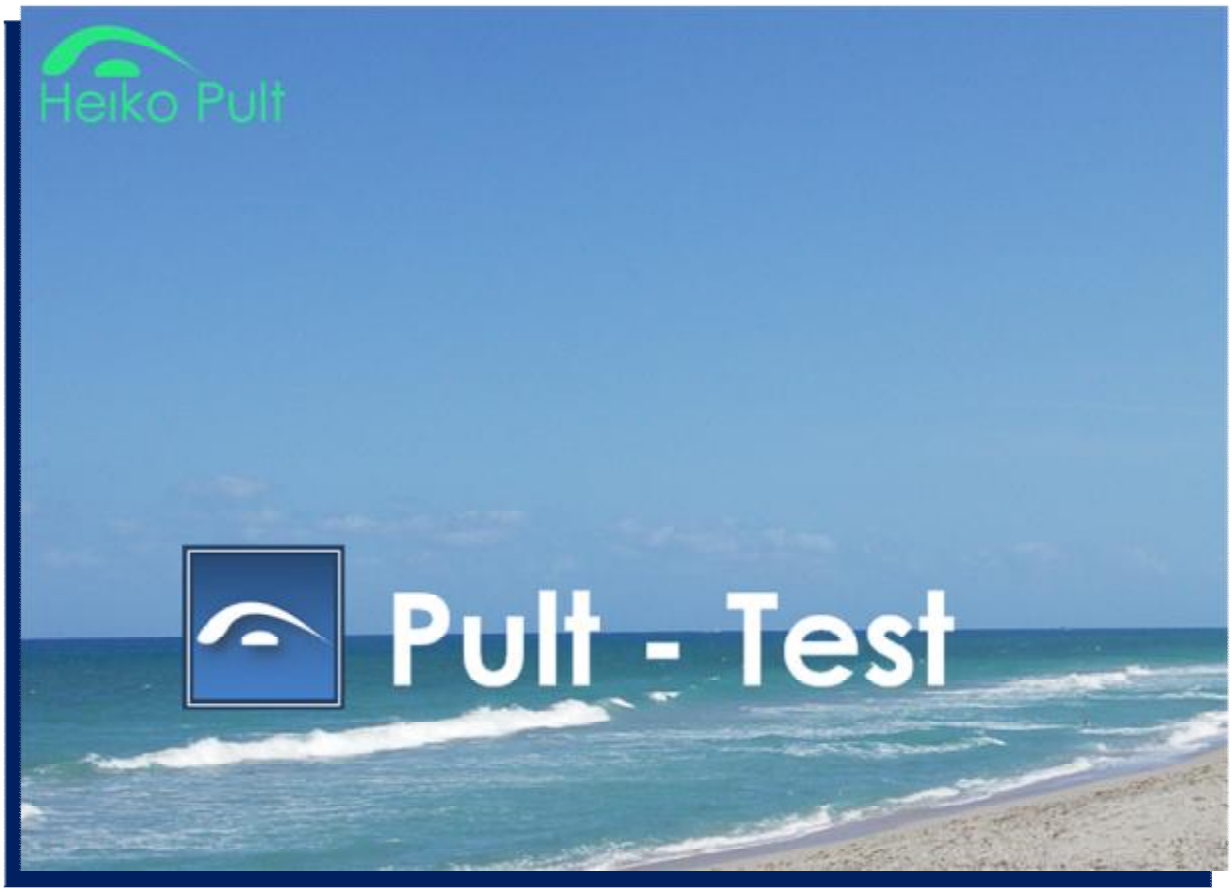
Awarded by the Peter Abel Prize 2009



Manual

(12.2009 EN draft)

Content:

The Two Crucial Questions in Dry Eye:

How can we predict contact lens wearing discomfort & dryness in new lens wearers?

How can experienced contact lens wearers be monitored and screened of dry eye symptoms?

Both might be the most important questions in clinical practice, since about 30-50% of all contact lens wearers claim dry eye symptoms.

However, we know from literature as well as from clinical practice, that dry eye symptoms are poorly predictable. In new contact lens wearers the clinician can react to discomfort after first some after cares, only; experienced contact lens wearers with increasing symptoms over years will mostly been overseen.

The new investigated method of Dr Heiko Pult and colleagues –named the PULT-Test- awarded by the Peter-Abel Prize 2009 of the German Contact Lens & Optometry Association (VDCO), will improve dry eye procedure in your contact lens practice dramatically.

This is a quick and exact method combining tear film tests and ocular signs with patient history resulting in an increased predictive ability (91%) of dry eye in lens wearers. This combination of tests is based on two special algorithms, easily calculated by the according *software*.

Modul I analyzes the risk of later dry eye in new contact lens wearer, Modul II diagnose dry eye in experienced lens wearers and is also able to monitor patients and to grade the degree of dryness and discomfort.

Enjoy it and increase your success in patient care!

Yours

Dr. Heiko Pult, PhD, MSc, FAAO, FBCLA, EAOO (founding member)

Delivery Content:

- CD
- USB-Dongle for activation of the program (copy protection).
- Manual as PDF

Installation:

Please copy the „exe“ file on your computers desktop and keep the dongle plugged in for lasting activation of the program at the computer.

The program will be started by double-clicking in that icon. 

Requirements:

USB-Port
CD-R drive
Windows > `98, not Windows NT or MAC
Adobe Reader for the manual

Language:

This software is available in German and English. The current language settings of your computer will be recognized and all non-German set computer will use the English mode of the PULT-test.

Modules:

Contact Lens Predicting Test I (P-Test I):

This test evaluates the risk of later dry eye in new contact lens wearers (contact lens induced dry eye (CLIDE)). The P-Test measures the risk of later CLIDE. The practitioner can decide by that result about type of lens material and care solutions for improved fitting options in CLIDE. Additional the patient can be educated about expected problems and procedure.

The P-Test I is a combination of the non-invasive analyzes of the tear film instability (NIBUT), evaluation of lid parallel conjunctival folds (LIPCOF) and history by use of the Ocular Surface Disease Index (OSID)

Contact Lens Predicting Test II (P-Test II):

This test is similar to the PULT-Test I but without evaluation of the NIBUT, if the proper technical equipment is not available.

Contact Lens Induced Dry Eye – Index (CLIDE-Index):

The CLIDE-Index analyzes the dry status in experienced contact lens wearers. It diagnoses CLIDE and measures the level of dryness and discomfort. In any longitudinal changes in that index, the practitioner can react quickly. This test is a combination of contact lens related history and LIPCOF.

Which Test Should be Used?

It has to be distinguished between naive lens wearers and experienced lens wearers. The naive contact lens wearers can only be observed and diagnosed by the PULT-test and the experienced by the CLIDE-Index only.
Combining NIBUT + LIPCOF + OSDI, the P-Test I is slightly exacter than P-Test II. However, this difference is minimal and P-test II is a perfect alternative if the NIBUT cannot be evaluated.

The CLIDE Index is for patient with at least 3 months experience in lens wear and should be included in every after care.

The Modules?

All modules are based on intense research. This resulted in proven algorithms of the optimal combination of subjective and objective dry eye tests.

P-Test I:

CLIDE= k_1 x (temporal LIPCOF + nasal LIPCOF) + k_2 x NIBUT + k_3 x OSDI – K

Increased LIPCOF and/or increased OSDI scores are indicators of later CLIDE. However, longer NIBUT values decrease that degree of risk.

P-Test II:

CLIDE= k_1 x (temporal LIPCOF + nasal LIPCOF) + k_2 x OSDI - K

Increased LIPCOF and/or increased OSDI scores are indicators of later CLIDE.

CLIDE-Index:

CLIDE= k_1 x dryness - k_2 x grittiness and scratchiness + k_3 x (temporal LIPCOF + nasal LIPCOF)

Increased LIPCOF and/or increased symptoms of dryness are indicator of CLIDE. However increases sensation of grittiness and scratchiness are not dry eye indicators! The latter are more related to too loose fitted contact lenses, deposits on the contact lens or lens defects, etc..

Therefore, in the CLIDE-Index module discomfort is asked too, even though it is not part of the formula. This is an additional indicator of the overall success of the contact lens fitting.

Results:

P-Test I:

OSDI: History evaluated by the Ocular Surface Disease Index.

NIBUT: Median of three measurements of the tear film instability.

Temporal LIPCOF: Degree of LIPCOF (0-3) of the temporal area of observation.

Nasal LIPCOF: Degree of LIPCOF (0-3) of the nasal area of observation.

Probability of CLIDE: That value shows the probability of later dry eye symptoms in lens wear. E.g. shows how likely the patient will mention / claim dry eye symptoms in later lens wear.

PPV - CLIDE: This is the positive predictive value of CLIDE by a prevalence of 43%.

Screening: "CLIDE –" has to be interpreted that the patient will not be in the group of later symptomatic lens wearers, "CLIDE +" indicates the potential symptomatics.

P-Test II:

OSDI: History evaluated by the Ocular Surface Disease Index.

Temporal LIPCOF: Degree of LIPCOF (0-3) of the temporal area of observation.

Nasal LIPCOF: Degree of LIPCOF (0-3) of the nasal area of observation.

Probability of CLIDE: That value shows the probability of later dry eye symptoms in lens wear. E.g. shows how likely the patient will mention / claim dry eye symptoms in later lens wear.

PPV - CLIDE: This is the positive predictive value of CLIDE by a prevalence of 43%.

Screening: "CLIDE –" has to be interpreted that the patient will not be in the group of later symptomatic lens wearers, "CLIDE +" indicates the potential symptomatics.

CLIDE-Index:

CLIDE-Index: Degree of CLIDE in experienced lens wearers

Screening: "CLIDE –" has to be interpreted that the patient will not be in the group of current symptomatic lens wearers, "CLIDE +" indicates the symptomatics.

Analyzes of the Results:

P-Test:

Please concentrate on “probability” in that test. The PPV get closer to the “probability” in higher degrees, in lower probability values, the PPV is higher. That’s because the PPV is calculated by the 43% prevalence of CLIDE. The PPV is more useful in research projects than clinical practice.

A probability of CIDE of ≥70% should result into a proper CLIDE fitting. In lower values (50-60%) later symptoms are not very likely, however please decide individually.

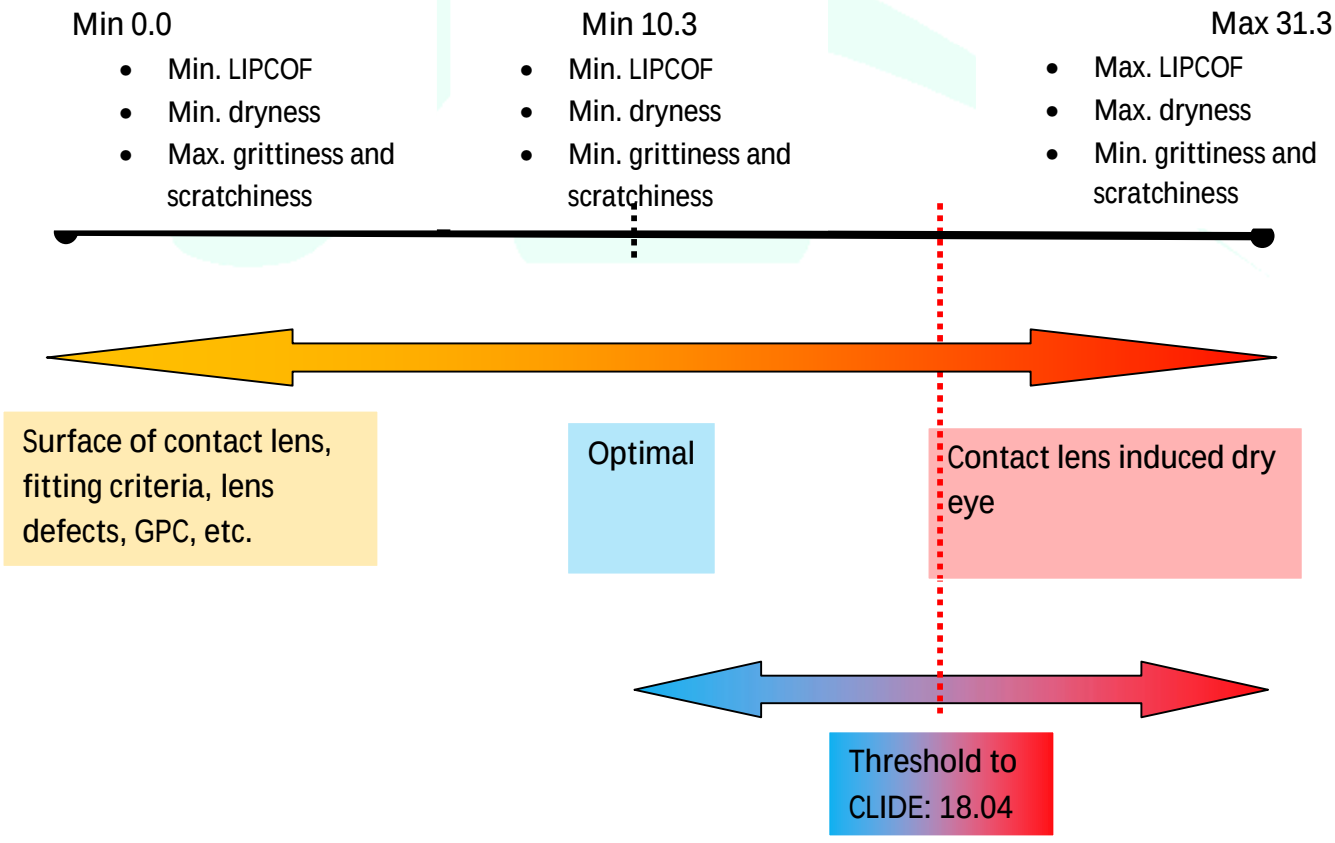
Nevertheless, it has to be noted, that new contact lens wearers are very often highly motivated. Therefore symptoms, which will be experienced from those patients in the first months, will be accepted. Practice tells us, that if the positive motivating factors are decreasing, the patient starts to claim these symptoms of discomfort and dryness in later stages. Therefore try to keep it save. Fit proper lenses in CLIDE risk candidates and observe seriously in following after cares using the CLIDE-Index.

CLIDE-Index:

The CLIDE-Index measures the degree of CLIDE in a scale from 0 to 31. Contact lens wearers with a degree of ≥18.04 are very likely CLIDE patients. Even they does not know, because high motivation and acceptance of some symptoms. Many contact lens wearers believe that lenses have to hurt in some way. Therefore keep those patients in short follow up intervals. General, any change of ≥ ±5.5 is abnormal.

Important: There are many options to improve contact lens wearing comfort. Therefore, a contact lens wearer can present with increased LIPCOF but no symptoms in the CLIDE-Index, since he has got the proper “treatment”.

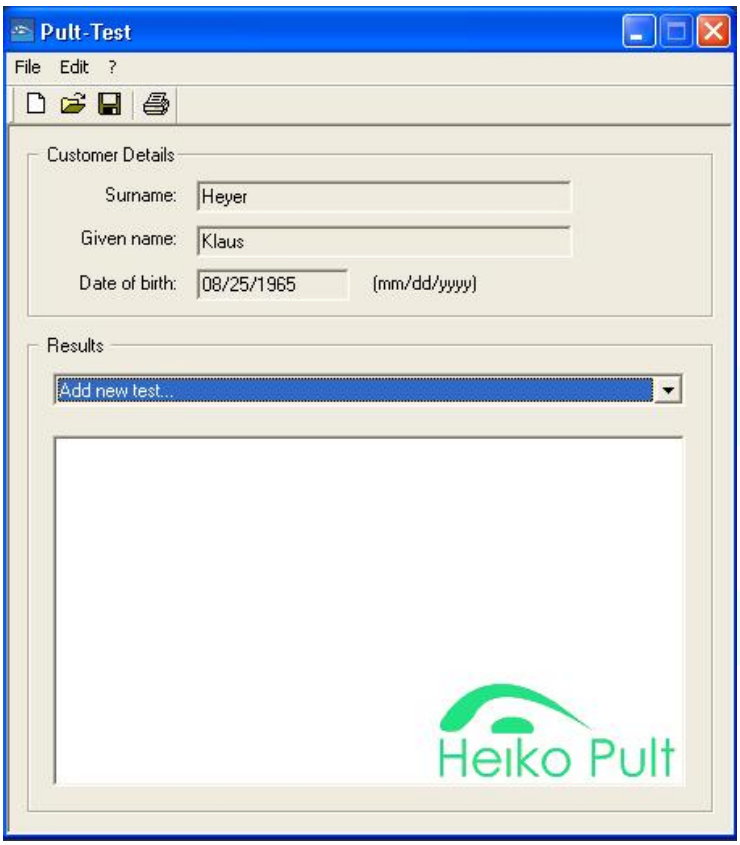
Example: A new lens wearer appears as risk candidate and is fitted with best type of lens and care regimes. Then he will still have increased LIPCOF but no symptoms in lens wear. The CLIDE-Index result shows higher LIPCOF but low symptoms and likely CLIDE +. In those cases you have to look very seriously on to the symptoms results in the CLIDE-Index. However, do not forget that this is still a risk candidate who has to be observed in short intervals. Therefore, always compare the CLIDE-Index results with the patients treatments and keep the risk in your mind.



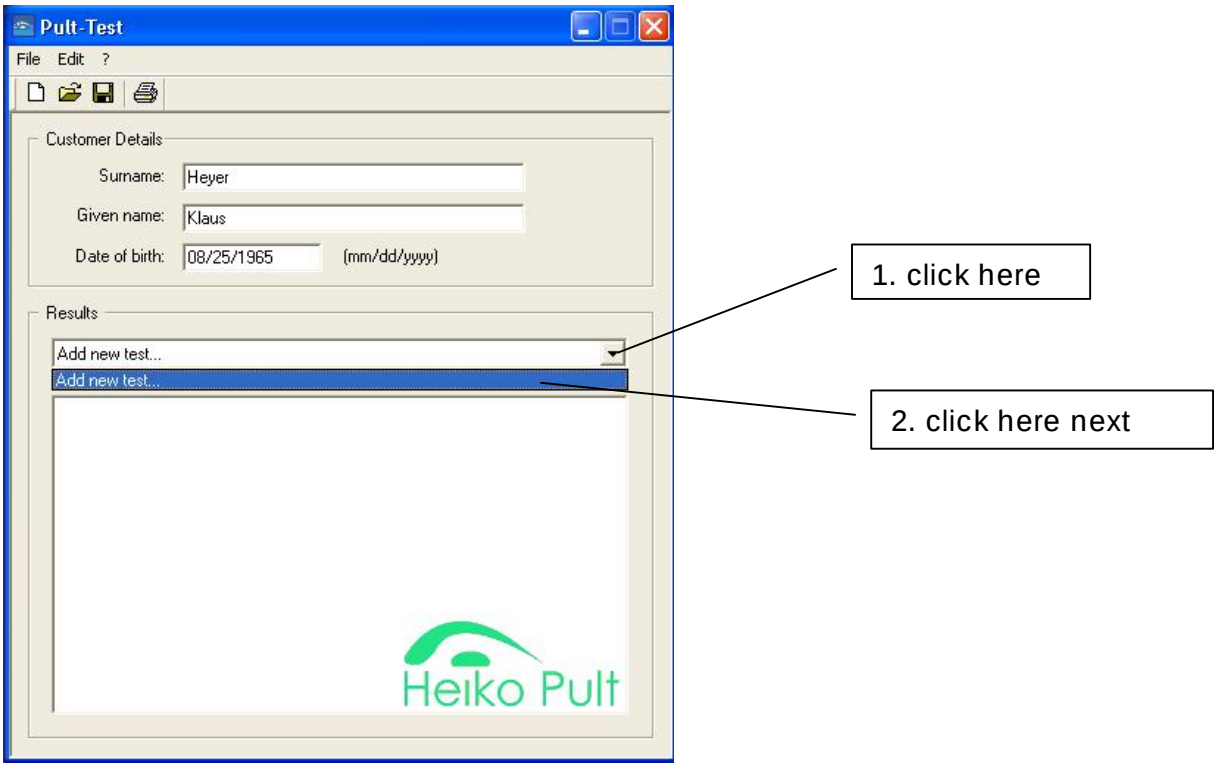
Working With The Program:

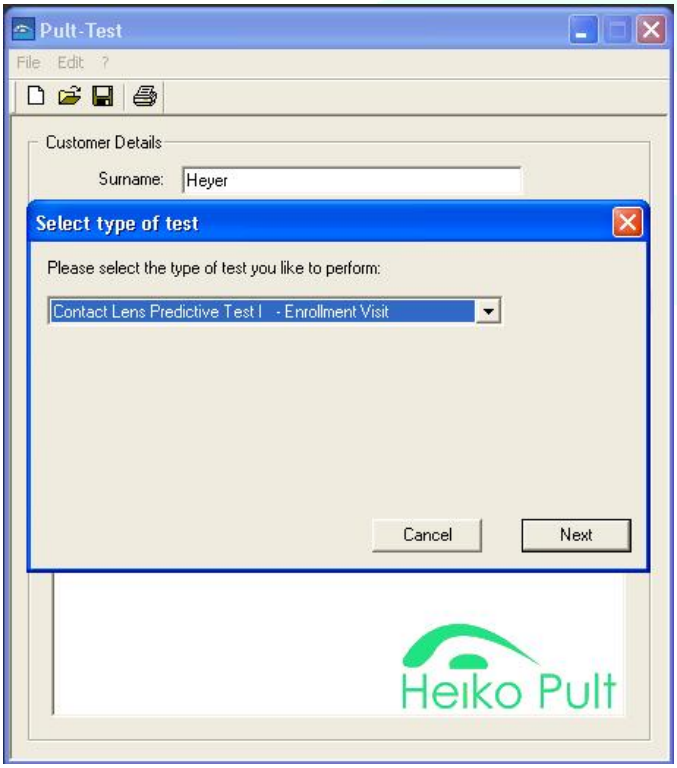
All data will be saved to name and date of birth. At the initial saving process you have to create a folder were the data have to be saved to, best option is PULT-Test Data. Every next patient will be saved to that one automatically.

Screenshots:

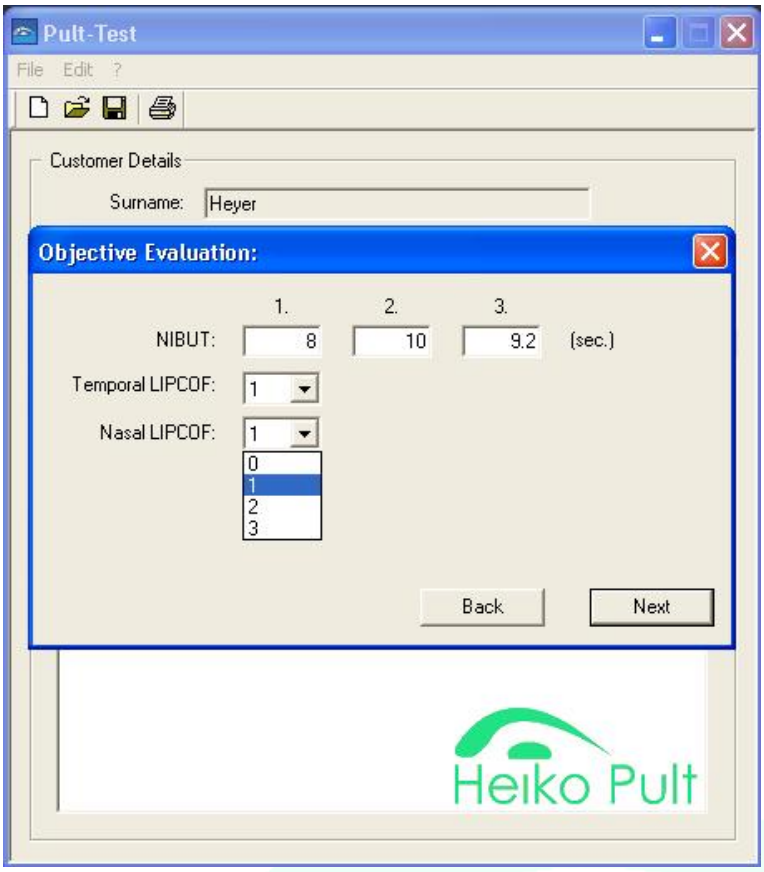


Open existing patient data or fill in name and date of birth in new patients.

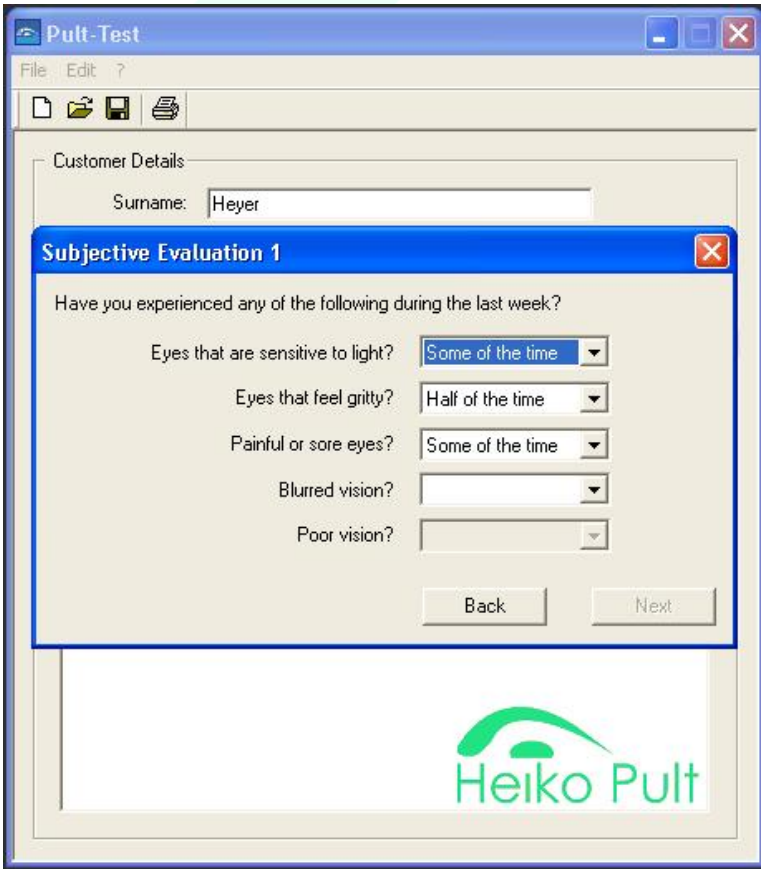




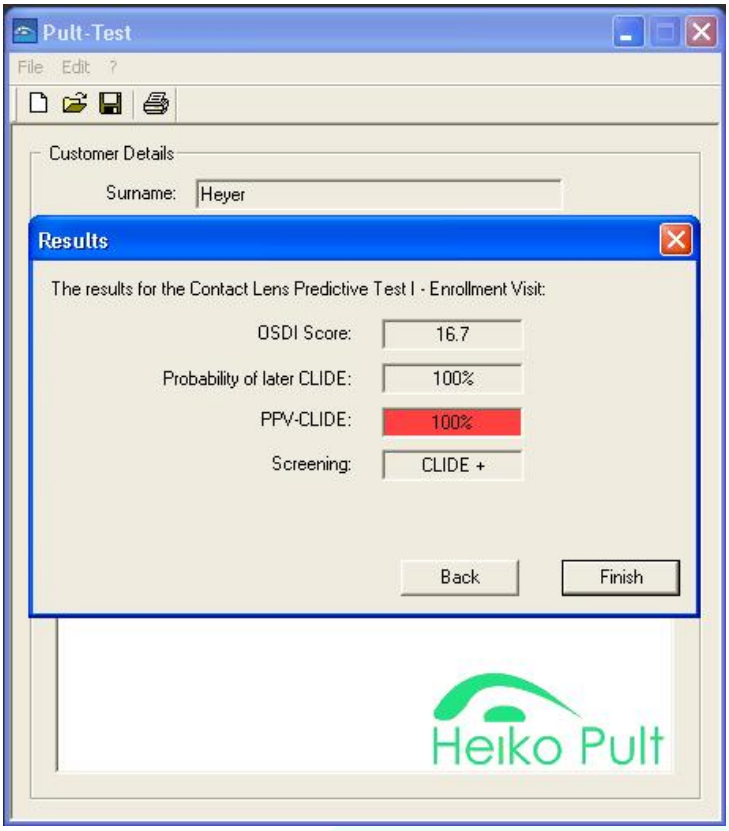
Choose the proper module.



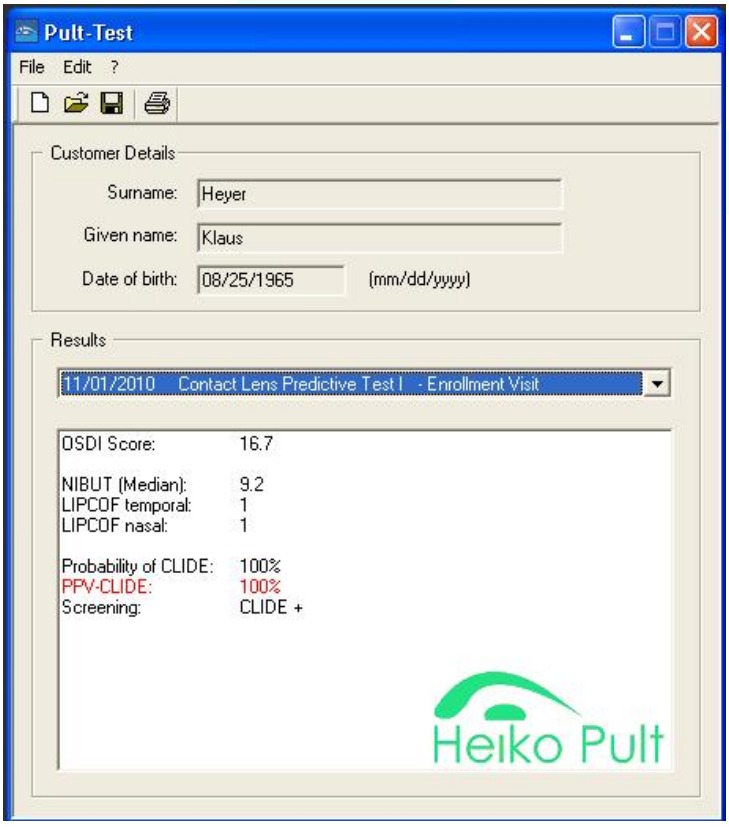
Fill in data and click “next”.



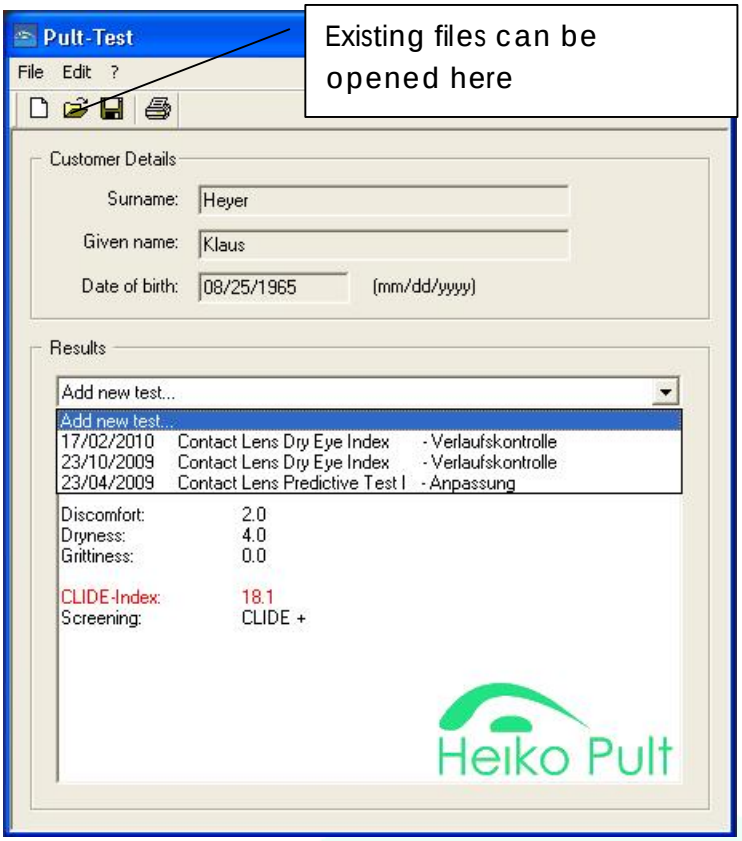
Fill in data and click “next”.



Results are shown, then end by clicking on “finish”.



All results can be seen then; you also can print them or open prior results to compare.



In an addiotinal after care of that patient you can proceed with the next test.
All data are archived.

Technique & Tests:

Not to be biased, please always start with objective evaluation.

The quality of the results depends on the exactness of observation. Therefore all tests are described as following.

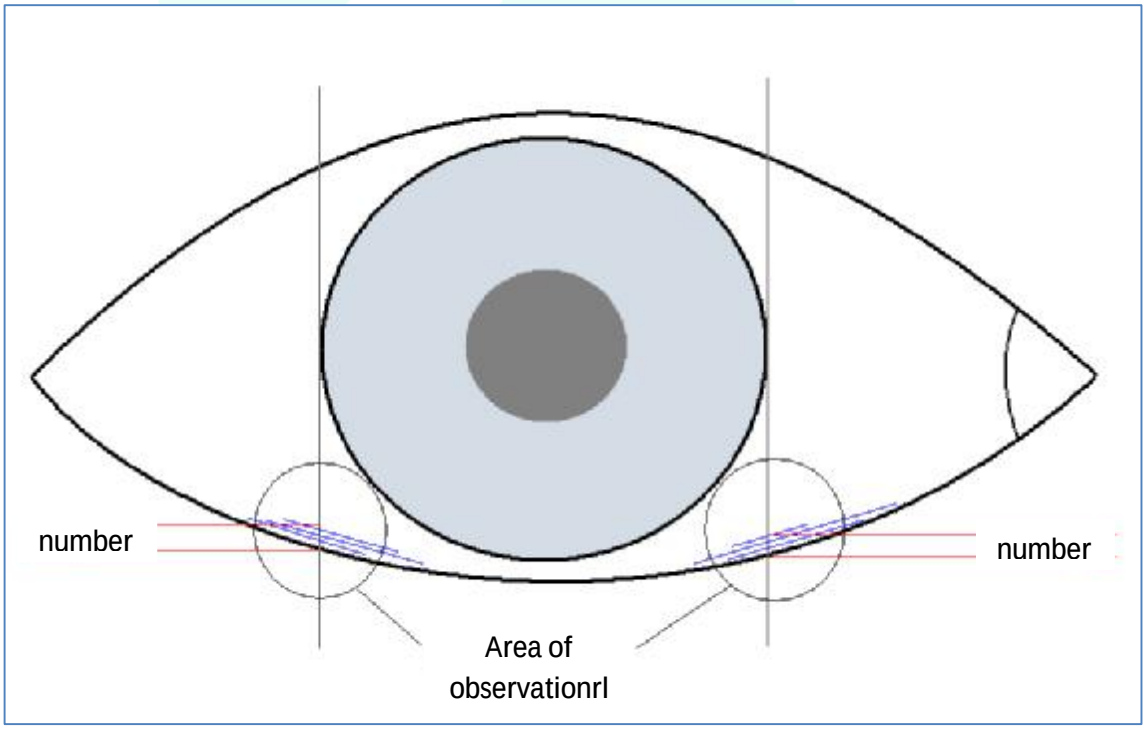
NIBUT:

NIBUT is the non-invasive break up time, to be evaluated by use of the Tearscope™ of Keeler or alternatively using a topographer. NIBUT should be the first proceeded observation at the patients eye, since any touching or glaring impacts the tear film.

LIPCOF:

LIPCOF are lid parallel conjunctival folds. It is very important to observe the right folds at the correct area.

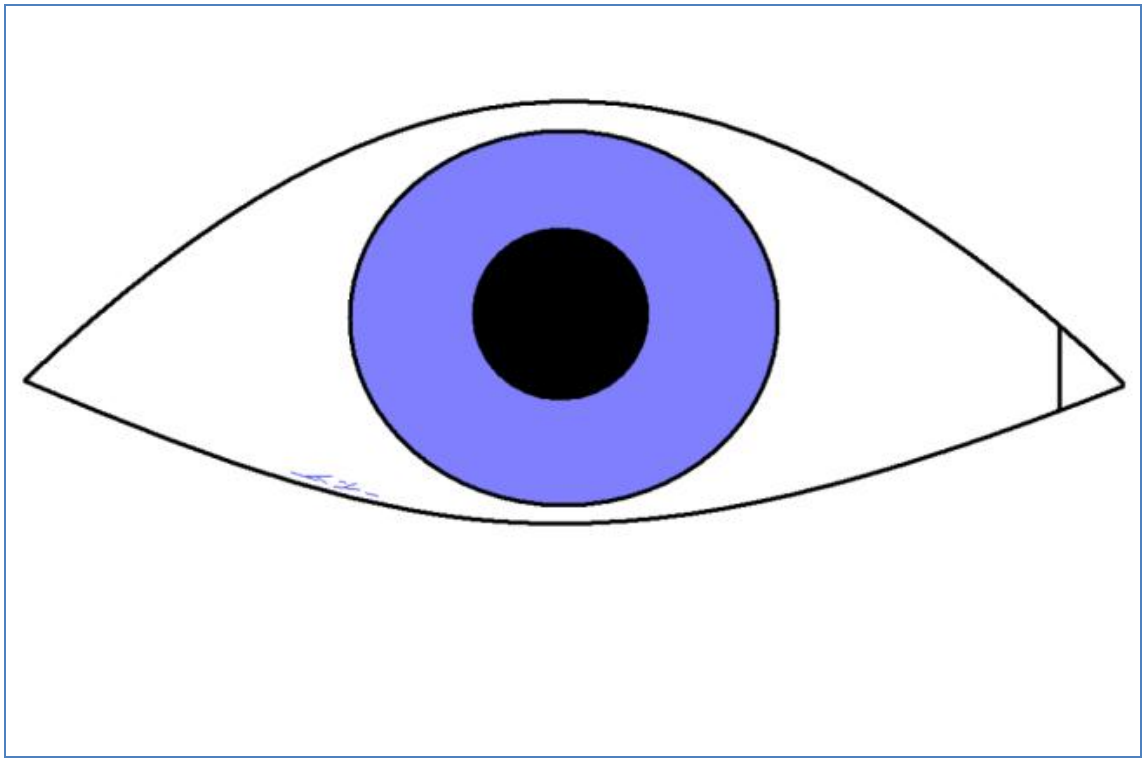
- Without worn contact lenses (can be observed immediately after removing lenses)
- Patient has to look straight forward
- No use of vital dyes like fluorescein
- 18-24x magnification of the slit-lamp microscope
- Go perpendicular from the lateral limbus down to the lower lid to view at the correct area of observation.



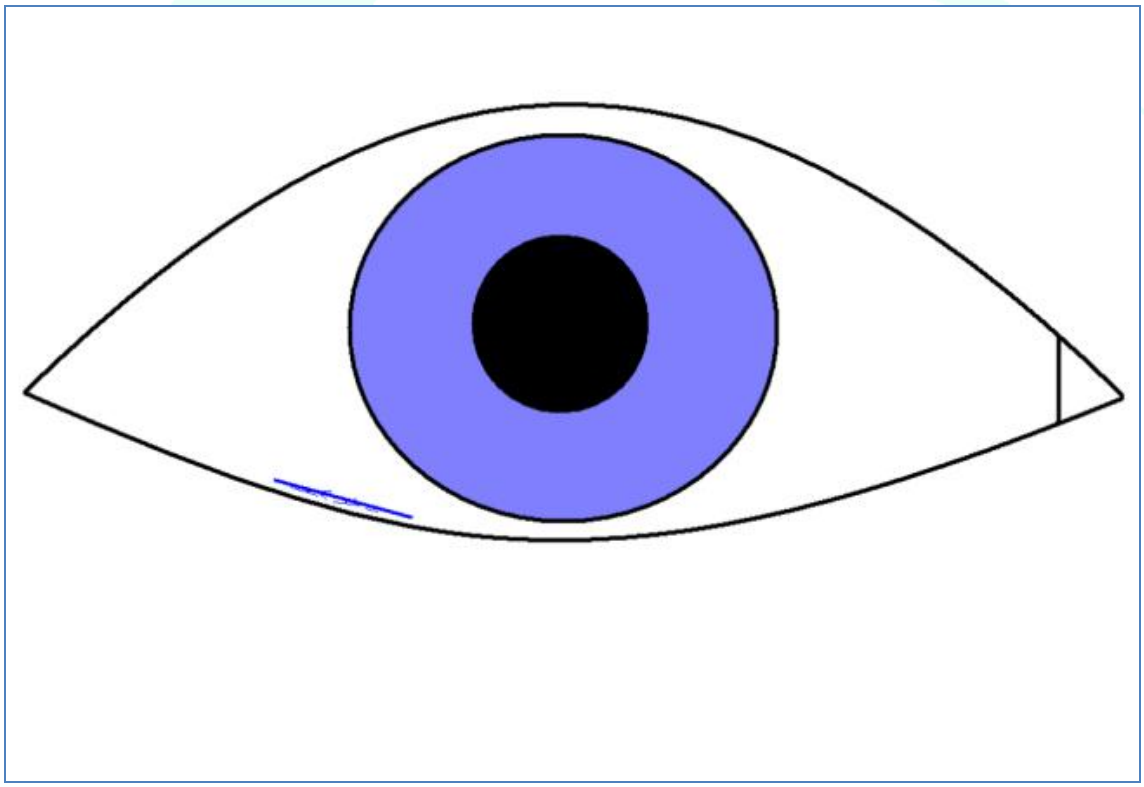
- Optimized grading scale:

	LIPCOF Grad
No permanent, parallel conjunctival fold	0
One permanent, parallel conjunctival folds	1
Two permanent, parallel conjunctival folds	2
More than two permanent, parallel conjunctival folds	3

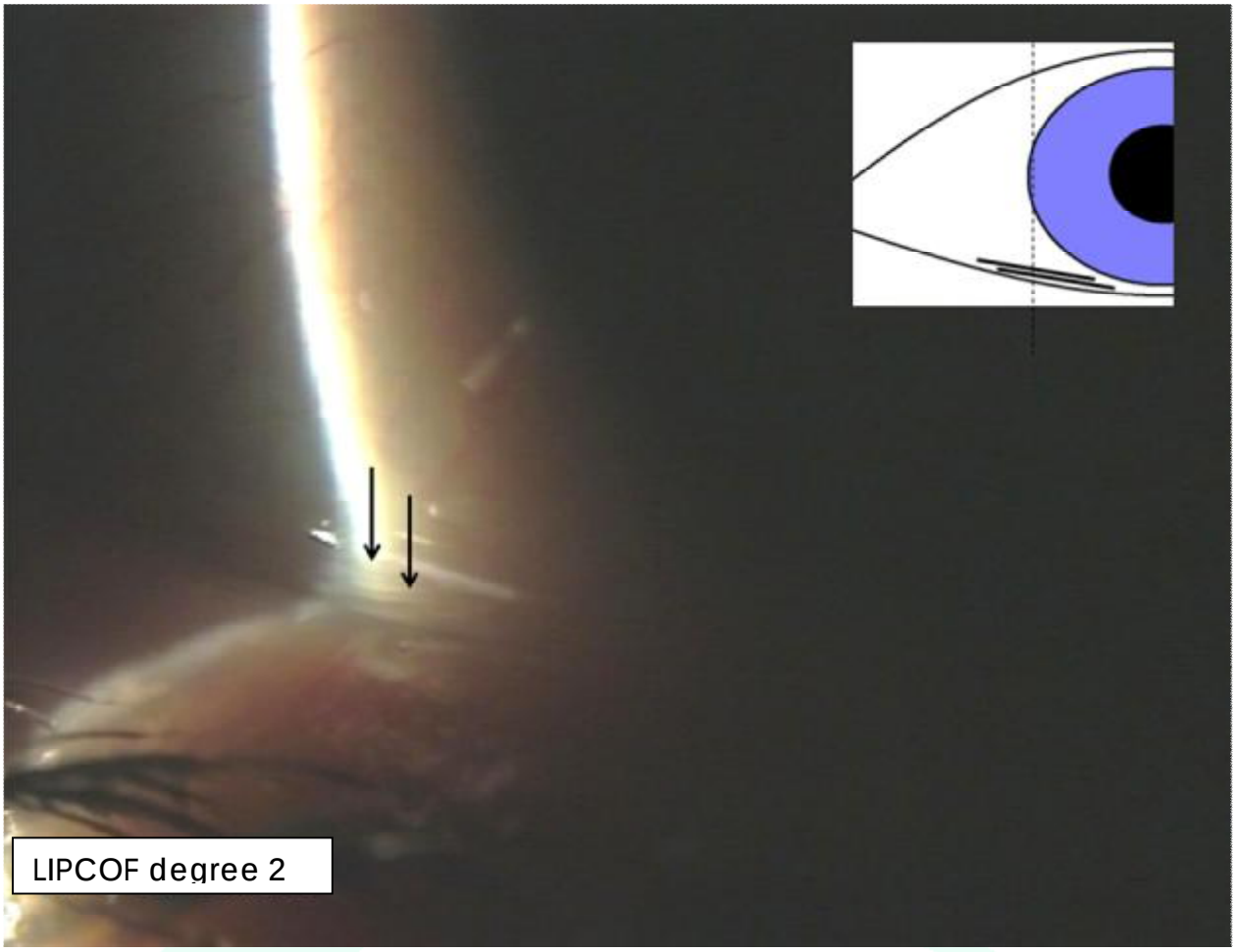
Please differentiate between lid parallel conjunctival folds, and disrupted micro-folds or conjunctival flaps!



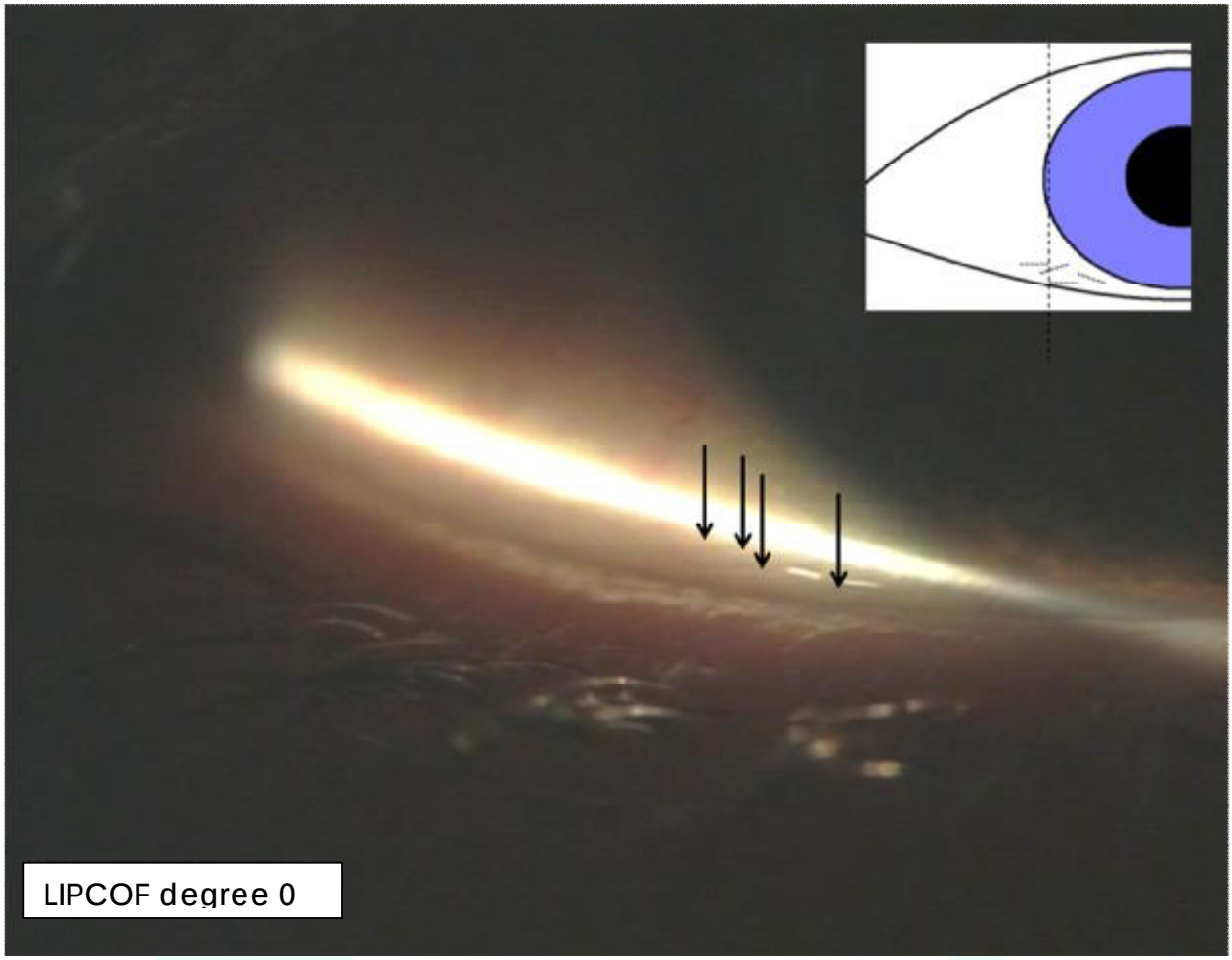
Some disrupted micro-folds, no permanent parallel conjunctival fold:
LIPCOF degree 0



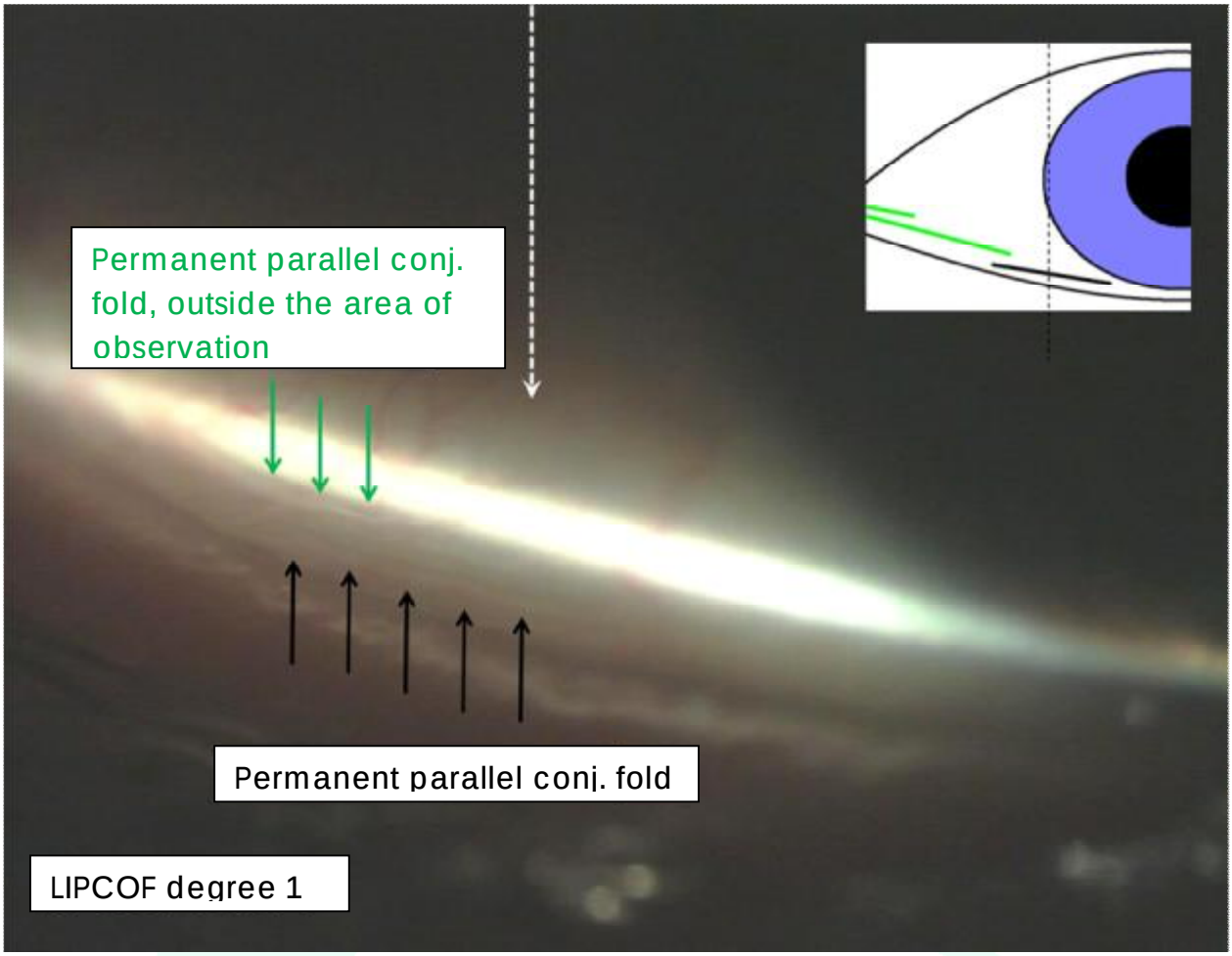
One clear, permanent and parallel conjunctival fold plus some disrupted micro-folds:
LIPCOF degree 1



Two clear, permanent and parallel conjunctival folds: LIPCOF degree 2



Four disrupted micro-folds but no clear permanent conjunctival fold:
LIPCOF degree 0



One clear, permanent conjunctival fold (black arrows) plus a second one outside the area of observation (green arrows): LIPCOF degree 1

Caution: As more you tend to the lid corners as higher the LIPCOF degrees appears. However, this would lead to over-classification. Please stay at the correct area of observation (black arrows).

Impressments:

Dr. Heiko Pult
Steingasse 15
69469 Weinheim
Germany
+49 (0) 174 90 250 90
ovr@heiko-pult.de
www.heiko-pult.de

Rights:

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