



Efficacy of Novel Tixel Treatment in Reducing Dry Eye Signs and Symptoms, a Prospective Multicentre Clinical Trial

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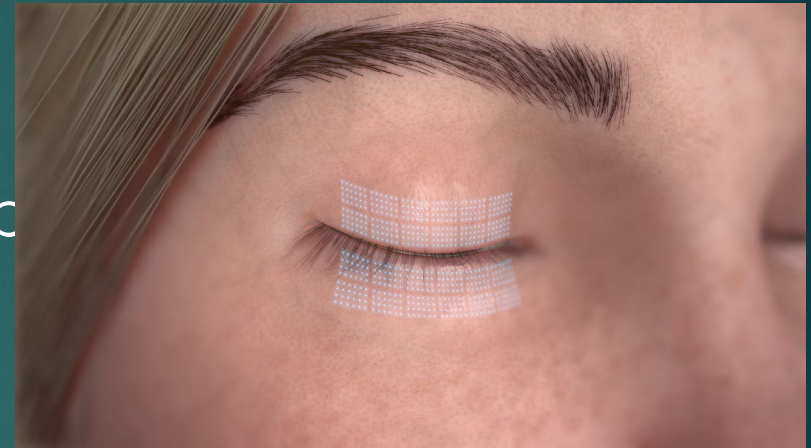
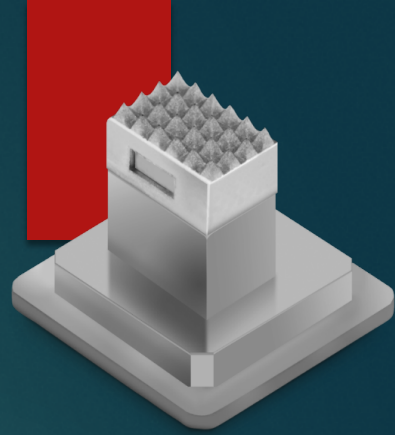
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DISCLOSURE FOR INVESTIGATOR-INITIATED STUDY FUNDED BY NOVOXEL

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**, **inflammation** and damage, and neurosensory abnormalities play key etiological roles.
- **There is a need for novel treatments for DED**



Methods

Design: - multicentre, prospective, controlled, open labelled study

- Midlands Eye, UK, Vallmedic Vision, Andorra and Khmer-Sight Foundation, Cambodia.

Baseline visit- first Tx,; **2nd visit** (t= 2w) 2nd Tx + first FU; **3rd visit** (t= 4w) + second FU, **4th visit** (t= 6w) third FU; **5th visit** (t= 18w) fourth FU

Inclusion Criteria

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

Clinical measurements

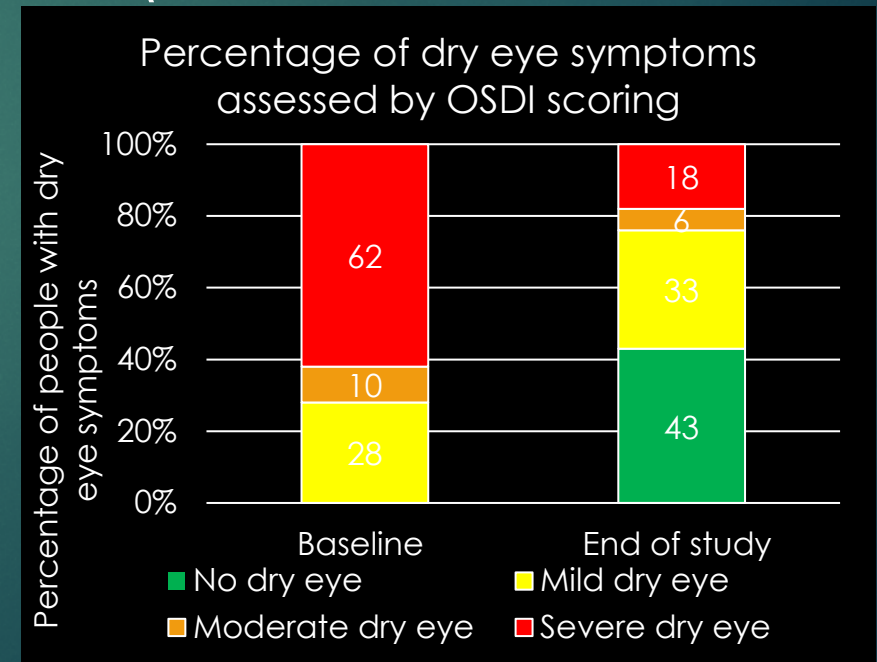
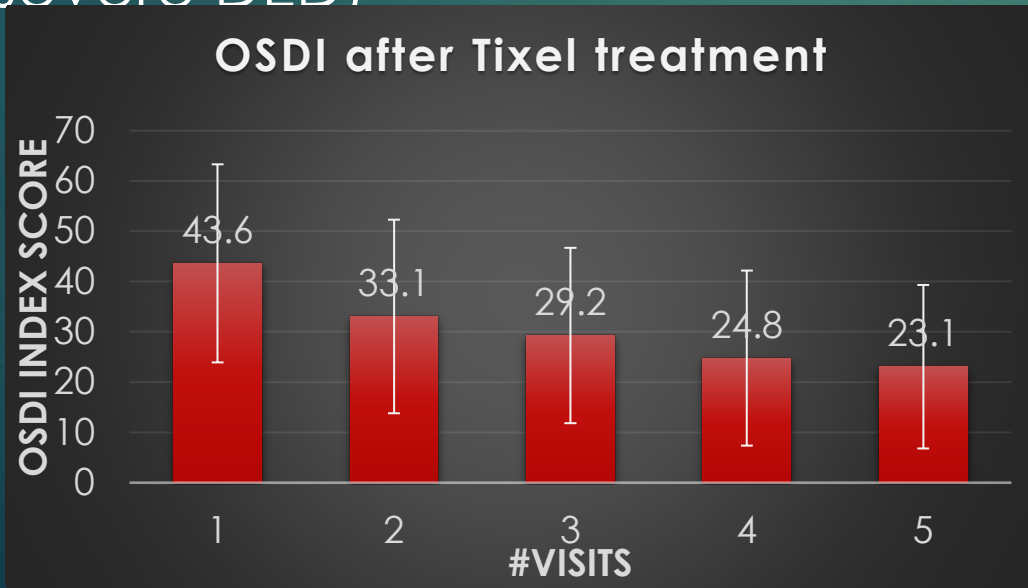
- DED symptoms by OSDI questionnaires
- Tear osmolarity (TearLab)
- NITBUT
- Corneal topography/keratometry
- Detailed slit lamp examination, lid and meibomium gland assessment
- Data from OD analysed and presented

Results

- 120 participants
- Average age 57.7 ± 13.8 years
- 87 females
- Mild erythema and no oedema, disappeared within 2 days
- No change in vision ($P=0.998$)
- No change in IOP ($P=0.894$) observed

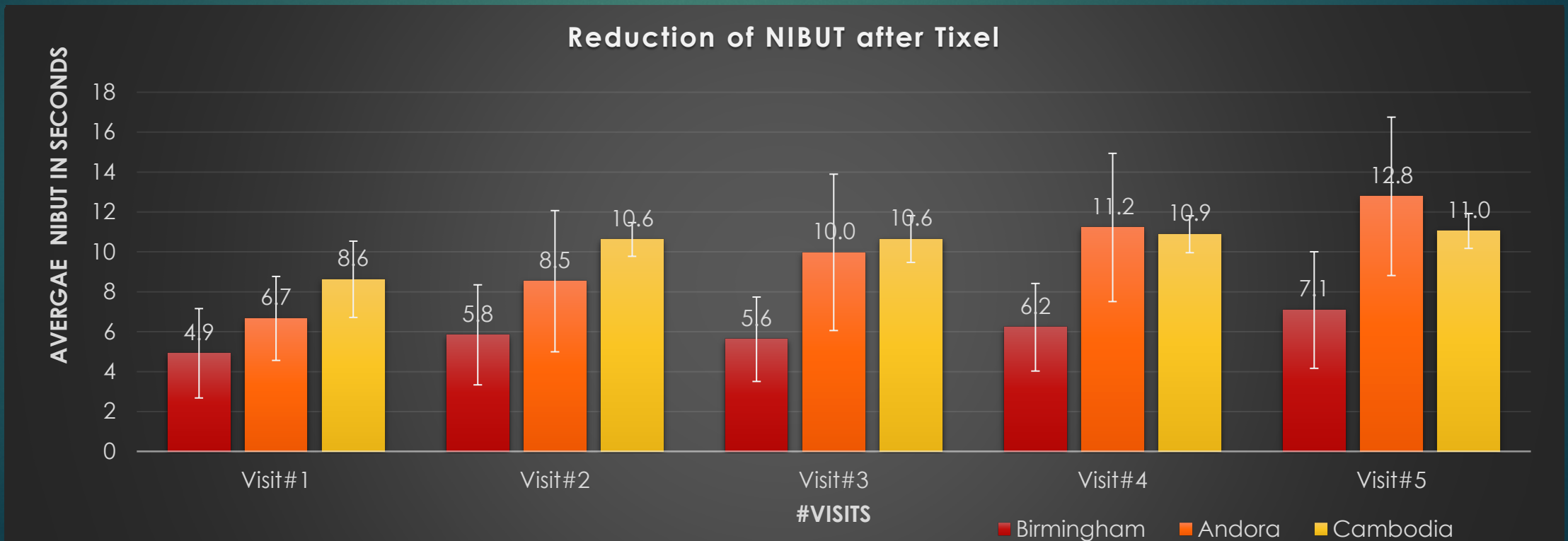
Results: OSDI impact on symptoms

- Improvement in mean OSDI score by 20.6 ± 13.5 ($P < 0.001$)
- 62%, 10% and 28% had moderate and severe symptoms at the start
- after Tixel 18%, 6%, 33% and 43% reported severe, moderate, mild and no dry eye respectively
- 16.8 ± 5.7 and 30.9 ± 9.9 OSDI index improvement for patients moderate and severe dry eye, clinically significant improvement (4.5 for moderate and 13.4 for severe DED)



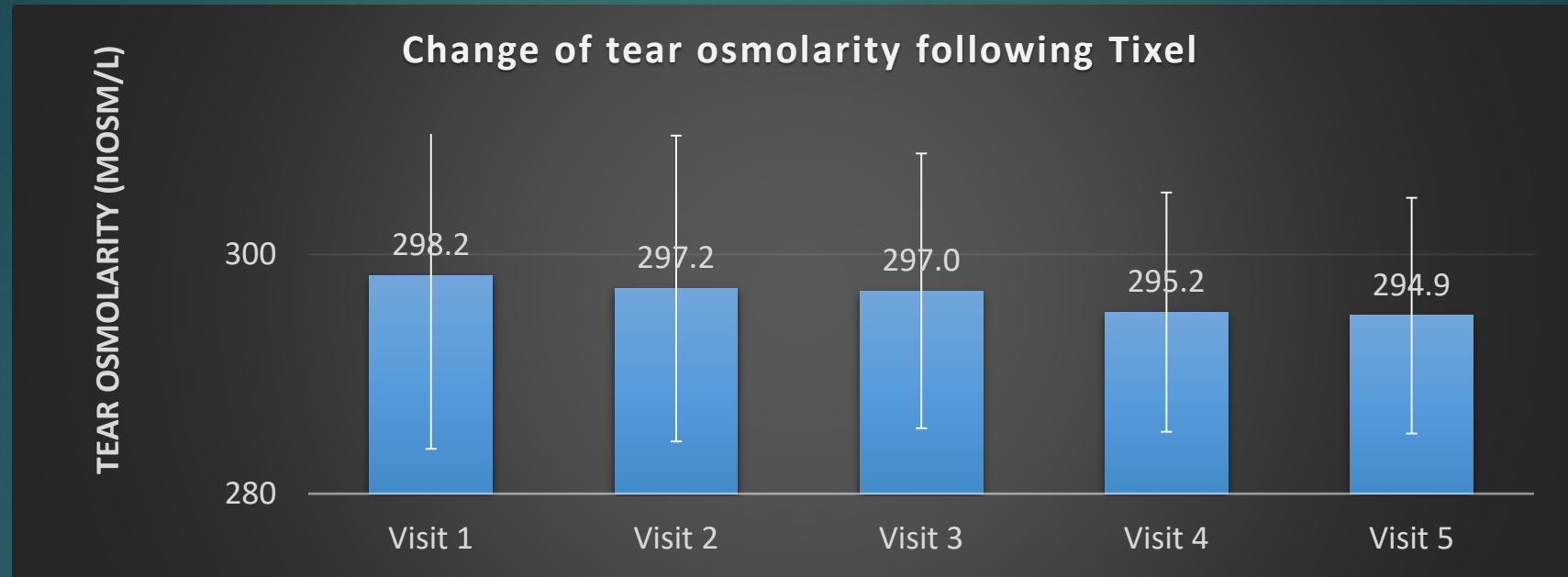
Results

- NIBUT improved 2.2 ± 0.9 in Birmingham centre, 2.4 ± 1.1 in Cambodia, 6.1 ± 2.9 in Andorra centre ($P < 0.05$).
- When all combined 53% improved NITBUT by $>2s$
- 39% improved NITBUT by $>3s$



Results

- Tear osmolarity reduced from 298.3 ± 14.6 mOsm/L to 294.9 ± 10.2 mOsm/L following the treatment ($P=0.059$)



Summary: Thermo-mechanical action based peri-orbital fractional skin treatment can significantly reduce DED signs and symptoms without any adverse event. This is a novel highly attractive treatment for DED.

Thank you