TECH UPDATE

Molding of Bioabsorbable Polymers Exposes Their Sensitive Side

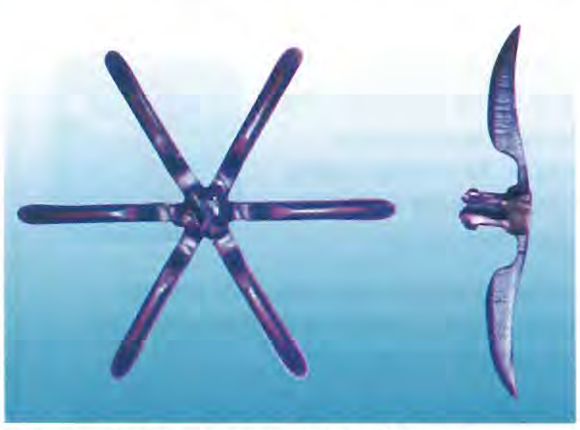
Process control, consistency, and cost-effectiveness are critical considerations when molding bioabsorbable materials

Valued for their ability to safely degrade in the body over time, bioabsorbable materials have had a profound impact on medical device development in recent years. In addition to their widespread use in such applications as fixation devices, sutures, and staples, bioabsorbable polymers are enabling the design of novel drug-delivery technologies, stents, and other medical devices that promise to improve patient care by reducing the risks associated with device removal and infection.

But designing a medical device with bioabsorbable polymers comes at a cost—and not just in terms of the hefty price tags they carry. The degradation and other properties that differentiate these distinct polymers also make them much more difficult to mold and process than their conventional polymer counterparts. Demonstrating extreme sensitivity to such factors as moisture and temperature, bioabsorbable polymers require the input of skilled molders to ensure consistency and quality in the final product. To get to that point, however, bioabsorbable polymers simply need to be handled with care.

Sensitivity Training

"On a very basic level, molding bioabsorbable polymers follows the same rules and principles as molding conventional polymers. However, these materials are, by definition, biodegradable and are in a constant state of flux; they change," notes Norman Akens, molding manager at **Medical Murray Inc.** (North Barrington, IL; www.medicalmurray.com).



A bioabsorbable implant from Medical Murray measures 14 mm and contains a snap feature and six living hinges.

"You have to be more aware of what you're doing."

Careful attention to a number of factors is critical when molding and handling bioabsorbable polymers. In particular, even slight variability in heat, shear, residence time, and moisture can result in part failure. And when dealing with such costly materials and the stringent requirements of the medical device industry, failure is not an option.

Because there is little room for temperature error or variance when molding bioabsorbable polymers, it is imperative to avoid accelerating or reversing the polymerization process, according to Tanner Hargens, senior biomedical engineer at Medical Murray. Crossing the material's temperature threshold, Hargens cautions, can result in excessive monomer, which, in turn, can have a considerable impact on the material. "That excessive monomer can cause mechanical changes, affect the degradation rate, or elevate the cytotoxicity score of the material," he says.

Even if the temperature is carefully controlled, however, degradation of the bioabsorbable material can still occur because of its sensitivity to residence time, according to Brent Borgerson, senior process engineer at **Matrix Tooling Inc./Matrix Plastic Products** (Wood Dale, IL; www.matrixtooling.com). Residence time of the resin, he adds, must be properly matched to the size of the injection unit, the cycle time of the part, and the size of the shot to yield optimal results. Incorrect runner sizes can influence residence time as well; if the runner is too small, the residence time could be too great.

In addition to having precise residence time requirements and a distinct temperature threshold, bioabsorbable polymers are extremely sensitive to moisture. As a result, they require careful material handling and storage to minimize exposure of the materials to moisture, which can affect degradation. Specialized drying processes and equipment are therefore critical components of the molding equation, helping to ensure consistency and preserve the materials's molecular weight.

"You want to get the material dry to its specification. Generally, that requires a vacuum dryer and a nitrogen bath atmosphere," Borgerson says. "You really want to control moisture. That means in the molding environment, relative humidity and any equipment that's used need to be controlled. Then, after a part is taken from the mold, it should be packaged quickly and correctly so that it doesn't pick up moisture from the atmosphere. If you want repeatable results, your moisture level has to be repeatable as well."

And while it is essential that molding partners have the dedicated processes, equipment, and expertise in place to mitigate these sensitivity issues, medical device manufacturers need to play their part as well. Medical device designers need to better understand the limitations and sensitivities of bioabsorbables and establish dedicated processes for receiving and storing the materials, according to Hargens.

Consistency is Key

Because bioabsorbable polymers are so easily affected by slight processing variations, they make it difficult to achieve repeatable results and consistency among different molding runs for a given part. "We see a lot of failures in the market where people come to us because they're getting parts that have some level of physical property in one order and parts that are very different with respect to physical properties in another order," comments Dennis Tully, president of **MTD Micro Molding** (Charlton, MA; www.mtdmicromolding.com).

To ensure lot-to-lot consistency, MTD and other molders of bioabsorbable polymers stress the importance of implementing dedicated processes and maintaining material handling consistency. Although these steps seem obvious, Tully notes, molders that do not specialize in bioabsorbable materials may not be as vigilant in enforcing process and handling consistency because these steps are typically not as critical when dealing with conventional materials. "It's important to understand the potential impact that each manufacturing step may have on the end result," he says. "Understanding that generally requires a commitment to testing and refining those manufacturing steps."

Testing is particularly important when dealing with bioabsorbable polymers because some manufacturing steps can cause molecular weight loss during processing. Although inevitable to some degree, molecular weight loss during processing can affect the behavior and reactions of the material once in the body, according to Akens of Medical Murray.

"The study of all of these manufacturing steps in relation to molecular weight means that [the molder] really needs the ability to test molecular weight in-house," Tully says. "If [the molder] doesn't have that ability, it's really going to be nearly

In producing medical device parts from bioabsorbable polymers, MTD stresses the importance of implementing dedicated processes.

impossible to collect this information intelligently going forward." It can also get costly, Tully adds. He says that molders that are not as experienced with bioabsorbable polymers would need to contract out the molecular weight testing, which can often be in the neighborhood of $180 per test. To provide context, Tully notes that MTD just completed a validation in which it performed 200 molecular weight tests. "It's testing the results of variables in each of these phases of manufacturing and seeing if they're significant to that molecular weight loss that really leads you to the end result of a consistent product," Tully says.

Waste Not, Want Not

Consistency and sensitivity issues are, of course, concerns associated with bioabsorbable polymers. But the biggest pitfall of these polymers in many manufacturers' eyes is likely their high cost. Thus, minimizing scrap and reducing waste are paramount when molding bioabsorbable materials.

"The majority of applications we see in bioabsorbables are small shot sizes and small volume," Akens of Medical Murray says. "If you try to run this on a standard machine, your waste would be very high." To minimize bioabsorbable material waste and reduce costs, Medical Murray employs the Sesame injection molding machine, which features a 2.5-mm injection cylinder and a double-plunger design that reduces shear rate. "I can shoot a very small part and have a very small amount of waste [using the Sesame]," Akens says. "Whereas, with a larger machine, you need to shoot at least 10% of the shot to be accurate and you need to build a lot of cavities, or you're throwing away a lot of material."

Companies such as Matrix Tooling and MTD rely on other methods for reducing waste, however. MTD, for instance, develops custom molds in order to test and optimize the flow path. A paucity of available mold-flow data for bioabsorbable polymers—compared with those available for conventional polymers—is a distinct handicap during this stage of the process, according to Tully. However, the development of these custom molds enables the company to change runner sizes and part thickness while attempting to mimic the process and how the material will react in the real-life application.

The use of surrogate materials can also come in handy for optimizing the process without wasting precious polymer. This tactic relies on the use of a conventional resin—for which there is available mold-flow data—that exhibits a similar mold flow. "Early in the R&D process, there's the possibility of using a similar resin to prove out the mold function," states Borgerson of Matrix Tooling. "You can do your mold-fill analysis and equation and predictions. But you want to try the mold out with a less expensive resin first before you move on to the super-expensive bioabsorbable resin." —*Shana Leonard*

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