tubing has the outstanding thermal, physical, and mechanical properties of PEEK. In materials such as polyethylene and polypropylene, it is desirable in some applications to minimize the crystallinity in the tubing for improved clarity and softness. But in other applications, it is desirable to increase the amount of crystallinity for improved stiffness and lubricity.

Most processors cool the polymer as it exits the die in a cooling tank filled with water. This is typically done in free extrusion or through a vacuum sizing tank. However, in both methods, the polymer cools through contact with water in the cooling tank. The variables that can affect the cooling process include water temperature, circulation of the water in the tank, length of the cooling tank, and line speed. All of these variables can affect the physical properties of the tubing.

Controlling the water temperature in the cooling tank can be critical in many applications. However, many processors do not use temperature controllers or have very crude control of their water temperature. This can result in significant variations in the cooling rate of the polymer from one lot/batch to another and from the beginning to the end of a lot. Processors that use tap water for cooling can see incoming water temperatures change 30°F or more from summer to winter. In addition, hot spots can be created in the cooling tank, especially in the area where the polymer first enters. This is why it is critical to circulate the water in the cooling tank, even if precise temperature controllers are used.

Many medical extrusion lines are sold with very small, undersized cooling tanks that may not be well suited for long production runs, for extruding larger-diameter and/or thick-wall tubing, or for extruding small, thin-wall tubing at higher line speeds, where there is insufficient time in the tank to properly cool the tube. High line speeds or short cooling tanks can result in insufficient residence time in the cooling tank. This can further result in tubing that exits the extrusion process with the inside still warm or hot and insufficiently set up. Once the tube exits the cooling tank, the cooling process can reverse itself and the tube can begin to rewarm itself from the inside out, since the center of the tube was not sufficiently cooled. This can create varying physical properties in the tube.

EXTRUSION EQUIPMENT AND ITS IMPORTANCE IN THE SUCCESS OF THE TUBE

It's important that medical device designers ensure their tube manufacturer has the expertise and equipment to manufacture a high-end tube for use in the medical device industry. In recent years, many industrial extrusion houses have entered the medical device extrusion business because they see higher profit margins than in industrial applications. However, these manufacturers often use extruders that are oversized for the production of medical-grade tubing, which can result in very long residence time. In many polymers, excessively long residence time will lead to thermal degradation.

In addition, some tubing manufacturers use old equipment or equipment that may not be maintained to the high standards of the medical device industry. Many older extrusion lines do not have state-of-the-art controls, resulting in widely varied processing temperatures and other parameters. This can result in inconsistent thermal history and inconsistent properties within a run or from run to run. This can also be true for properly designed equipment that is not well maintained or properly calibrated. For example, a temperature controller on an extrusion line may operate in a temperature range from 300° to 600°F or more. If that temperature controller is off by 1%, it is off by 5°

at 500°F. If it is off by 5%, it is off by 25° at 500°F. With some materials, a process change of 10° can result in a dramatic difference in the properties of the tube.

Medical tube manufacturers typically have very small extruders. When medical devices require larger-diameter tubing than these small extruders were designed to produce, processors may run the extrusion lines at their maximum output, with high screw speeds. This can be detrimental to many polymers that are shear sensitive. Shear-sensitive polymers run at high-screw RPM can suffer the same type of degradation found when a polymer is heated for too long or gets too hot. It is important to recognize and understand that there are numerous interactions taking place during the extrusion process.

CONCLUSION

The performance characteristics of medical extrusions are only partially determined by the tubing dimensions. As demonstrated in this article, process parameters, equipment, and material characteristics all play important roles in determining the end properties of an extruded tube.

When choosing a tubing supplier, medical device engineers should take into account the criticality of the application in the finished medical device and the importance of the performance characteristics of that tube in ensuring the proper function of the device. Since it is not possible or practical to specify or even measure every critical characteristic of a given tube, it is advisable to choose a tubing supplier that has a demonstrated history extruding similar materials in similar sizes used in similar applications. Engineers should also ensure that the supplier has an appropriate level of understanding, process controls, and expertise for the intended tube application/materials.

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