

## Introduction

Dry eye disease (DED) is characterised by hyperosmolarity, ocular surface inflammation, damage and neurosensory abnormalities.<sup>1,2</sup>

The transplantation of human amniotic membrane (AM) has been used for many ophthalmic indications including many related to inflammation of the ocular surface.<sup>3</sup>

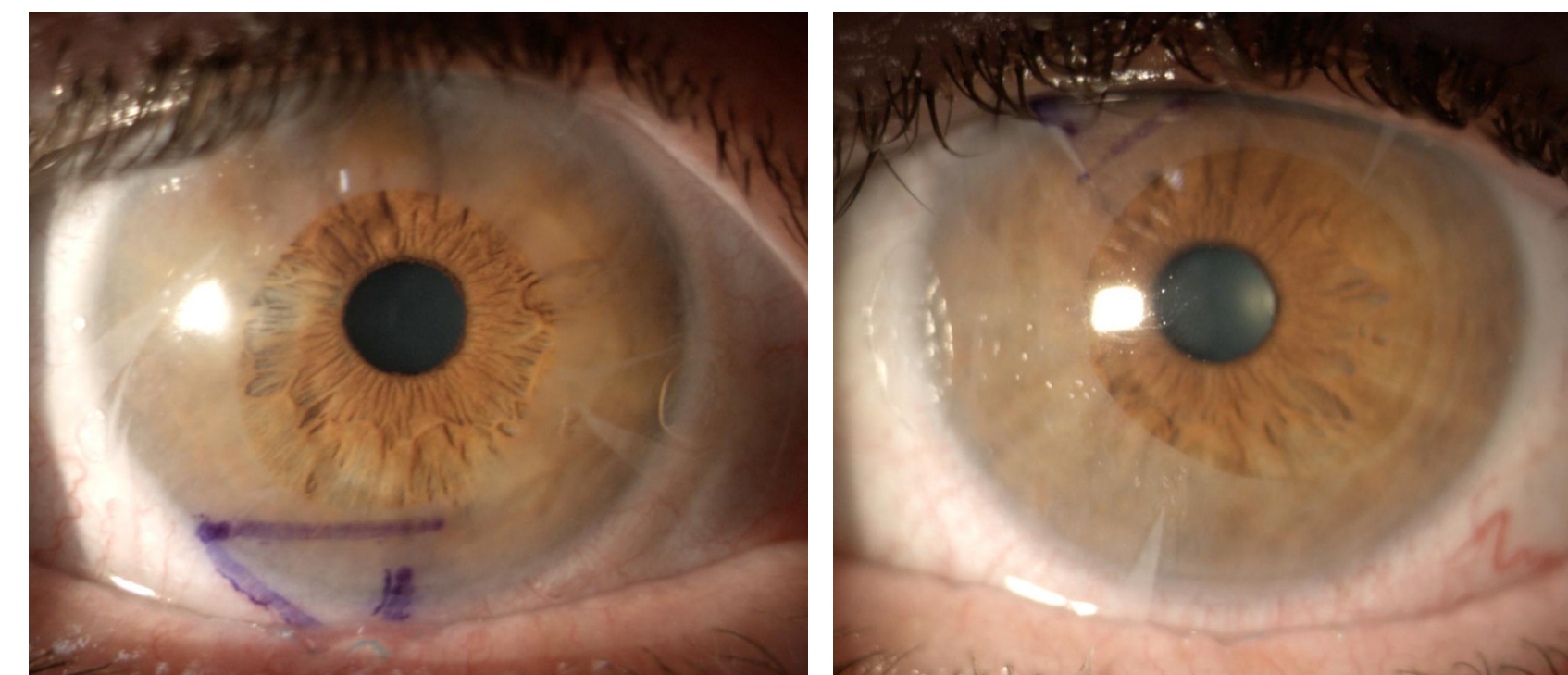
## Purpose

To examine changes in symptomatology and pathology following application of a new design of bandage contact lens (BCL) OmniLenz® with or without Omnigen® dehydrated AM, placed underneath in patients with moderate-to-severe DED.

## Methods

The randomised-controlled trial (NCT04553432);

- Enrolled 42 participants (aged 52±20 years, 31 females).
- Applied bilateral 18mm, plano powered OmniLenz (NuVision Biotherapies) with or without a 17mm diameter with 6mm central 'window' AM (Omnigen, NuVision Biotherapies).



Symptomatology	Homeostasis signs	Ocular surface and tear film signs
Days 0, 15, 30, 90 & 180	Days 0, 15, 30 & 90	Days 0, 15, 30 and 90

Ocular Surface Disease Index (OSDI)

Non-Invasive Break-Up Time (NIKBUT)

Tear Meniscus Height (TMH)

Symptom Assessment Questionnaire in Dry Eye (SANDE)

Ocular surface staining

- Corneal
- Conjunctival
- Lid wiper

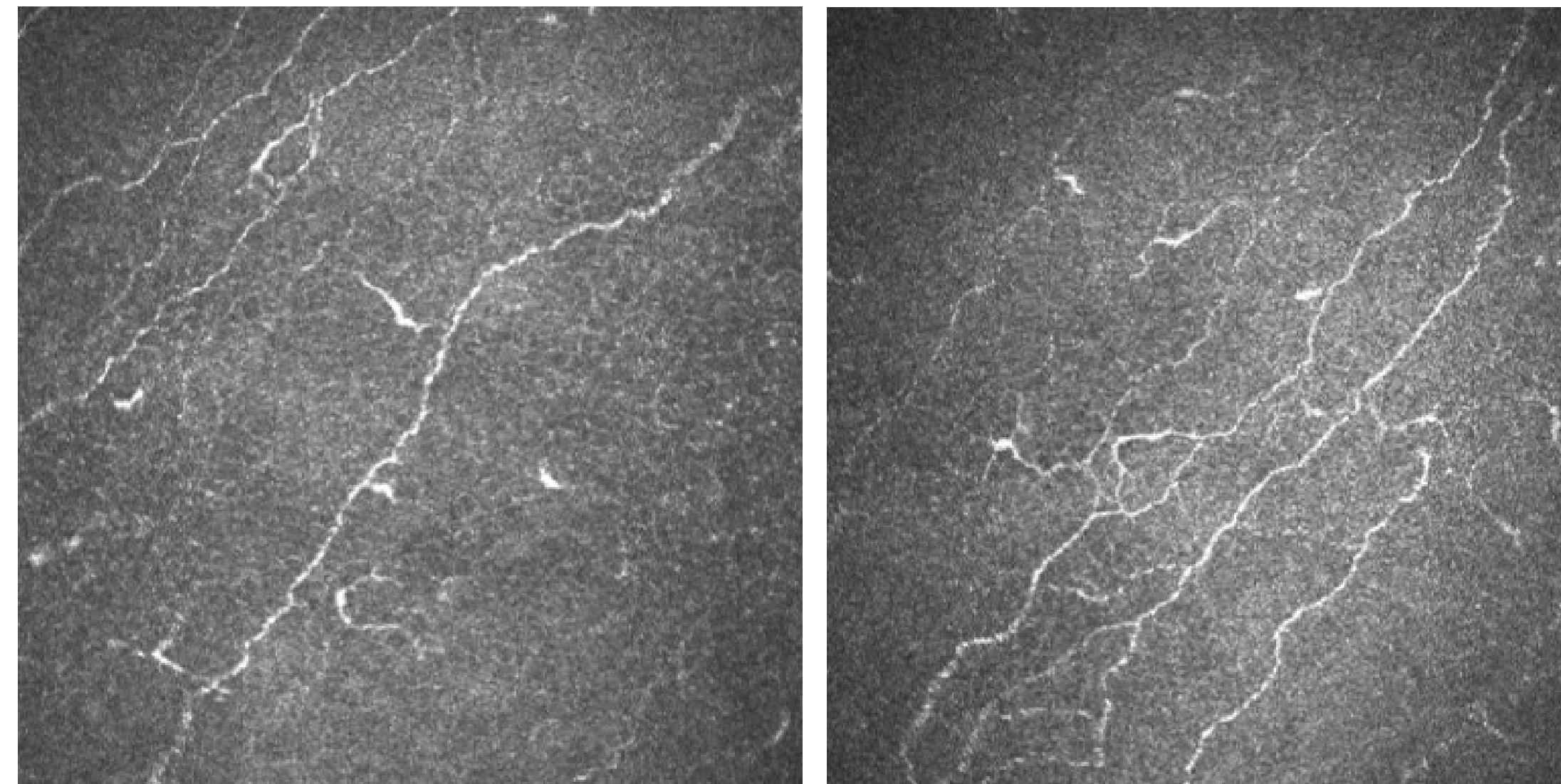
Ocular Hyperaemia

Lipid Layer Thickness (LLT)

In Vivo Confocal Microscopy imaging (IVCM)

## Results

After 3 months (2 consecutive treatments):



Baseline corneal nerve status

3 months post treatment corneal nerve status

Significant **decrease** in:

- **OSDI:** 55.8 to 18.8 (p<0.001)
- **SANDE (p<0.001):**
  - Frequency 68 to 40
  - Severity: 58 to 49

- **Corneal staining:** 1.33 to 0.90 (p=0.032)
- **Conjunctival staining:** 1.81 to 1.17 (p<0.001)

- **LWE**
  - length: 1.90 to 0.93 (p=0.001)
  - width: 1.76 to 0.66 (p<0.001)

Significant **increase** in:

- **Corneal nerve fibre length:** 13.3 to 14.8 (p=0.021)
- **Corneal nerve branch density:** 43.1 to 45.6 (p=0.001)
- **Tear meniscus height:** 0.24 to 0.35mm (p = 0.017)

## Discussion

- First ever randomised-control trial to treat moderate-to-severe dry eye binocularly with a bandage contact lens
- Omnigen AM, applied with OmniLenz BCL, decreases DED symptomatology by 71%.
- Corneal nerves and branches have been noted to increase after treatment delivery at 1 month and lasting up to 3 months.
- Omnigen delivers clinically rapid and significant benefits in moderate and severe DED.

## Conclusions

Treatment for just 1 week:

- Significantly improved dry eye symptoms as well as the ocular surface for at least 3 months.
- Promoted corneal nerve regeneration, making this an exciting short-term new treatment for moderate to severe dry eye disease.

## References

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2. Belmonte C, Nichols JJ, Cox SM, et al. TFOS DEWS II pain and sensation report. Ocular Surface 2017;15(3):404-437, doi:10.1016/j.jtos.2017.05.002
3. Meller D, Pauklin M, Thomassen H, et al. Amniotic Membrane Transplantation in the Human Eye. Deutsches Arzteblatt International 2011;108(14):243-U22, doi:10.3238/arztebl.2011.0243

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