predict the failure probability *F* for a certain pharmaceutical formulation and process, realistic values of the radial compression stresses σ that are induced by the frozen lyo cake are necessary. From this, the fracture probability can be calculated for stresses applied by the expanded lyo cake and the minimum strength of a glass vial that is required to perform below a particular (given) fracture probability would be accessible. Unfortunately, the real stresses inside a vial caused by the frozen and expanded lyo cake are difficult to determine. However, some authors report on the application of strain gages to measure the strain on the outer surface of a vial (12,13).

Fractography

A fractographic analysis (i.e., the investigation of the fracture pattern and the determination of the fracture origin by means of microscopy) is useful to learn more about the weak points of a glass container. When investigating the crack pattern of a burst vial (Fig. 6), one can locate the fracture origin and thus find the mechanical weak points of the sample. In some cases, significant specific damages introduced during production or processing the vials (e.g., chatter marks or severe scratches) can be detected. Thus, fractography is an essential technique to support product development and improvement.

FINITE ELEMENT METHODS

The FEM is a useful method to calculate mechanical stresses and strains in solid articles. It is possible to investigate complete stress and strain distributions for the surfaces and the bulk of a glass container, even for complex geometries. On the basis of FEM results, a great improvement of a glass vial in terms of mechanical robustness was achieved by optimizing its geometry (11): The flat shape of the bottom part of a standard vial (Fig. 7) was changed to a more

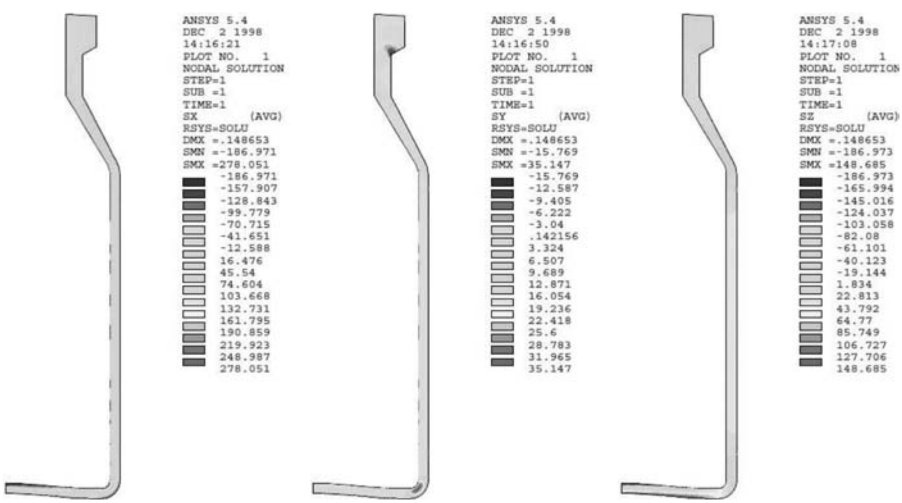

FIGURE 7 Stress distribution for a standard glass vial under hydrostatic pressure of $p = 30$ bar. Left: axial stresses; middle: radial stresses; right: tangential stresses.