# New Promise in Blepharitis Treatment

# JETT PLASMA LIFT MEDICAL

## For Ophthalmology

**The only direct current plasma device for blepharitis treatment in the world!**

Certified medical device!

# JETT PLASMA LIFT MEDICAL

## Ophthalmology Set

JETT PLASMA LIFT MEDICAL

+

Plasma Pen extension

+

Ophthalmology applicators

+

Metal stand

# JETT PLASMA LIFT MEDICAL

## For Ophthalmology

The set is equipped with a Plasma Pen extension, light, and ergonomic pen.

It can be easily operated by your forefinger and the handheld switch and ensures optimal ease of use and mobility.

# JETT PLASMA LIFT MEDICAL

## Ophthalmology Set

Equipped with 6 applicators

- 4 silver applicators for contact electroporation treatment
- 2 golden applicators for mini-invasive procedures

# JETT PLASMA LIFT MEDICAL

## Ophthalmology Set

Gold applicators create plasma easily by holding the tip a few millimeters above the skin.

Silver applicators when in contact with the skin, are for electroporation rejuvenating treatments of the face and any body parts. Their effect on meibomic glands is being further studied.

# PMCF Study – JETT PLASMA LIFT MEDICAL

**IN PROCESS**

## STUDY DESIGN

- A prospective, multi-centered, controlled (single blind placebo) and randomized Post Marketing Surveillance Study evaluating the safety and efficacy of the JETT PLASMA LIFT MEDICAL for ***eye mucosa treatment with silver applicators to decrease symptoms or cure blepharitis.***

## RANDOMIZATION

- From **1-110 patients** will be randomly assigned to either the active treatment (66 occurrences) or the placebo treatment (44 occurrences).

## MONITORING PLAN

- An entrance examination is performed before the treatment itself.

After the initial examination, the **treatment** takes place, which will be performed 4 times.
Between the treatments, there should be a time interval of 7 days.
After the last treatment, a **checkup** will be performed after 1 week, 4 weeks and 12 weeks after the last treatment.

# PMCF Study – JETT PLASMA LIFT MEDICAL

**IN PROCESS**

PRIMARY ENDPOINTS:

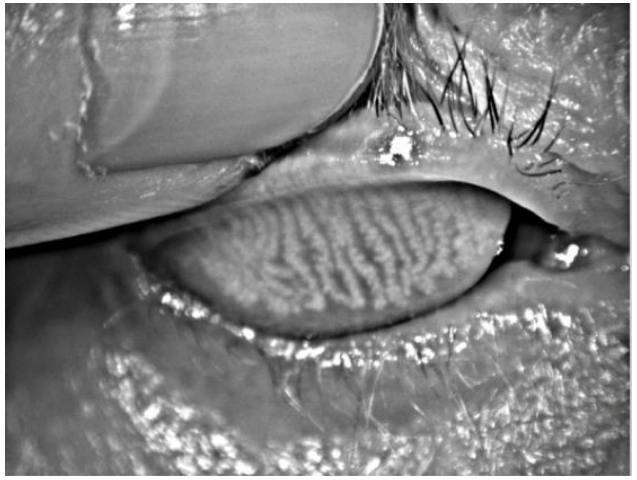
- to determine the change of the OSDI index after series of 4 treatments using JETT PLASMA LIFT MEDICAL medical device

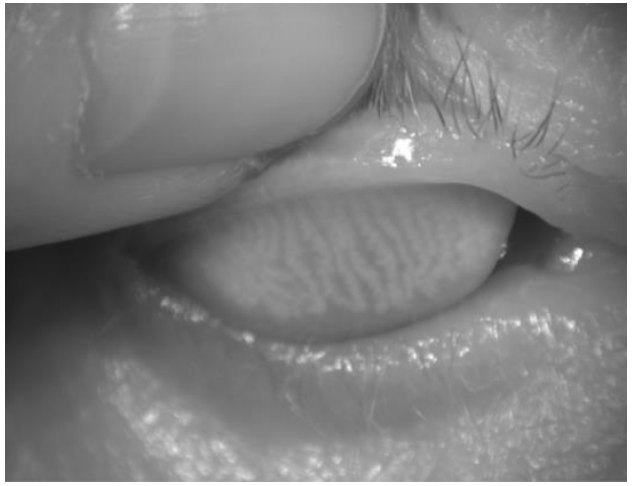
SECONDARY ENDPOINTS:

- find out previously unknown and monitor known side effects and detect new contraindications,
- identify and analyze emerging risks based on real evidence,
- collect long-term experience with patients in clinical practice,
- patient **satisfaction** using 5 point scale

# Blepharitis = Meibomian Gland Dysfunction

- Patented technology of Direct Current generates stable, very precise and targeted plasma stream.
- Release of meibomian gland margins
- Softening of gland content, loosening and liquefaction of sebum and removal from the glands thanks to the generated heat
- Anti-inflammatory effect – thrombosis of the vascular system round the Meibomian glands may play a role in reducing the local release of inflammatory mediators





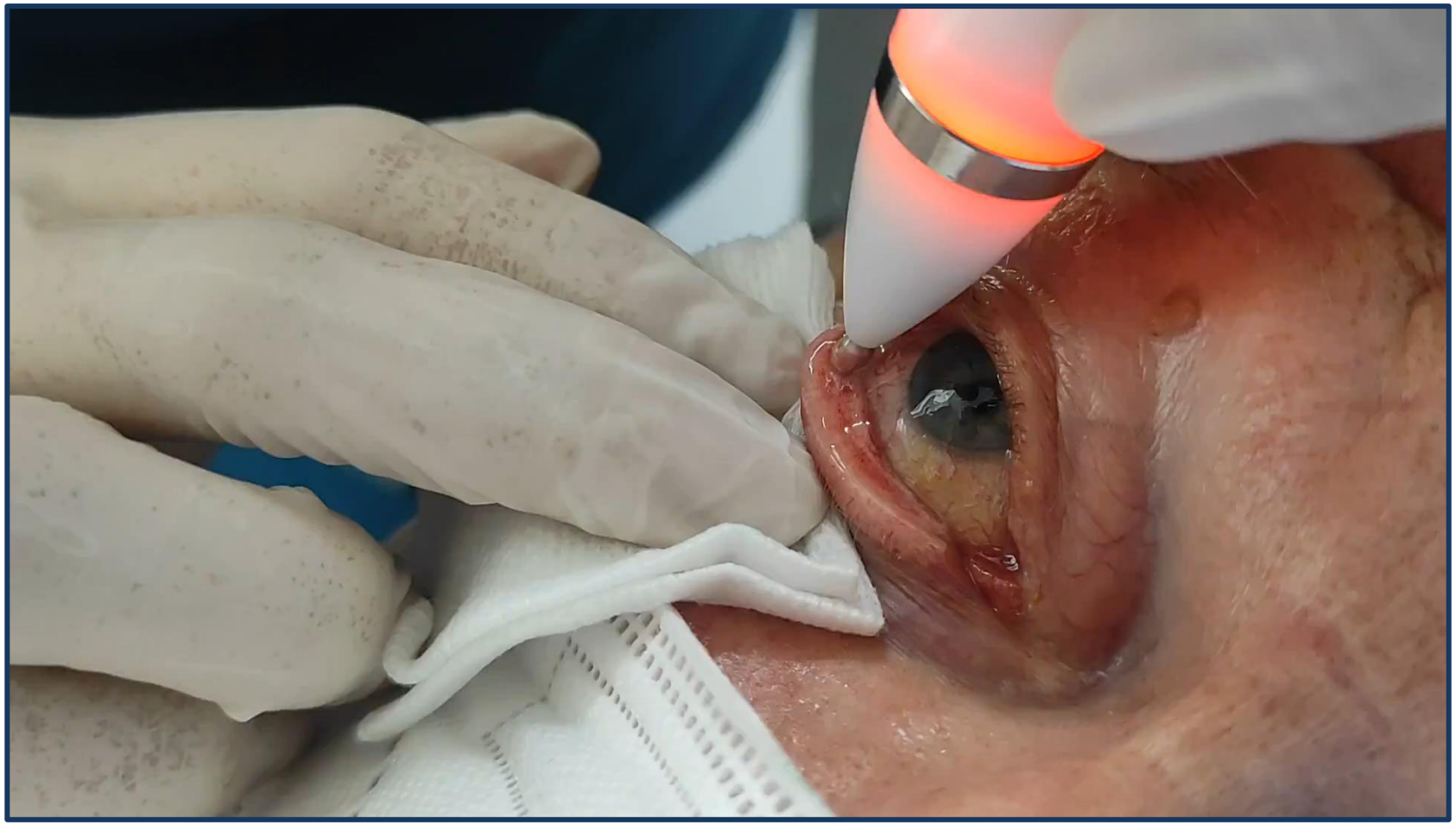
# Blepharitis = Meibomian Gland Dysfunction

Elimination of the bacterial flora in the glands and their surroundings

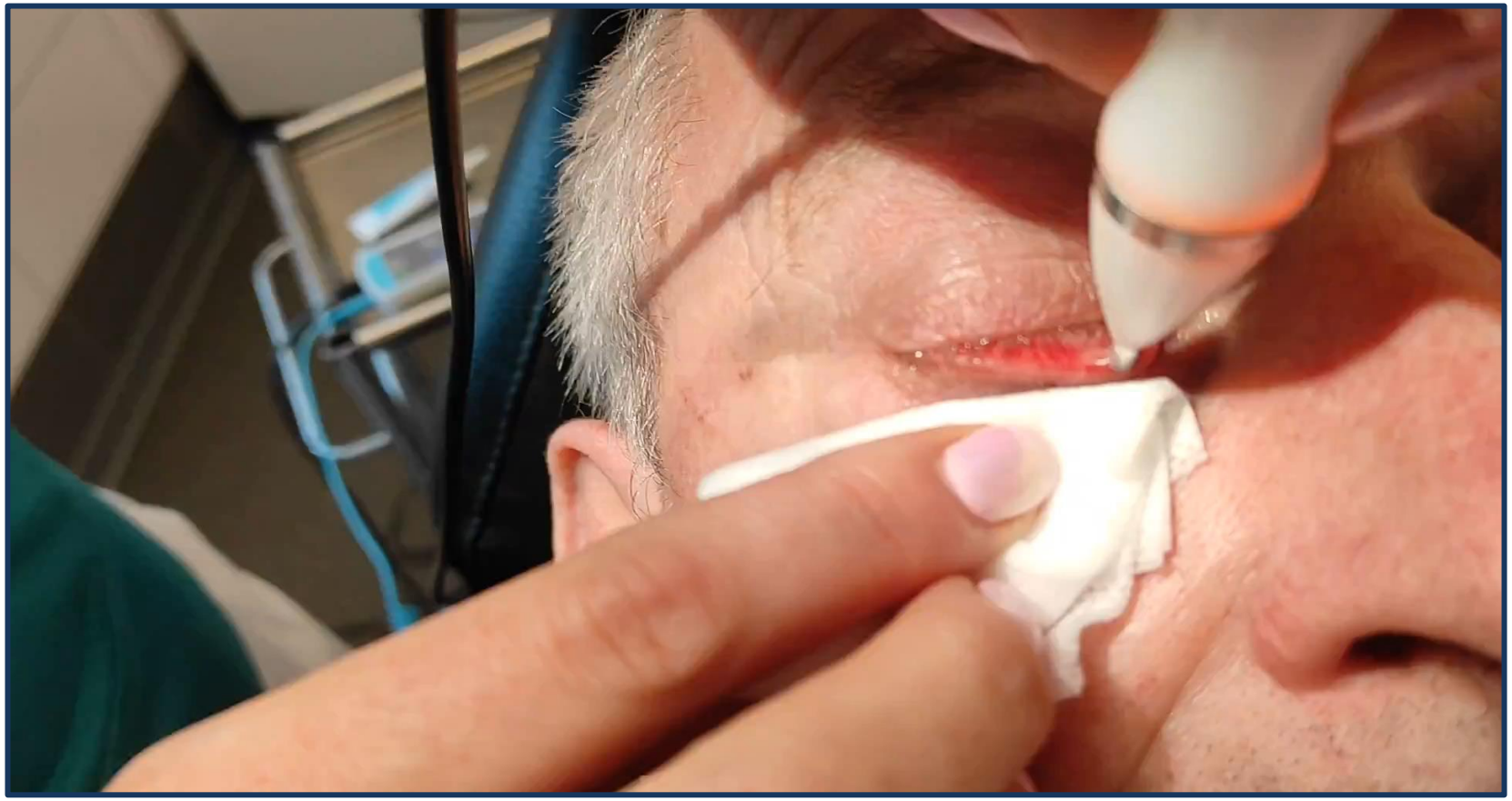
Increase of elasticity of the ligament fibers round the glands and their outlets (due to DC current)

Plasma helps to increase production of the non-inflamed Meibomian glands

# Blepharitis Treatment



# Blepharitis Treatment



# PMCF Study – The Primary Endpoint

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

**HAVE YOU EXPERIENCED ANY OF THE FOLLOWING *DURING THE LAST WEEK*:** (Side 1)

| | 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 | |
|---|---|---|---|---|---|---|
| 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 (ATM)? | 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)

# PMCF Study – The Primary Endpoint

**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 | |
|---|---|---|---|---|---|---|
| 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 air conditioned? | 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:

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

# PMCF Study – Preliminary Results

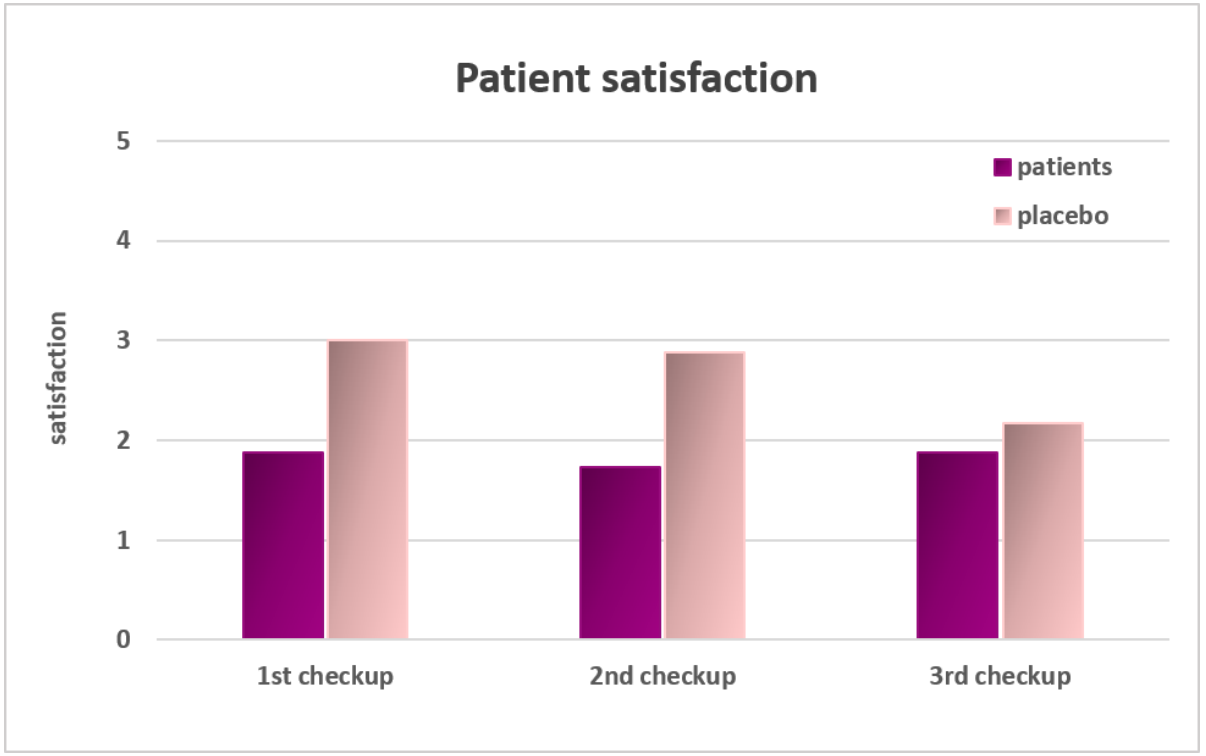
Comparison of subjective vaginal laxity symptoms in **group of 52 patients** with active JPLM treatment and **placebo group of 17 patients** as a negative control (underwent all checkups).

Each patient's satisfaction was recorded by **QUESTIONNAIRE** at the beginning of study and then gradually over the course of the study using:

- **OSDI** **Ocular Surface Disease Index** questionnaire – 12 questions, 0 - 100 points scale

**Excellent results with significant improvement of blepharitis symptoms and OSDI!**

# PMCF Study – Preliminary Results

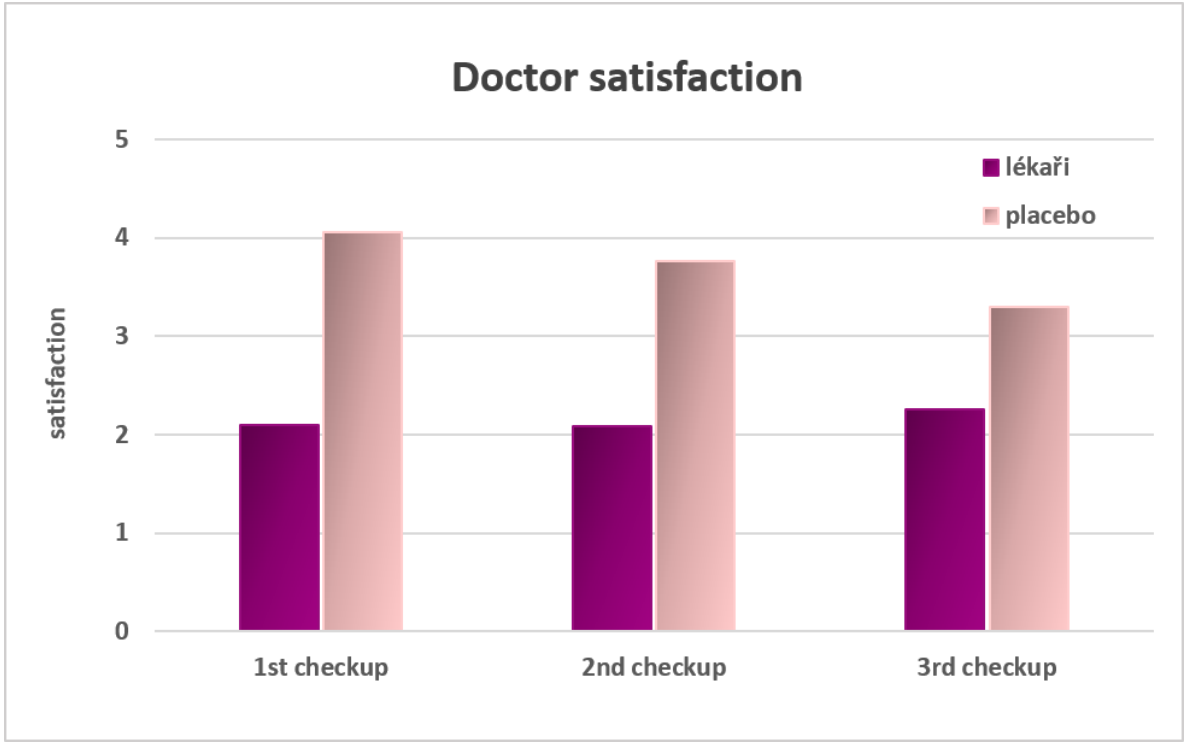



Comparison of subjective symptoms improvement in a group of patients with active treatment and placebo
(The evaluation is based on a scale from 1 (very satisfied) to 5 (very dissatisfied).

Average points difference before treatment compared to after 1.,2. and 3. checkup
(after 1 week, 4 weeks and 12 weeks)

**The overall average patient satisfaction with active treatment was 1,8.**
**The overall average patient satisfaction with placebo treatment was 2,7.**

# PMCF Study – Preliminary Results

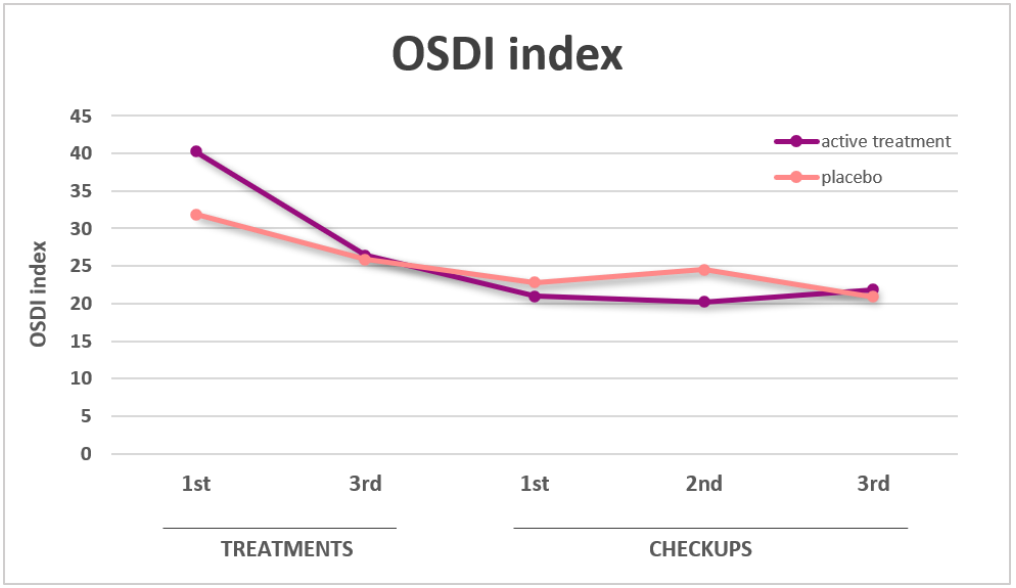



Comparison of doctor satisfaction in a group of patients with active treatment and placebo (The evaluation is based on a scale from 1 (very satisfied) to 5 (very dissatisfied).

Average points difference before treatment compared to after 1.,2. and 3. checkup (after 1 week, 4 weeks and 12 weeks)

**The overall average doctor satisfaction with active treatment was 2,1.**
**The overall average doctor satisfaction with placebo treatment was 3,9.**

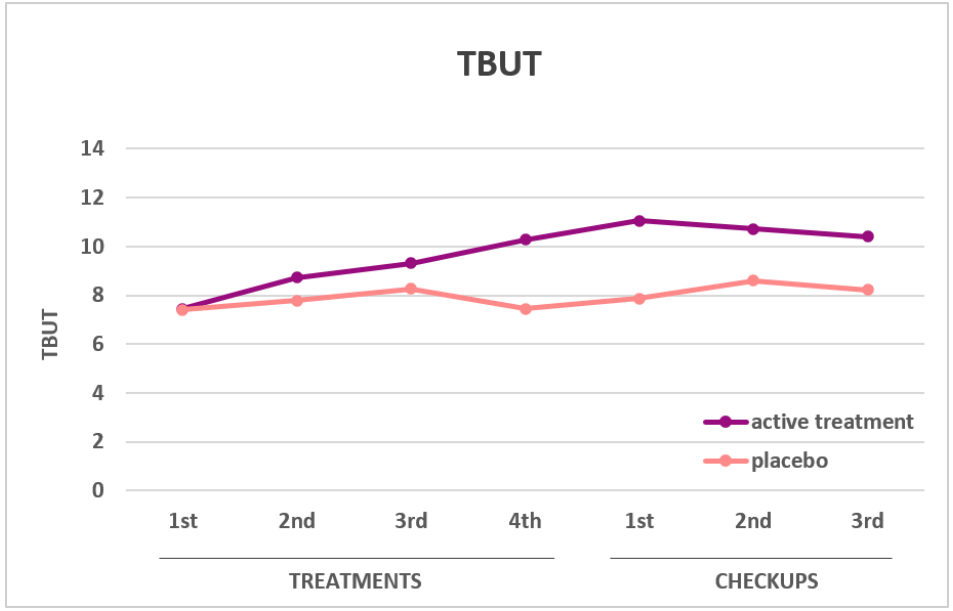
# PMCF Study – Preliminary Results OSDI




**The average value of the OSDI index in the group of patients with active treatment was 40,71 at the 1st treatment, then it decreased to 26,43 at the 3rd treatment and further decreased to relatively balanced values around 21 (20,98; 20,23, 21,87 respectively).**

**For patients with placebo treatment, the OSDI index also decreased, from OSDI 31,87 gradually to OSDI index 20,93.**

# PMCF Study – Preliminary Results TBUT

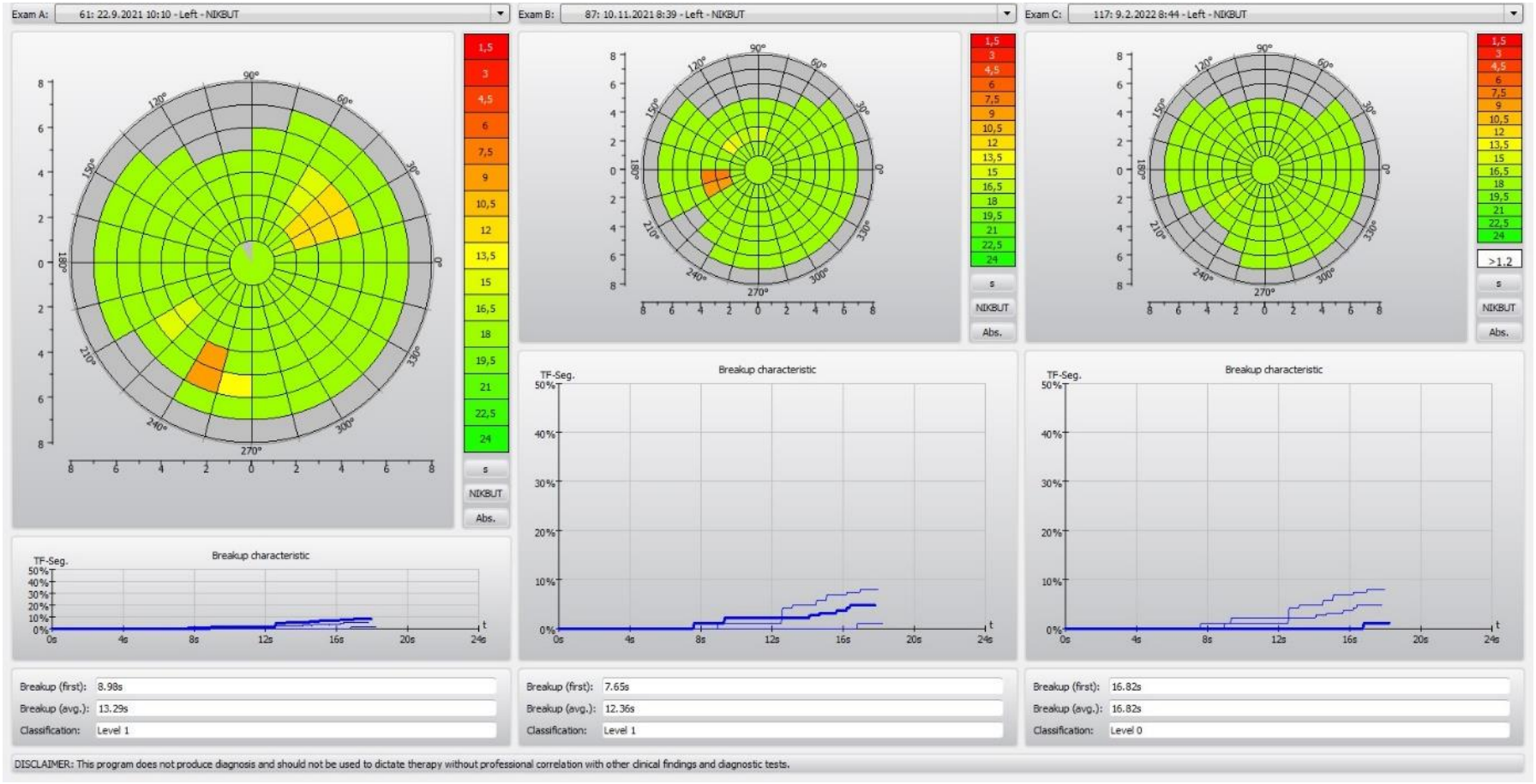



**The average value of TBUT in the group of patients with active treatment was 7,5 at the first treatment, followed by a gradual increase in other treatments to 8,7; 9,3 and 10,3. Subsequent inspections then to further improve TBUT in the end up to 10,4.**

**Patients treated in the placebo group had only a slight increase in TBUT, from 7,4 before 1st treatment to 8,2 after the last checkup.**

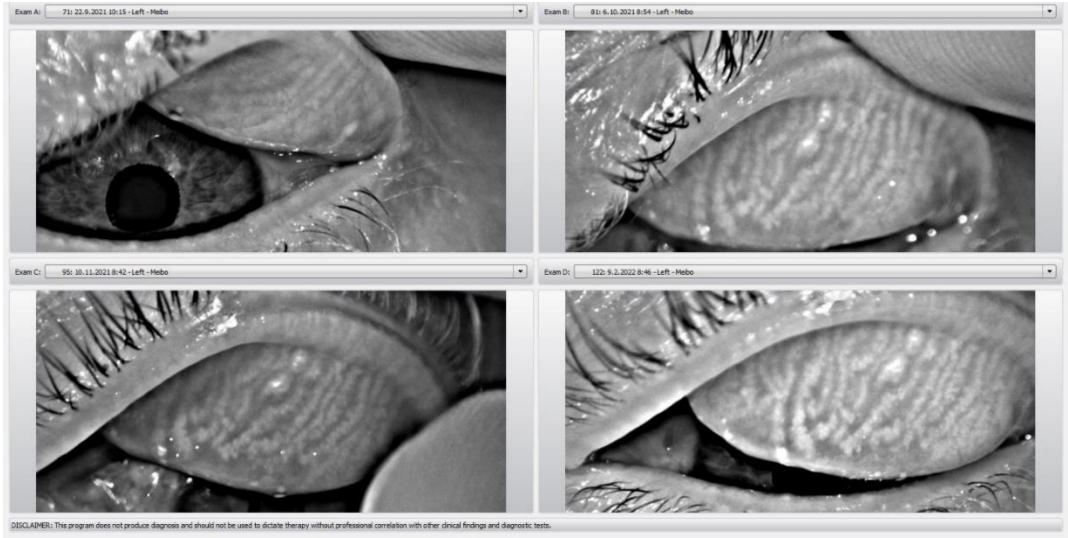
# PMCF Study – Preliminary Results TBUT

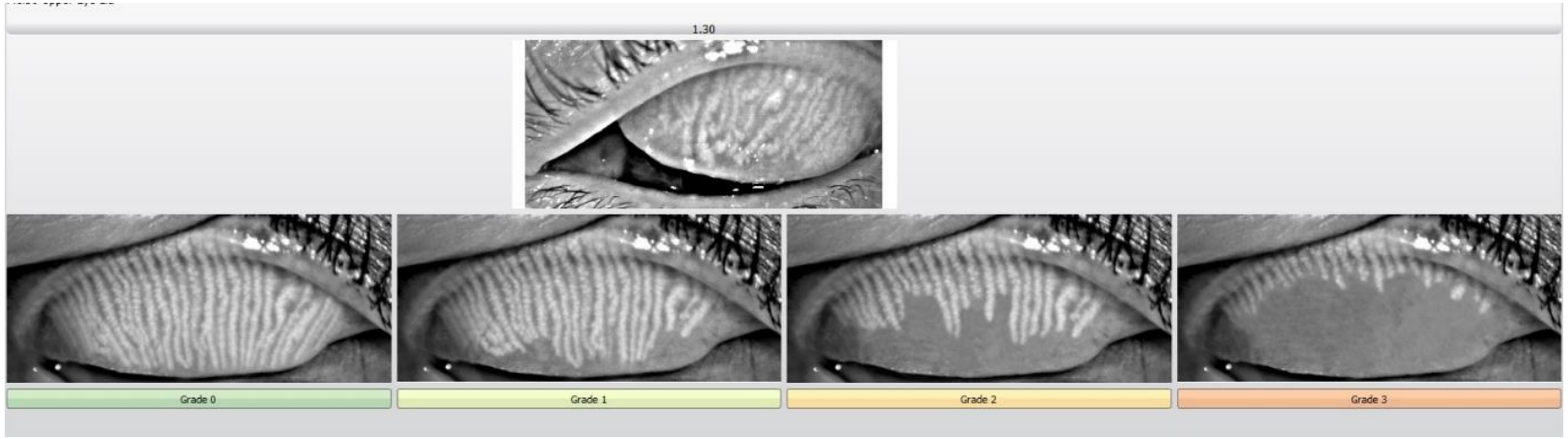
Tears break-up time test (TBUT, measured by physicians) and NIKBUT
(Oculus Keratograph M) during the treatment



# PMCF Study – Preliminary Results Jenvis Meibo Scale

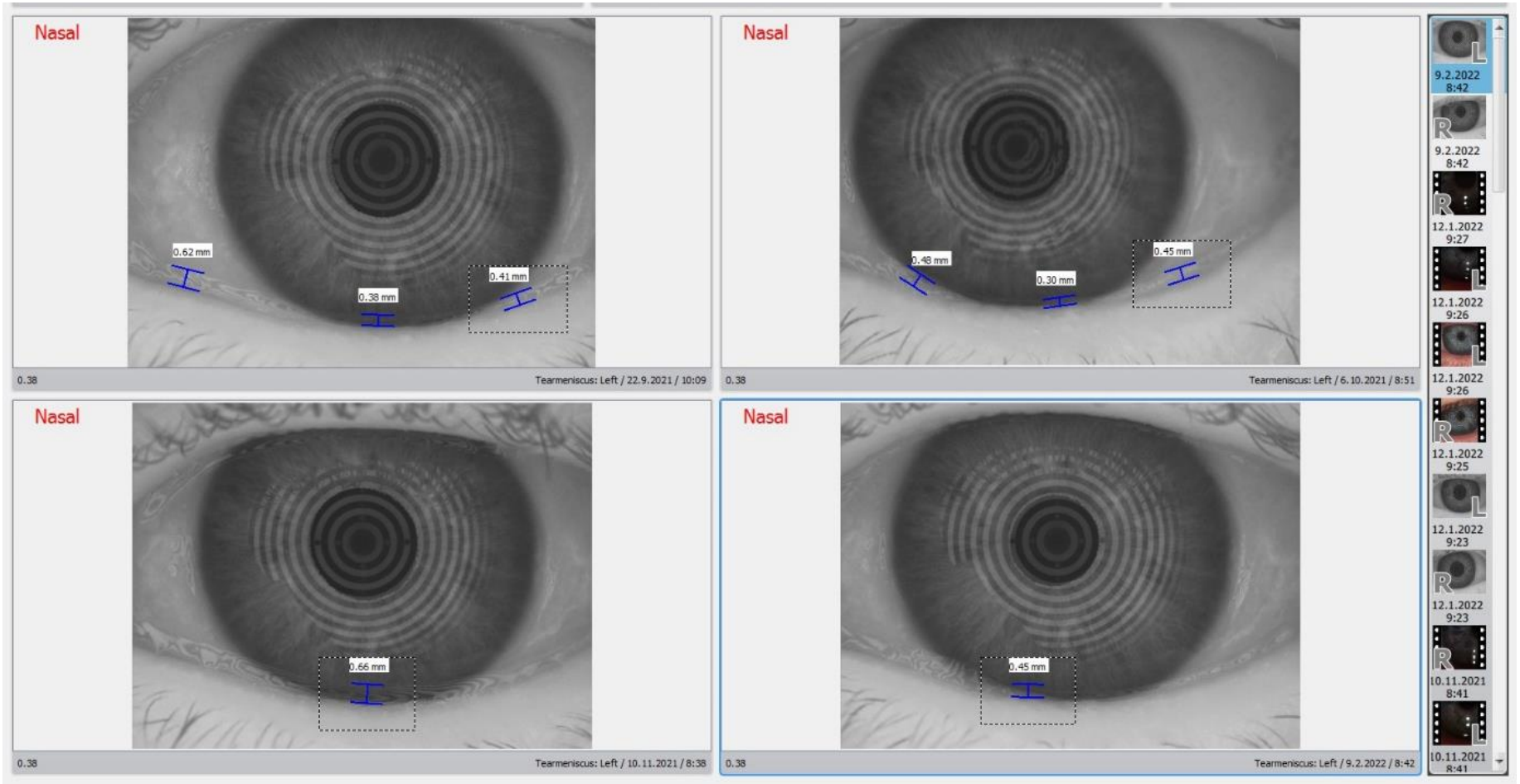
To monitor the changes in meibography by Oculus Keratograph 5M (Jenvis Meibo scale)



# PMCF Study – Preliminary Results Tear Meniscus

The measurement of the height of the tear meniscus



# Case Report: Blepharitis

| | |
|---|---|
| Sex and age | Man, 75 years |
| Diagnosis | Chronic blepharitis and dry eye syndrome since 2014 |
| Treated with | JETT PLASMA LIFT MEDICAL with Plasma Pen |
| Used applicator | Golden ophthalmic applicator |
| Discharge intensity | Degree 5 |
| Anaesthesia | Local anaesthesia (Supracain 4 % 0.2 ml s.c., Benoxi drops) |

The patient has been treated for chronic blepharitis and dry eye syndrome since the year 2014.

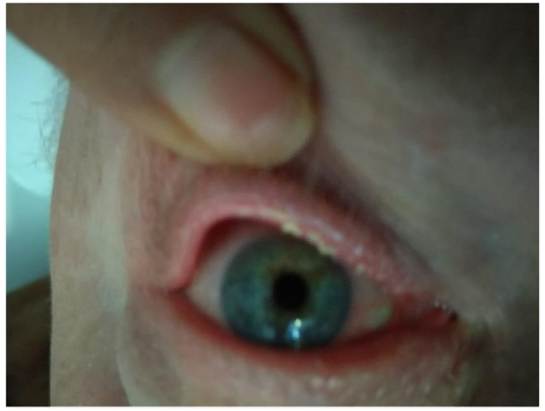
Local therapy: Blefagel for eyelids, topical antibiotics in case of trouble, artificial tears, eyelid hygiene, warm compresses, massages. Eyelid expressions were performed repeatedly according to the patient's condition.

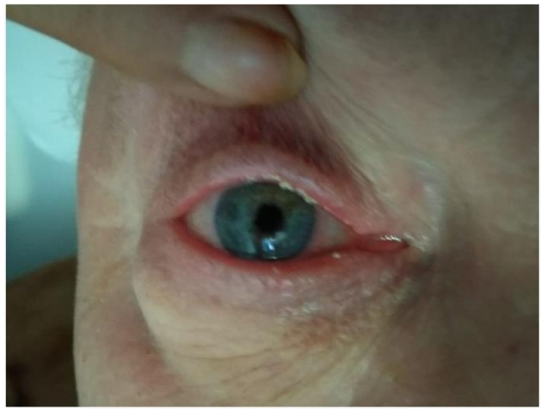
# Case Report: Blepharitis

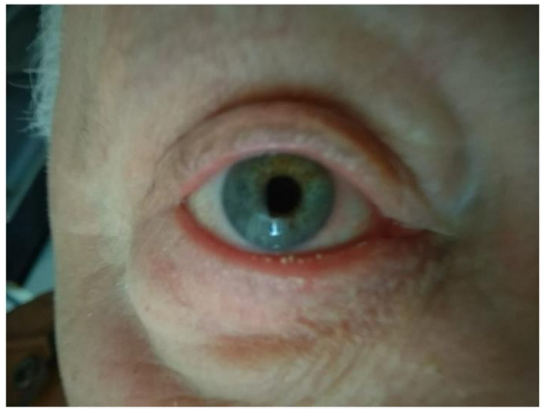
- Objective finding before treatment: red and swollen eyelid margins, signs of meibomitis, mild conjunctival reaction, calm front segment.
- Objective finding 14 days later: the eyelids are calm, without swelling, the margins are pink without swelling, individual outlets of Meibomian glands are visible, from which a little secretion can be released after 14 days.
- The following check-up after 1 month: the patient is without complications, continues the eyelid hygiene 3 times a week. The condition is stabilized.
- During the check-up 3 months after treatment: the patient reports worsening of the condition lasting for 14 days. Massive whitish secretion was released by expression, the eyelids are quite calm. Tobradex was prescribed. Check-up was recommended after a week.

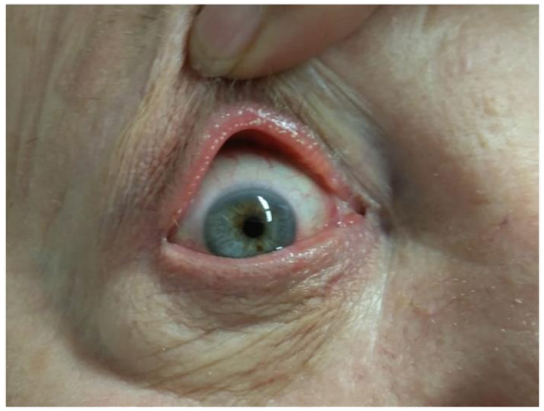
# Case Report: Blepharitis

Before

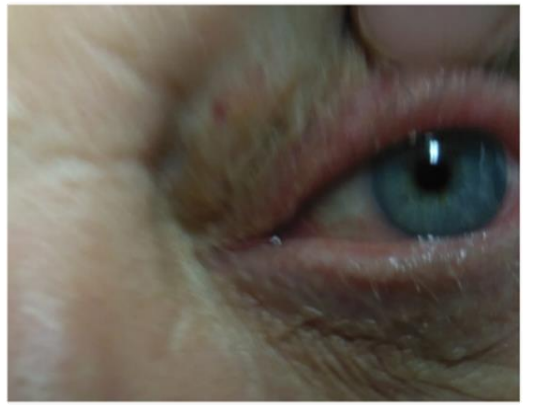


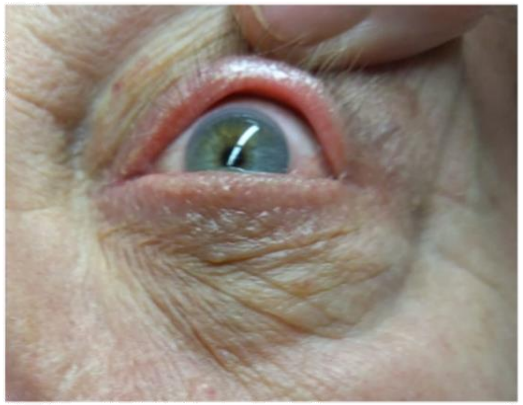






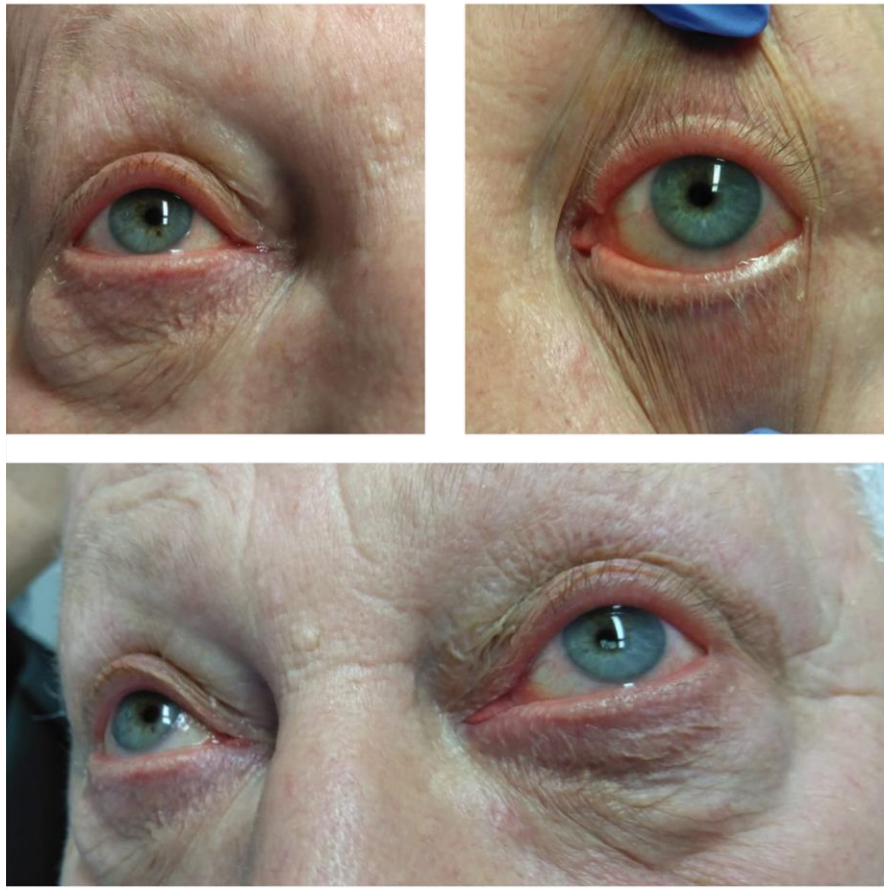
After 1 week



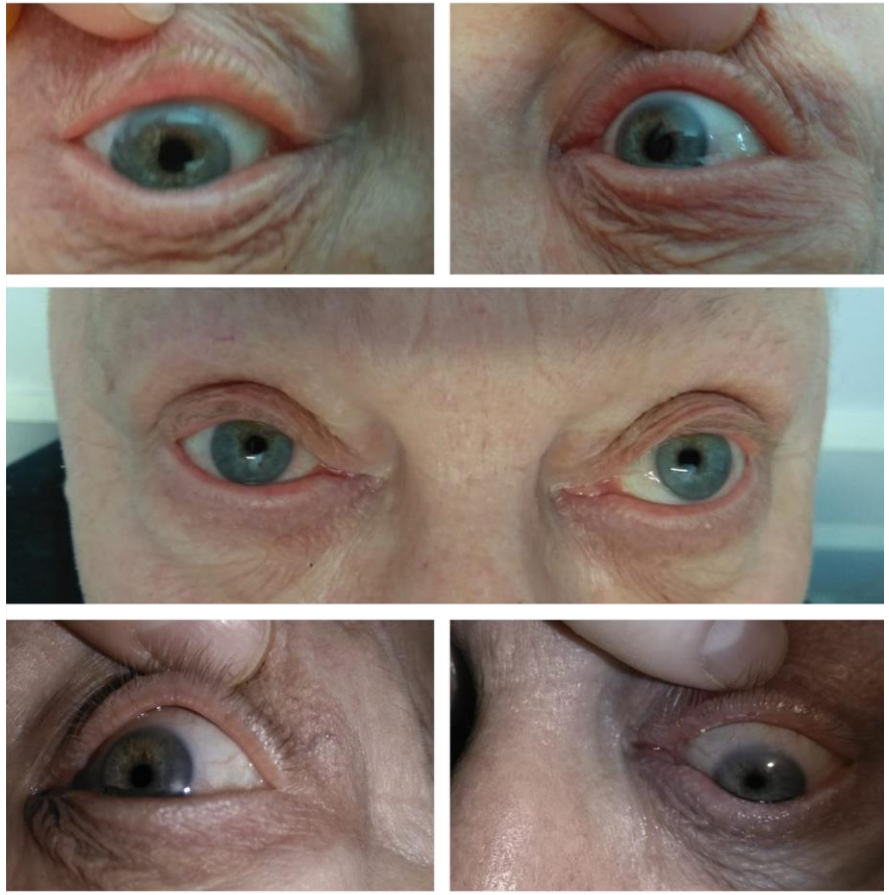


# Case Report: Blepharitis

After 1 month



After 3 months



# Conclusion

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.

# In Cooperation with

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MUDr. Ivana Macejová – *Oftum Bohemia, Prague, Czech Republic*

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