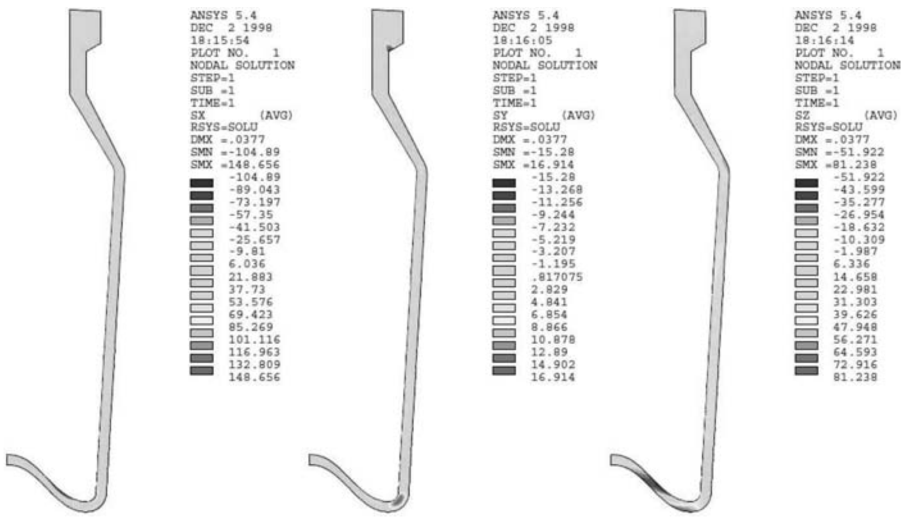

FIGURE 8 Stress distribution for a glass vial with optimized geometry under hydrostatic pressure of $p = 30$ bar. Left: axial stresses; middle: radial stresses; right: tangential stresses.

"champagne-bottle" geometry (Fig. 8). With this geometrical modification, improved heat conduction in combination with enhanced mechanical stability (reduced fracture probability) was realized. Additionally, to further reduce mechanical stresses during the lyophilization process, the shape of the barrel of the vial was changed from cylindrical (Fig. 7) to conical geometry (Fig. 8). With these modifications, the rate of vial breakage was reduced up to 60%. When the frozen lyo cake expands during the cooling step, the radial stresses introduced to the inner walls of the vial increase. At a certain value of radial compression stresses, the ice starts to melt creating a thin film of liquid water between the inner wall of the vial and the frozen lyo cake. This thin film of water acts as a lubricant and supports a detachment of the lyo cake from the vial walls, which results in an instant motion upward where the radius of the vial is greater, and thus the radial stresses are reduced.

SCHOTT TopLyo^{TM} AS AN EXAMPLE FOR OPTIMIZED VIALS FOR LYOPHILIZATION

Reduced risk for glass breakage and improved heat transfer during the freeze-drying process are demands that are met by the improved geometric design and the hydrophobic coating of SCHOTT TopLyo^{TM} vials. This novel and high-quality product was developed for the special requirements of lyophilization.

Apart from the geometric aspect, TopLyo vials exhibit a hydrophobic layer on the inner surface that is applied by SCHOTT PICVD (plasma impulse chemical vapor deposition) coating technique in a validated process (18). A covalent bond is formed between the glass matrix and the layers, which is stable to usual pharmaceutical procedures such as washing, autoclaving, sterilization, and depyrogenization (heat treatment of 300°C), and also against mechanical