# **BAUSCH+LOMB** Non-Invasive Tear Break-Up Time Evaluation of Six Unique Daily Disposable Lens Materials After 10 Hours of Wear.

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# Introduction

In today's digital world, where contact lens (CL) wearers concentrate on digital content for work and recreation, maintaining a persistent tear film over the surface of a CL is an important factor for successful CL wear.<sup>1-3</sup> Material chemistry can play an important role in stabilizing tears.<sup>4</sup>

Biotrue ONEday (BOD) daily disposable CLs are made of a novel, bio-inspired material, nesofilcon A. This material has 78% water content and has the outer surface of the lens designed to mimic the lipid layer of the tear film to prevent dehydration. Previous studies have demonstrated that neosfilcon A can retain shape and optical image quality better than other hydrogel and silicone hydrogel daily disposable CLs when exposed to controlled experimental dehydration conditions.<sup>1,2</sup> It has also been shown that after 16 hours of lens wear, nesofilcon A exhibited loss of only 1.5% of water compared to 6.5% and 7.0% in etafilcon A and narafilcon A, respectively.<sup>3</sup>

The purpose of this study was to evaluate the Non-invasive tear break up time (NITBUT) of today's contemporary daily disposable CLs after 10 hours of wear.

#### **Methods**

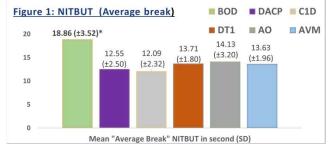
Twelve CL wearers were masked and randomly assigned to wear one pair of lenses per day on 6 individual days. Lenses evaluated were delefilcon A (DT1), etafilcon A (AVM), nelfilcon A (DACP), nesofilcon A (BOD), senofilcon A (AO), and somofilcon A (C1D). After 10 hours of wear, automated "Average Break" NITBUTs were measured objectively using an Oculus Keratograph 5M instrument with infrared illumination. The advantage of using infrared illumination during measurement is to avoid bright light that may stimulate the eye and affect the tear stability.

The "Average Break" represents the average time for the tear to break in all 4 segments on the surface of the lens. Five measurements were taken on NITBUT, the highest and lowest values were excluded and the remaining 3 were averaged to obtain the mean NITBUT for each subject/lens combination.

The study has obtained IRB approval by Southwest Independent IRB, Inc in the US.

### Results

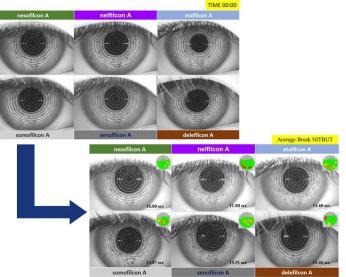
**Quantitative assessment** – Pre-lens tear film NITBUT (in sec) for average break were obtained from all 12 subjects across all 6 lens types. The mean "average" NITBUT value was  $13.71 \pm 1.80$  sec for DT1,  $13.63 \pm 1.96$  sec for AVM,  $12.55 \pm 2.50$  sec for DACP,  $18.86 \pm 3.52$  sec for BOD,  $14.13 \pm 3.2$  sec for AO and  $12.09 \pm 2.32$  sec for C1D. Normality tests showed that the data appeared to be normally distributed. One-way ANOVA with post-hoc Tukey HSD Calculator showed that the "average" NITBUT amongst all groups was significantly different (p<0.0001). Post-hoc analysis (with Scheffé, Bonferroni and Holm multiple comparison tests) shows that the "average" NITBUT value for BOD was significantly better than all other 5 types of lenses. Results are shown in Figure 1.



<u>Qualitative assessment</u> – Pre-lens tear film can also be evaluated by observing the quality of the placido ring images projected onto the cornea. During the NITBUT measurement, the instrument also captures a video of the entire pre-lens tear film changes from immediately after a blink (time 0) to excessive blur or distortion of the reflected placido rings images, making continued detection impossible (with a max. of 25 secs after blink).

Figure 2 shows the pictures from a representative subject who has the "Average break" NITBUT value for all 6 lens types that closely matches the mean "average break" value for all 12 subjects of each corresponding lens types. The upper picture shows the placido ring images taken at time 0 and the lower picture shows the images at the Average Break time. The quality of the placido ring images for all 6 lens types are equally clear at time 0. At end of measurement, the placido ring images for nesofilcon A are still round and clear whereas the images for most of the other lens types has become distorted or broken indicating the pre-tear tear film with these lenses has become unstable.

#### Figure 2: Representative subject at time 0 and Average Break time



# Conclusion

There are many factors, such as material, water content, and surface properties of the contact lens, that could be associated with tear evaporation.<sup>5</sup> The contemporary daily disposable lenses evaluated represent 6 unique material chemistries. Tear break up in all 4 segments of the pre-lens surface can impact comfort and visual outcomes of the lens wearer after 10 hours of lens wear. The nesofilcon A (BOD) lens can provide more stable pre-lens tear film (from both quantitative and qualitative analysis), as evidenced by the NITBUT measured across all 4 segments of the pre-lens surface.

## References

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