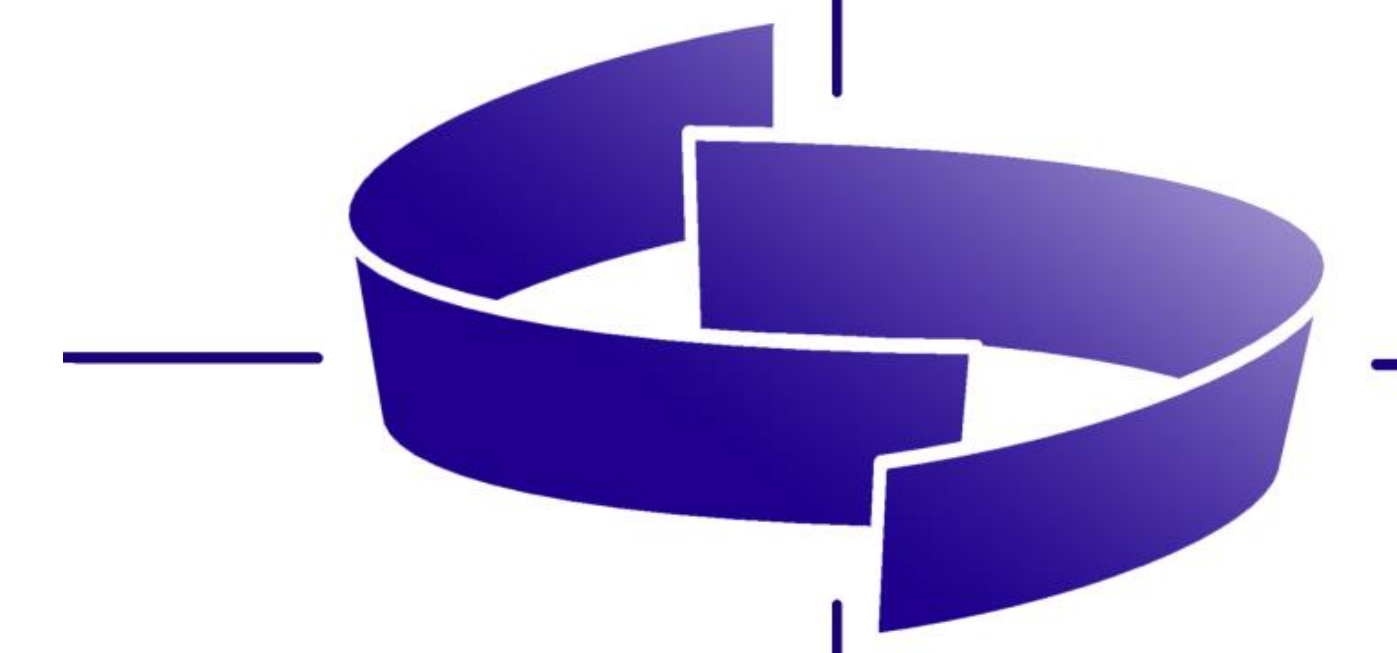


Subjective Comparison of Pre-Lens Tear Film Stability of Daily Disposable Contact Lenses Using Modern Video Topography



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Introduction:

Contact lens wettability is an important property for the physiological compatibility, visual quality and comfort of the contact lens^{1,2} (CL). Different wetting agents are used in daily disposable contact lenses (DDCL) to support these factors. To evaluate the in vivo surface wettability, a method is needed which allows an evaluation of a large area of the CL and visualise tear film stability.

Purpose:

Evaluation of the in vivo tear film stability of three different DDCLs using the ring mire projection of the Keratograph 5M (Oculus) after 8 and 12 hours of wear.

Methods:

Study design: prospective, randomized, observer masked, cross-over

Subjects: 28 (22 female), age 25 ± 4 years

Contact lenses: nelfilcon A (with bonded and mobile wetting agents PVA, HPMC and PEG),
 etafilcon A (with bonded wetting agents PVP),
 omafilcon A (from biocompatible PC without additional wetting agent)

In vivo video recordings were taken of the pre-lens tear film by using the ring mire projection of the Keratograph 5M (K5M, Oculus) during the right eye was open for at least 25 seconds. The distortion of the ring mire represents a tear film instability.

Three masked observers

determined pre-lens non-invasive keratograph-drying-up time (PL NIK-DUT) in seconds (168 videos) post blink after 8 hrs and 12 hrs of wear

graded surface wettability (0=no visible distortion to 3=distortion in > 1/3 of the ring reflection zone) at 5, 10, 15, 20 and 25 seconds (4200 pictures) post blink after 8 hrs and 12 hrs of wear

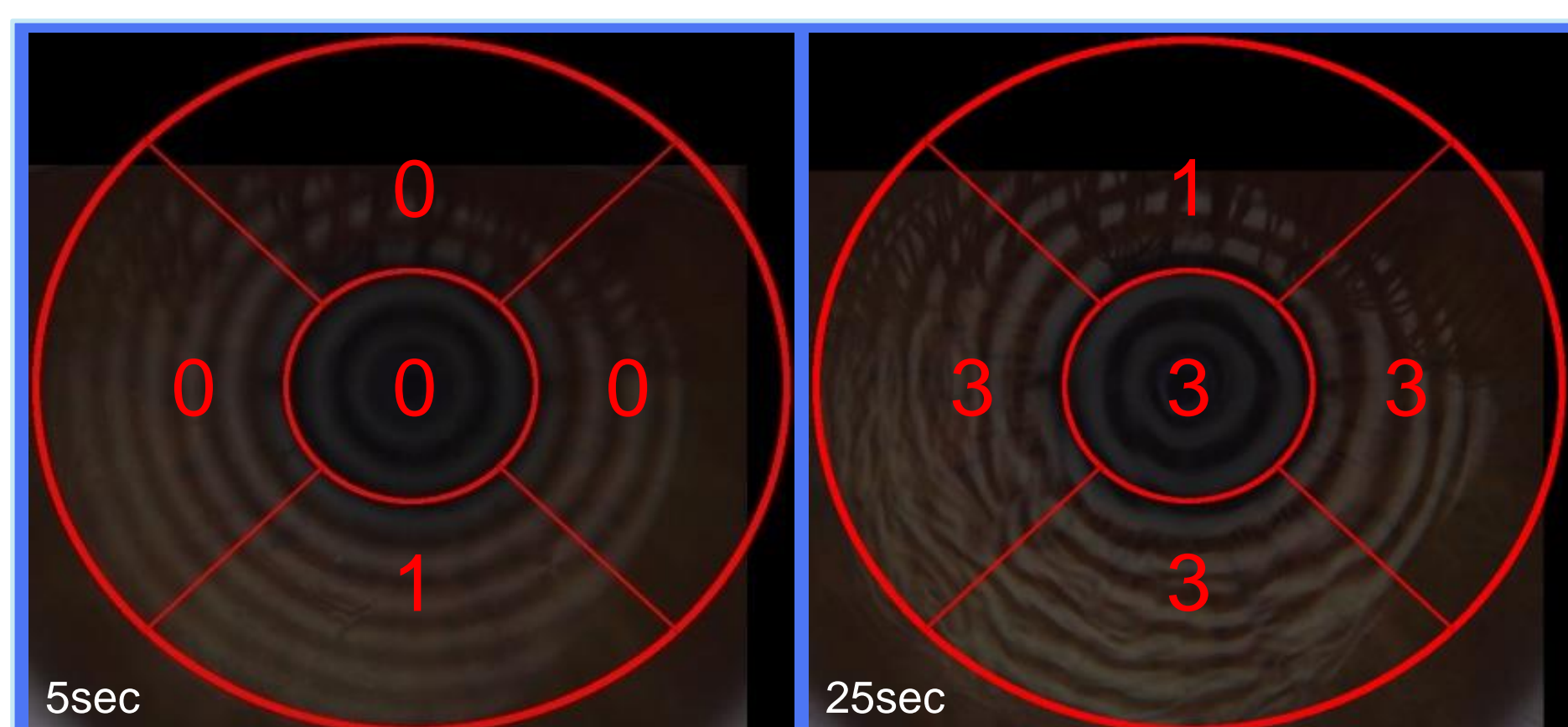


Fig. 1: Example for a subjective grading after 5 and 25 seconds post blink. Therefore ring mire reflection of pre-lens tear film was separated in five sections (central, superior, nasal, inferior and temporal (C, S, N, I and T)).

Results:

Subjectively determined PL NIK-DUTs:

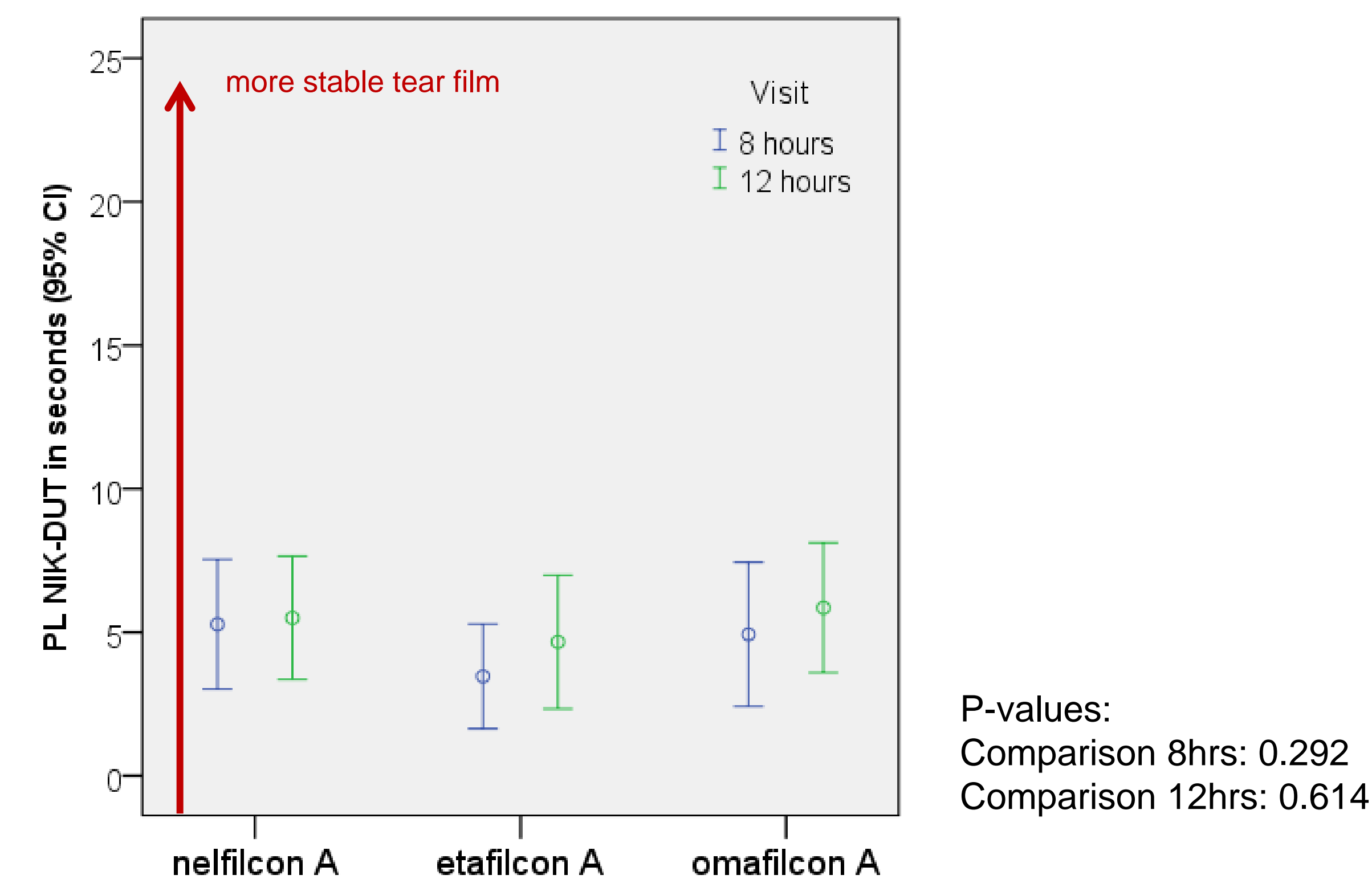


Fig. 2: PL NIK-DUTs in seconds (95% CI) of the three DDCL compared to the two visits

Tab. 1: Descriptive results of the PL NIK-DUT of the three DDCL over the two visits

DDCL	Mean of medians in s		SD in s		95% CI in s	
	8 hrs	12 hrs	8 hrs	12 hrs	8 hrs	12 hrs
nelfilcon A	5.28	5.50	5.71	5.43	{3.02 – 7.54}	{3.35 – 7.65}
etafilcon A	3.46	4.66	4.52	6.00	{1.64 – 5.29}	{2.33 – 6.99}
omafilcon A	4.94	5.85	6.34	5.73	{2.42 – 7.43}	{3.59 – 8.12}

Subjectively graded surface wettability:

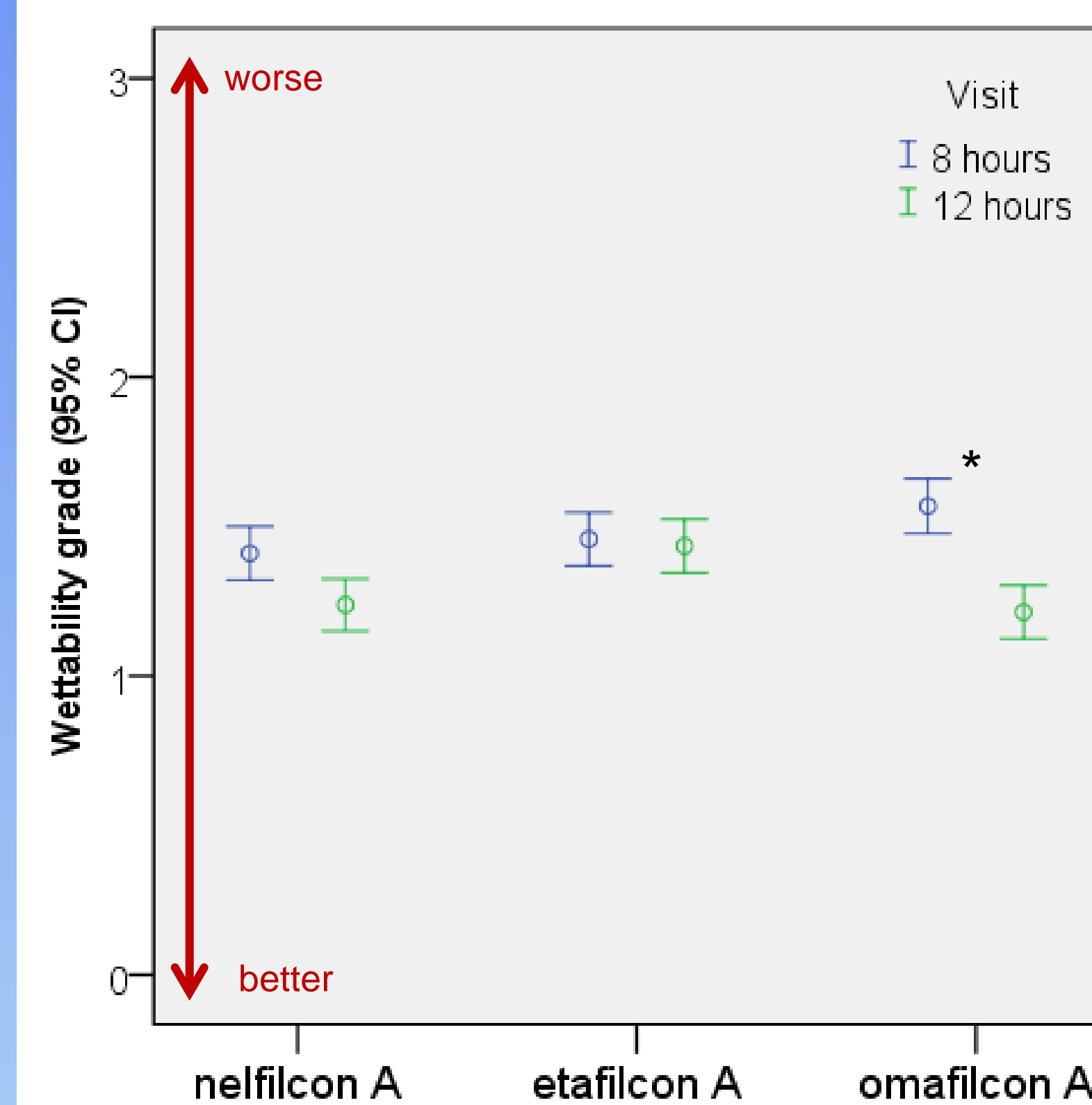


Fig. 3: Wettability grading (95% CI) of each DDCL comparing the two visits, *p<0.001 (Friedmann-Test)

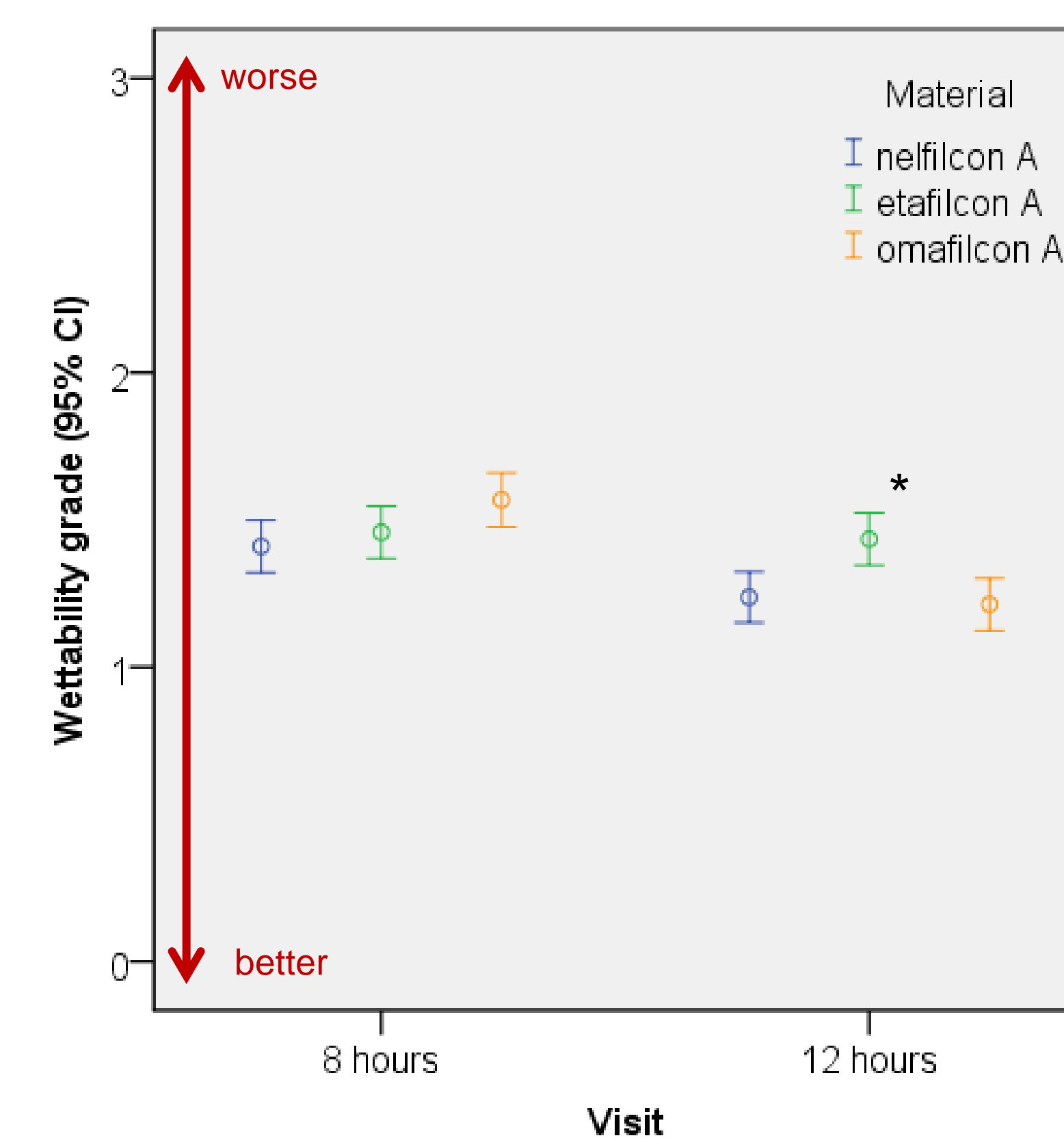


Fig. 4: Wettability grading (95% CI) at each visit comparing the three DDCLs, *p=0.001 (Kruskal-Wallis-Test)

Discussion:

This method was shown to be suitable to evaluate tear film stability with contact lenses on eye. The measure of surface wettability over the interblink period was more sensitive than the time to first distortion.

Nelfilcon A, designed to release a wetting agent over time, provides a consistently stable tear film across 12 hours of wear. Nelfilcon A and omafilcon A provide better on-eye lens wettability after 12 hours of wear compared to etafilcon A.

To prevent a subjective influence, future studies will focus an objective method to determine PL NIK-DUT and to grade surface wettability.

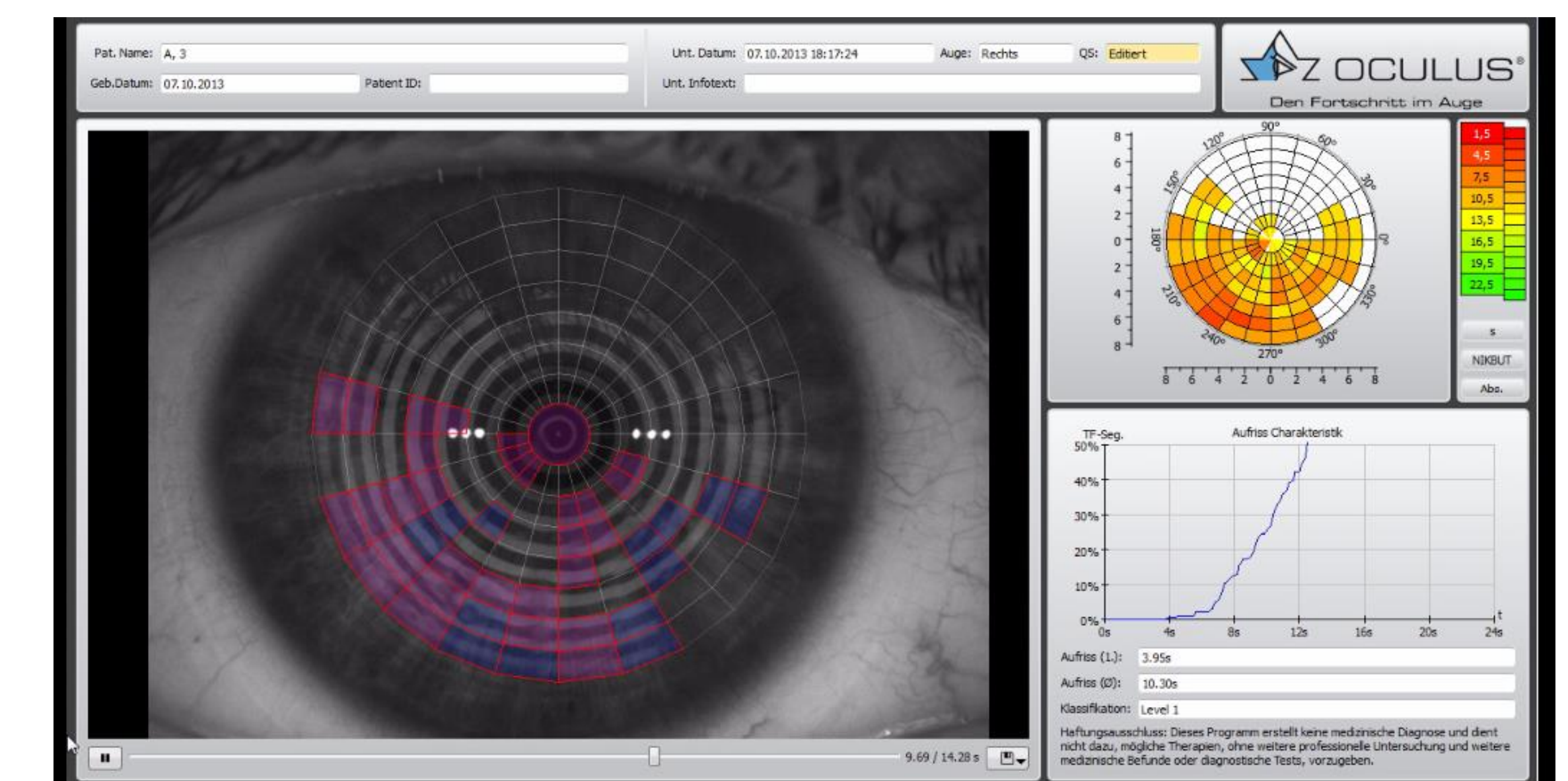


Fig. 5: Screenshot of an objective method with the Keratograph 5M, taken from present investigations

Conclusion:

The study shows that the in vivo pre-lens tear film can be evaluated over a large area by using the Keratograph 5M. To conclude the results DDCLs with mobile wetting agents (nelfilcon A) as well as DDCLs from biocompatible PC (omafilcon A) can have a positive impact of the tear film stability after 12 hours of lens wear.

References:

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- Nicolson P. C. und Vogt J.: Soft contact lens polymers: an evolution. Biomaterials. 22(24), 2001, S. 3273-3283

Acknowledgements:

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