# Comparison of Pre-Lens Tear Film Stability of Nelfilcon A with Different Optical Designs Using Placido Ring Projection

[1]Sebastian Marx, [2]Cecile Maissa, [2]Julia Wittekind, [3]Wolfgang Sickenberger

[1]JENVIS Research Institute, Jena, Germany; [2]Alcon Vision Care, Dailies; Fort Worth, TX, USA; [3]Ernst-Abbe-University, Jena, Germany

Introduction

- Contact lens wear is known to be one of the causes of tear film (TF) instability,[1] increased evaporation rate,[1-3] and dry eye symptoms,[4-7] leading to decreased ocular comfort towards the end of the day[8] and reduced wearing time.[9]
  - In cases in which the TF is unable to fully wet the contact lens surface, there is a decrease in TF optical quality, hence visual impairment, an increase in deposition,[10] and reduced comfort.[11]
  - Further, aging has been associated with significant changes in the tear lipid layer and a significantly higher TF evaporation specifically in patients older than 45 years.[12,13] This reduction in TF stability and efficacy is associated with a higher incidence of tear-related problems in an aging population.
- Although several techniques are available, there are no established methods for an objective assessment of the pre-lens TF stability.
- More recently, corneal topography has been used to assess the pre-lens noninvasive tear breakup time (PL NITBUT), enabling the observation of a much larger zone, covering more than the optical zone of a contact lens.
  - Circular mires are projected onto the corneal surface, the reflection on the TF is observed, and the time (PL NITBUT) is recorded at the first observation of mire distortion.[14]
  - Although the time to first TF break is often used as the clinical marker of contact lenses on eye wettability, recent findings have shown that this measurement alone is insufficient to fully characterize on-eye contact lens wettability.[15]
- The Keratograph 5M (K5 Oculus; OCULUS Optikgeräte GmbH, Wetzlar, Germany) device can project placido ring mires onto the lens surface and capture a video of the reflected image via snapshots taken every 5 seconds for 25 seconds (Figure 1). Newly developed software allows simultaneous detection of areas and times of destabilization after the blink.
- The primary objective of this study was to evaluate the pre-lens TF characteristics of nelfilcon A daily disposable contact lenses with toric or multifocal design compared with those with a spherical design over 12 hours of wear.
- The secondary objective was to evaluate the day-to-day and intersubject variability of TF characteristics assessed using the Oculus K5 imaging system.

Figure 1. Images of tear film with ring mires projection recorded every 5 seconds for 25 seconds post-blink

| T = 0 sec | T = 5 sec | T = 10 sec | T = 15 sec | T = 20 sec | T = 25 sec |
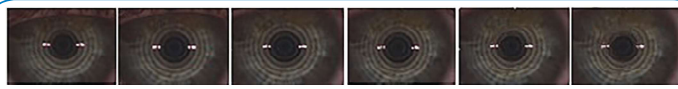
Methods

- Prospective randomized bilateral crossover study in presbyopes and astigmats aged ≥18 years adapted to soft contact lenses (Figure 2).
  - Presbyopes were assigned to nelfilcon A Dailies® Aqua Comfort Plus® (DACP) multifocal lenses, followed by DACP sphere lenses or vice versa.
  - Astigmats were assigned to DACP toric lenses, followed by DACP sphere lenses or vice versa.
  - After a washout period, all subjects wore DACP sphere lenses for retesting.

Figure 2. Study design

4 x 2 incomplete crossover design with one repeat period
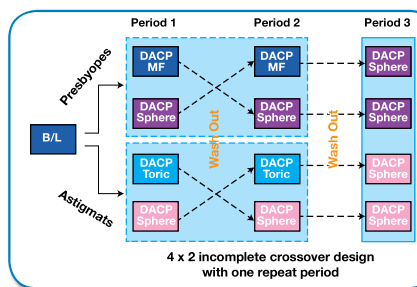
- Each lens was worn for 12 hours; during each period, videos of the ring mires system projected onto the ocular/lens surface using the K5 Oculus-Imaging Live Mode and NIKBUT Mode were recorded for 3 consecutive blinks for 25 seconds post-blink.
  - Before contact lens insertion; pre-ocular TF (POTF).
  - 5 min, 8 h, and 12 h after contact lens insertion; post-lens TF (PLTF).
- Videos assessed subjectively using the TF-Scan software.
- Surface wettability grading:
  - Grade 0 = full wettability
  - Grade 1 = mild distortion and hazing
  - Grade 2 = clearly visible ring distortions ≤ 1/3 of the assessed area
  - Grade 3 = clearly visible ring distortions > 1/3 of the assessed area
- TF parameters analyzed on the K5 Oculus NIKBUT videos included:
  - Time to first break (NIKBUT to first distortion)
  - Maximum % distortion over 25 seconds post-blink
  - Area under the curve (AUC) % distortion over 25 seconds post-blink
  - The percent distortion at 5 and 10 seconds

Results

Table 1. Baseline demographic characteristics

|	Presbyopes (N=22)	Astigmats (N=21)	Overall (N=43)
Age, yr			
Mean ± SD	51.7 ± 8.1	25.8 ± 4.5	39.0 ± 14.6
Range	40 to 69	21 to 37	21 to 69
Sex, n (%)			
Male	6 (27.3)	5 (23.8)	11 (25.6)
Female	16 (72.7)	16 (76.2)	32 (74.4)

Habitual lens characteristics at baseline

- Fourteen presbyopes (63.6%) used reusable lenses and 6 (27.3%) used daily lenses.
  - Lens material was silicone hydrogel in 14 (63.6%) and non-silicone hydrogel in 6 (27.3%).
- Twelve astigmats (57.1%) used reusable lenses and 5 (23.8%) used daily lenses.
  - Lens material was silicone hydrogel in 13 (61.9%) and non-silicone hydrogel in 5 (23.8%).

Results

- Average wettability for grades 0 and 1 after 12 hours of wear by presbyopes were similar for DACP multifocal (MF) and DACP sphere lenses at each post-blink timepoint (Figure 3A).
- The percentage of presbyopes with average wettability grades of 2 or 3 after 12 hours of wear was similar for DACP multifocal and DACP sphere lenses at each post-blink timepoint (Figure 3B).

Figure 3. Average wettability grades after 12 hours of wear of DACP MF and DACP sphere lenses during periods 1 and 2 (presbyopes)
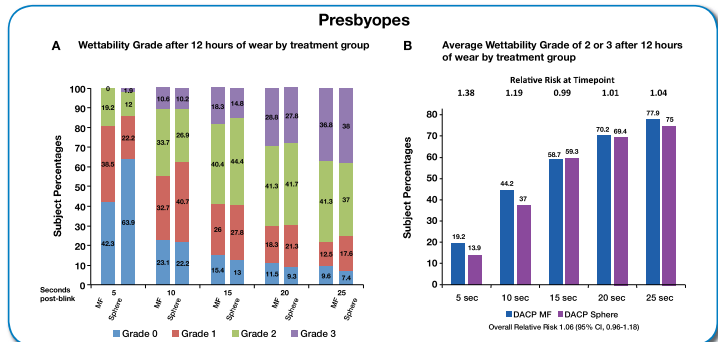
- Average wettability for grades 1 and 2 after 12 hours of wear by astigmats were similar for DACP toric and DACP sphere lenses at each post-blink timepoint (Figure 4A).
- The percentage of astigmats with average wettability grades of 2 or 3 after 12 hours of wear was similar for DACP toric multifocal and DACP sphere lenses at each post-blink timepoint (Figure 4B).

Figure 4. Average wettability grades after 12 hours of wear of DACP Toric and DACP sphere lenses during periods 1 and 2 (astigmats)
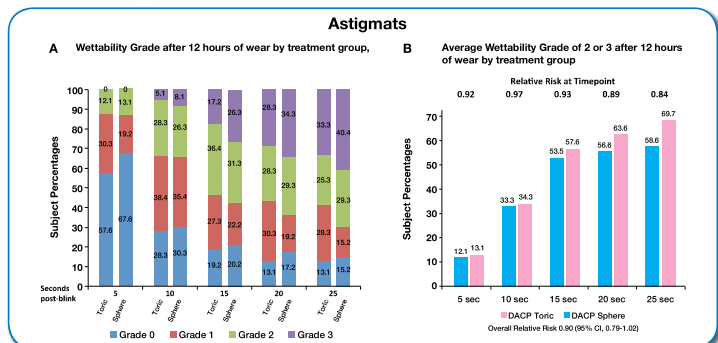
Inter-subject variability

- In presbyopes, within each testing condition (POTF, PLTF), the inter-subject variability, expressed as the coefficient of variation (COV), ranged from 47% to 80% for the time to first distortion, from 70% to 111% for AUC % distortion, and 60% to 95% for the max. % distortion (Table 2).
- In astigmats, within each testing condition (POTF, PLTF), COV ranged from 48% to 72% for time to first distortion, from 82% to 185% for AUC % distortion, and from 77% to 170% for the max. % distortion (Table 2).

Table 2. Inter-subject variability for DACP sphere lenses

	Presbyopes				Astigmats			
	Period 1 or 2		Period 3		Period 1 or 2		Period 3	
	Median (Min., Max.)	COV (%)	Median (Min., Max.)	COV (%)	Median (Min., Max.)	COV (%)	Median (Min., Max.)	COV (%)
Time to first distortion (sec)								
Pre-ocular	8.6 (2, 25)	65.8	8.9 (2, 25)	68.7	15.8 (3, 25)	48.1	18.7 (2, 25)	48.4
5 min	5.7 (1, 25)	79.8	6.8 (2, 16)	53.4	9.5 (2, 25)	59.5	7.3 (3, 24)	67.2
8 h	7.2 (2, 24)	61.7	9.2 (3, 18)	47.2	8.3 (2, 25)	72.1	10.8 (2, 25)	63.6
12 h	8.8 (2, 25)	62.7	6.9 (2, 20)	64.3	7.2 (3, 25)	65.6	8.6 (4, 24)	54.8
AUC % distortion								
Pre-ocular	133.2 (0, 392)	88.5	46.9 (0, 430)	111.3	21.3 (0, 705)	176.5	5.0 (0, 732)	185.4
5 min	482.2 (0, 938)	69.6	336.1 (19, 1106)	84.5	172.4 (0, 765)	92.9	274.2 (1, 683)	82.7
8 h	295.9 (1, 957)	82.8	229.2 (8, 1020)	90.9	396.5 (0, 1171)	94.2	177.6 (0, 1297)	120.3
12 h	251.7 (0, 861)	80.6	408.8 (7, 975)	78.1	213.0 (0, 975)	101.2	289.5 (4, 837)	88.1
Maximum % distortion over 25 sec blink								
Pre-ocular	16.7 (0, 32)	79.0	10.4 (0, 28)	95.2	5.5 (0, 51)	132.7	0.5 (0, 60)	170.5
5 min	44.2 (0, 81)	60.4	34.2 (3, 88)	70.5	18.8 (0, 70)	84.2	27.6 (1, 64)	77.1
8 h	34.6 (1, 84)	65.1	30.7 (1, 79)	75.9	32.8 (0, 86)	87.5	25.5 (0, 75)	93.4
12 h	31.3 (0, 70)	69.0	30.9 (1, 73)	67.8	23.4 (0, 85)	84.3	26.0 (1,65)	80.9

Table 3. Mean (±SD) differences for DACP sphere lenses between Period 3 and Periods 1 & 2 for time to first distortion, AUC % distortion, and maximum % distortion

	Presbyopes	Astigmats		Presbyopes	Astigmats		Presbyopes	Astigmats
Time to first distortion, sec			**AUC % distortion**			**Maximum % distortion**		
Pre-ocular	1.1 ± 11.9	0.9 ± 5.5	Pre-ocular	-30.3 ± 183.8	21.7 ± 183.6	Pre-ocular	-3.3 ± 14.1	0.7 ± 13.6
5 min	-0.3 ± 7.2	-0.7 ± 5.7	5 min	-28.9 ± 362.1	-11.0± 181.5	5 min	-3.9 ± 29.2	1.2 ± 15.5
8 h	1.2 ± 5.7	1.0 ± 7.6	8 h	-49.5 ± 279.4	-64.11 ± 351.5	8 h	-4.3 ± 19.0	-4.9 ± 25.5
12 h	-1.1 ± 5.7	-1.0 ± 7.7	12 h	69.6 ± 257.4	14.57 ± 265.5	12 h	3.9 ± 18.2	0.8 ± 20.1

Conclusion

- The surface wettability of DACP multifocal and toric daily disposable contact lenses was at least as good as that of the spherical design after 12 hours of lens wear.
- Wettability is not affected by the optical design of the lens.
- This method was successful in determining the inter- and intra-subject variations in TF characteristics measurements over 25 seconds post-blink.

References

1. Craig JP, Willcox MD, Argüeso P, Maissa C, et al. The TFOS International Workshop on Contact Lens Discomfort: report of the contact lens interactions with the tear film subcommittee. *Invest Ophthalmol Vis Sci.* 2013;54(11):123-56 2. Guillon M, Maissa C. Contact lens wear affects tear film evaporation. *Eye Contact Lens.* 2008;34(8): 326-30. 3. Thai LC, Tomlinson A, Doane MG. Effect of contact lens materials on tear physiology. *Optom Vis Sci.* 2004;81(3):194-204. 3. Thai LC, Tomlinson A, Doane MG. Effect of contact lens materials on tear physiology. *Optom Vis Sci.* 2004;81(3):194-204. 4. DEWS 2007. The definition and classification of dry eye disease: report of the Definition and Classification Subcommittee of the International Dry Eye Workshop. *Ocular Surface.* 2007;5(2):75. 5. Caffery BE, Richter D, Simpson T, et al. The Canadian Dry Eye Epidemiology Study. In: Sullivan DA, Dartt DA, Meneray MA, eds. Lacrimal Gland, Tear Film, and Dry Eye Syndromes 2. New York: Plenum Press, 1998:805-6. 6. Guillon M, Maissa C. Dry eye symptomatology of soft contact lens wearers and nonwearers. *Optom Vis Sci.* 2005;82(9):829-34. 7. Nichols JJ, Ziegler C, Mitchell GL, Nichols KK. Self-reported dry eye disease across refractive modalities. *Invest Ophthalmol Vis Sci.* 2005;46(6):1911-4. 8. Dumbleton K, Woods C, Jones L, et al. Patient and practitioner compliance with silicone hydrogel and daily disposable lens replacement in the United States. *Eye Contact Lens.* 009;35(4): 64-71. 9. Richdale K, Sinnott LT, Skadahl E, Nichols JJ. Frequency of and factors associated with contact lens dissatisfaction and discontinuation. *Cornea.* 2007;26(2):168-74. 10. Jones L, Senchyna M, Glasier MA, et al. Lysozyme and lipid deposition on silicone hydrogel contact lens materials. *Eye Contact Lens.* 2003;29 (1 Suppl):S75-9; discussion S83-4, S192- 4. 11. Guillon M, Maissa C. Use of silicone hydrogel material for daily wear. *Cont Lens Anterior Eye.* 2007;30(1):5-10. 12. Maissa C, Guillon M. Tear film dynamics and lipid layer characteristics—effect of age and gender. *Cont Lens Anterior Eye.* 2010;33(4):176-82. 13. Guillon M, Maissa C. Tear film evaporation—effect of age and gender. *Cont Lens Anterior Eye.* 2010;33(4):171-5. 14. Wiedemann D, Sickenberger W, Michel M, Marx S. Development and realisation of a new non-invasive method for tear film assessment using a corneal topographs. Presented at the 88th Annual Meeting of the American Academy of Optometry, San Francisco, CA, November 2010. 15. Guillon M, Maissa C. Beyond non invasive break up time: a novel method to quantify contact lens on eye wetting kinetics over the full interblink period. Presented at the 7th International Tear Film and Ocular Surface Conference, Taormina, Sicily, Italy, September 18-21, 2013.