A Matter of Materials: Extrusion

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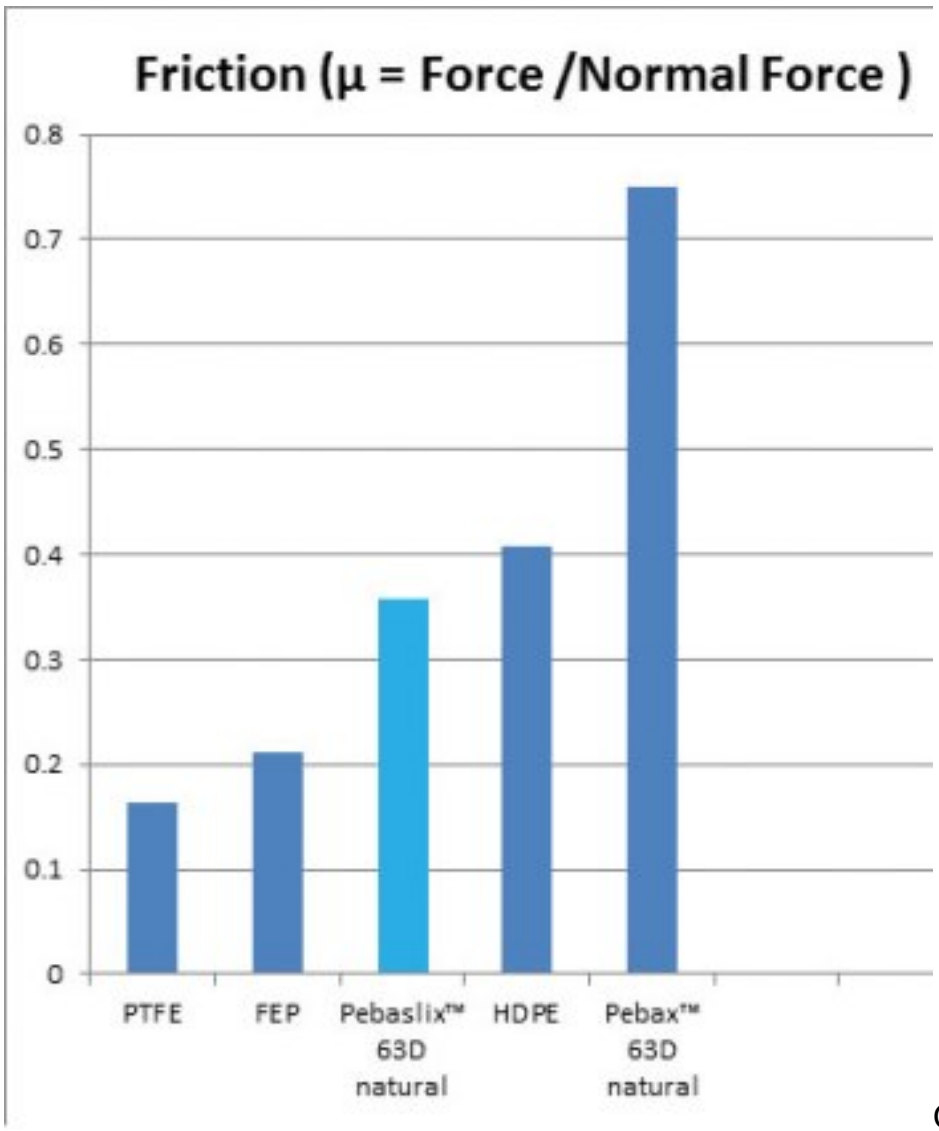
New material offerings are critical to medical device manufacturers as they provide new opportunities in the development of cutting edge technologies. This three-part round-up features three new materials that are impacting medical device manufacturing in the areas of adhesives/coatings, molding, and extrusion. This part focuses on extrusion.

With today's medical catheters becoming increasingly smaller and more complex, it has become nearly impossible to meet new product performance requirements capable of enabling the next generation clinical applications without the development of new materials and the integration of those materials with existing manufacturing processing technologies. For example, the competing requirements for flexibility, ultrathin walls, torque response, and kink resistance are often combined with the need for lubricity—allowing the passage of other devices or motion between catheter surfaces.

The use of PTFE, FEP, or HDPE as a liner has been effective at lowering friction. These materials are often specified for catheter designs despite their limitations. For example the use of PTFE limits sterilization options, increases stiffness, has higher cost, and requires reflow processing complexities. Attempts to meet low friction requirements while avoiding the limitations of using existing material options in catheters has led to the development of hydrophilic coatings for interior lumens and the tubing's exterior. This alternative, however, poses additional issues such as the requirement for an aqueous environment, which is not always present in many applications.



Other attempted solutions to the friction problem have been to add lubricious agents into the base resin of the tubing being produced. Several possibilities have been explored, from PTFE particles to erucamide additives. The PTFE particles may be distributed throughout the thermoplastic. However, due to the melting point difference between the fluoropolymer and the thermoplastic, the PTFE particles do not fully disperse into the thermoplastic resin, creating a less than optimal result. Adding erucamide to a base polymer will reduce the co-efficient of friction but, over a short period of time, it will leach to the surface of the tube, leaving a chalk-like contaminant substance that becomes source of particulation.

In seeking a solution to these problems, Duke Empirical [1] has developed a class of new materials that are being introduced into the market called PebaSlix and PolySlix. These new materials are lubricious and have low friction by a proprietary patent pending process that combines certain additives with the backbone of PEBA and/or polyurethane. The additives are fully dispersed into the thermoplastic, utilizing the full benefit of the additive without changing the mechanical properties, processability, or sterilization methods. PebaSlix and PolySlix with their non-leaching, fully dispersed properties can be bonded and processed in the same manner as traditional PEBA and urethane and are available in a variety of durometers. Material biocompatibility testing is underway and master file data will soon be made available for customer’s regulatory applications. The chart shows the

reduced coefficient of friction of PebaSlix compared to standard Pebax, as well as other, traditionally considered low-friction materials such as PTFE, FEP, and HDPE.

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Click here to view the molding focus [2]; click here to view the adhesives/coatings focus [3].

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