Solution Related in Vitro Dewetting behavior of Different Soft Contact Lens Materials

Sebastian Marx[1], Julia Eckstein[1], Felix Zimmermann[1], Wolfgang Sickenberger[2]
[1]JENVIS Research Institut Jena, [2]Ernst-Abbe University of Applied Sciences Jena

Introduction

The wettability of the contact lens surface is, among the oxygen transmissibility, a very important material property that has a crucial impact on the physiological tolerance of a contact lens. In general, the wettability is defined as the tendency of liquid to spread over the surface when exposed to a solid object. [1,2] If inconsistent wettability of the contact lens surface is present, visual impairment, increased affinity for deposits [3] and reduced comfort are the consequences. [4] A high long term compatibility of contact lens materials results from the combination of both, the increased oxygen transmissibility and the improved wettability. [5-8] But the high oxygen transmissibility is associated with material-dependent hydrophobic surface characteristics [8], which leads to poorer in vivo wettability. [9,10] The most common methods of evaluating the wettability of contact lens surfaces is via contact angle [11-14], with the most prevalent techniques being "Sessile Drop" [12,15] and "Captive Bubble". [9,11] The disadvantage of both methods is the small area that is analyzed. A new approach of the in vitro contact lens wettability analysis is the in vitro measurement of the drying-up time by means of a modified corneal topographer (horizontally mounted Keratograph 5M, Oculus) [16], the so called Non-Invasive Keratograph Drying-Up Time (NIK-DUT). [17] The NIK-DUT measurement is based on the projection of an illuminated ring pattern onto the contact lens surface and its reflection from it.

Purpose

The primary objective of the study is to determine the in vitro dewetting characteristic curves of different hydrogel and silicone hydrogel Daily Disposable Contact Lenses (DDCLs) measured out of their specific blister solutions using the NIK-DUT procedure to determine the short term dewetting characteristics.

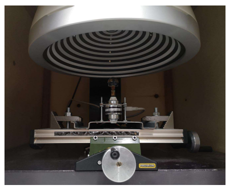
The secondary objective is to measure the in vitro dewetting characteristic curves of the same lenses soaked in saline solution (control) and in artificial tear solution (ATS) to determine the long term dewetting characteristics.

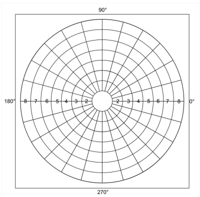
Following exploratory endpoints:

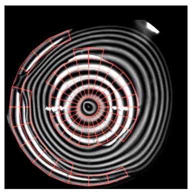
1) Area under curve (AUC)2) Time at 25% dried up surface (NIK-DUT_S25):
2) Time from starting the measurement manually directly after placing the lens onto the stage, till the time at which 25% of all segments show a dry-up area
3) Time at 50% dried up surface (NIK-DUT_S50): Time from starting the measurement manually directly after placing the lens onto the stage, till the time at which 50% of all segments show a dry-up area

Material and Methods

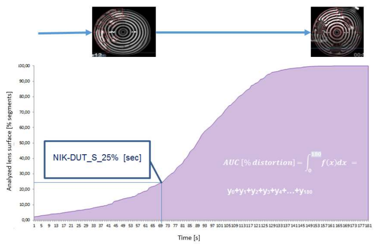
To analyse in vitro contact lens (CL) surface dewetting, the novel technique Non-Invasive Drying-Up Time (NIK-DUT) was applied. For that a horizontal-positioned corneal topographer (OCULUS Optikergeräte GmbH Wetzlar, Germany) projected illuminated placido ring pattern onto the CL surface and distortions and gaps were recorded as dewetting on the CL surface.



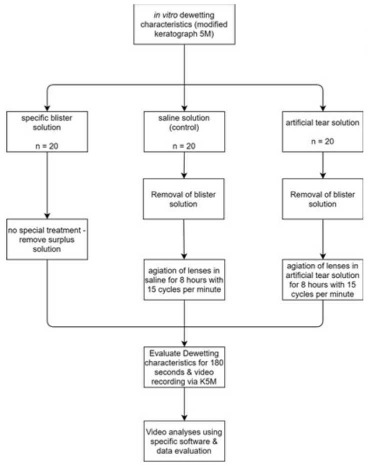


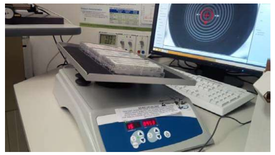


Dewetted area was measured over a time of 180 seconds using a sophisticated software which was controlled by a trained investigator. Determined front soft CL surface was divided into 169 segments which can be defined as "dried up" or "moisten", depending on the reflection of the ring patterns. Resulting area under curve (AUC) was used to evaluate time depending dewetting process as well as NIK-DUT_S25 (time when 25 % of segments have been dried up) and NIK-DUT_S50 (time when 50 % of segments have been dried up).



Twenty soft daily disposable (DD) CLs (power -3.00 D) each of different materials (nelfilcon A, delefilcon A, senofilcon A, stenfilcon A, somofilcon A, narafilcon A) were measured out of there specific blister solution, out of saline solution (control) and out of specific artificial tear solution. CL out of blister solution were measured directly without specific treatment. Lenses measured in saline solution and artificial solution were agiated in mentioned solution for at least 8 hours with 15 cycles per minute using an orbital shaker. Excess liquid was removed carefully using filterpaper before each measurement.

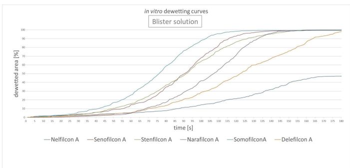




Results

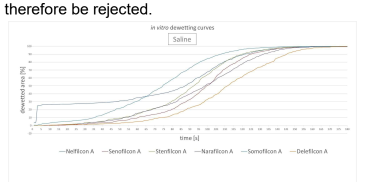
Every averaged measurement set consisting out of twenty single measurements has been transferred to SPSS version 21 for statistical analysis. The Kruskal Wallis test was performed in order to investigate if the not normal distributed, independent measurement sets were statistically different. The six different DD lens materials were grouped for blister solution, saline solution and ATS. All groups showed intra and intergroup differences. A post hoc analysis was performed (results not shown in this poster).

Blister Solution: The Kruskal Wallis test shows a highly significant result (p<0.001) for the dewetting area per time, NIK-DUT_S25% and NIK-DUT_S50% out of the blister solution. The null hypothesis that all material groups provide the same dewetting behavior of the CL surface must therefore be rejected.



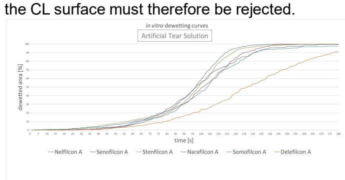
material	AUC [cum%] Mean ± SD	NIK-DUT_S25 [s] Mean ± SD	NIK-DUT_S50 [s] Mean ± SD
Nelfilcon A	3161,04 ± 15,86	95,35 ± 63,40	47,20 ± 66,97
Delefilcon A	6166,38 ± 33,54	101,80 ± 19,28	125,25 ± 21,38
Senofilcon A	9398,20 ± 51,57	77,95 ± 19,49	90,00 ± 16,93
Stenfilcon A	9225,63 ± 39,74	72,20 ± 16,71	88,65 ± 14,19
Narafilcon A	7821,98 ± 41,09	94,30 ± 17,07	105,75 ± 17,23
Somofilcon A	10762,47 ± 40,73	60,90 ± 15,80	76,30 ± 10,98

Saline Solution: The Kruskal Wallis test shows a highly significant result (p<0.001) for the dewetting area per time, NIK-DUT_S25% and NIK-DUT_S50% out of the saline solution. The null hypothesis that all material groups provide the same dewetting behavior of the CL surface must therefore be rejected.

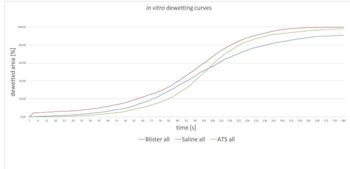


material	AUC [cum%] Mean ± SD	NIK-DUT_S25 [s] Mean ± SD	NIK-DUT_S50 [s] Mean ± SD
Nelfilcon A	11091.72 ± 30.61	57.45 ± 38.05	73.50 ± 40.60
Delefilcon A	7115.03 ± 38.84	96.35 ± 13.70	113.15 ± 15.20
Senofilcon A	8483.39 ± 41.51	82.85 ± 16.50	100.60 ± 11.01
Stenfilcon A	9236.85 ± 41.02	75.85 ± 19.85	89.35 ± 14.24
Narafilcon A	8622.40 ± 39.27	80.25 ± 23.45	96.60 ± 19.81
Somofilcon A	10910.44 ± 38.72	54.90 ± 19.71	70.95 ± 15.84

Artificial Tear Solution: The Kruskal Wallis test shows a significant result (p<0.05) for the dewetting area per time, NIK-DUT_S25% and NIK-DUT_S50% out of the artificial tear solution. The null hypothesis that all material groups provide the same dewetting behavior of the CL surface must therefore be rejected.



material	AUC [cum%] Mean ± SD	NIK-DUT_S25 [s] Mean ± SD	NIK-DUT_S50 [s] Mean ± SD
Nelfilcon A	8857.55 ± 43.62	84.40 ± 13.09	95.20 ± 10.38
Delefilcon A	5532.60 ± 31.61	101.80 ± 19.28	125.25 ± 21.38
Senofilcon A	8248.62 ± 42.19	88.90 ± 15.84	102.15 ± 17.08
Stenfilcon A	8812.99 ± 42.01	83.80 ± 19.57	95.25 ± 17.29
Narafilcon A	8435.34 ± 40.67	84.55 ± 16.36	100.70 ± 16.79
Somofilcon A	8045.44 ± 39.76	88.95 ± 18.16	100.85 ± 18.38



Solution comparison: AUC values also were calculated depending on the solution. Therefore, all measurements per solution have been averaged and compared. AUC values for blister solution, saline solution and artificial tear solution were 7755,9 ± 37,1; 9243,3 ± 38,3 and 7988,8 ± 40,0; respectively.

Conclusion

The NIK-DUT data which was achieved from the out of blister solution measurements show the slowest dewetting for the nelfilcon A material and its blister solution followed by the delefilcon A material in combination with its blister solution. The fastest dewetting was seen in somofilcon A material and its blister solution. Some materials showed very similar results when measured out of saline solution or blister solution. Those material and blister solution combination can have potential for optimization. An optimized blister solution is important as it supports the initial comfort when inserting the lens. The assessments of all materials out of ATS in comparison to the control solution, which was unpreserved saline solution showed an improvement when using ATS. However differences which have been present in saline investigations almost disappeared when using ATS. The only exception is the dewetting behavior of delefilcon A out of ATS which outperformed all other materials when measured out of ATS. This may be the results of the unique water gradient technology which binds superficially water and likes to interact more with ATS than other lens surfaces

References

1 Carre, A.; Woehl, P.: Spreading of Silicone Oils on Glass in Two Geometries. Langmuir, 22: 134-139, 20062
2 Johnson, R.E.; Dettre, R.H.: Wetting of Low-Energy Surfaces. In: Berg, J.C. (ed.): Wettability (Surfactant Science Series), New York, CRC Press, Vol. 49: 1-73, 19933
3 Jones, L.; Senchyna, M., Glasier, M.A. et al.: Lysozyme and Lipid Deposition on Silicone Hydrogel Contact Lens Materials. Eye & Contact Lens: Science and Clinical Practice, Vol. 29 (1): 75-79, 20034
4 Guillon, M.; Maissa, C.: Use of Silicone Hydrogel Material for Daily Wear. Contact Lens & Anterior Eye, Vol. 30 (1): 5-10, 20075
5 Tighe, B.: Silicone Hydrogels: Structure, Properties and Behavior. In: Sweeny, D.F.: Silicone Hydrogels: Continuous Wear Contact Lenses. Edinburgh, Butterworth-
6 Heinemann, pp. 1-27, 20046 Weikart, C.M.; Matsuzawa, Y.; Winterton, L.; Yasuda, H.K.: Evaluation of Plasma Polymer-Coated Contact Lenses by Electrochemical Impedance Spectroscopy. Journal of Biomedical Materials Research, Vol. 54: 597-607, 20017
7 Weikart, C.M.; Miyama, M.; Yasuda, H.K.: Surface Modification of Conventional Polymers by Depositing Plasma Polymers of Trimethylsilane and of Trimethylsilane + O2. Journal of Colloid and Interface Science, Vol. 211: 28-38, 19998
8 Kunzler, J.F.: Silicone Hydrogels for Contact Lens Applications. Trends Polym. Sci.: Vol. 4: 52-59, 19969
9 Maldonado-Codina, C.; Morgan, P.B.; Schnider, C.M.; Efron, N.: Short-Term Physiological Response in Neophyte Subjects Fitted with Hydrogel and Silicone Hydrogel Contact Lenses. Optometry and Vision Science, Vol. 81: 911-921, 200410
10 Brennan, N.A.; Coles, M.L., Ang, J.H.: An Evaluation of Silicone-Hydrogel Lenses Worn on a Daily Wear Basis. Clinical and Experimental Optomerty, Vol. 89: 18-25, 200611
11 Cheng, L.; Radke, C.J.: Wettability of Silicone-Hydrogel Contact Lenses in the Presence of Tear-Film Components. Current Eye Research, Vol. 28: 93-108, 200412
12 Ketelson, H.A.; Meadows, D.L.; Stone, R.P.: Dynamic Wettability Properties of a Soft Contact Lens Hydrogel, Colloids and Surfaces B. Biointerfaces, Vol. 40: 1-9, 200513
13 Tonge, S.; Jones, L.; Goodall, S.; Tighe, B.: The Ex Vivo Wettability of Soft Contact Lenses. Current Eye Research, Vol. 23: 51-59, 200114
14 Willis, S.L.; Court, J.L.; Redman, R.P. et al.: A Novel Phosphorylcholine-Coated Contact Lens for Extended Wear Use. Biomaterials, Vol. 22: 3261-3272, 200115
15 Lorentz, H.; Rogers, R.; Jones, L.: The Impact of Lipid on Contact Angle Wettability. Optometry & Vision Science, Vol. 84: 946-953, 200716
16 Siewert, B.-E.; Marx, S.; Sickenberger, W.: An in vitro Study to determine the Wettability of Hydrogel and Silicone Hydrogel Contact Lenses in Combination with different Lens Care Solutions by using a Corneal Topographer. Jenvis Research Institute, Jena, Germany, internal pilot study, 201117
17 Marx, S; Sickenberger,W: A novel in-vitro method for assessing contact lens surface dewetting: Non-invasive keratograph dry-up time (NIK-DUT). Contact Lens and Anterior Eye

Contact

Sebastian Marx, JENVIS Research, E-mail: s.marx@jenvis-research.com

Acknowledgements

Alcon Vision Care funded the IIT project.