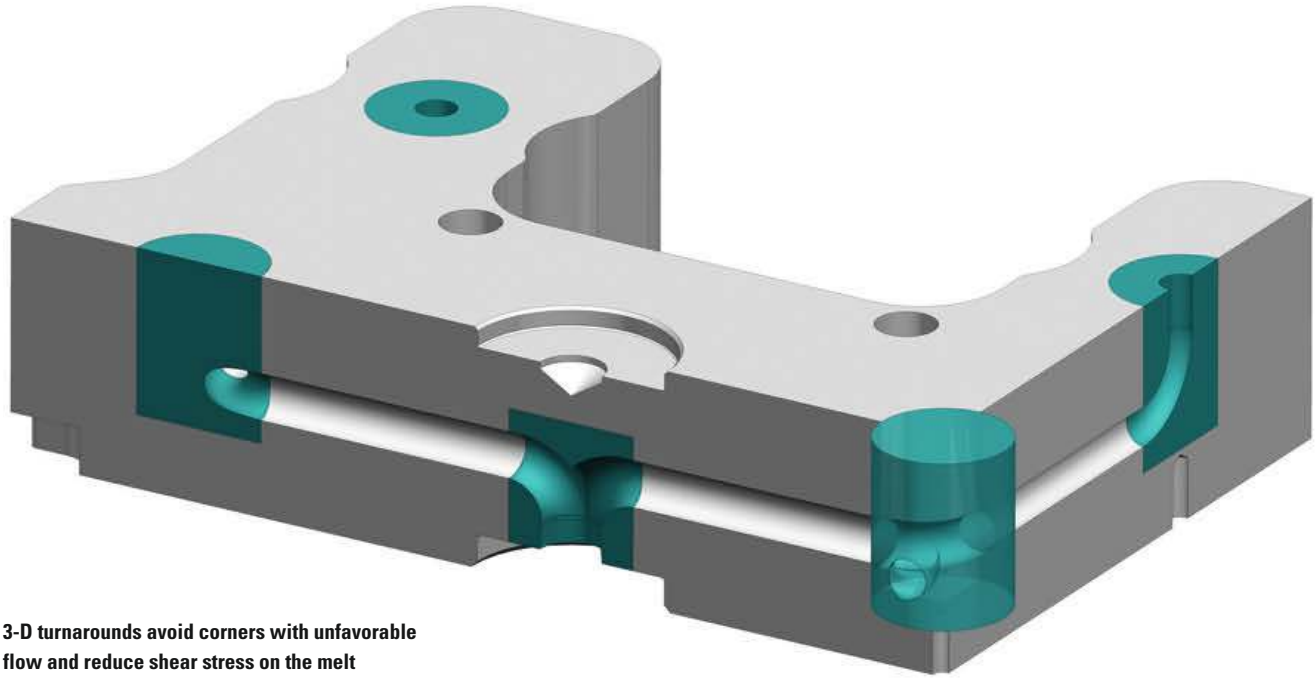
Reliable and Efficient Processing of COC and COP

Mold-Making. Thanks to their outstanding properties, cyclo-olefin polymers and copolymers have become extremely popular over the last few years for the production of pharmaceutical primary packaging. The high demands imposed on the processing of these transparent copolymers can be met with a specially dedicated hot runner system.



3-D turnarounds avoid corners with unfavorable flow and reduce shear stress on the melt

EBERHARD DENGLER
DOMINIK SINZINGER

Maximum safety and reliability still enjoy top priority when it comes to complex injection molding applications for medical products. But nowadays, medical product safety no longer overshadows the aspect of production costs. In particular, producers want to be able to boost the efficiency and productivity of high-volume disposable items. So, there is a need here for solutions that combine maximum safety and reliability with the economic efficiency that dominates other industries.

Cyclo-olefin copolymers (COCs) and cyclo-olefin polymers (COPs) are becoming increasingly important in the pharmaceutical industry because their specific properties are superior to those of glass. Unlike conventional polyolefins, these amorphous polymers are characterized by high purity and crystal-clear transparency. They offer excellent physical properties, such as an effective barrier to water vapor, and have particularly low levels of leachables and extractables. This property range is rounded out by good mechanical strength values (in particular, a high breaking strength), resistance to acids and alkalis as well as good biocompatibility.

Due to the fact that they can be injection molded into more complex shapes, COCs/COPs are set to replace glass in a number of medical applications. The latter include pharmaceutical primary packaging – i.e. packaging means such as vials or pre-filled syringes that come into direct contact with drugs. Prefilled syringes, currently experiencing strong market growth due to the significant advantages that they offer, often contain so-

Translated from Kunststoffe 5/2014, pp. 81–83
Article as PDF-File at www.kunststoffe-international.com; Document Number: PE111685

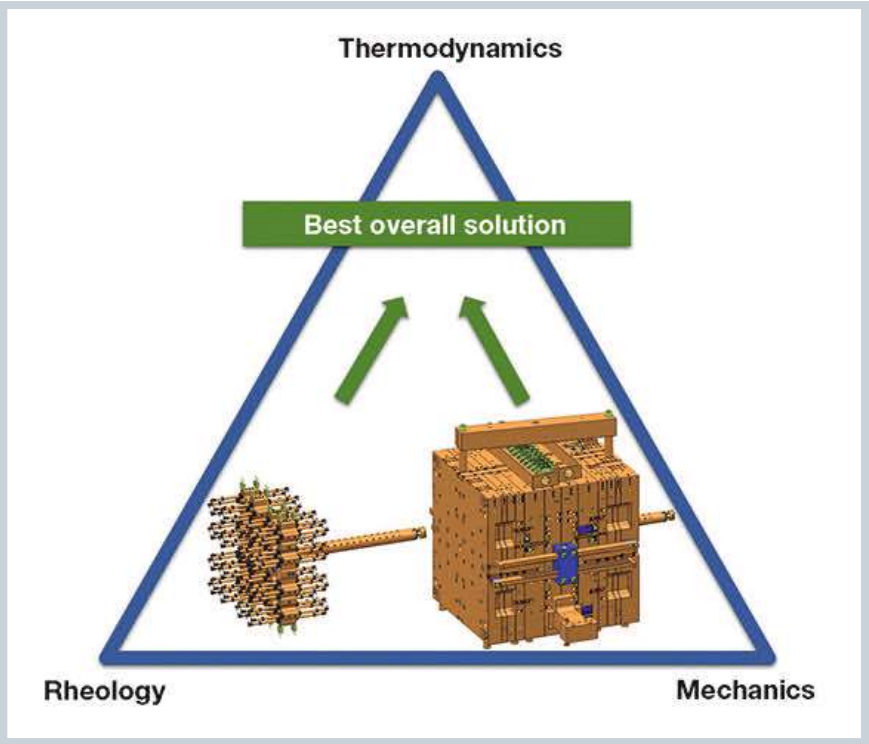


Fig. 1. Molds tailored rheologically, thermally and mechanically to their application ensure high parts quality and productivity

tem and the injection molding process is made more difficult by the requirement for minimal shear stress at high injection speeds.

Schöttli AG, headquartered in Diessenhofen, Switzerland, boasts extensive know-how in this field thanks to years of experience in the development and production of high-precision, efficient injection molds and to its one-stop solutions for the mass-production of medical plastic parts. The mold-making specialist has already created multi-cavity molds for COC/COP applications, for instance.

It has now taken its compact, modular mold concept for single and symmetrical side-gating of rotationally symmetrical cylindrical parts and adapted it to the specific requirements of the materials to be processed. For this, it utilizes a "medical-grade" hot runner and nozzle system for direct side-gating with one or two gates. Schöttli's own hot runner systems, with "integrated mold design", enable it to act as a one-stop shop for molds tailored rheologically, thermally and mechanically to the customer's application **(Fig. 1)**.

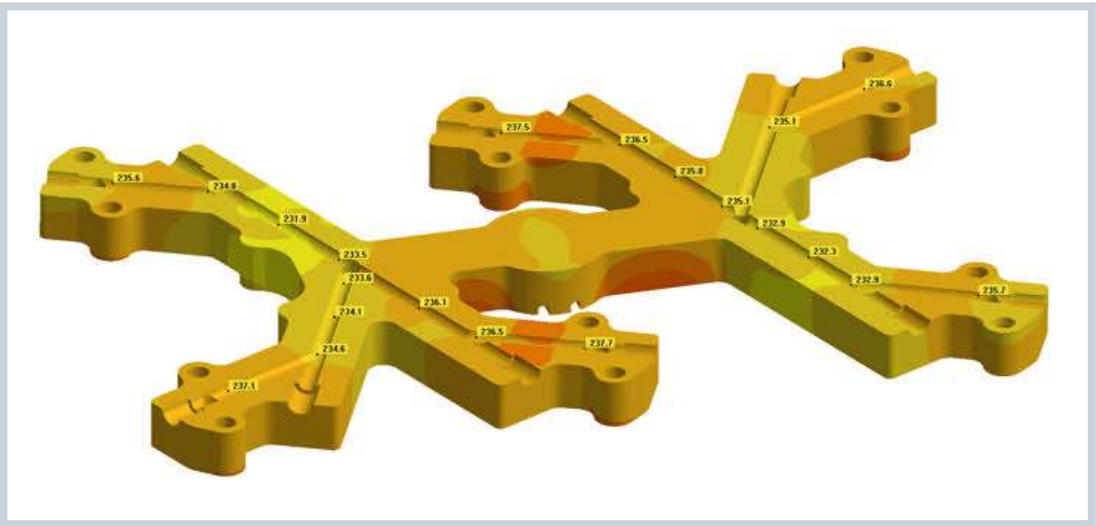


Fig. 2. The aim is to attain a homogeneous temperature distribution combined with minimal shear stress in the hot runner and nozzle system

called parenteral preparations, which are defined in the pharmacopoeia as "sterile preparations intended for injection or infusion into the human or animal body".

High Technical Requirements during Processing

One of the key advantages of pre-filled syringes is patient safety. Such syringes always ensure that the right medication is administered in the correct dosage and concentration and that the risk of contamination is minimized. Two further factors in their favor lead to substantial cost savings in health care, especially as regards expensive drugs: a longer shelf life and the fact that the excess quantity needed to ensure accurate dosing is much lower than that drawn by a doctor administering a conventional syringe.

But COC/COPs are characterized by more than just the above-mentioned material properties. They also meet technical requirements, such as high melt viscosity and a narrow process window for the processing temperature. Thermal sensitivity under conditions of high shear often gives rise to the dreaded quality problems of yellowing and black spots. As a result, the designing of the hot runner sys-

Harmonious 3-D Deflections and Optimized Nozzle Design

The specialists at Schöttli set out to achieve a homogeneous temperature distribution combined with minimal shear stress in the hot runner and nozzle system by running coupled thermal and rheological simulations **(Figs. 2 and 3)**. This means that each hot runner is individually tailored to the requirements of the injection molded part and the material used. The outcome is an optimum temperature profile and a constant flow rate along the system's entire flow path – this has been achieved by, among other things, →

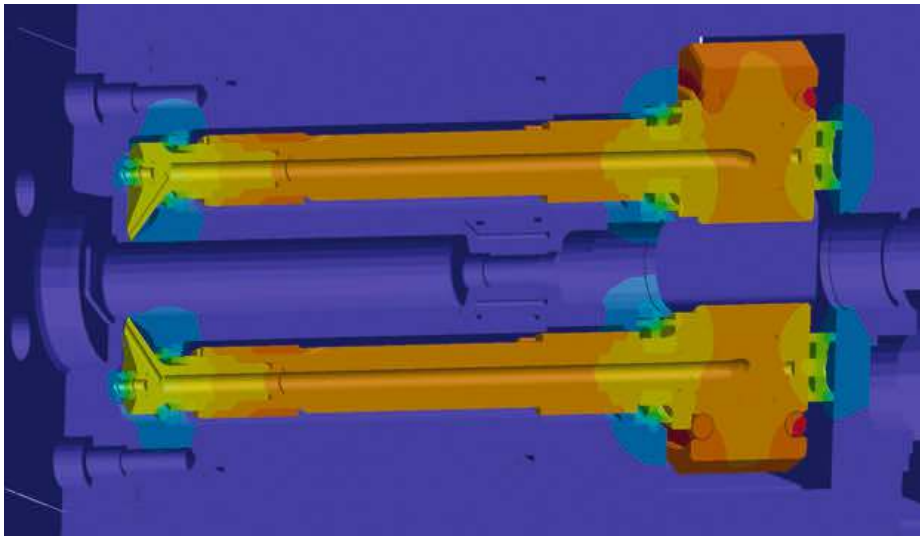


Fig. 3. FEA simulation of the hot runner: the goal is to reduce the flow of heat from the hot runner into the mold

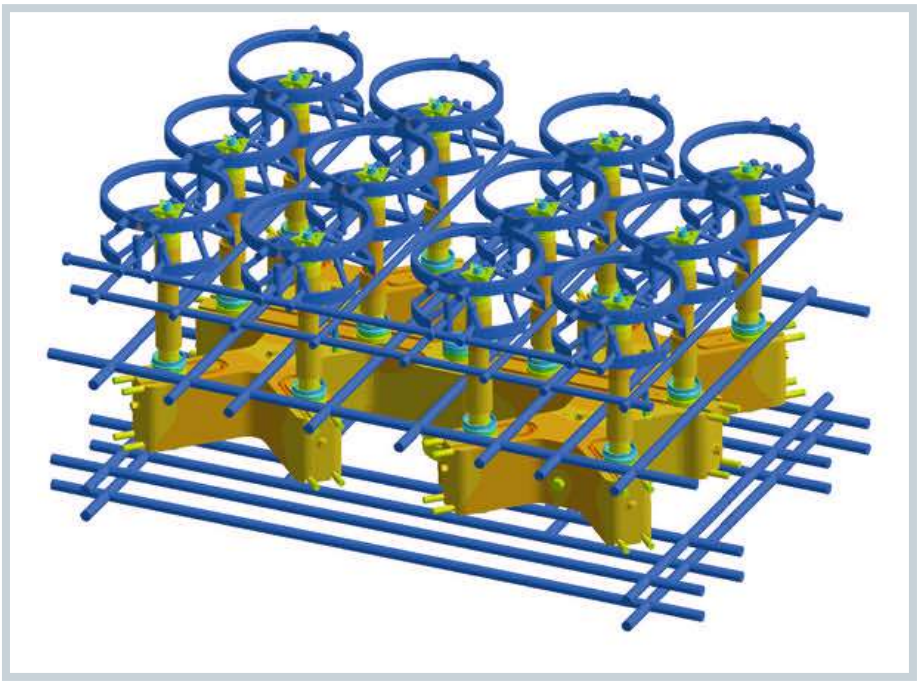


Fig. 4. The key to shorter cycle times primarily lies in optimizing thermal management. This lowers the energy consumption as well (figures: Schöttli)

optimizing the flow channel cross-sections, imparting a special surface finish to the flow channels, and using 3-D turnarounds in the hot runner manifold that prevent dead spots and therefore the risk that material degradation might lead to black spots.

Traditional, bored flow channels in conventional hot runner manifolds have rectangular turnarounds due to manufacturing tolerances. To avoid unfavorable flow spots here, Schöttli uses 3-D turnarounds in these areas **(Title figure)**. In this way, harmonious, radial turnarounds are created which enable a constant flow rate, and thereby lower the shear stress on the melt.

A major advantage of the optimized nozzle is the high quality of the gate, which is designed to be hygienically clean and "particle-free." In other words, the medical products will not become contaminated by dislodged particles.

The drop in melt temperature at the gate, which is necessary for an economical cycle time, is achieved by ensuring that the cooling rate for amorphous polymers such as COC/COP in the gate area is a multiple of that for semi-crystalline polymers. The sophisticated nozzle design, in conjunction with Schöttli's optimized energy management system **(Fig. 4)**, holds the key to achieving a high cooling rate and short cycle times.

Two Gates Are Better than One

To guarantee the required precision and quality with minimum wear of the mold parts, Schöttli prefers symmetrical, two-sided lateral gating of cylindrical parts with large flow path/wall-thickness ratio, such as the syringe bodies mentioned here. This arrangement avoids core deformations caused by one-sided stress and ensures uniform wall thickness over the article's entire cross-section. As a result, overall wall thickness can be reduced and valuable raw material saved.

Conclusion

High-precision molds with a hot runner system specially adapted to medical applications allow reliable and efficient processing of COC/COP molding compounds. Such demanding injection molding solutions require that processors can be assured of high product and process reliability, coupled with commensurately high output, long service life, low maintenance outlay and low energy consumption. ■

THE AUTHORS

EBERHARD DENGLER, born in 1969, is Product Manager, Medical, at Schöttli AG, Diessenhofen, Switzerland.

B. ENG. DOMINIK SINZINGER, born in 1986, is Product Manager, Medical, at Schöttli AG, Diessenhofen, Switzerland.