Dry eye OmniLenz application of Omnigen Research Study (DOORS)

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Introduction

Dry eye disease (DED) is characterised by hyperosmolarity, ocular surface inflammation, damage and neurosensory abnormalities.[1, 2]

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

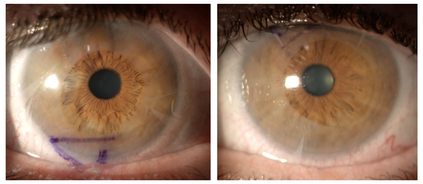
Purpose

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);

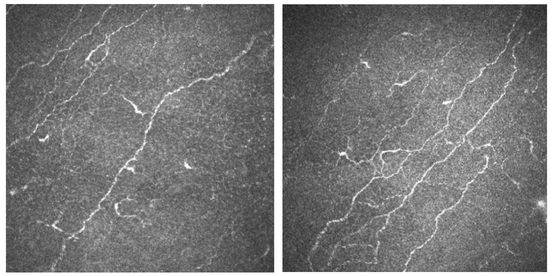
- Enrolled 42 participants (aged 52±20 years, 31 females).
- Applied bilateral 18mm, plano powered OmniLenz (NuVision Biotherapies) with or without a 17mm diameter with 6mm central 'window' AM (Omnigen, NuVision Biotherapies).



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, Thomasen 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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