

Comparison of tear film stability assessment procedures by non-invasive and fluorescein tear breakup time measurement

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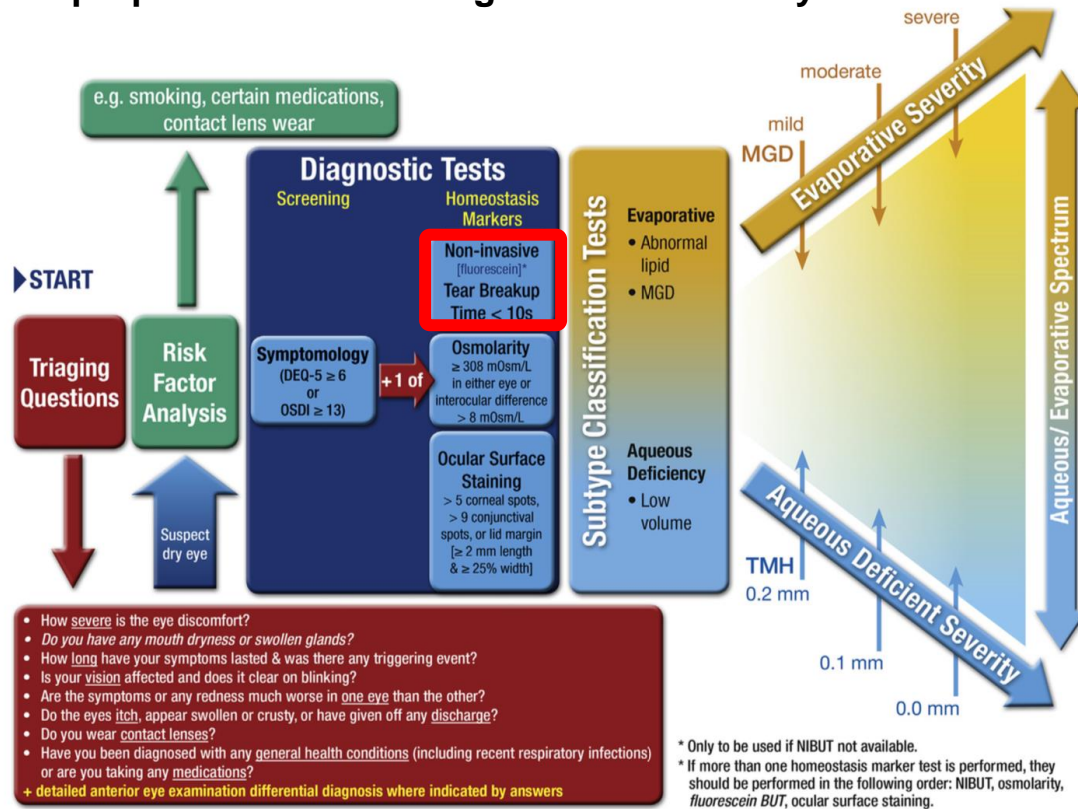
Optics and Optometry Research Center (COMiB), Università degli Studi di Milano-Bicocca



Tear film stability assessment



DEWS II proposal for a DED diagnostic test battery



BCLA CLEAR - Evidence-based contact lens practice

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3.2.1. Tear film

The tear film is an essential component in contact lens wearing comfort [139] and can impact contact lens drop out (section 7.3 and see CLEAR Maintenance Report and CLEAR Anatomy Report) [127,140]. Consequently, an appropriate examination of the tear film, the ocular surface and quantification of symptoms, is vital in contact lens fitting and aftercare [14,141]. The tear film should be observed in its natural appearance with non-invasive techniques [142], such as using cold light illumination (section 3.6.1). The pre-lens tear film can also be observed to assess the *in vivo* wettability which is affected by lens deposition [139] and by the lens material and surface characteristics (see CLEAR Maintenance Report) [140].

“Dry eye is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film, and accompanied by ocular symptoms, in which **tear film instability** and hyper-osmolarity, ocular surface inflammation and damage, and neuro-sensory abnormalities play etiological roles.”

Structure and composition

Lipidic layer

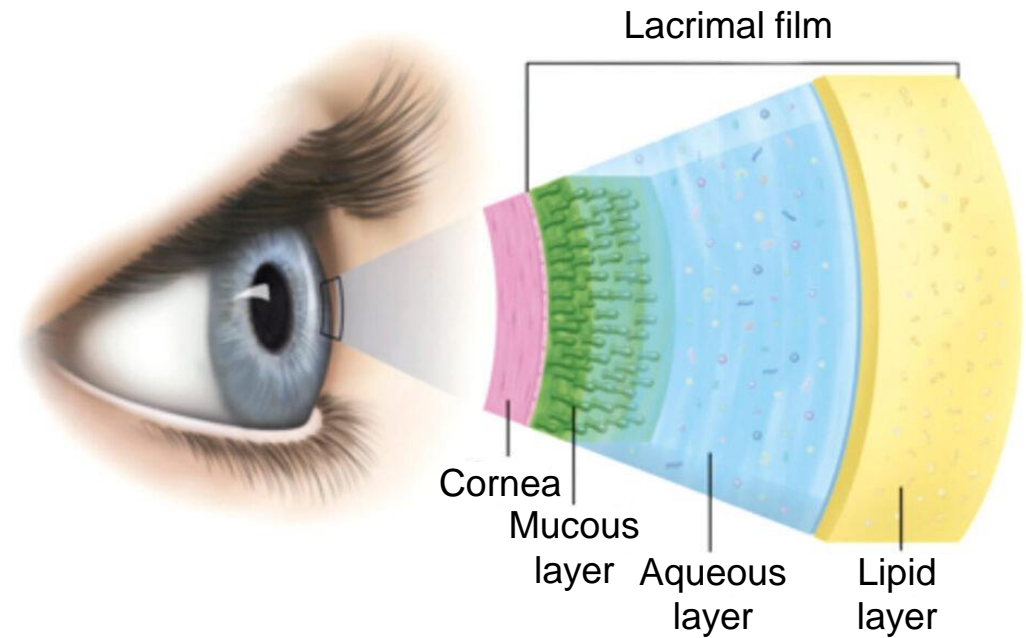
- Lipids

Aqueous layer

- Water, protein, electrolytes

Mucin layer

- Mucins



Tear film instability assessment: Breakup time



Experimental Eye Research
Volume 117, December 2013, Pages 28-38



“tear film stability is measured by its lack of stability”

Review

Tear film stability: A review

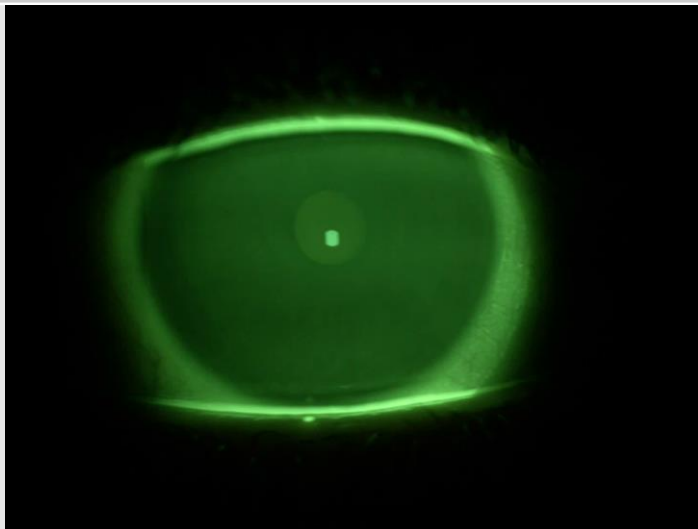
Deborah F. Sweeney,^a Thomas J. Millar,^b Shiwani R. Raju,^b

Fluorescein breakup time

fBUT

(Norn, 1969)

★ 10 seconds



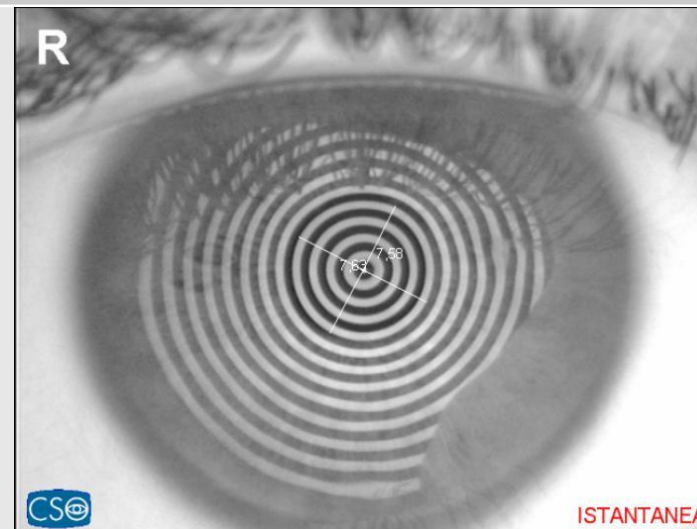
Non invasive breakup time

NIBUT

(Lamble et al, 1976; Holly 1981)

★ 20-45 seconds

(Guillon & Guillon, 1994)



Tear film instability assessment: Breakup time



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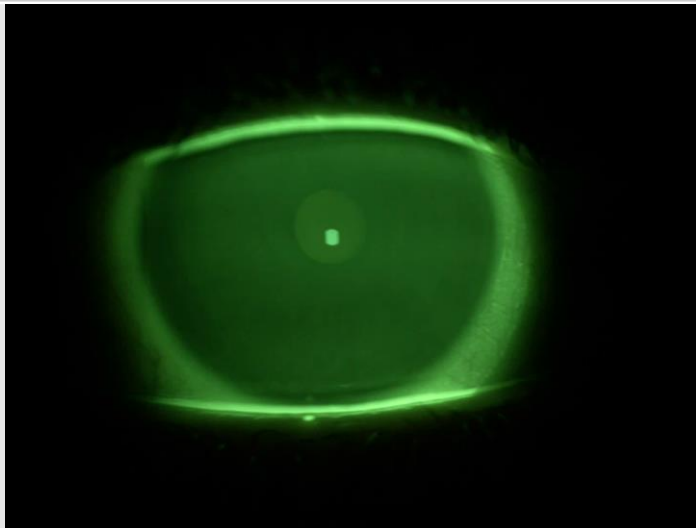
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Fluorescein breakup time

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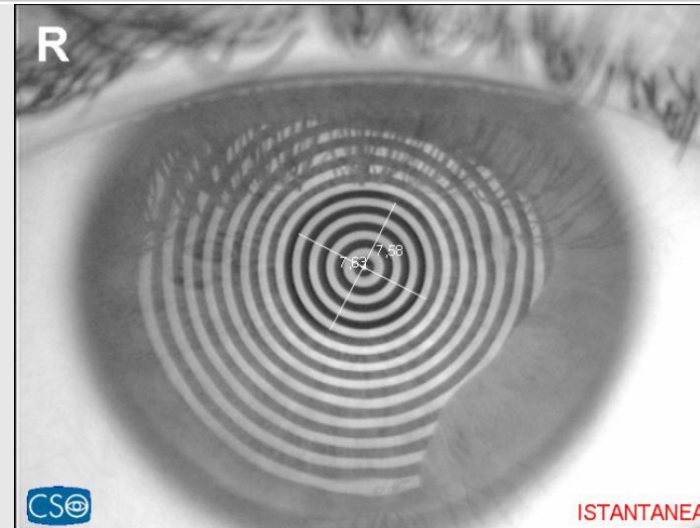


Non invasive breakup time

NIBUT

(Lamble et al, 1976; Holly 1981)

★ 20-45 seconds ▲
(Guillon & Guillon, 1994)



NIBUT vs. fBUT measurements: agreement and repeatability



AIM: To evaluate the agreement and repeatability of three different devices in measuring the non-invasive tear breakup time (NIBUT) and the relationship with the standard fluorescein breakup time (fBUT).

Subjects

Inclusion Criteria:

- Age ≥ 18 years
- Not Contact Lens wearers
- Absence of any known ocular pathology and not being subjected to refractive surgery or ocular drug treatment
- Absence of any known general pathology
- not taking any ocular or systemic medication known to affect the ocular surface
- not being in state of pregnancy

43 healthy participants

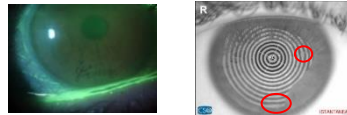
- 27 females
- mean age 23.1 ± 2.1 years

NIBUT vs. fBUT measurements: agreement and repeatability



Instruments

- Non-Invasive

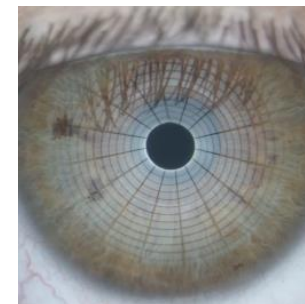
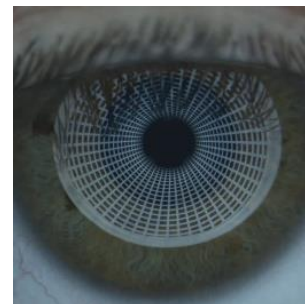


EasyTear View+
(Easytear,
Rovereto)

Polaris
(CSO, Firenze)

Sirius Plus
(CSO, Firenze)

- Clinically performable



- Automated assessment



NIBUT vs. fBUT measurements: agreement and repeatability



Study design Semi-randomized crossover study

Random order



EasyTear View+
(Easytear, Rovereto)

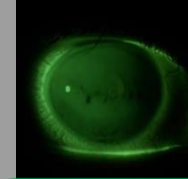


Polaris
(CSO, Firenze)



Sirius Plus
(CSO, Firenze)

Semi-randomized sequence
across participants



fBUT



The overall measurement procedure was repeated in a further session on the same day (about 2 hours of difference)



EasyTear View+
(Easytear, Rovereto)

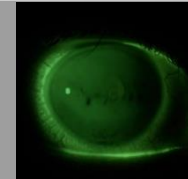


Polaris
(CSO, Firenze)



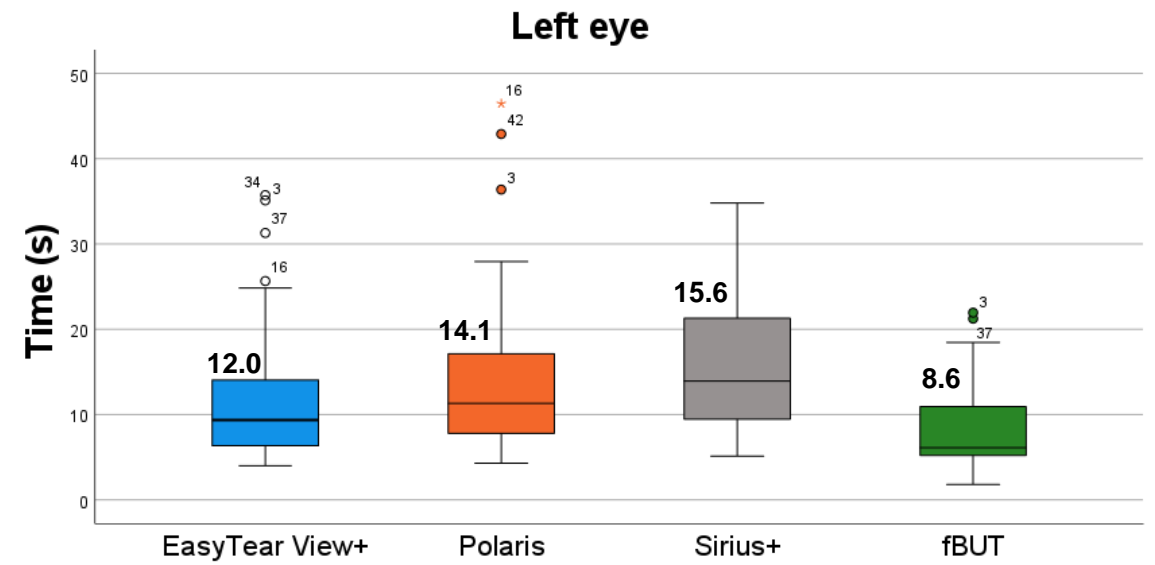
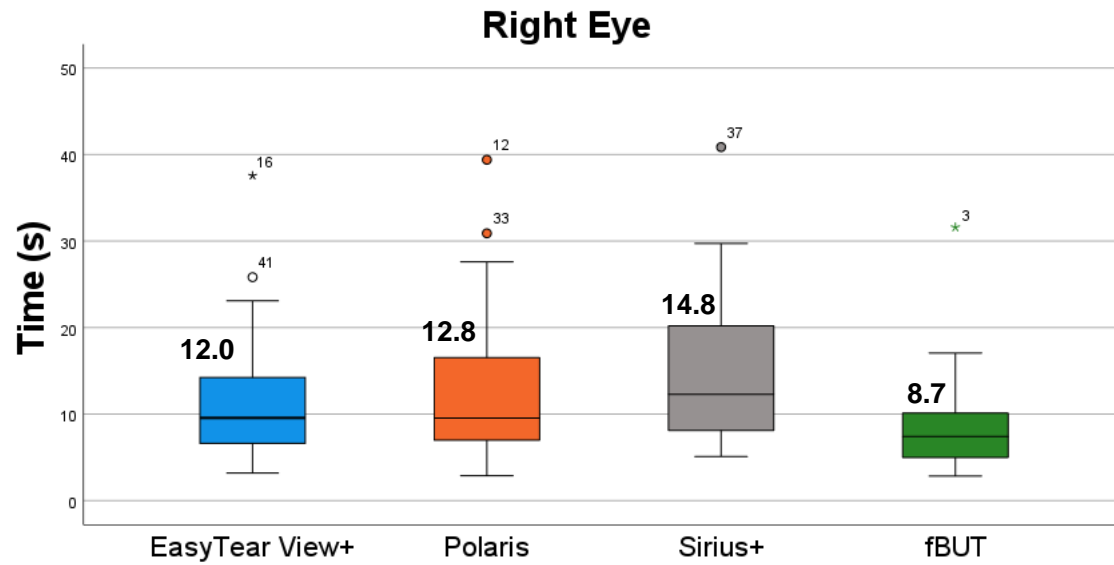
Sirius Plus
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Semi-randomized sequence
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fBUT

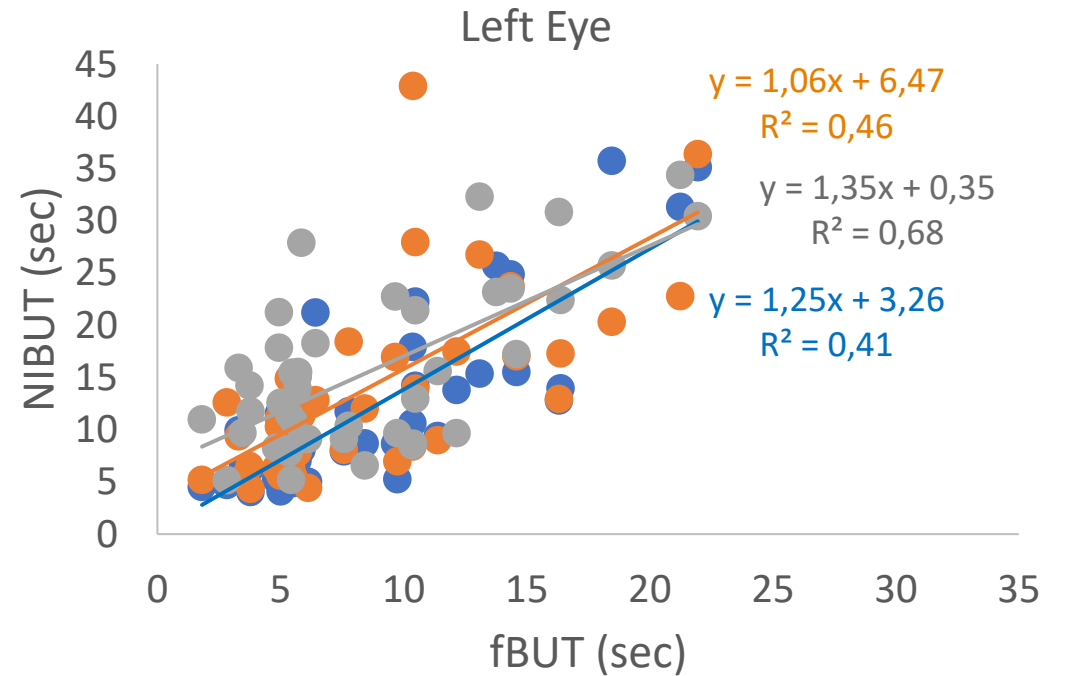
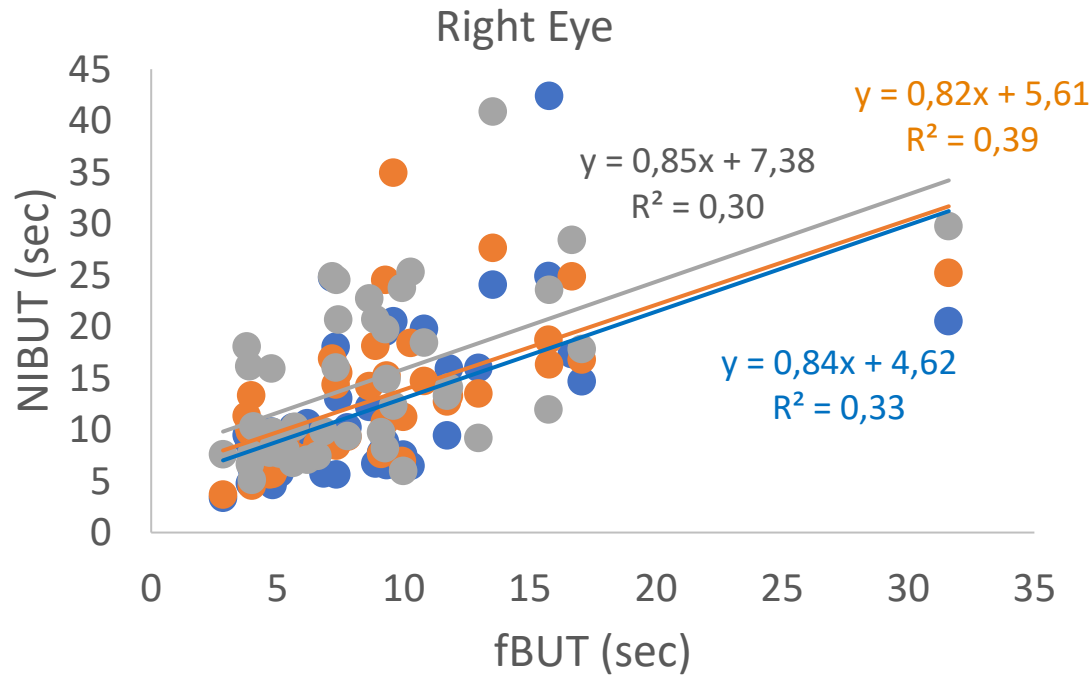
NIBUT vs. fBUT measurements: agreement



	Easytearview+	Polaris	Sirius plus	fBUT
Easytearview+				
Polaris	Wilcoxon; P=0.14			
Sirius plus	Wilcoxon; P<0.05	Wilcoxon; P<0.05		
fBUT	Wilcoxon; P<0.01	Wilcoxon; P<0.01	Wilcoxon; P<0.05	

	Easytearview+	Polaris	Sirius plus	fBUT
Easytearview+				
Polaris	Wilcoxon; P<0.01			
Sirius plus	Wilcoxon; P<0.01	Wilcoxon; P=0.07		
fBUT	Wilcoxon; P<0.001	Wilcoxon; P<0.001	Wilcoxon; P<0.001	

NIBUT vs. fBUT measurements: correlation



Easytearview+

Polaris

Sirius plus

	Easytearview+	Polaris	Sirius plus
fBUT	Spearman rho=0.59 (p<0.001)	Spearman rho=0.70 (p<0.001)	Spearman rho=0.53 (p<0.001)

Easytearview+

Polaris

Sirius plus

	Easytearview+	Polaris	Sirius plus
fBUT	Spearman rho=0.77 (p<0.001)	Spearman rho=0.71 (p<0.001)	Spearman rho=0.50 (p<0.001)

NIBUT vs. fBUT measurements: Test-retest reliability



Right Eye

■ Test ■ Retest

Left Eye

■ Test ■ Retest

Wilcoxon:
p=0.52
ICC: 0.76



Easytear



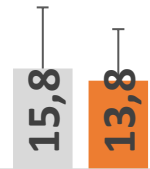
Wilcoxon:
p=0.24
ICC: 0.37



Polaris



Wilcoxon:
p=0.08
ICC: 0.78



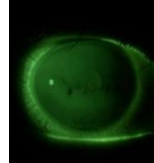
Sirius



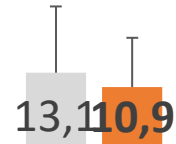
Wilcoxon:
p=0.38
ICC: 0.71



fBUT



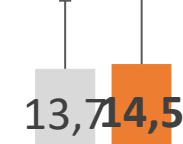
Wilcoxon:
p=0.12
ICC: 0.76



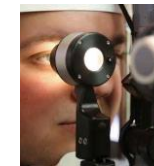
Easytear



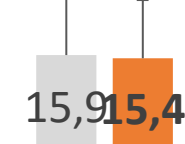
Wilcoxon:
p=0.50
ICC: 0.81



Polaris



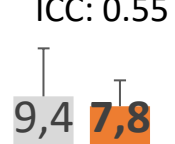
Wilcoxon:
p=0.90
ICC: 0.57



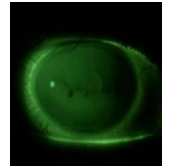
Sirius



Wilcoxon:
p=0.74
ICC: 0.55



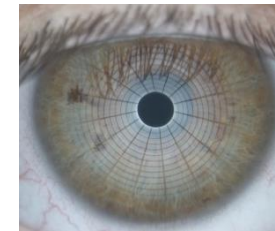
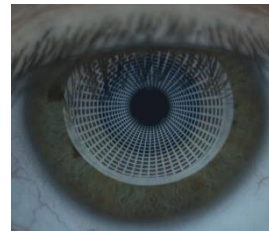
fBUT



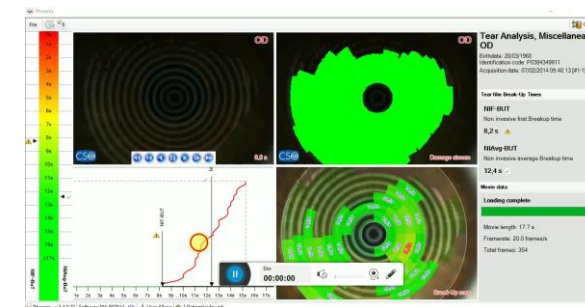
Conclusions

so what?

- BUT measured with fluorescein instillation resulted significantly shortened compared to all NIBUT procedures.
- FBUT and NIBUT showed extremely high variability
- NIBUT devices appeared performing differently each other (different brightness, total area investigated and grid pattern)



- New information available with automatic NIBUT (such as break-up map) but need to be investigated



The «Dream Team»



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*Thank you for your
attention!*