Prediction of Glass Cartridge Robustness in Assembly line Loading

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• The loading determined by non-linear material behavior.
• FE-model for stress prediction and it’s key parameters.
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Scope

Our drug contained cartridges must be able to withstand both:

- Component handling on the assembly line.
- Device assembly loading.
- In-use loading (general user handling).
- Loading relating to foreseeable misuse (drop, bending etc.).

Thus a safety margin towards failure must be quantified.
A Traditional Approach to Structural Robustness

**Case:** Circular steel rod of diameter \( d \) in tension

The constant axial force \( F \) is a design specification

The design stress can be calculated as:

\[
\sigma_{\text{nominal}} = \frac{F}{A} = \frac{4F}{\pi d^2}
\]

The failure criterion, \( \sigma_{\text{yield}} \) is typically a minimal value supplied by the material vendor.

The safety factor must then only account for the diameter tolerance:

\[
S_f = \frac{\sigma_{\text{yield}}}{\sigma_{\text{nominal}}}
\]
Now – What if…. 

Multiple forces $F_1, F_2, F_3$ are varying and dependant on:
- Interfacing component geometry
- Variation having different distributions
- Assembly equipment settings

The failure criterion is not well established and dependant on both material properties and processing.

The design stress depends on the rate of the loading: $F(t)$.

Then…
The safety factor can neither be calculated from nominal dimensions nor be based on a worst case scenario!
Introduction: Final Assembly of a disposable Insulin pen

- Assembly rig
- Dose mechanism module
- Cartridge module
Introduction: The assembly rig
Introduction: How is the Cartridge loaded?

Component section view

Stress view from Explicit FE-model

Cartridge
Introduction: How is the Cartridge loaded?

Component section view

Stress view

Interfacing thermoplastic part with 4 deformation ribs which support the cartridge.
**Introduction: How is the Cartridge loaded?**

- Elastic-plastic deformation of the ribs cause bending stresses in the cartridge.
- The rotational orientation of the cartridge can be regarded random.

Rib axial section stress view

4 zones of max stressing on the outer rim
Procedure for Determining the Safety Factor

- Determine the nominal cartridge loading from the interfacing component.
- Choose the predominant dimensions and the corresponding tolerances that influence the loading.
- Set up a virtual model based Design of Experiments study (DoE) having a number of selected combination of parameter values.
- Run FE-analyses on the 10 sets.
- Run a DoE based on these combinations to evaluate parameter sensitivity and distribution of the applied stress.
- Determine the stress based strength of the cartridges and its distribution.
- Calculate the statistical based safety factor.

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<thead>
<tr>
<th>series</th>
<th>Pattern</th>
<th>Nut Thickness</th>
<th>Nut Radius</th>
<th>Cartridge</th>
<th>Nut-Cartridge Position</th>
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The Nature of the Rib Deformation Response

- Typical stress/strain behavior of an amorphous thermoplastic is highly non-linear and rate dependent:
Dynamic Explicit FE-analysis model

- Reduced model including only relevant components.
- The model takes rate dependency of the materials into account.
- The short duration of the assembly can be simulated in real time.

The Cartridge is pushed into engagement using forced displacement.
## Guiding dimensions

<table>
<thead>
<tr>
<th>Pos</th>
<th>Parameter (type)</th>
<th>Expected distribution</th>
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<tbody>
<tr>
<td>$D_1$</td>
<td>Deformation rib thickness (dimension)</td>
<td>Normal</td>
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<tr>
<td>$D_2$</td>
<td>Deformation rib distance to centre line (dimension)</td>
<td>Normal</td>
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<tr>
<td>$D_3$</td>
<td>Cartridge to rib axial penetration (displacement)</td>
<td>Normal</td>
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<tr>
<td>$D_4$</td>
<td>Cartridge outer diameter (dimension)</td>
<td>Normal</td>
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<tr>
<td>$D_5$</td>
<td>Cartridge rotation relative to deformation ribs (angle)</td>
<td>Stochastic</td>
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</table>

![Diagram](image)
FE-analyses

- 10 analyses were ran with different geometry/position combinations of D₁ to D₄ having applied stress as the output parameter.
- Remark that this is not a full factorial EoD – rather a preliminary study.

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Outer rim tensile stress (output parameter)
Max Tensile Stress Comparison

Thin rib with largest nut rib diameter combined with small diameter cartridge

All nominal dimensions

Thick rib with narrow nut rib diameter combined with large diameter cartridge

= Worst Case
When does glass fail?

Prerequisites:

- Tensile stresses are present and critical for onset of cracking.
- In the stressed area imperfections are present
  - Small imperfections such as micro-cracks are inevitable in all practical glass samples especially on their outside surfaces
- The stress level and the size of the defect is such that the Griffith criterion is met -> brittle fracture.

\[ \sigma_f \sqrt{a} \geq \sqrt{\frac{2E\gamma}{\pi}} \]
Approach:

- A uniform tensile hoop stress state obtained from internal pressure on the inside.
- This will capture the strength of the weakest imperfection.

Length = 65 mm

Outer Diameter = 11.3 mm
Burst Measurement of Glass Strength Variation

1. Red line: 10 % Quantile = Burst pressure of weakest 10 % per tested glass cartridge batch
Failure limit vs. loading rate

- Furthermore the failure stress of glass is depending on the loading rate.
- The figure shows the probability of failure vs stress level for various loading rates, ranging from 0.01 MPa/s to 1000 MPa/s.
- This can be used to relate the failure stress levels of the slow burst measurements to the high loading rate in the assembly line.
- The strength amplification factor due to loading rate dependence:

\[ S_a = 1.15 \log \left( \frac{v_{assembly}}{v_{burst-test}} \right) \]
The purpose of the first narrow scoped analysis was to have an indication on the parameter sensitivity.

The relative nut to cartridge axial position (D₃) had most impact on imposed stress variation.

The DoE confirmed our assumption on worst case parameter combination.

| Term                  | Estimate | Std Error | t Ratio | Prob>|t| |
|-----------------------|----------|-----------|---------|------|
| Nut-Cartridge Position| 12,926829| 2,406165  | 5,18    | 0,0066* |
| Nut Thickness         | 37,333333| 20,46865  | 1,82    | 0,1422  |
| Cartridge             | -13,66667| 10,23428  | -1,34   | 0,2527  |
| Nut Radius            | 7,4520256| 8,185239  | 0,91    | 0,4141  |
Safety Margin Considerations

- No cartridge cracking is acceptable.
- What measure should be used for the distribution overlap (if it exists)?
- Could the glass strength distribution be more narrow if the process were altered?
- Are there any assembly settings that may limit the loading on the cartridge?

**Distribution of the Imposed critical cartridge stress in the final assembly (Could be fitted to a known distribution)**

**Distribution of the Strength of the cartridge glass (Weibull)**

**Challenge: What distribution overlap is reasonable?**

Stress
Preliminary Safety factor Calculation

- For this study, the highest imposed tensile hoop stress (Worst Case) out of the FE analysis is used as a preliminary measure.
- Taking the velocity dependence of the glass strength into account, the safety factor can then be calculated as:
  
  \[ S_f = \frac{\text{Lowest burst stress} \cdot \text{strength amplification factor}}{\text{Maximum imposed stress}} \]
Further work

- The DoE should be full factorial (16 combinations or more).
- From these results a distribution should be fitted.
- A reasonable measure for distribution overlap (imposed cartridge stress vs. strength) must be agreed upon (e.g. ppm).
Conclusion

• Conventional calculation of Safety Factors is not suitable for non-linear load cases with many dependencies.
• Combining the virtual DoE with the experimentally determined glass strength provided:
  • Failure prevention for complex load cases in high volume production.
  • Ability to specify entities of the device design and assembly setup more precisely.
  • Improved the link between R&D and production in the device development.