NEW MATERIAL DEVELOPMENTS FOR MEDICAL DEVICES: POLYMERS WITH IMPROVED TRIBOLOGY

Here, in the context of the interactions and friction between moving parts in contact inside drug delivery devices, particularly inhalers, Kirsten Markgraf, PhD, T&I Product Development, POM, and Wendy Johnson, Medical Marketing Manager, Engineered Materials, both of Celanese, review the performance of various polyoxymethylene acetal copolymer grades, and introduce two new grades optimised for sliding applications.

INTRODUCTION

Many drug delivery devices contain moving parts. As these parts move, such as in an inhaler, they must effectively slide against other parts. The device must function smoothly with a low co-efficient of friction and low noise or wear. This performance has to be achieved in complex design environments including movements against different types of materials, operating across a range of temperatures and chemical environments and with a range of speeds and forces in operation.

This paper reviews the performance of different polyoxymethylene (POM) acetal copolymer grades, with and without external lubricants. It also includes the review of two new grades of tribologically modified polymers that operate effectively without the aid of external lubricants. These are specifically suited for use in sliding applications versus a wide range of polymeric counterparts as well as metals.

POLYMER COMBINATIONS

When identical unmodified polymers slide against each other, there is a tendency towards high friction and it is best to avoid these pairings. However, it may be the case that these combinations are favourable because of other interactions and/or requirements, e.g. laser marking, suitable

![Figure 1: Sliding behaviour of POM/POM versus POM/PBT.](image-url)
sterilisation techniques or mechanical specifications. For combinations of unmodified POM-on-unmodified POM the static and dynamic co-efficient of friction shows a large difference resulting in a high risk of noise during sliding.

Changing to a combination of dissimilar materials may provide a solution. For example, a POM-on-POM combination may generate noise whilst a POM-on-polybutylene terephthalate (PBT) pairing may run silently during use (Figure 1). This is due to the relatively small difference between the static and dynamic co-efficients of friction in the POM-on-PBT combination.

**USE OF EXTERNAL LUBRICATION**

Lubricants on the surface of the part create a film during operation and provide exceptionally low friction between sliding components (Figure 2). Lubrication can either be achieved through coating parts (post-siliconisation) or internal lubrication. The downside of external lubrication is the management of the secondary process, potential migration of the lubricant to undesired locations in the device and the drug, chemical resistance issues, device-to-device consistency, and efficiency after long-term storage of the device.

**USE OF INTERNAL LUBRICATION**

Internal lubrication of polymers is achieved either in production via the use of master batches in the injection moulding process, or as a ready-to-use compound directly from the raw material supplier. It is difficult to match the extremely low levels of friction achievable by surface film lubrication. However, when the right lubricant is used for the combination of base polymers involved, excellent results can be achieved. Some lubricants have excellent dispersion within the polymer (e.g. waxes) and migrate to the surface of the polymer during injection moulding. Others form discrete pockets of lubricant (e.g. PTFE) requiring a running-in phase to get some initial surface wear to optimise lubrication potential.

Figure 3 gives an overview of the sliding performance of unmodified POM-on-unmodified POM, resulting in the highest coefficients of friction as well as versus POM with different tribological modification (internal lubricants).

Modifiers that improve sliding performance in POM may strongly influence the
mechanical properties of the material, as depicted in Figure 4. Silicone oil is commonly used but can result in a significant plasticising effect on the polymer. Waxes provide modest improvement in tribological performance at low cost while PTFE provides further improvement, but with a significant running-in period to achieve full effect. At higher concentrations there is a mould deposit risk.

LATEST DEVELOPMENTS

Recently developed medical POM grades, the new Hostaform MT® SlideX™ grades from Celanese, exhibit low co-efficients of friction versus unmodified POM such as Hostaform MT®8U01, and with a similar stick-slip performance as external lubrication of MT®8U01 with silicone oil (Figure 5).

The new grades enable low friction in POM-on-POM pairings and with a range of other counterparts (Figure 6), without sacrificing mechanical performance.

The two new Hostaform MT® SlideX™ grades are distinguished by their viscosities. Hostaform MT® SlideX™ 1203 is a standard-flow injection moulding grade. A high-flow version, Hostaform MT® SlideX™ 2404, is offered for thin-walled, complex part designs. The new Hostaform MT® SlideX™ grades are the latest development in the area of tribologically modified poly-oxymethylene to meet low co-efficients of friction versus a variety of thermoplastics with medical compliance.

CONCLUSION

There is not one commercial speciality polymer that can meet all the demands of the tribological systems of drug delivery devices. However, the new Hostaform MT® SlideX™ grades are supported by data demonstrating very low friction, low wear and low noise performance when used with a broad range of partner materials, including POM-on-POM combinations and, furthermore, demonstrate excellent mechanical behaviour.

REFERENCES

3. According to VDA 230-206 “Examination of the stick-slip behaviour of material pairs Part 1”.