# Clinical Study

## A prospective study assessing the impact of Tixel, a novel treatment on dry eye symptoms and signs

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# Introduction

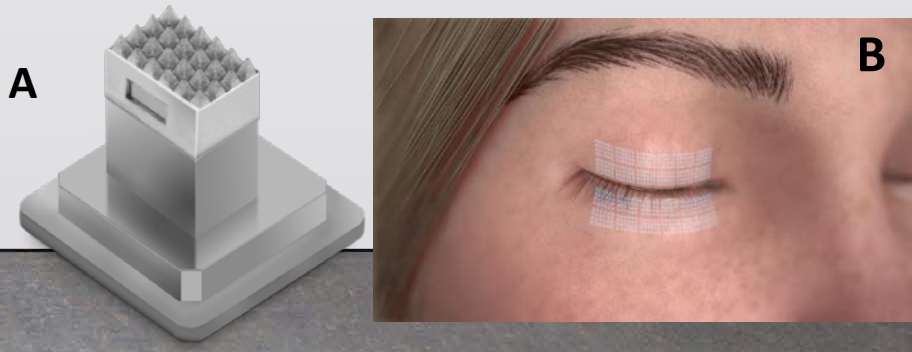
- TFOS DEWS II : DED is a multifactorial disease of the ocular surface characterized by:
  - a loss of homeostasis of the tear film,
  - accompanied by **ocular symptoms**,
  - in which **tear film instability** and **hyperosmolarity**, ocular surface **inflammation** and damage, and neurosensory abnormalities play etiological roles.[1]
- It is estimated that DED is afflicts
  - more than 344 million people worldwide
  - 20.8% people in the UK,[2]
  - 50% of patients in some Asian countries
- Overall management of DED still remains **something of an art**
- There is a need for novel treatments

1. Craig JP et al. Ocul Surf. 2017;15(3):276-83; 2. Jones L et al. Ocul Surf. 2017;15(3):575-628

# Methods-Tixel

- Tixel is a fractional skin rejuvenation system, relying on direct thermal energy delivery (no laser, RF etc)
- The energy is transferred via a continuously sterile, thermal titanium element located on the applicator
- Tixel tip consists of 24-pins; 4 × 6 pyramids is 0.3 cm2
- The tip is kept at a constant 400°C: enables continuous sterilization
- The applicator moves the tip forward to create contact (8 ms)
- Non-ablative microthermal effect created (0.18 mJ/point)
- No disposables

*Figure 1: (A) Titanium 24-pin Tip used for thermomechanical heat transfer to tissue. (B)*



# Methods – Study

**Aim:** To determine the effects of a thermo-mechanical action based peri-orbital fractional skin treatment Tixel® on dry eye signs and symptoms.

**Design: -** Prospective, controlled, open labelled study

Conducted at three study centres: Midland Eye, UK, Vallmedic Vision, Andorra and Khmer Sight Foundation, Cambodia.

Ethics approval and study followed the tenets of declaration of Helsinki

- Study visits -

1. Baseline, Screening, Enrolment* and first Tx
2. (t= 2w) Second Tx, First Follow up (FU)
3. (t= 4w) Third Tx, Second FU
4. (t= 6w) Third FU
5. t= 18w) Fourth FU

# Methods – Study

## Inclusion Criteria

- OSDI score >13, NITBUT ≤ 10 secs
- Age ≥ 18 years;

## Exclusion Criteria

- Pregnant or breastfeeding, lesions in the periorbital area, severe blepharitis, conjunctivitis, other concomitant anterior eye disease, fragile skin or impaired skin healing
- Outdoors/sunbed tanning last 4 weeks, or during the study period, H/O Herpes Simplex
- Skin cancer, immunosuppressive medication, collagen disorders, Previous orbital invasive/ablative procedures within 3 months, herbal treatment (oral or topic)

# Methods – Study

- DED symptoms by OSDI questionnaires
- Tear osmolarity (TearLab)
- NITBUT
- Corneal topography/keratometry
- Detailed slit lamp examination, lid and meibomium gland assessment
- Data from OD analysed and presented

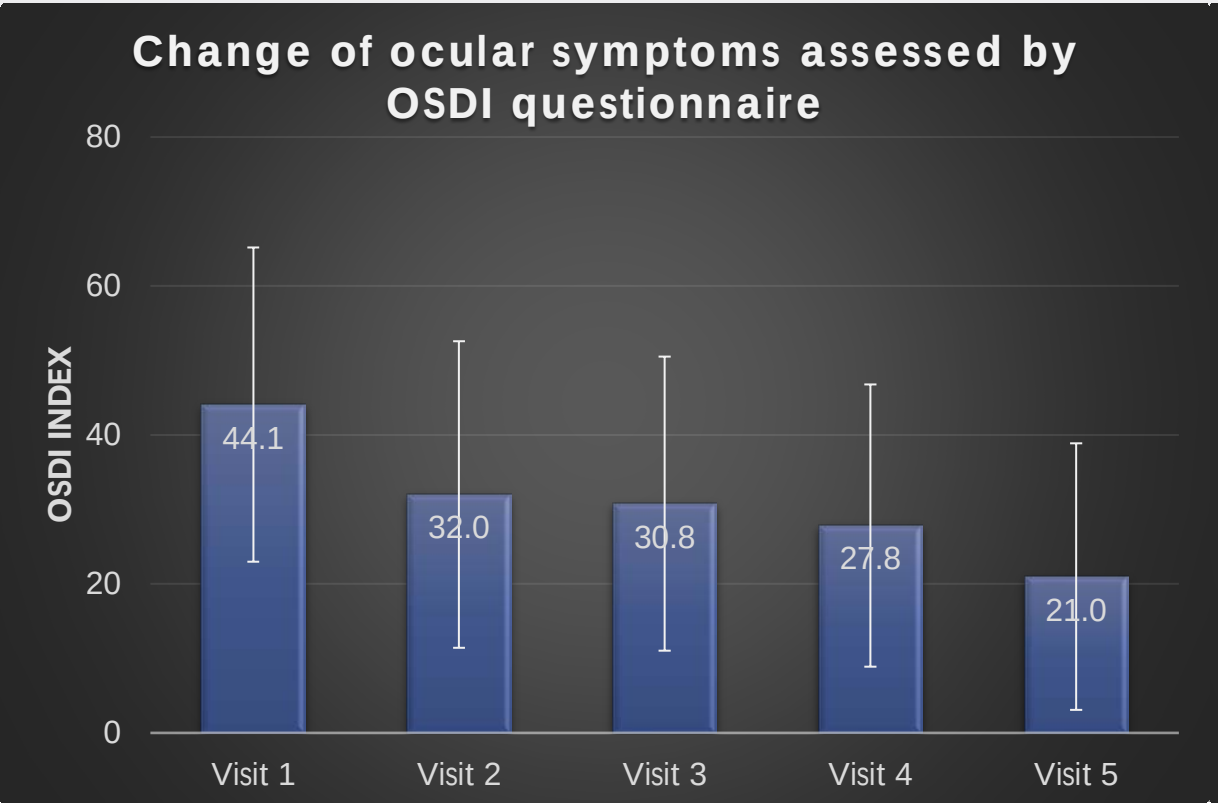
# Results

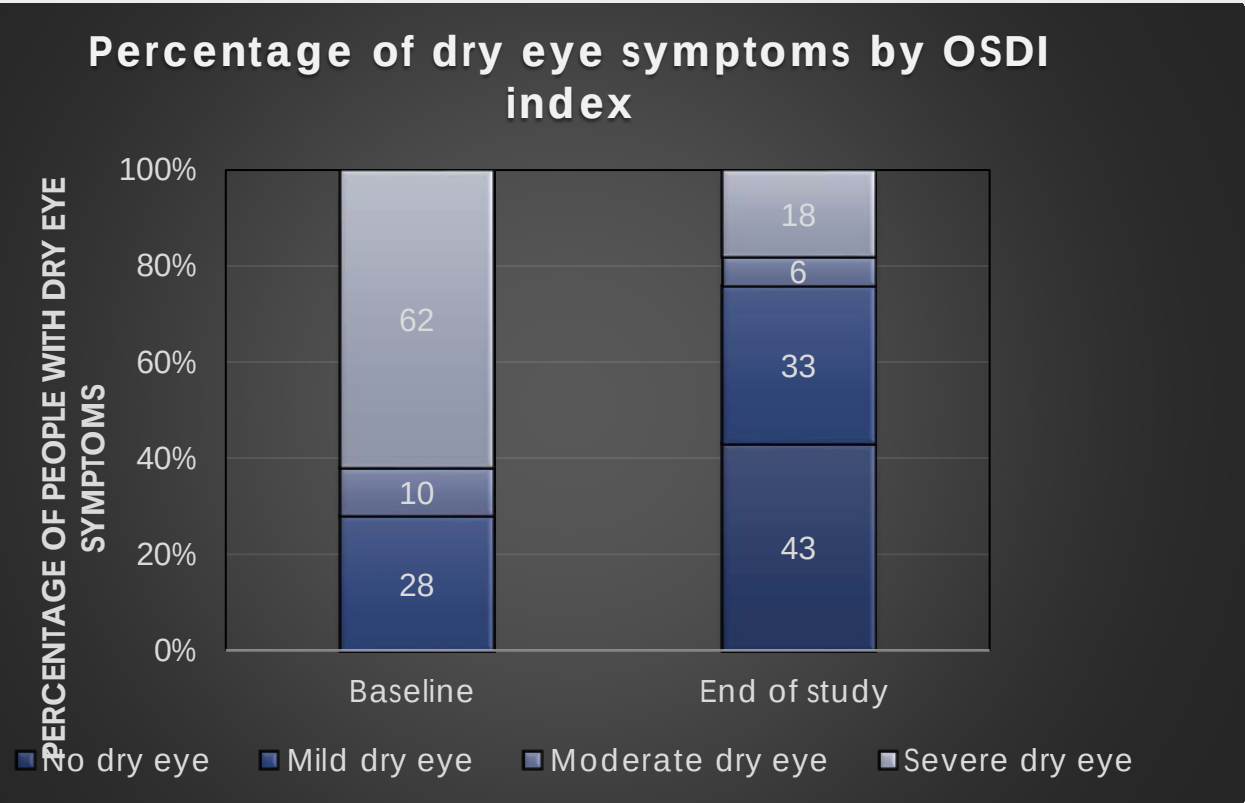
- 113 participants
- Average age 55.5±14.6 years
- 83 females
- Mild erythema and no oedema, disappeared within 2 days
- No change in vision (P=0.998) or IOP (P=0.894) observed

# Results: OSDI

**Impact of Tixel on DED symptoms:**

- Improvement in mean OSDI score by 23.1±13.0 (P<0.001)
- 18.9±6.7 and 32.9±9.2 OSDI index improvement for patients moderate and severe dry eye
- Clinically significant improvement (4.5 for moderate and 13.4 for severe DED)

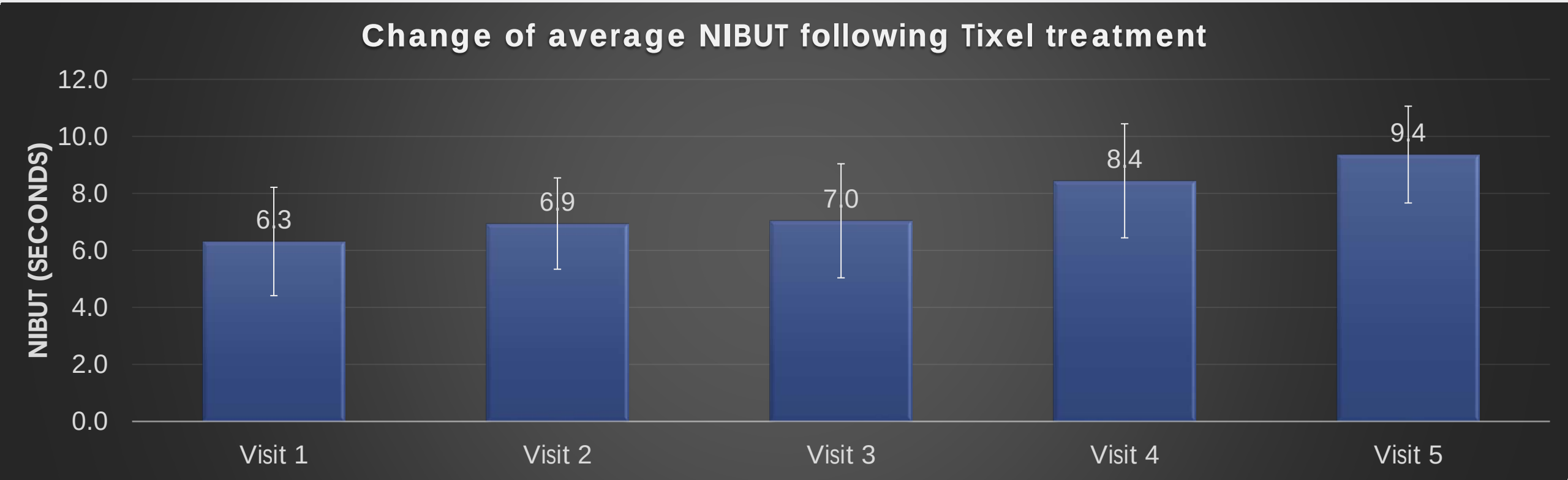


# Results

**Impact of Tixel on OD Non-Invasive Tear Break Up Time (NITBUT)**

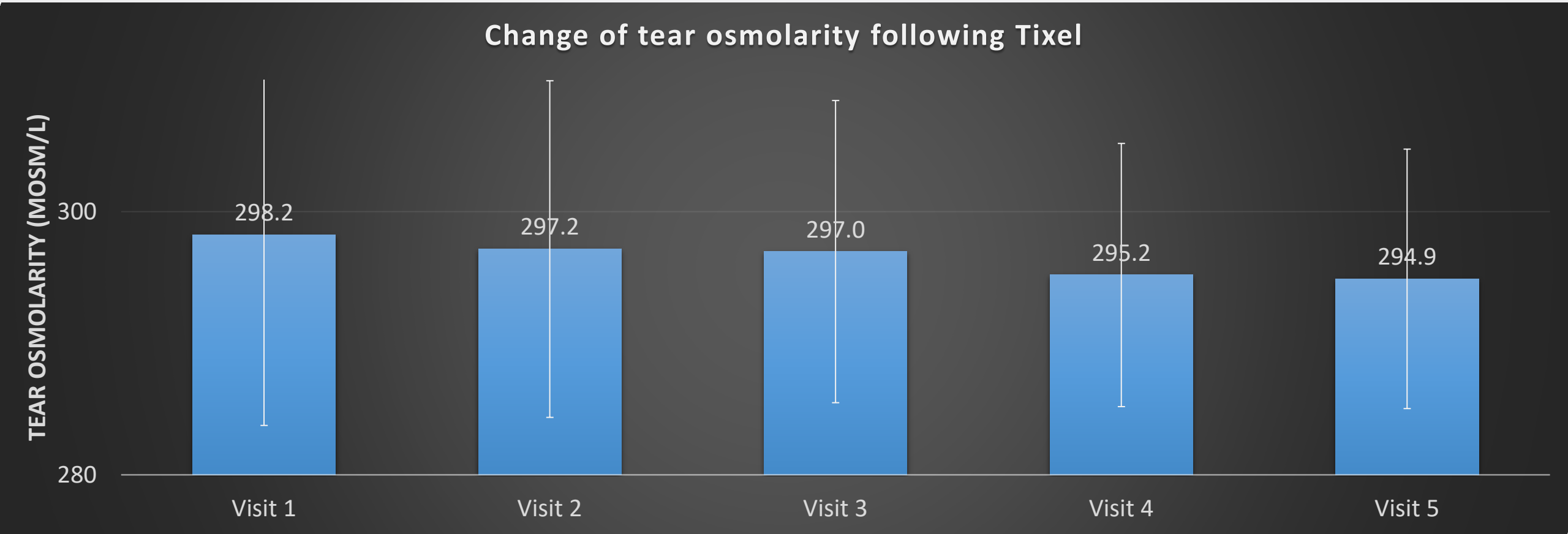
- NIBUT improved by mean 3.1s(P<0.001)



# Results

**Impact of Tixel on OD osmolarity:**

- Tear osmolarity in OD reduced from 298.7±14.6 mOsm/L to 294.9±10.2 mOsm/
- The overall improvement (reduction) was 3.8±0.9 mOsm/L (P=0.056).



# Discussion

## Comparison of Tixel with IPL

| Parameter | Tixel | IPL[3] |
|---|---|---|
| Population | 113 | 57 |
| No. of Treatments | 3 | 4 |
| Change in OSDI | 23.1 ± 13.1 (from 47 to 25) | 7 ± 17 (from 28 to 21) |
| Change in NITBUT | 3.1 | 0.4 |
| Reduction in Osmolarity (Avg.) | 3.8 | 2 |

[3] **Randomised double-masked placebo-controlled trial of the cumulative treatment efficacy profile of intense pulsed light therapy for meibomian gland dysfunction**
Ally L. Xue, Michael T.M. Wang, Susan E. Ormonde, Jennifer P. Craig
Published in Ocular Surface 18 (2020)

# Conclusion

- Tixel improved OSDI scores >23
- OSDI minimum clinically important difference is 4.5 for moderate & 13.4 for severe DED [3]
- NITBUT improved by >3s in 41% of patients
- Osmolality reduced by 3.8 mOsm/L
  - Minimum clinically significant reduction 5 mOsm/L
- Presumed mainly MGD impact

3. Asiedu K et al. *Eye Contact Lens*. 2017;43(4):262–266.