Understanding Slow Crack Growth to Create Safer Medical Devices

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Background

When an in-spec or in-use medical product exhibits delayed cracking, a number of basic questions arise during the quality review process.

1. What was the failure mode?
2. Could the failure have been predicted?
3. How could the failure have been avoided?

One root cause of crack-type failures is a phenomenon referred to as slow crack growth (SCG). This whitepaper seeks to assist readers in answering the above questions when their products exhibit SCG, and to provide information that will help in the design of medical devices that are more resistant to it. An understanding of SCG, including its prediction and prevention, can help medical product developers create safer devices.

What is Slow Crack Growth (SCG)?

SCG is the slow and stable growth of a crack due to load stress with minimal evidence of plastic deformation. That is, the part will initially appear to tolerate the stress loading well and will not exhibit any early signs of failure. In this state, subcritical cracks can develop. The cracks grow with time until the affected product fails. The rate of failure is determined by the stress, the temperature, and in some cases, chemicals that act as activation agent decreasing the time to failure.

At a molecular level, SCG involves the separation of molecular strands, the chains of polymer units that are bound together to make up a polymer resin. No chemical degradation of the resin occurs during SCG failure. Instead, the chains experience physical separation.

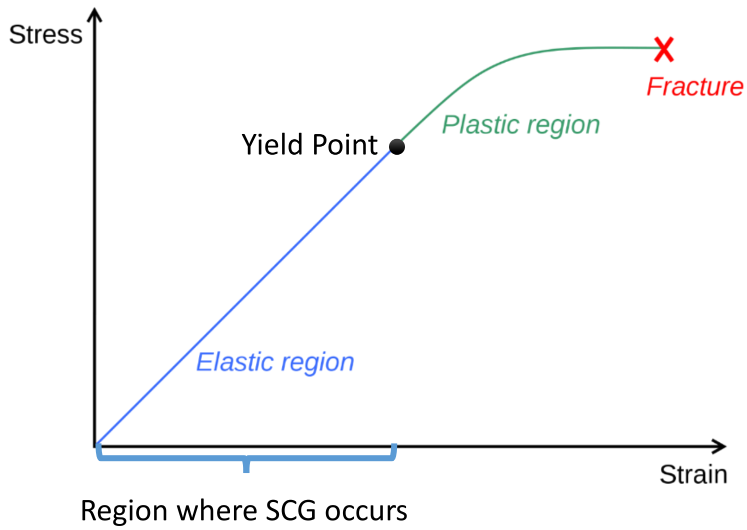

Figure 1: SCG process

SCG occurs when a polymer is strained within its elastic region. See Figure 1. As greater stress is applied, the polymer enters its region of plastic deformation and eventually fails through breakage or some type of elongation.

The curve in Figure 1 is for "short time testing" of a standard shape and shows a polymer being able to sustain loads indefinitely. In reality, polymers are formed into more complex shapes and sustain loads for extended, although not indefinite, time. When stress is applied for an extended time, subcritical cracks may develop. The gradual formation of these subcritical cracks will eventually lead to a critical crack failure. This is the essence of slow crack growth.

Predicting SCG

When predicting SCG, short-term properties provide limited guidance. SCG requires sustained stress, including residual stresses, applied stresses, or concentrated stresses due to polymer shape or applied forces. Understanding of the behavior under long term stress is required for predicting SCG.

Predicting SCG is particularly complicated because resin resistance typically varies by grade and can even vary by lot. Molecular orientation relative to the applied force also plays a role as it can allow for the separation of molecular strands more or less easily.

Yielding, the point when the polymer experiences plastic deformation, will dominate at higher stresses and temperatures, and is easier to predict. SCG often does not provide visual clues and takes longer to assess in a development process.

The following equation, however, can aid in predicting SCG. Note that t is time to failure.

$$t = Rk^{-n}e^{\frac{Q}{T*r}}$$
$$k = YS\sqrt{a}$$

- R=resin resistance to SCG
- a=defect/stress concentration size
- Y=geometric factor
- S=global stress surrounding the defect
- T=absolute temperature
- r=the Ideal Gas Law Constant
- Q=the activation Energy
- n=a constant, generally 2.5<n<4

This formula calculates time to failure as the product of the resin characteristics, compounded by the local and global stresses shown as a stress intensity factor, and modified by an activation energy associated with environmental factors such as temperature and the presence of external agents.

Environmental Stress Cracking (ESC) and Chemical Attack

ESC is a special case of SCG, and occurs when solvents accelerate the rate of stress cracking to minutes or hours. ESC still requires stress for the part to crack. However, this stress can easily be supplied by “frozen-in” stresses from part manufacturing processes in many situations.

Chemical attack is distinguished from both ESC and SCG. Chemical attack is when an outside agent directly attacks the polymer chains and causes chain scission or shortening of the polymer units. This results in bulk degradation of the physical properties of the material and not just polymer chain separation. Chemical attack can create crazing or sloughing and produce powdering or chalking at the part surface, but can still be very difficult to distinguish visually. Laboratory analysis is needed to verify chemical attack and distinguish it from ESC.

Factors Affecting SCG

Resin

As mentioned previously, SCG occurs when polymer molecules disentangle and separate. Accordingly, the molecular structure of the resin in question impacts the occurrence and rate of SCG to the degree it allows for or resists this disentanglement.

One aspect of a resin’s molecular structure that affects disentanglement is chain-branching, which is strongly correlated to a polymer’s relative density. Higher branching helps prevent slow crack growth as the branching facilitates an entanglement of strands within the molecules that better resists separation, as shown in the model comparison in Figures 3 and 4.

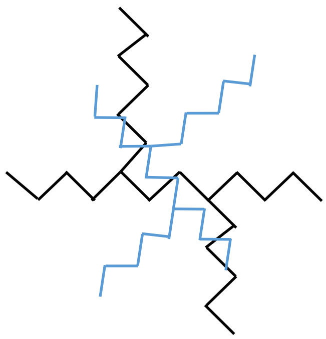

Figure 2: Increased resin molecule branching

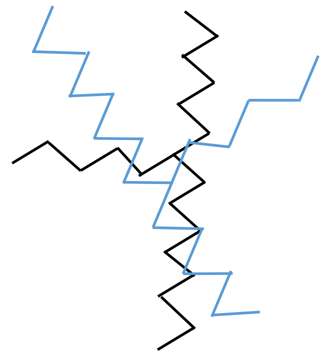

Figure 3: Decreased resin molecule branching

In addition, the higher the molecular weight and the broader the molecular weight distribution, the more resistant the resin will generally be to SCG. Higher molecular weight materials have longer chains, and longer chains generally correlate to stronger chain to chain interaction and more resistance to chain disentangulation. Broader molecular weight materials can form strong networks of packed molecules of different sizes. This also assists in resisting chain disentangulation, but it is the weakest factor.

Internal Factors

Internal factors affecting SCG in a part include aspects fundamental to the design and manufacture of it. These can determine the residual stresses the part experiences as well as how it handles applied stress generally.

SCG factors in extruded tubing and injection molded parts are the same, and include where stress is applied and concentrated and how much is residually present. However, each of these factors is controlled differently. Stress in extruded tubing is controlled by the cooling rate, draw down rate, packaging, and post processing. Stress in molded parts is controlled by mold design, including gating, fill rates, any assembly processes, and then, similarly, cooling rates and any post processing.

External Factors

External factors that affect SCG include the presence of solvents, disinfectants, and surfactants, which can speed up SCG (see Figure 4) through a decrease in the activation energy for the polymer in question.

Temperature is also a particularly important factor. For example, a change in temperature of 10°C can double the rate of crack formation.

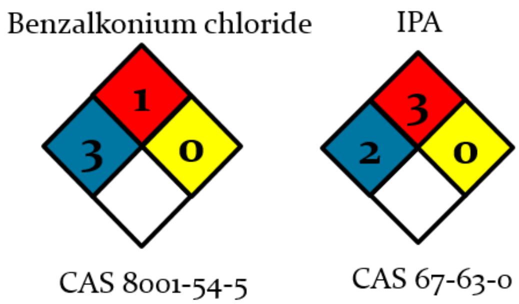

Figure 4: Common chemicals that can increase the rate of SCG

Importance of Understanding SCG

While SCG is not in every professional’s zone of awareness, understanding it can help in both development and failure mode determination. SCG is one of the most common defects that can negatively impact product performance.

Adding to its importance, the word “slow” in SCG should not be taken as necessarily denoting an extended duration. Commercial HDPE, for example, can be rated to resist SCG formation for as little as 15 hours, which means the part can crack in less than one day if it experiences concentrated stress.

While medical tubes are typically elastomeric materials or copolymers with good SCG resistance, certain engineering demands mean that other materials more prone to SCG, such as polyolefins, are seeing increased use in medical applications.

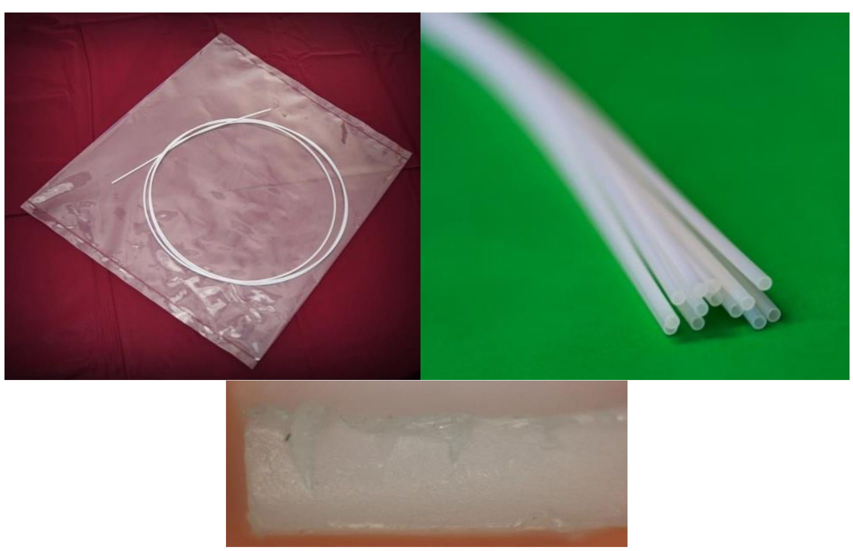

Figure 5: Common medical tubing products capable of SCG and an example of cracking

Conclusions

This whitepaper highlights a number of important considerations for both product development and failure mode determination.

In development, it is critical to select the appropriate material for the product to minimize SCG. The typical SCG rating for PE, commonly used in medical devices, ranges from less than 24 to greater than 10,000 hours. It is important to compare the rating of the material to the end use exposure it will experience to the various SCG inducing and intensifying factors discussed above.

Additionally, it is important to control packaging stress during design and development to minimize the risk of SCG failures. Factors to consider are coil radius, clipping, and hard part impingement.

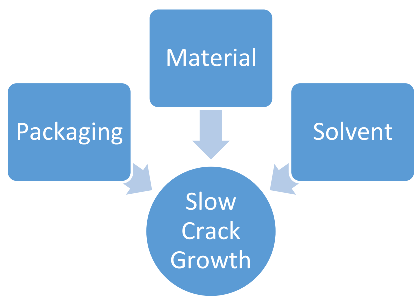

Figure 6: Material choice, packaging, and solvent exposure all impact SCG

Further, it is important to know what solvents and surfactants the product will be exposed to and to minimize the exposure where practicable. Consider whether an isopropyl alcohol wipe-down is necessary for pre-assembly cleaning. Disinfecting of components may be superfluous if a sterilization process is also included after product assembly.

Designing the right process in manufacturing is also important for minimizing SCG. Cooling more gradually and optimizing part and mold design can help.

During assembly, over-torqueing and snap fitting create concerns for SCG, as well as the use of solvent bonding for assembly. Post process actions such as annealing for stress relief can help prevent SCG. This is especially important to keep in mind if part design is already qualified.

Summary

This paper shows that time-dependent failure modes such as SCG can impact device quality and reliability. Incorporating awareness of SGC in design and development stages can help avoid this failure mode. On the other hand, subtle process changes can help if a design is locked in.

Last, suppliers can be valuable partners in development and when unexpected challenges arise.

For more information, please contact Christian Herrild.