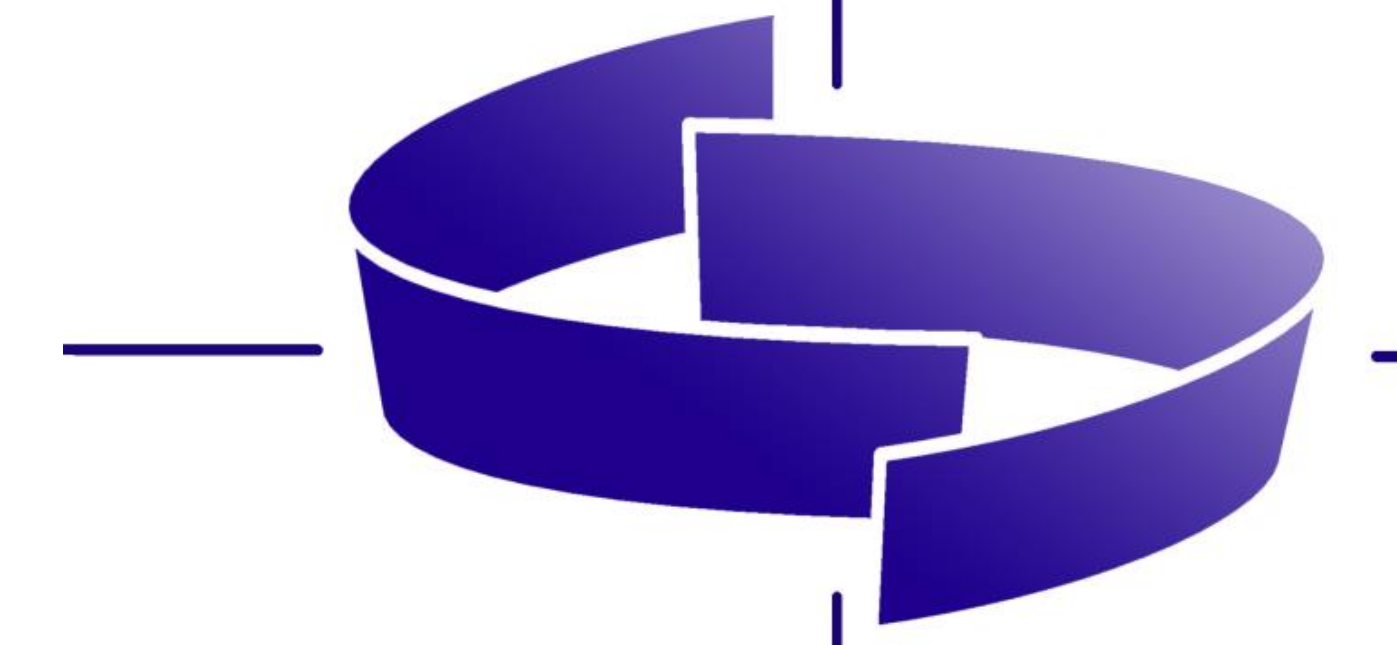


Study to measure the tear film stabilisation and possible reduction of subjective symptoms by application of lipid-containing lubricants



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Introduction:

Approximately 15 million German citizens have signs of dry eye on¹. Symptoms such as burning, itching or tears running impairs the people in their personal activities and their quality of life². Important components in treatment of the symptoms are tears substitutes. On the one hand they reduce the destabilization of the lipid phase and on the other hand they minimize the increased evaporation of the aqueous layer.

Purpose:

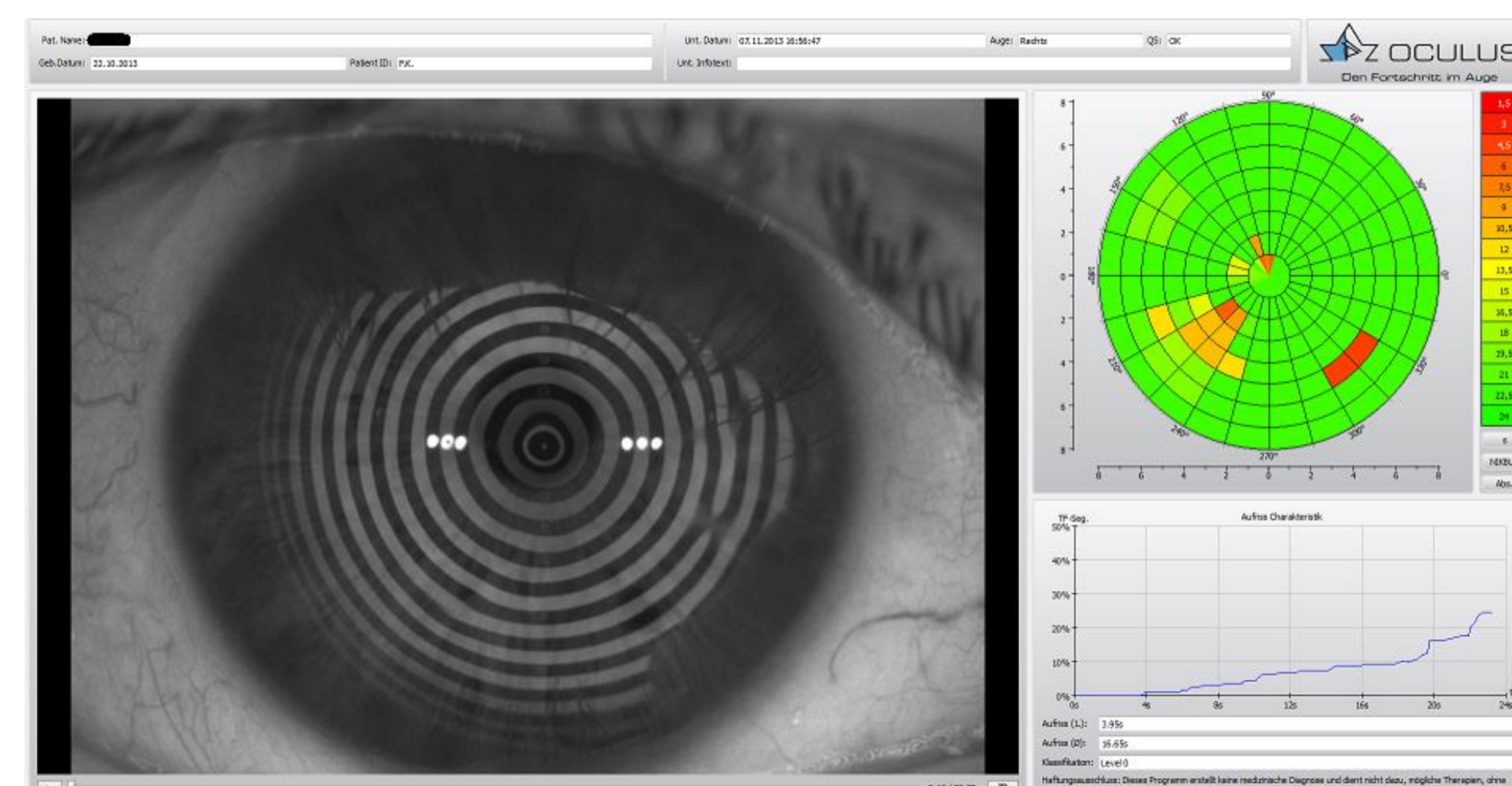
The aim of the thesis was to investigate if the application of lipid-containing lubricants can have a positive effect on the stabilisation of the tear film. There were a comparison between a lipid-containing spray and lipid-containing drops. Furthermore, the consistency between patients perception and stabilisation of the tear film were evaluated.

Methods:

The single centre study was conducted at a single site with open label design and two parallel groups. 24 patients with symptoms of dry eye and no use of rewetting lubricants before the study were enrolled (n = 24; with an averages age of 59 +/-9 years; 66.7 % female and 33.3 % male patients). Two different test product were used. A lipid-containing tear film substitution in a bottle (Systane Balance, Alcon) was dispensed to one group while parallel group was dispensed with a lipid-containing spray (LipoNit, Optima Pharma). Patient were randomly allocated into one of both group while the baseline visit. Three appointments at a distance between 12-16 days were performed apart. Quality and quantity tear film tests to the right eye were performed by using the *Keratograph 5M (Oculus)* and a slit lamp *SL120 (Zeiss)*. On each appointment three NIK-BUT-measurements (before, directly after, 30 minutes after application) were performed. During the waiting time until the last NIK-BUT-measurement a questionnaire (OSDI) was completed by the patient.

Qualitative tear film test³:

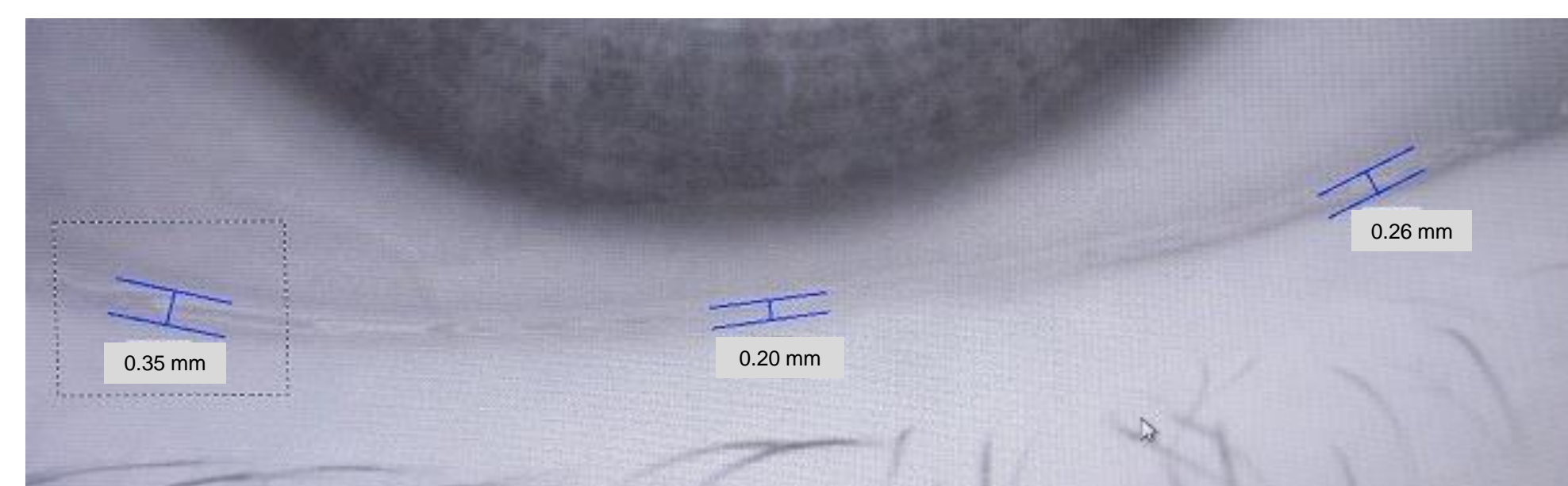
→ Non-invasive Keratograph-Break-Up-Time (NIK-BUT)



▲ Fig.1: NIK-BUT display of evaluation with Keratograph 5M (Oculus)

Quantitative tear film test³:

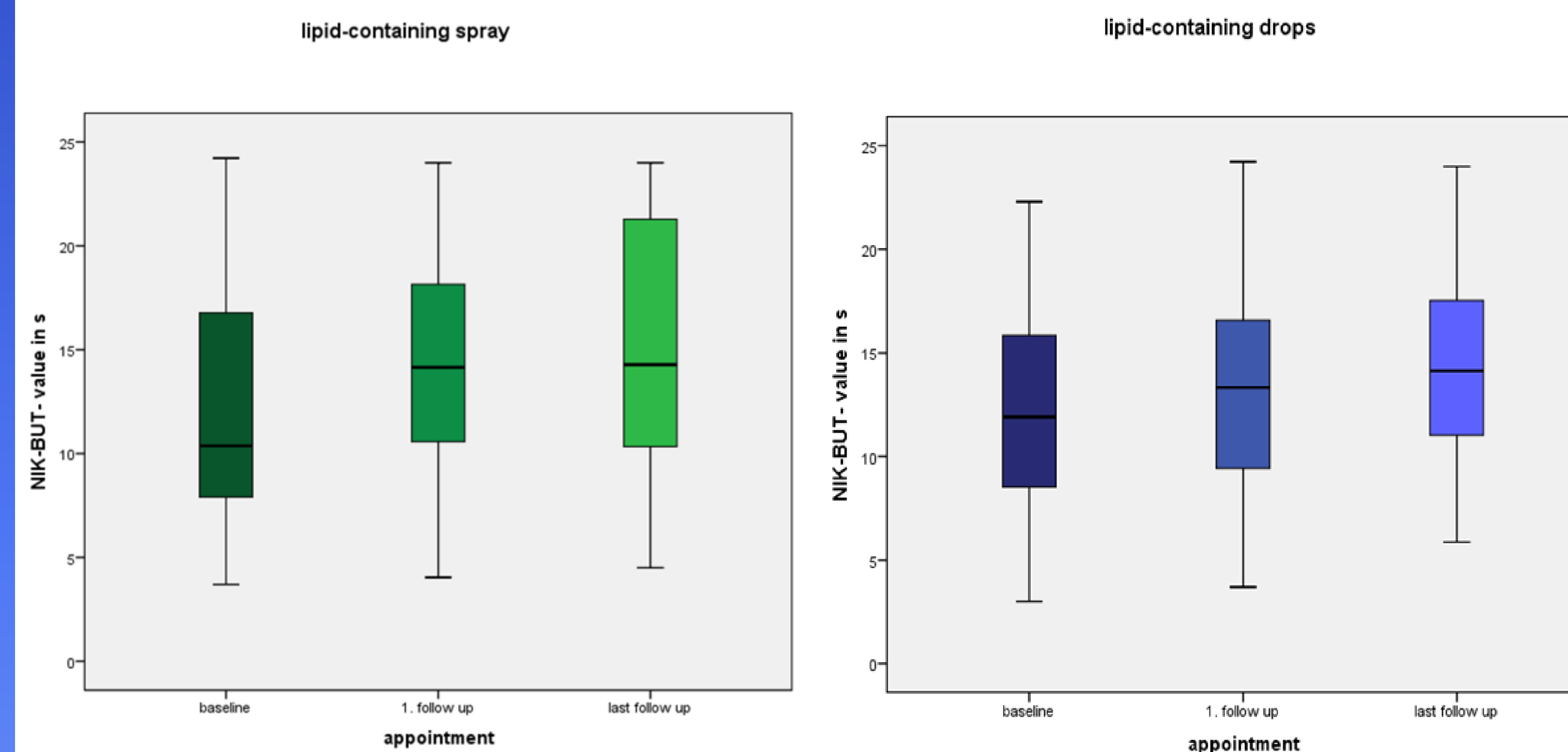
→ Tear meniscus height



▲ Fig.2: Measurement of the tear meniscus height with Keratograph 5M (Oculus)

Results:

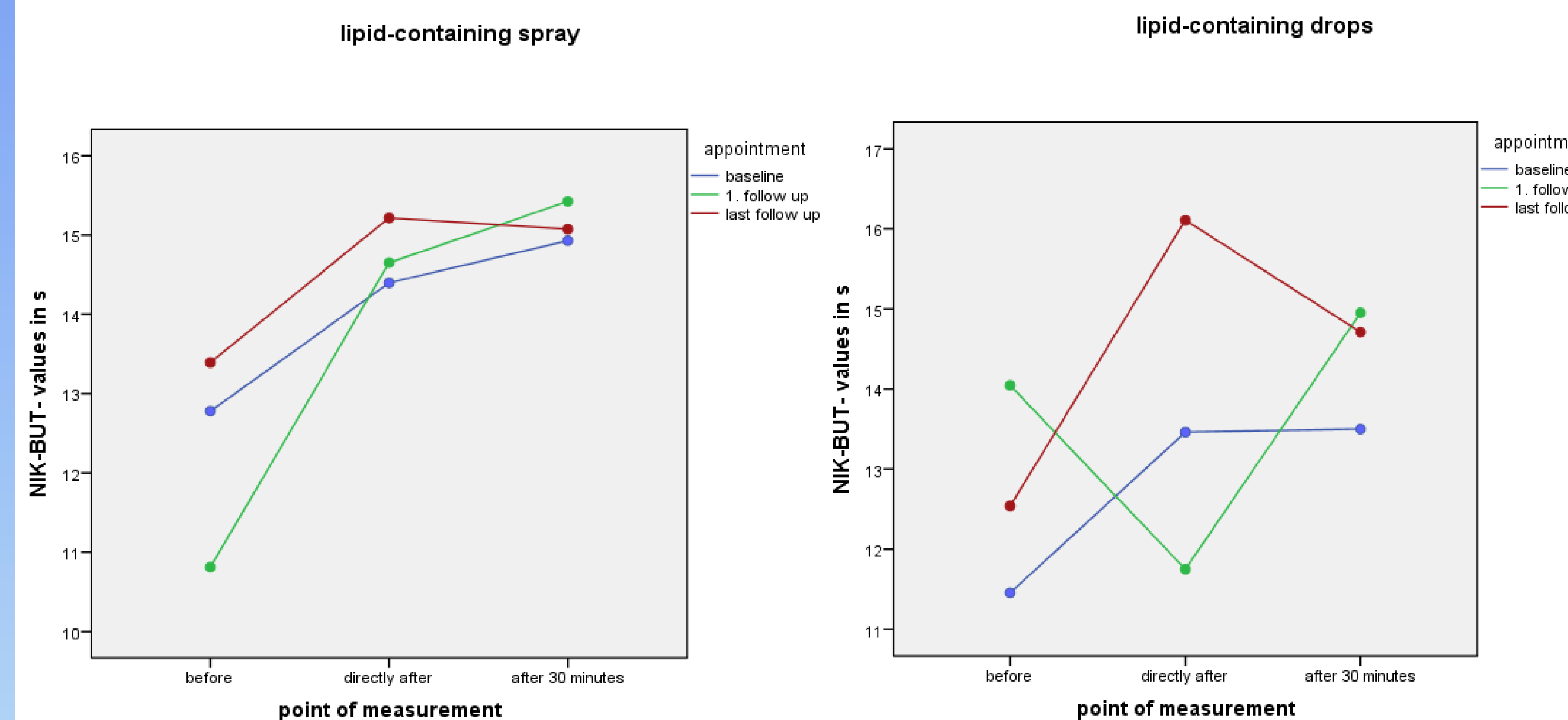
The results of the NIK-BUT-measurement were normally distributed and there was no significant difference between the lubricants. An impact of both lubricant compounds has been demonstrated immediately after application(short term) and from visit to visit(long term). For the first group NIK-BUT values yielded baseline was 11.9 +/- 4.9 seconds in average. At the last follow up visit the NIK-BUT was measured with 14.1 +/- 5.5 seconds in average. For the second group NIK-BUT values at baseline was 10.4 +/- 6.1 seconds in average and increased to 14.3 +/-6.3 seconds at the last follow up visit at 4-5 weeks after baseline.



▲ Fig.3: NIK-BUT-values in seconds in long term

▲ Fig.4: NIK-BUT-values in seconds in long term

The measured tear film stability before, directly after and 30 minutes after application has increased from baseline to the last visit. There was an increase of 23.8% (before), 3.8% (directly after) and 0.9% (after 30 minutes) for the lipid-containing spray. The group using lipid-containing drops showed an increase before application by 22.6%, directly after by 19.6% and after 30 minutes by 8%.



▲ Fig.5: NIK-BUT-value in seconds at short term

▲ Fig.6: NIK-BUT-value in seconds at short term

For the tear meniscus height and OSDI-score no correlation could be demonstrated. There was a huge discrepancy between NIK-BUT-classifications and the OSDI-scores^{4,5}.

visit	testing parameter	Spearman's correlation coefficient	correlation
baseline	tear meniscus height before& OSDI-Score	-0.121	weak
1. follow up	tear meniscus height before& OSDI-Score	-0.084	non
last follow up	tear meniscus height before& OSDI-Score	-0.288	weak
baseline	NIK-BUT before& OSDI-Score	0.443	less
1. follow up	NIK-BUT before& OSDI-Score	0.235	weak
last follow up	NIK-BUT before& OSDI-Score	0.488	less

▲ Tab.1: Results of Spearman correlation

Conclusion:

There is no correlation between patients feeling and objective measured parameters like NIK-BUT or tear meniscus height. In average over all appointments the patients overvalued the increase of tear film stability after using lipid-containing spray (LipoNit) or drops (Systane Balance). Using of lipid-containing lubricant during a period of 4 weeks lead a stabilisation of tear film. This effect was measured by qualitative and quantitative tear film tests. In special the increase of NIK-BUT-values was by 23% in average. This effect is regardless of their form of application.

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Contact: