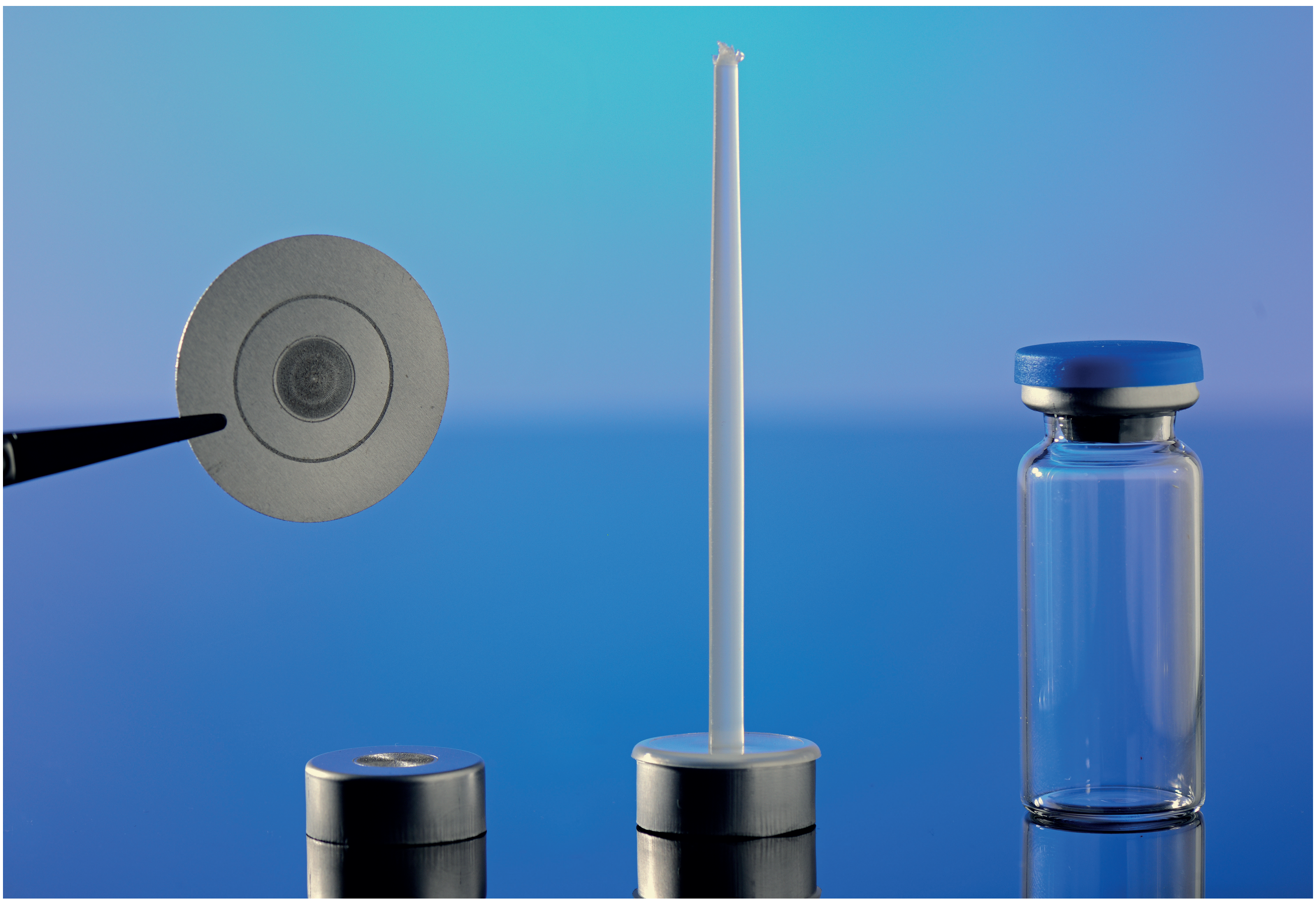
Combined Deep-Drawing and Backmolding Process with Mechanically Interlocking Joint

Process Chain for the Production of Hybrid Medical Products

Pharmaceutical crimp caps generally consist of a thin aluminum sheet and a plastic component, and are used to seal medical vials, for example for vaccines. Through a combined deep-drawing and backmolding process with previous inline laser treatment of the thin aluminum sheet, the process can be significantly shortened. The media-proof joining together of the two materials is carried out through a mechanically interlocking connection.



A crimp cap for injection vials is manufactured in a two-step process. © Fraunhofer ILT

Medical vials and small injection bottles are frequently sealed with so-called crimp caps. These consist of an aluminum component that guarantees a long-lasting seal and a plastic component that allows easy opening of the crimp cap. At present, both components are usually produced in separate processes and subsequently compressed together, which necessitates a large number of handling and cleaning steps as well as high machine and tooling requirements. At the same time, the potential of the individual materials and their interplay in the hybrid component are only utilized to a limited extent.

In order to reduce the manufacturing work and improve the product quality, a group of several companies and research institutes (**Table 1**) has developed a mechanically interlocking process for joining the plastic together with the thin aluminum sheet. In this process, undercut microstructures are incorporated through laser radiation into the metal component, which, during subsequent backmolding, serve as interlocking elements. The joining together of the two components is to be carried out in a combined deep-drawing and backmold-

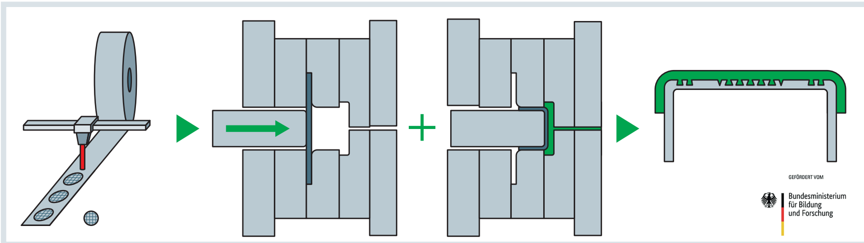


Fig. 1. Process for the production of mechanically interlocking plastic/aluminum crimp caps: cutting out and structuring of the thin metal sheet, insertion into the mold, forming, backmolding. Source: IKV; graphics: © Hanser

ing process, which offers high potential for automation (**Fig. 1**).

To do this, suitable laser structuring parameters have first to be identified in order to create undercut microstructures in the 200 µm thick sheet component. In addition, it has to be proven that deep-drawing of the structured sheets is possible, because the microstructure can considerably weaken the metal sheet because of its low thickness. The aim is to implement the combined process fully automatically in a pilot production cell.

Laser Treatment of Thin Aluminum Sheets

The innovative joining technology, which combines the advantages of an interlocking joint and an adhesive joint, offers extensive potential for heavy-duty hybrid materials. Through the interlocking connection of the two materials, it is possible to dispense with adhesive agents or pretreatment, so that the choice of plastic component and its use in medical technology is no longer restricted. If the interlocking elements are small enough and arranged in high density on the surface, the connection between the materials can be assumed to be a quasi "full-area joint". As a result – as with an adhesive joint – the load is applied homogeneously over the joining area. The laser microstructuring of the thin aluminum sheet should also enable a quasi "full-area" interlocking joint.

For the microstructuring of the metal surface by laser ablation, both continuous and pulsed radiation sources are currently used [1]. With high intensities ($I \geq 10^8\ W/cm^2$) and the use of a continuously emitting radiation source, the material ablation is carried out predominantly by evaporation. With a structuring in the form of lines, the structural geometry is changed by a repetition of the process. Through the geometry of the resultant microstructure and its configuration, undercuts are created [2] into which the plastic melt can flow. The strength of the joint can be influenced by different structural configurations [3, 4]. Until now, this structuring approach has only been studied for material thicknesses > 0.7 mm, so that the distor- »

Company	**Task in the project**	**Internet address**
Fraunhofer-Institute for Laser Technology (ILT)	Development of the laser treatment processes	www.ilt.fraunhofer.de
KraussMaffei Technologies GmbH	Injection molding machine with automation	www.kraussmaffei.com
Chair of Plastics Processing at RWTH Aachen University	Development of the deep-drawing and backmolding process	www.ikv-aachen.de
Pulsar Photonics GmbH	Automation of the laser process and process control	www.pulsar-photonics.de
Röchling Medical Solutions SE	Validation of the crimp caps	www.roechling.com
Siegfried Hofmann GmbH	Mold development, gripper and automation concept	www.hofmann-impulsgeber.de
SimpaTec GmbH	Simulation of the forming and injection molding process	www.simpatec.com

Table 1. Project participants and their fields of research.

Info

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Acknowledgements

The project that serves as a basis for this report was financed with funds from the Federal Ministry for Education and Research under funding number 03XP0291.

References & Digital Version

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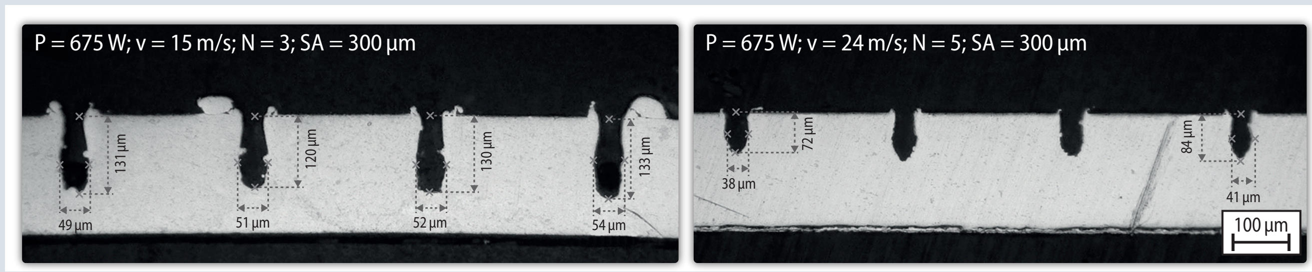

Fig. 2. Optimization of the structure geometry for thin aluminum sheet: through the scanning velocity and the number of passages, the geometry of the structure is adjusted. © Fraunhofer ILT

tion of the metal component through the structuring process could be neglected.

Compromise between Bond Strength and Aluminum Sheet Damage

The microstructures in this project are produced by the Fraunhofer Institute for Laser Technology (ILT), Aachen, Germany, with a Singlemode fiber laser (Rofin FL 020C, manufacturer: Coherent Inc.) in combination with an intelliScan$_{se}$ 20 scan head (manufacturer: Scanlab GmbH). The laser has a maximum output of 2 kW and, with the optical system used here, a beam radius of approx. 20 µm is generated. The laser beam is diverted by two mirrors in the scan head, whereby, for example, lines or circles can be created.

By varying the laser beam power P, the scan velocity v, the number of passages N, the structure gap and the structure orientation, the geometry of the microstructure can be influenced. The material for the sheet metal used here is an AlFeSi alloy (EN AW-8011 H44, manufacturer: Aluminium Féron GmbH & Co. KG). Increasing the scan velocity shortens the interaction time between the laser beam and the aluminum surface, and the proportion of evaporated material increases accordingly. Consequently, the burrs at the opening of the structure can be reduced and the reproducibility of the structure form increases (**Fig. 2**).

Because of the reduced material ablation, comparatively more passages are needed for the undercut. The aim of generating a structure with undercut at a depth of < 100 µm was achieved in the project. This structure depth represents a compromise between high bond strength and minimum damage to the thin sheet.

Apart from the microstructuring for the hybrid product, pre-damage is introduced by laser radiation in order to expose the rubber stopper when using the medical vial and to achieve a tightness structure. The laser also cuts out the circular blank from the aluminum sheet. In this project, the laser process is automated by Pulsar Photonics GmbH. Pulsar additionally integrates a camera-based quality control into the laser treatment unit.

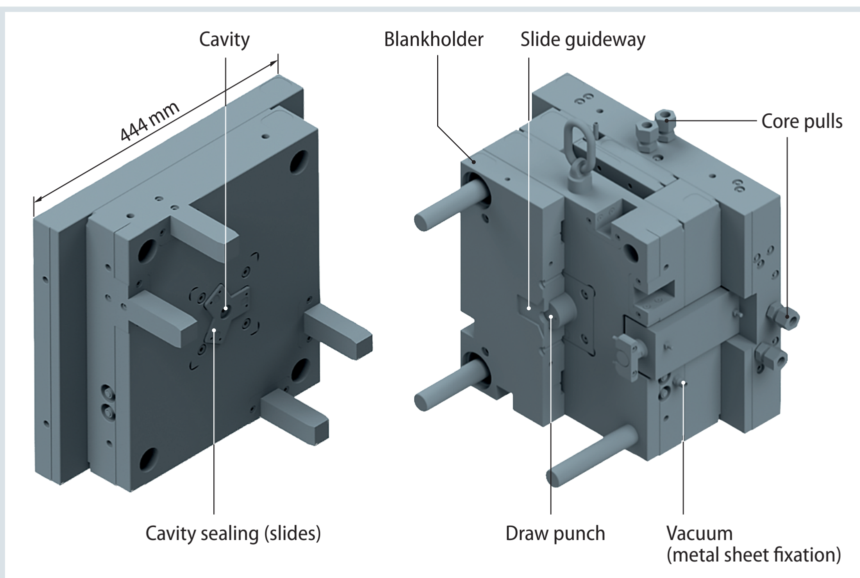

Fig. 3. Mold concept for the combined deep-drawing and backmolding process. Source: Hofmann; graphics: © Hanser

Deep-Drawing of Structured Thin Aluminum Sheet

For the combined deep-drawing and backmolding process, Siegfried Hofmann GmbH developed and manufactured a prototype single-cavity mold. This was put into operation at the Institute for Plastics Processing (IKV) in Aachen. Various mold components, namely the draw punch, draw die and blankholder, were designed according to the relevant standards. In accordance with DIN EN ISO 8362, a diameter of 20.3 mm was selected for the punch of the deep-drawing tool for crimp caps of nominal size 20 [5]. The circular metal blanks with a size of approx. 32 mm are fixed by means of a vacuum in the mold (**Fig. 3**). Subsequently, the clamping force is applied via a core puller and the forming process is triggered by the movement of the draw punch.

In order to evaluate the deep-drawing process of the structured thin metal sheet in advance, SimpaTec GmbH is simulating this procedure. It is analyzing in particular the influence of the microstructure and the process parameters on the deep-drawing in order to prevent selected parameters leading to failure of the structure during the deep-drawing process. Apart from that, an examination is made of how the deep-drawing process changes the geometry, for example the opening width of the microstructure.

Summarizing, it was found that, in the middle range with a structure depth of approx. 100 µm, structured thin metal sheet with a thickness of 200 µm can be formed by deep-drawing without any negative influence on the microstructure. This is a prerequirement for backmolding the caps and thus for the production of the mechanically interlocking caps.

Backmolding in the Single-Cavity Mold

In the combined deep-drawing and injection molding tool, a slider concept is used to enable backmolding of the deep-drawn sheets and to seal the cavity against the draw gap. This is necessary because the clearance is larger than the thickness of the metal sheet component. In the single-cavity mold, a cold runner sprue gate is used. After the deep-drawing process, the mold is closed, whereby the cavity is sealed off by the slide bar. After the injection, the composite with the thermoformed sheet metal component is produced in the microstructures through solidification of the plastic component – in this case the copolymer PP PCGR40 (manufacturer: Sabic AG) (**Fig. 1**). The bond strength is first tested in a vertical draw-off test. In initial trials, the bond strength between two star-shaped configurated microstructures and a circular microstructure is varied (**Fig. 4**). With the star-shaped microstructures, the minimum structure gaps are 100 µm and 150 µm. The circular structure configuration has a structure gap of 150 µm. For all test specimens, the area of the joint is 78.5 mm^2.

The star-shaped structure with a structure gap of 100 µm achieves, with a cumulated structure length of 518 mm – in other words the total length of the microstructures in the bond area – a draw-off force of 23.4 ± 4.4 N. By increasing the structure gap to 150 µm and thus shortening the cumulated structure length to 324 mm, the draw-off force falls to 15.2 ± 6.9 N. The circular structure (structure length of 429 mm) achieves a draw-off force of 27.3 ± 2.1 N.

The results show that, with the same structure type, the accumulated structure length correlates with the bond strength, because, with a higher structure length, more anchoring points are available in the joining surface. In addition, there is an influence of the structure configuration or the way the structure is oriented to the direction of load. Because of the thermal influence of the laser treatment and the low material thickness between the structures, the minimum structure gap cannot be reduced at will [6]. Here, further tests are needed to increase the bond strength.

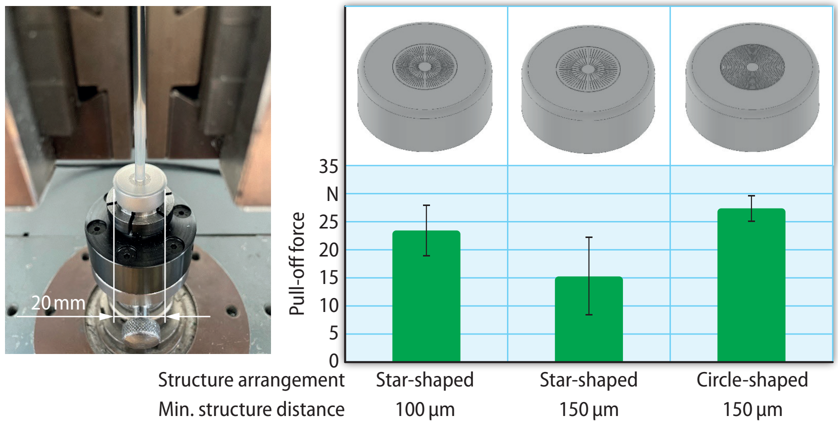

Fig. 4. Testing the bond strength in a vertical draw-off test (left). Result (right): the vertical draw-off force of the plastic component depends on the structural configuration. Source: IKV; graphics: © Hanser

Outlook

It was possible with the prototype tool to demonstrate the feasibility of the planned process route. In the next steps, the combined deep-drawing and backmolding process is to be further automated under the leadership of Krauss-Maffei Technologies GmbH and implemented in a pilot production cell. The process will be transferred to a 4-cavity mold. At the same time, the draw-off force of the plastic component is to be further increased. For this purpose, further variations of the laser structure configuration and process parameters of the injection molding process are to be carried out at IKV in cooperation with the ILT. Finally, Röchling Medical Solutions SE will validate the produced crimp caps. ■