Opening the Door to Material Substitution

Breaking the hold on single-source suppliers creates a less costly and more sustainable material supply chain for medical device manufacturers

Moving from prototype to full production can be costly

Today, many medical device manufacturers are relatively "cemented in" using one material provider. Oftentimes, they are not aware of the full scope of materials available on the market that might fill an application.

In the prototype or early-launch stages of a product, the focus is not concentrated on the cost of every material used in a device. But as volumes increase, price becomes an issue and suddenly an OEM may find it is being held captive by a single-source supplier. At this point it is often time to switch from a specialty material to a standard material.

Other reasons driving the need for material substitution might be changes in the regulatory environment, such as a ban on certain material classes or ingredients in compounds.

Reverse engineering steps in

Finding the best match for a specific material begins with reverse engineering the part in order to match compatible materials. First, perform a micro-CT scan to digitally model the entire part. Relying on the drawings alone might not be enough, since the properties of the real part are most important.

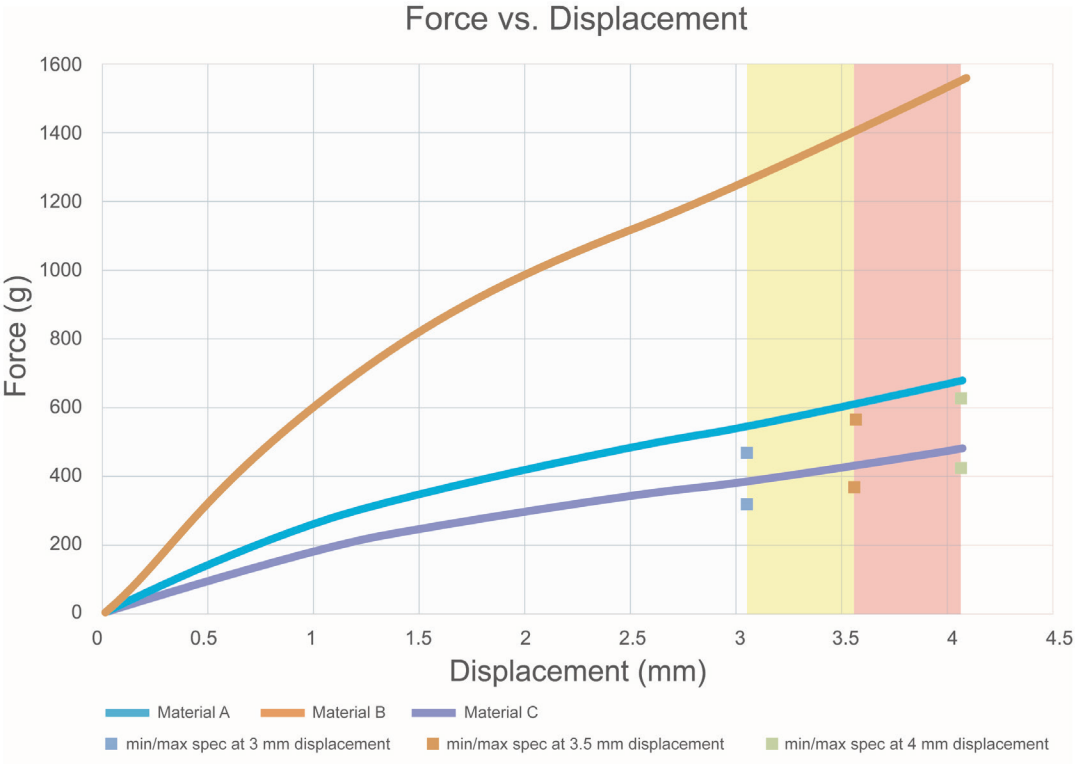
Next, feed the model into a 3D CAD program, and then adapt a finite element analysis (FEA mesh) to start simulating the entire part. The benefit of having the real part available is to characterize its mechanical properties depending on what is important in the component's application. In some cases, this might be tensile testing; in other cases, force displacement might be the relevant criterion. This data will determine the target properties and is a crucial input parameter for the simulation, in addition to the 3D model itself.

Finally, the simulation can be fed with material models from existing and available raw materials. Multiple materials may be selected, provided the mechanical data exists in a database. Otherwise these properties need to be determined in material characterization, which a good supplier can perform.

In the simulation, each material is evaluated on the mechanical properties that have been determined from the original part. The outcome will display the range of each material in regard to the desired specification.

If the specification cannot be met just by substituting the material alone, a modification of the part geometry might be necessary. The benefit of having the 3D model set up for this is that results from this potential modification can be evaluated right away without having to do expensive and time-consuming molding or prototyping.

Of course, all materials must meet medical device standards. The determination of material properties in the elastomeric world requires very specialized knowledge. In this simulation, both material characterization and material modelling capabilities come together with the know-how of interpreting the simulation results.



Graph depicts the behaviors of three different materials. The squares indicate the specification window at each displacement. The target material will be between the squares. In this example, the purple line (Material C) is the closest match.

Device manufacturers reap the benefits

The case here can better explain the challenges and why the process requires specific capabilities. Not all suppliers can support material substitution.

A medical device customer had a valve seal created from an isoprene rubber, in this case a proprietary rubber formulation that only one supplier formulated and offered at a set price. In the beginning, this was not an issue, but now the manufacturer required more volume and simply could not get it from their material provider.

The valve seal had to fulfill specific mechanical properties and have certain characteristics. First, the part was 3D-imaged and the force displacement characteristics were simulated based on existing part measurement data to determine if required characteristics were met. Using the same model, the material

characteristics and the required parameters for liquid silicones were uploaded from the Freudenberg global material database, enabling identification of the material of choice from the silicone world. The process was done without actual prototyping or using the material in a mold and saved the OEM both time and money.

Not limited to one application

Material substitution is not limited to molding; it also applies to extrusion. It is also not limited to classical rubber vs. silicone. However, using newer material like silicone will provide a lower cost and a faster cure process.

Many medical device manufacturers are stuck with single-provider materials and are looking for less costly solutions that offer more price flexibility. Using hard data, advanced technology and smart engineering, a skilled manufacturing partner can replace materials with similar principles and offer a valuable resource to improve margins while improving part manufacturability and sustainability at the same time.

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