

Financial Disclosure

Support for This Study Has
Been Received from
Advanced Medical Optics

Assessing Microvacuoles in Hydrophobic Acrylic IOLs

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Prevalence of Glistenings

- Acute onset of small refractile opacities represent water vacuoles inside optic
 - ◆ Temperature changes allow water to collect within gaps formed by non-homogenous polymerization
 - ◆ Injection molded vs. lathe-cut material may cause more gap formation
 - ◆ Vacuoles are distinctly visible because of differences in refractive index

Prevalence of Glistenings

- Questions posed by the occurrence of glistenings:
 - ◆ How prevalent are these opacities?
 - ◆ Do they get worse over time?
 - ◆ How severe are they and how do they affect VA or contrast sensitivity?
 - ◆ Does lens Handling or pre-op environmental conditions cause them to be present at the time of implantation?
- These concerns must be measured and assessed scientifically

Glistenings

- How do these optic phenomena impact visual quality?
 - Reduced Visual Acuity
 - Reduced Contrast Sensitivity
 - Increase in light scatter
 - Vaseline Vision Dysphotopsia

Glistenings in Literature

- D. Dhaliwal et al, Visual significance of glistenings seen in the AcrySof intraocular lens. *J Cataract Refract Surg.* 1996; 22:452-457.
 - Methods: 17 patients who had AcrySof® were evaluated by SLE, VA, contrast and glare testing. 10 patients had silicone PCIOL in opposite eye, evaluated by same criteria.
 - Results: All 17 patients with acrylic lens had some lenticular glistenings, ranging from trace to 2+. Analysis revealed statistical difference in contrast sensitivity results between acrylic and silicone eyes

Glistenings in Literature

- G. Christiansen et al. Glistenings in the AcrySof intraocular lens: Pilot Study. *J Cataract Refract Surg.* 2001; 27:728-733.
 - Methods: 42 AcrySof® eyes over 4 year implantation period evaluated for VA, glare, contrast sensitivity, SLE
 - Results: All 42 had some degree of glistening, 64% trace, 1+ 5%, 2+ 5%, 3+ 7%, 4+ 2%
 - Snellen acuity in severe glistening ($\geq 2+$) was $\frac{1}{2}$ line lower and one full line lower in glistening $>2+$ vs. mild glistening
 - 93% of eyes with glistening $\geq 1+$ had been in eye for more than 1 year
 - Contrast sensitivity not affected

Glistenings in Literature

- D. Tognetto et al. Glistenings in foldable intraocular lens: Pilot Study. *J Cataract Refract Surg.* 2002; 28:1211-1216.
 - Methods: Prospective study, 273 patients randomized to received 1 of 7 IOLs of various materials, including silicone, hydrogel, and acrylic types
 - Results: Glistening observed in all IOL groups. Percentage of patients with glistenings ranged from 40-68%.
 - Conclusion: AcrySof® group had a higher percentage and greater density of glistenings.

Glistenings in Literature

- A. Waite et al. Glistenings in the Single-Piece, Hydrophobic, Acrylic Intraocular Lenses. *Am J Ophthalmol.* 2007; 144:143-144.
 - Methods: Consecutive patients with single-piece AcrySof® were examined at 12, 24, 36 months post-surgery; VA, glare and contrast sensitivity evaluated. Glistenings analyzed for size/density by computer pgm.
 - Results: All IOLs had glistenings. Neither size, density, nor severity index correlated with acuity, glare or wavefront analysis, although high spatial resolution contrast acuity had borderline correlation with the severity index and did progress over time.

Glistenings in Literature - Conclusions

- Glistenings develop to some degree in all IOLs, but appear most prevalent in AcrySof® group: higher percentage of lenses affected and in higher density
- Glistenings progress over time
- Glistening effect on visual function and contrast sensitivity is unknown and warrants further study

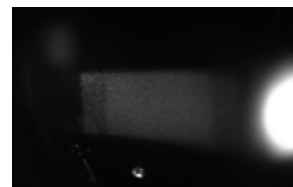
Determining Severity Grade of Microvacuoles

Case Study

Female, implanted with Acrysof® MA60BM OU

- OD 12/96, OS 1/97
- Glistenings: OD Grade 1, OS Grade 3
- OS: UCVA 20/70 BCVA 20/30⁻²

OS:
Grade 3
250-1250
Size 20 μ

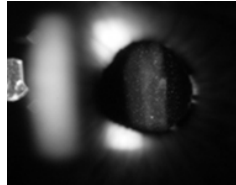


Case Study

Female, implanted with Acrysol® MA60BM OU

- OD 10/03
- Glistenings: OD Grade 3
- OD: UCVA BCVA

OD:
Grade 3
250-1250
Size 20µ



Prospective Study Underway

- Evaluate the percentage of IOLs with glistenings at 6, 12, and 24 months
- Aim for 20+ patients time point
- Rate the severity of these glistenings, 0 (none) 1+, 2+, or 3+.
- Correlate the severity of glistenings with
 - Best corrected vision
 - Glare disability (BAT on Medium)
 - Contrast sensitivity

In House Prevalence Study

20 Patients Recalled at Random

5 Groups:

1Day Post-OP

6 Months Post Op (+-1 Month)

1 Year Post Op (+- 2 Months)

2 Years Post-Op (+- 3 Months)

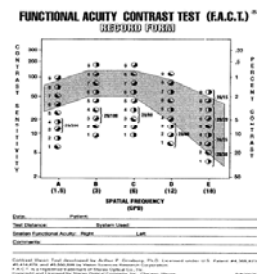
3 Years Post-Op (+- 4 Months)

4+ Years Post-Op

Results:

- 1 Day: 0/20
- 6 Months: 3/20 (1-1+; 2-2+)
- 1 Year: 7/20 (5-1+, 2-2+)
- 2 Years: 13/21 (5-1+, 8-2+)
- 3 Years: 21/25 (10-1+, 9-2+, 2-3+)
- 4+ Years: 9/20 (6-1+, 3-2+)

Average Best Corrected Acuity (BCA), Glare (BAT on Medium) and Contrast Sensitivity (5 Spatial Frequency Numbers Added Together)



RESULTS

Glistening Grade	Best Visual Acuity	BAT Glare Acuity	Contrast Sensitivity

Preliminary Conclusions:

- Glistenings in Acrysof Acrylic IOLs are not present on day one, but appear to be acquired, increasing in both incidence and severity with time, affecting the majority of Implanted Lenses by 3 years
- 1+ and 2+ Glistenings do not appear to significantly affect Vision, Glare Disability, or Contrast Sensitivity; 3+ glistenings may adversely affect Vision, Glare and Contrast

**This Study Is
Continuing**

**I Hope To Have More
Definitive Results Available
For Next Year's Meeting**

**(If My Techs Don't Lynch Me Before
Then)**

THANK YOU