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TREATMENT OF BLEPHARITIS AND ASSOCIATED DRY EYE DISEASE BY PLASMA EMISSION

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Disclosure for JETT PLASMA LIFT MEDICAL

In compliance with COI policy, ESCRS requires the following disclosures to the session audience:

Shareholder	No relevant conflicts of interest to declare.
Grant / Research Support	No relevant conflicts of interest to declare.
Consultant	No relevant conflicts of interest to declare.
Employee	No relevant conflicts of interest to declare.
Paid Instructor	No relevant conflicts of interest to declare.
Speaker Bureau	No relevant conflicts of interest to declare.
Other	No relevant conflicts of interest to declare.

Presentation includes discussion of the following off-label use of a drug or medical device:
JETT PLASMA LIFT MEDICAL

Dry Eye Disease (DED)

Definition, Prevalence

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 instability and hyperosmolarity, ocular surface inflammation and damage, and neurosensory abnormalities play etiological roles.[1]

Prevalence of DED:

- 11% of people over 40 years old
- 75% of people over 60 years old
- Epidemiological evidence suggests that DED is **mainly evaporative** [2] and is often associated with **MGD** (Meibomian gland dysfunction)
- 70,2% prevalence of **MGD** in Caucasian populations [3]

1. Craig JP, Nichols KK, Akpek EK, et al. TFOS DEWS II definition and classification report. Ocul Surf 2017;15:276-83.

2. Stapleton F, Alves M, Bunya VY, et al. TFOS DEWS II epidemiology report. Ocul Surf 2017;15:334-65.

3. David K Murakami, Caroline A Blackie, Donald R Korb; The Prevalence of Meibomian Gland Dysfunction in a Caucasian Clinical Population. *Invest. Ophthalmol. Vis. Sci.* 2015;56(7):2508.

The New Modality of Treatment of DED by Plasma Emission

JETT PLASMA LIFT MEDICAL: non-ablative treatment

The device based on the physical principle of direct current performs membrane depolarisation, reversible electroporation, and generates heat

This process can change

- polarity of the cell membrane → permeability for nutrients and associated anti-inflammatory effect
- improve the liquefaction of the volume of the meibomian gland, dissolve the plug on its orificium and make tears more balanced

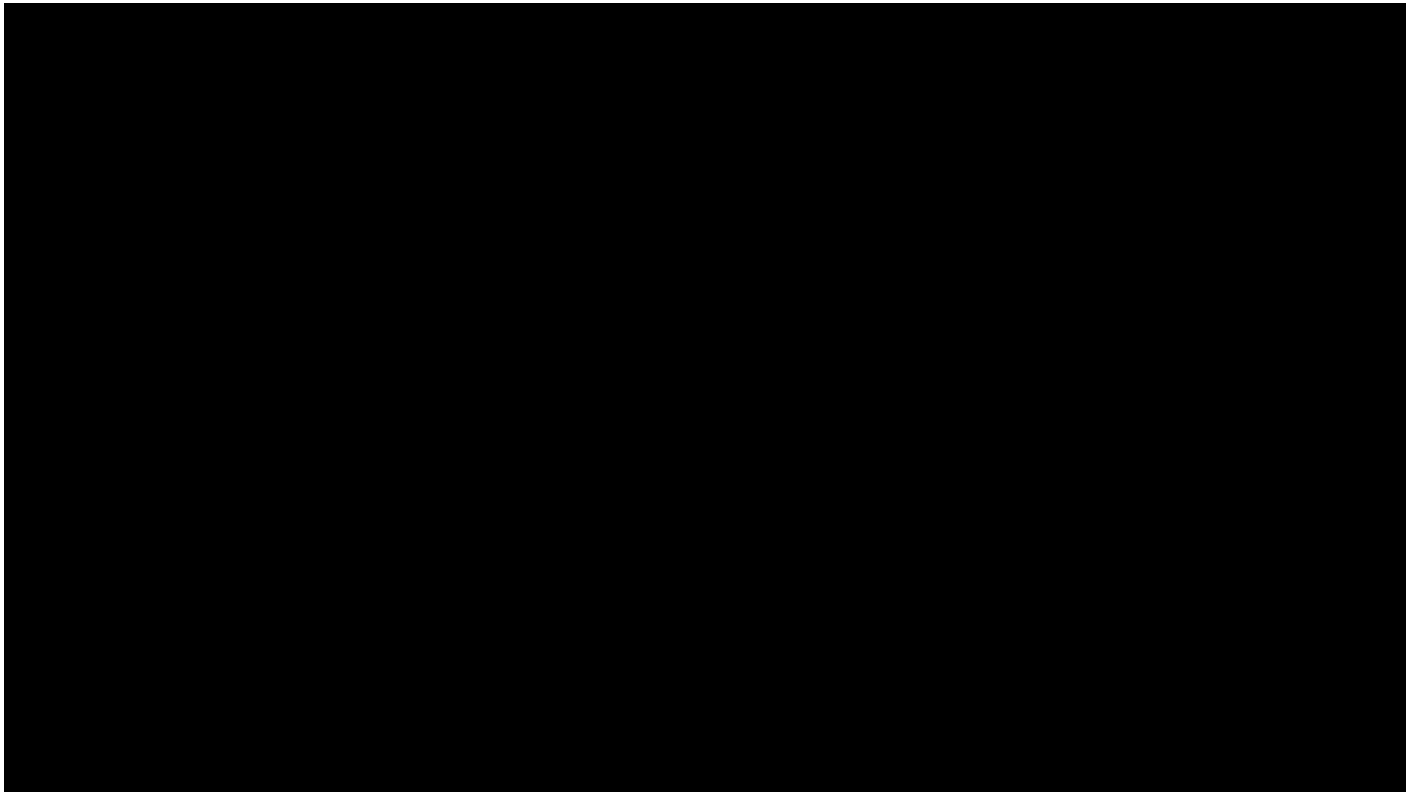
The New Modality of Treatment of DED by Plasma Emission

Prospective, multicentred, randomised, and single-blind controlled study

The aim: To evaluate the efficacy and safety of treatment of blepharitis and meibomian gland dysfunction by plasma emission (JETT PLASMA LIFT MEDICAL) by non-ablative treatment

- 77 patients (age 34- 88 years) was treated with plasma emission by a silver applicator
- acceptable intensity (1-6)
- These patients were treated four times (spacing after one week),
- followed by follow-up after 1 week (1st check-up), 1 month (2nd check-up), and 3 months (3rd check-up)
- The placebo group (22 patients), which served as the control group, was treated with an intensity of 0

Treatment



The Primary Objective

To evaluate the changes in the OSDI index (Ocular Surface Disease Index©)

Have you experienced any of the following during the last week?

	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light?	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0
Subtotal score for answers 1 to 5			(A)		

Have problems with your eyes limited you in performing any of the following during the last week?

	All of the time	Most of the time	Half of the time	Some of the time	None of the time	Not applicable
6. Reading?	4	3	2	1	0	N/A
7. Driving at night?	4	3	2	1	0	N/A
8. Working with a computer or bank machine?	4	3	2	1	0	N/A
9. Watching TV?	4	3	2	1	0	N/A
Subtotal score for answers 6 to 9			(B)			

Have your eyes felt uncomfortable in any of the following situations during the last week?

	All of the time	Most of the time	Half of the time	Some of the time	None of the time	Not applicable
10. Windy conditions?	4	3	2	1	0	N/A
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A
12. Areas that are airconditioned?	4	3	2	1	0	N/A
Subtotal score for answers 10 to 12	(C)					

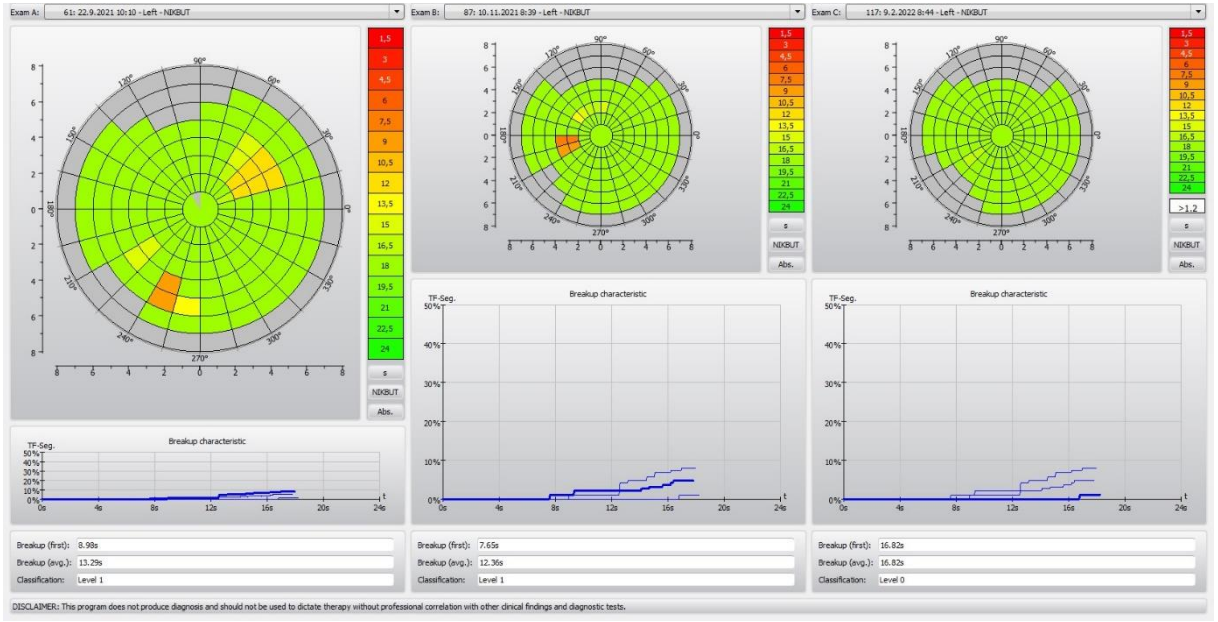
Add subtotals A, B and C to obtain D (D = sum of scores for all questions answered)	(D)
Total number of questions answered (Do not include questions answered N/A)	(E)

The OSDI© is assessed on a scale of 0 to 100, with higher scores representing greater disability.
The OSDI score is calculated as follows:

$$\text{OSDI} = \frac{\text{D (sum of scores)} * 25}{\text{E (number of questions answered)}}$$

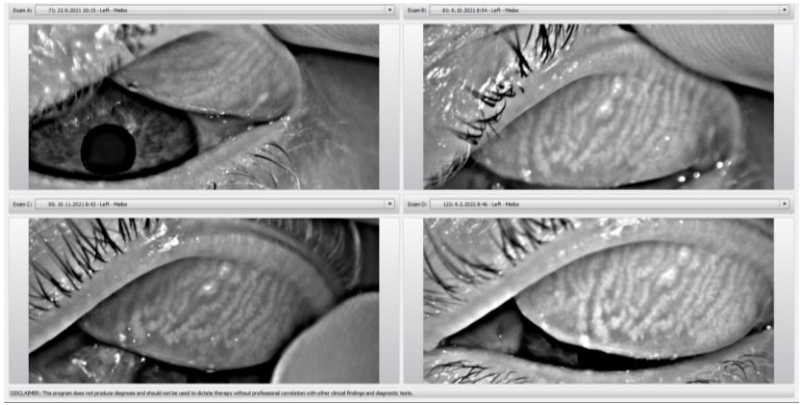
The Primary Objective

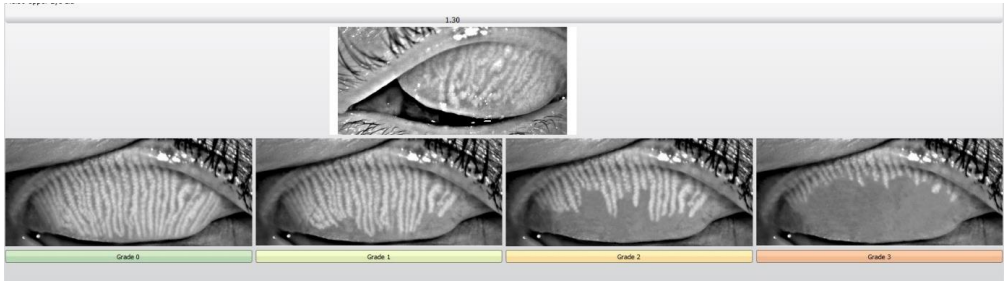
Tears break-up time test (TBUT, measured by physicians) and NIKBUT (Oculus Keratograph M) during the treatment



Other Goals

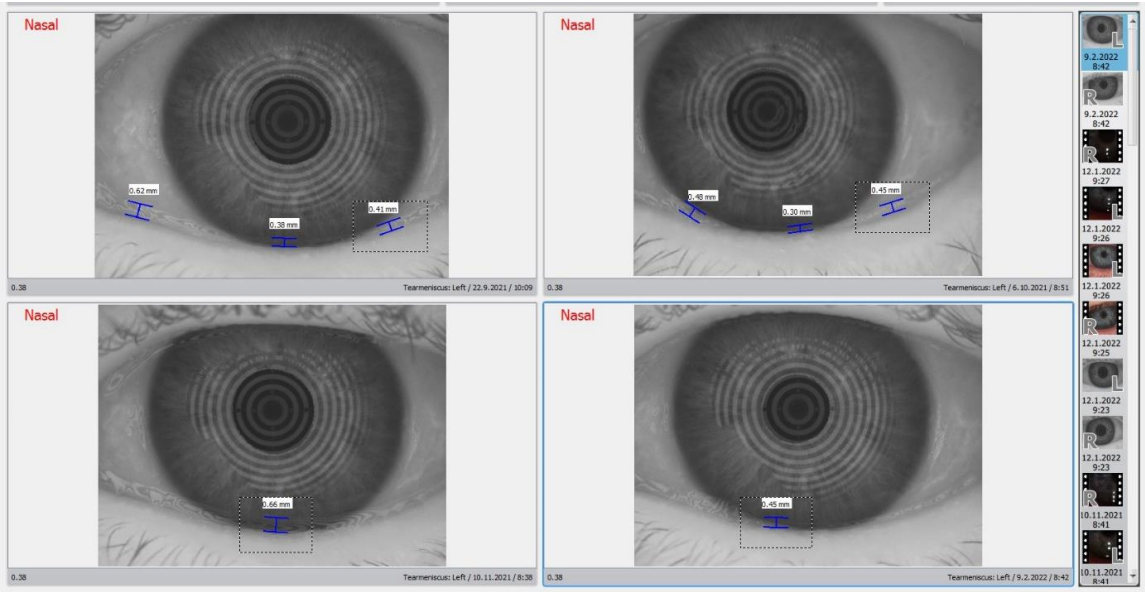
To monitor the changes in meibography by Oculus Keratograph 5M (Jenvis Meibo scale)





Other Goals

The measurement of the height of the tear meniscus



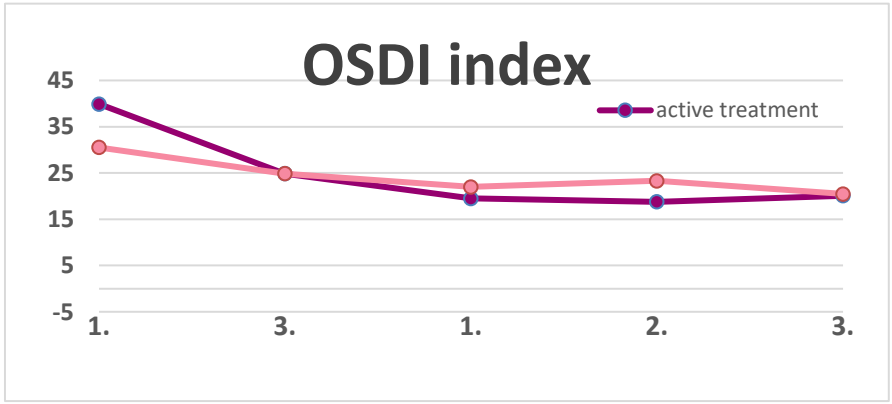
Results OSDI

There has been an improvement in OSDI of **97,4%** at the final check-up.

The average value in the group of patients with active treatment:

- before 1. treatment: 38,92
- 3. treatment: 24,44 (an improvement of 37 %)
- check-ups: further reduction of values around 19 (19,47; 18,39; 19,99 respectively).

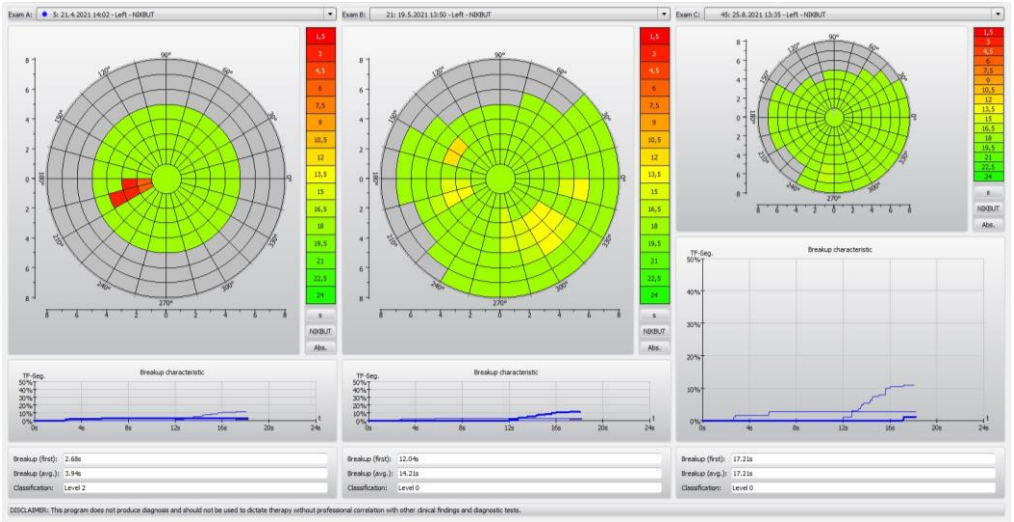
The controlled group improved from an average of 28,9 to 23,53, respectively, a 19 % improvement.



Results TBUT

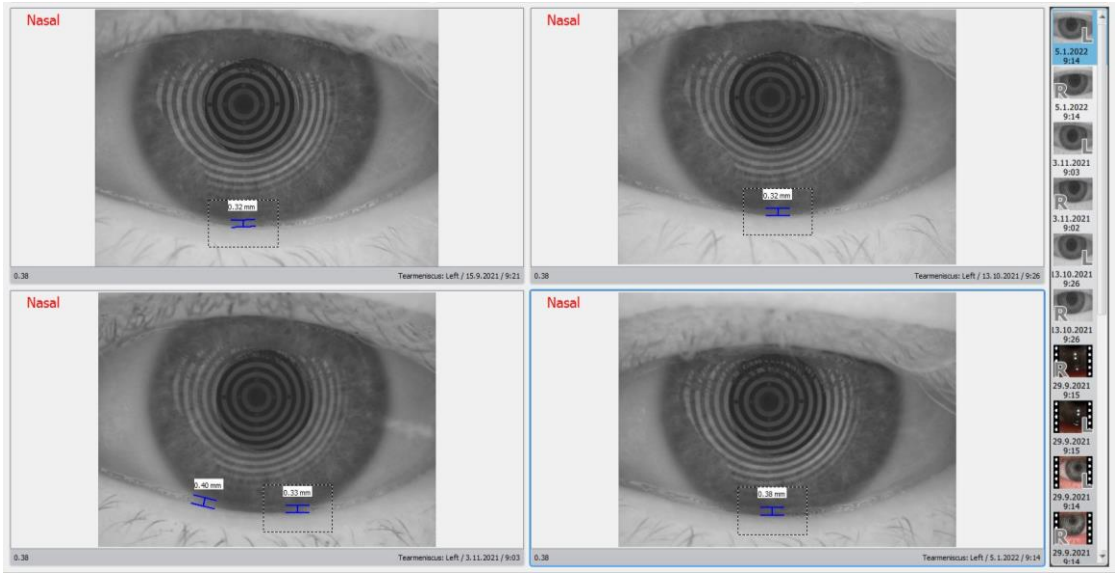
The average value of TBUT in the group of actively treated patients

- 7,5 sec (3,5-14 sec) at the beginning,
- followed by an increase in other treatments to 8,7, 9,3, and 10,3 sec in an average improvement of 21 %.
- Subsequent check-ups improved TBUT up to 10,4 (±2,461, an **improvement of 40 %**).
- NIKBUT (Oculus Keratograph 5M) was **extended at 78,4%** of patients on average by 4,243 seconds.



Results: Tears Meniscus

Before treatment: 0,42 (± 0,221)
1. check-up: 0,41 (±0,228)
3. check-up: 0,47 (±0,270) → Not significant changes

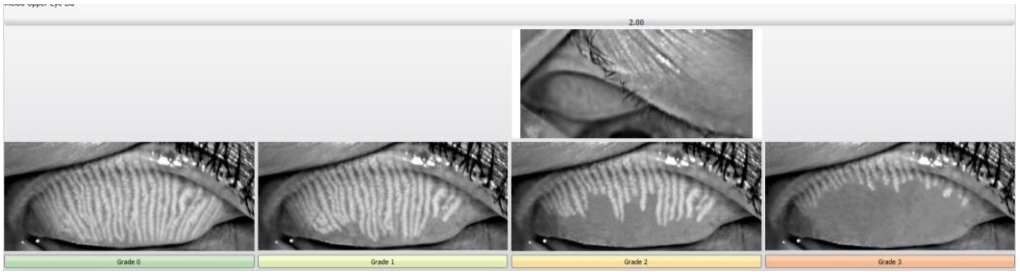


Results: Meibomography (Jenvis -Meibo Scale)

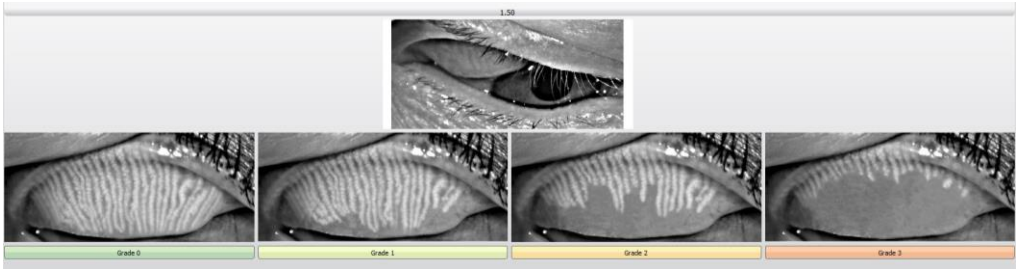
Evaluating by Jenvis-Meibo scale: **Improvement** in the actively treated group

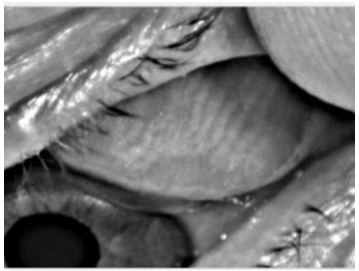
- 51,35% of patients at the first check-up,
- 57,14 % at the 3. check-up

Before treatment

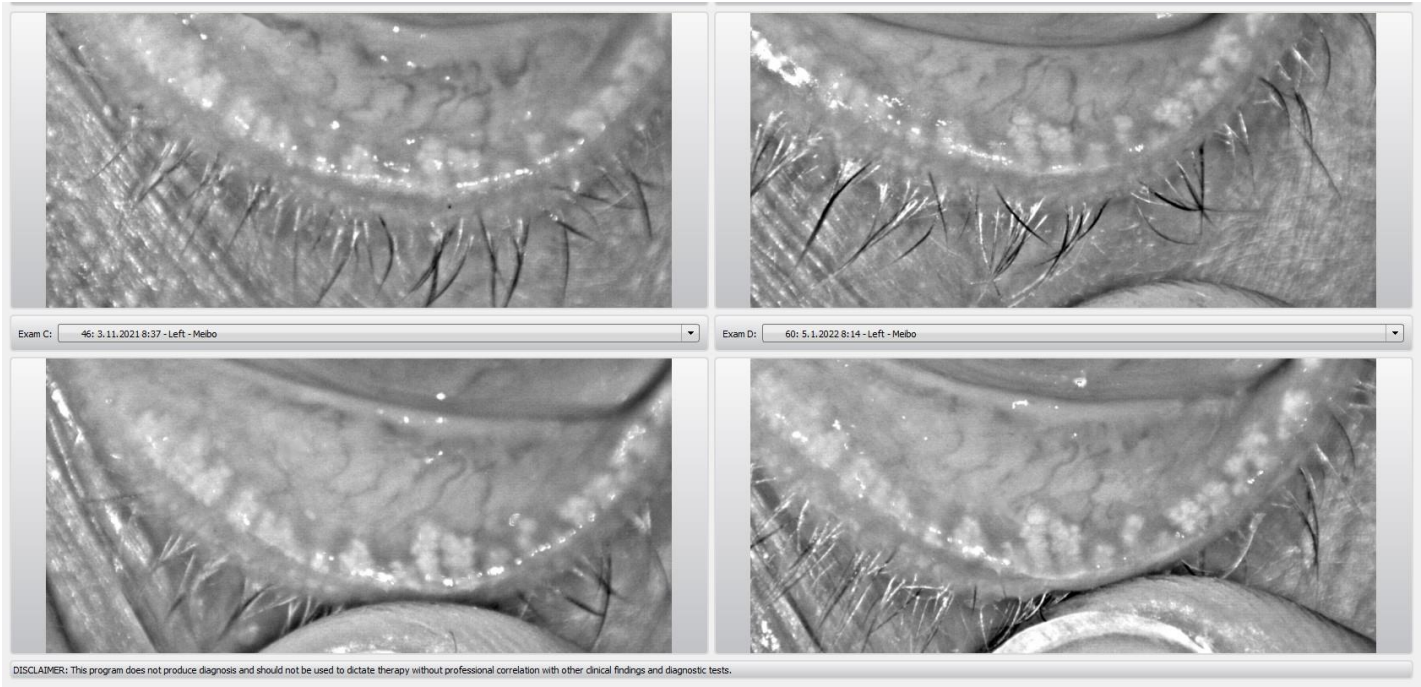


3. check-up





Results: Meibomography



Conclusions

This study has so far confirmed the efficacy and safety (the evaluation did not reveal any adverse events) of treatment with the medical device JETT PLASMA LIFT MEDICAL with silver applicators to alleviate the condition or completely cure blepharitis, Meibomian gland dysfunction indication, and associated dry eye disease.