Prediction of Glass Cartridge Robustness in Assembly Line Loading

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Abstract
Each year Novo Nordisk produces multimillion injection devices incorporating drug contained glass cartridges. These cartridges will inevitably be subjected to various loadings in both line feeding systems and in the device assembly rigs. It is obviously crucial to preserve the structural cartridge integrity and avoid any form of cracking and fragmentation of the glass for the full life time of the devices.

The robustness is quantified by a safety factor against cracking. As shown in figure 1, it implies that both assembly line loadings and the strength of the sub-supplied cartridges are determined along the location of max stress in relation to the rotary position of the weakest region.

These figures can be used to specify the loading for the incoming inspection and prevent future device designs from overloading the cartridges.

The cartridge glass is brittle with a low cracking energy and sensitive to impact loading. The glass strength is determined by microscopic manufacturing related imperfections (which have no influence on the performance and integrity of the final device) and is both loading mode and rate dependant. Thus a conventional material property such as the ultimate stress cannot be used to calculate a safety factor.

Matters are further complicated by loadings being tolerance dependant and by the fact that each cartridge has a randomised position of the weakest region relative to the maximum loading. This calls for a statistical based calculation of the safety factor. Figure 2 shows an example on a safety margin without distribution overlap. In some cases a limited distribution overlap might be acceptable.


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Michael Walter
1. Establishing a Failure criterion of the Glass Cartridge

1.1 Critical region
The critical region of the cartridge is the exterior surface of the open end of the cartridge. This is both due to the loading and due to the presence of microscopic imperfections in this region. Glass only fails in tension (R. E. Mould, 1953: 235).

1.2 Determination of the quasi-static cartridge failure stress
The quasi-static failure stress of the cartridge is found by pressurizing the cartridge as shown in figure 3. The pressure generates a uniform hoop stress on the exterior surface of the open end of the cartridge.

\[
\sigma_{	ext{hoop}} = \frac{P D_{\text{inner}}}{2t}
\]

Where \( P \) is the pressure, \( t \) the wall thickness and \( D \) the diameter.

The theoretical strength of the cartridge is dictated by the size of the largest defect in the critical region. According to Griffith Criterion (A.A. Griffith (1920)):

\[
\sigma_f = \sqrt{\frac{2E \gamma}{\pi a}}
\]

Where \( \sigma_f \) is the failure stress, \( E \) is the youngs modulus, \( \gamma \) is the surface energy density, and \( a \) is the \( 1/2 \) crack length.

1.3 Loading rate
The failure stress of glass depends on the loading rate as depicted in figure 4. The figure shows the likelihood of failure vs. stress level for various loading rates. The failure stress increases approximately 15 % per stress rate decade.
1.4 Failure limit for the assembly application

Using the loading rate dependence of figure 4, the quasi static failure stress of the pressure test can be converted to the corresponding stress of the high velocity assembly loading.

The stress and strain rate of the test was calculated from the pressure ramp of the test equipment and a linear approximation between pressure and stress.

The strain rate of the analysis is an parameter of the field output. The stress rate can then be derived from the strain rate. The rate of the quasi-static pressure test is only 4.4 MPa/s. The app. 10 mm axial displacement of the assembly process is completed in less than 10 ms. The stress rate in the cartridge driven by the transient forces from the interfacing components during assembly is approximately 70 GPa/s, i.e. the ratio between the two is 1.6e4. Using the 15 % rule of figure 4 gives us the strength amplification factor of the glass due to fast loading (equation derived from the logarithmic form of figure 4):

\[ S_a = 1.15 \log(1.6e4) = 1.8 \]  

So the glass failure distribution is estimated to be 80 % higher for the assembly loading considered here than the quasi-static pressure test.

2. Analysing the Cartridge Loading in the assembly rig

A set of four thermoplastic deformation ribs embedded in an interfacing device component determine the combined axial-radial loading of the Cartridge. The intention of these ribs is to compensate for rather large tolerances of the cartridge length which results in a high degree of post yield deformation.

**Figure 4. Loading rate dependency of failure stress for glass (SCHOTT Technical Glasses, 2010: 12)**

**Figure 5. Radial rib loading pattern on the Cartridge**
In order to capture the stress impact of the main key contributing parameters, a refined Explicit Finite Element model was made:

![Figure 6. FEA explicit dynamic assembly analysis model](image)

The model included all relevant geometry along with elastic and viscoelastic/plastic material response and velocity-load input. The maximum tensile stress of the cartridge was sampled over the critical cartridge rim region for a suitable number of time frames. The key glass loading contributing parameters were identified as:

**Table 1. Key parameters contributing to the glass loading**

<table>
<thead>
<tr>
<th>Pos</th>
<th>Parameter (type)</th>
<th>Expected distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>D&lt;sub&gt;1&lt;/sub&gt;</td>
<td>Deformation rib thickness (dimension)</td>
<td>Normal</td>
</tr>
<tr>
<td>D&lt;sub&gt;2&lt;/sub&gt;</td>
<td>Deformation rib distance to centre line (dimension)</td>
<td>Normal</td>
</tr>
<tr>
<td>D&lt;sub&gt;3&lt;/sub&gt;</td>
<td>Cartridge to rib axial penetration (displacement)</td>
<td>Normal</td>
</tr>
<tr>
<td>D&lt;sub&gt;4&lt;/sub&gt;</td>
<td>Cartridge outer diameter (dimension)</td>
<td>Normal</td>
</tr>
<tr>
<td>D&lt;sub&gt;5&lt;/sub&gt;</td>
<td>Cartridge rotation relative to deformation ribs (angle)</td>
<td>Stochastic</td>
</tr>
</tbody>
</table>

![Figure 7. Section cut of the cartridge and interfacing components](image)

**3. Sensitivity of the Load Contributing Parameters to the Tensile Cartridge Stress**

A design of experiments (DoE) study was based on 9 runs each having a randomised combination of the above parameters – except D<sub>5</sub> which was not included initially due to the stochastic nature.

A statistical analysis performed in JMP software from SAS revealed the qualitative parameter sensitivity shown on the following page:
The workflow in summary:

4. Example on Evaluation of the Safety Factor

The safety margin towards failure obviously has to be calculated based on a statistically determined acceptance criteria. Such criteria are usually decided on a company level. In this example, the lower 10 % quantile of the measured cartridge failure pressure distribution and corresponding hoop stress distribution is selected for the safety factor calculation. In figure 9 the safety margin is depicted as the pressure between the highest stress value of the analysis DoE and the 10 % quantile value of the weakest batch. This distribution has to be calculated on a batch level (Figure 9) since a rather large inter batch variation is expected. Next the value of the lowest 10 % quantile can be held against the largest implied stress from the DoE calculation of section 3.

The safety factor $S_f$ can now be calculated as:

$$S_f = \frac{\text{Lowest burst stress-strength amplification factor}}{\text{Maximum imposed stress}}$$  (4)
If using the 10 % quantile criterion and the weakest batch and calculating stresses using (1) & (3) we get a safety factor of:

\[ S_f = \frac{27.1 \, MPa}{16 \, MPa} = 3 \]

It must be emphasised that Novo Nordisk of course uses more narrow criteria than the 10 % quantile.

5. Discussion and Further Refinement

From the beginning of this work it became evident that a traditional safety factor calculation where a nominal material loading is held against a given failure criterion would simply not suffice. The safety factor calculation as a robustness measure for such high volume production with many contributing parameters and a - inevitable - high batch variation requires a more comprehensive set of input data. The statistical assessment of both glass failure, distribution and geometry tolerances contributed to a much improved robustness against cartridge failure. This improved robustness can be achieved by securing high quality of the supplied cartridges (high pressure distribution) and production parameter adjustment (displacement profile and forces). In the FE-model it was mandatory to include rate dependency of thermoplastic deformation response (due to the viscoelastic nature of the thermoplastics used) for the best possible modelling of the loading safety factor prediction.

Further refinement of this model is needed to capture the effect of the stochastic rotational position of the cartridge in the device, which will have a positive impact on the safety factor. Also a more realistic statistical acceptance criterion has to be used.

Acknowledgments

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