CRISTALENS

Glistening evaluation on the hydrophobic material CBK 1.8 from the Cristalens group

What is glistening?

Glistening is when predominantly aqueous bubbles called microvacuoles form, over time, in the material used to manufacture hydrophobic implants. All hydrophobic materials are more or less affected by glistening.

These microvacuoles have a lower refractive index of light than the polymer, which is why they appear as water droplets inside the polymer.

Microvacuoles form around hydrophilic microdomains[1], or due to variations in the solubility of water in the polymer[2].

Many sources agree that below a certain threshold, glistening has no impact on the patient's vision.

Cristalens group's hydrophobic material

Cristalens' hydrophobic material:

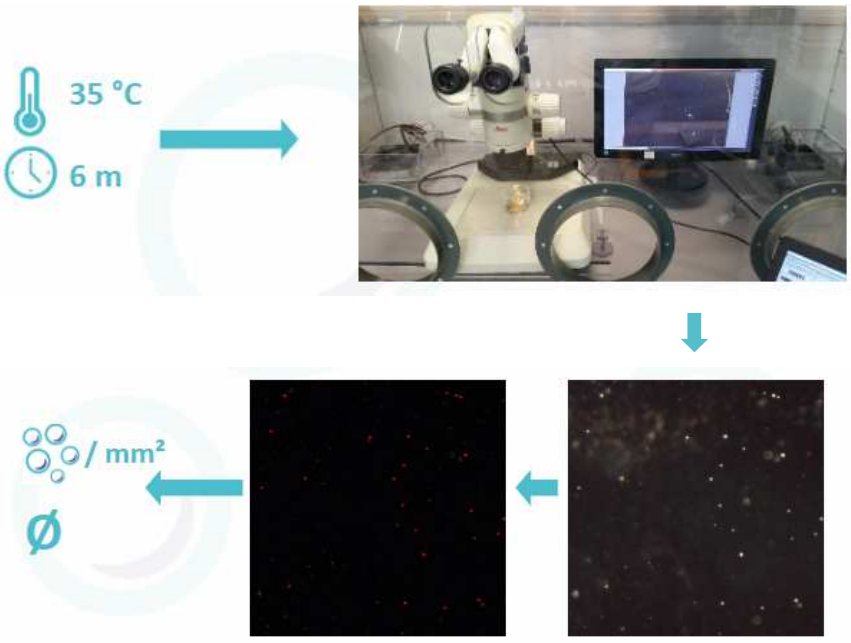
Cristalens manufactures its own hydrophobic material Made in France: the hydrophobic CBK 1.8. This material is very pure and produces little glistening.

Assessment of glistening on CBK material 1.8:

In order to assess this phenomenon quickly, one solution is to provoke a thermal shock (which causes glistening). This method, while fast, is not very reliable.

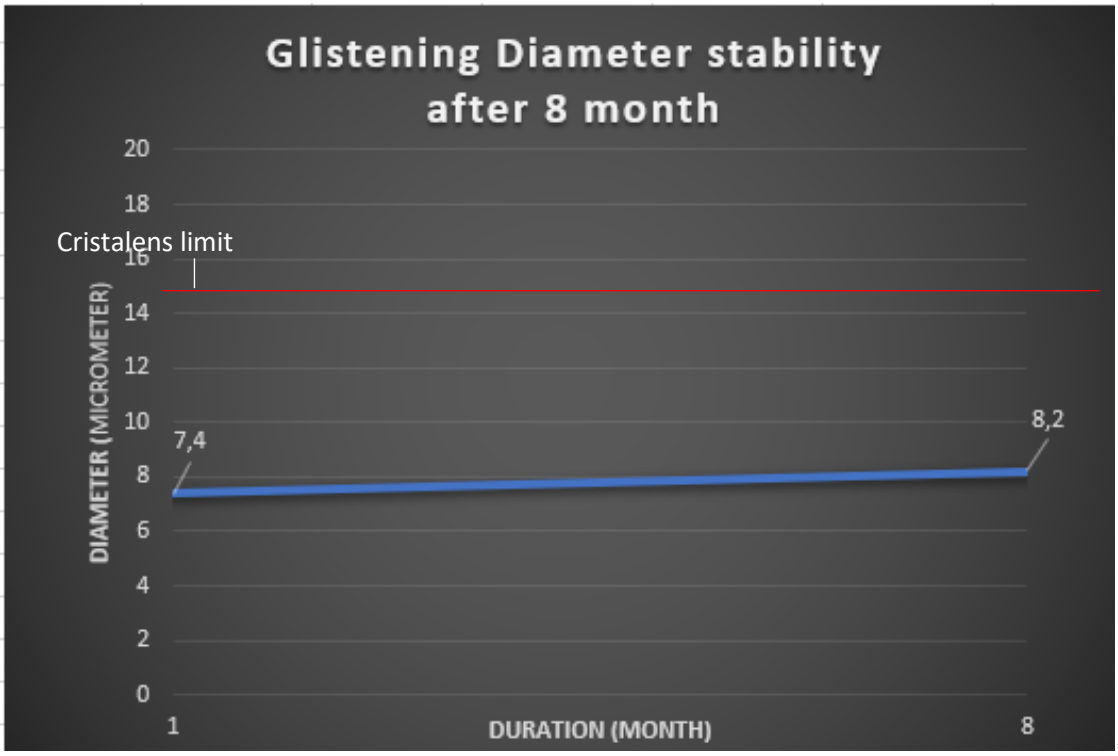
In order to obtain more reliable results, Cristalens stores its implants for 6 months at 35° C before evaluating glistening, using a microscope (50x, dark-filed mode) equipped with a camera.

The images are then analyzed using the LEICA Application Suite software.

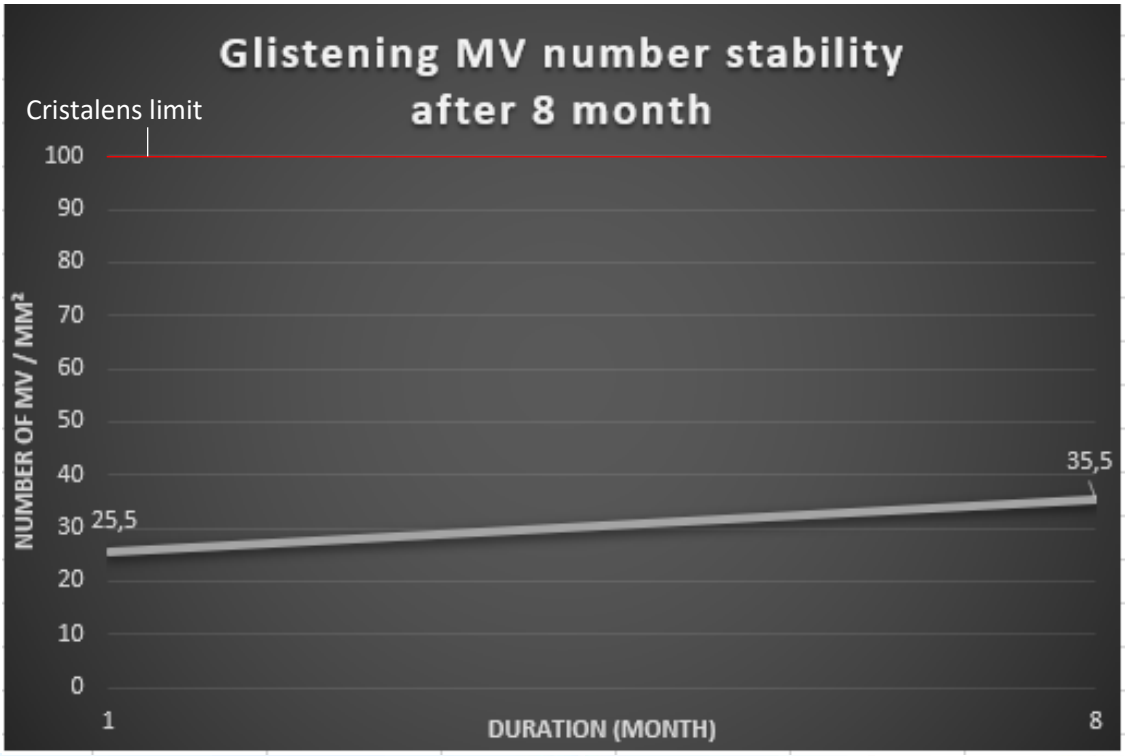


At Cristalens, the acceptability threshold is set at 100 microvacuoles per mm² and an average diameter of less than 15 µm.

For several years, Cristalens has been working continuously to improve its hydrophobic material, which has resulted in very low levels of glistening.



Cristalens now achieves a result at 27 days of 11 to 57 microvacuoles per mm² with a diameter between 6.7 and 8.7 µm and a result at 6 and 8 months of 23 to 43 microvacuoles /mm² with a size between 7.6 and 9.4 µm



Conclusion

The results obtained are well below the acceptability threshold.

The evolution is therefore not very significant over time. It should be noted that the examination itself produces a thermal shock at the origin of the glistening, which implies that a batch checked every month will have a higher rate of glistening than a batch checked only once at 6 months.

Cristalens will continue its tests and observations on the subject over the next few months, always with the aim of being able to substantiate this stability long term.

Based on existing bibliography*, and in view of these results, with the hydrophobic material CBK 1.8, the visual acuity of the patient will not be impacted by glistening.

Bibliography*

[3]Weindler et al. have reported no degradation for visual acuity for lenses with 100 MV/mm² with a diameter of 15µm

[4]DeHoog et al. confirmed that 0.001% glistening volume only induces a relative decrease in lens image quality of 10% or less.

[1]Saylor DM, Richardson DC, Dair BJ, Pollack SK. Osmotic cavitation of elastomeric intraocular lenses. Acta Biomater 2010; 6:1090–1098

[2].Kato K, Nishida M, Yamane H, Nakamae K, Tagami Y, Tetsumoto K .Glistening formation in an AcrySof lens initiated by spinodal decomposition of the polymer network by temperature change. J Cataract RefractSurg 2001; 27:1493–1498

[3]Weindler JN, Łabuz G, Yildirim TM, Tandogan T, Khoramnia R, Auffarth GU. The impact of glistenings on the optical quality of a hydrophobic acrylic intraocular lens. J Cataract Refract Surg 2019; 45:1020-1025

[4]DeHoog E, Doraiswamy A. Evaluation of the impact of light scatter from glistenings in pseudophakic eyes. J Cataract Refract Surg 2014; 40:95-103