# The Influence of Scleral Lens Parameters and Fitting Characteristics on Corneal Oedema Under Open and Closed Eye Conditions

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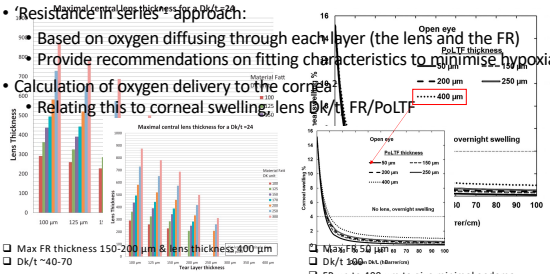
## Theoretical modelling of oxygen transmission

- Resistance in series[1] approach:
  - Based on oxygen diffusing through each layer (the lens and the FR)
  - Provide recommendations on fitting characteristics to minimise hypoxia
- Calculation of oxygen delivery to the cornea[2]
  - Relating this to corneal swelling; lens Dk/t, FR/PoLTF




- Max FR thickness 150-200 µm & lens thickness 400 µm
- Dk/t ~40-70

- Max FR 50 µm
- Dk/t 100
- FR up to 400 µm to give minimal oedema

1. Michaud, 2012. 2. Kim, 2018

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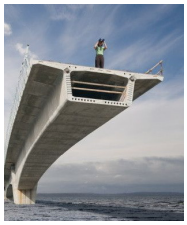
## Limitations of previous research

- **Theoretical models**
  - The behaviour of $O_2$ and $CO_2$ across the cornea is difficult to predict[1]
  - Assume no tear exchange
  - Typically use central lens thickness only
  - Do not agree with empirical data or clinical experience
- **Empirical studies**
  - Narrow range of FR thickness
  - Minimal data on closed eye conditions
  - Small sample size for lens thickness studies
  - No study has measured corneal oedema with a lens fenestration



1. Papas, 2014

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## AS-OCT repeatability

**Aim**

- To determine optimum number of B scans and volumetric protocol

**Participant details**

- 15 participants aged between 20 – 37 years
- Visual acuity of 0.00 logMAR or better
- No ocular pathology or contraindications to contact lens wear

**Methodology**

- Spectralis Anterior Segment OCT used to capture images (3.9 µm axial resolution)
- Custom written software used to manually segment OCT images

**Statistical Analysis**

- Bland-Altman plots
  - Comparing number of B scans (single line) and number of lines (volumetric) along with intraobserver and intrasession comparisons
  - 95% limits of agreement with exact 95% confidence intervals[1]

1. Carkeet, 2015

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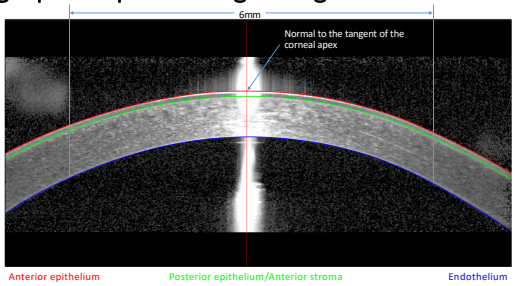
## Segmented Spectralis OCT image

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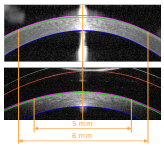
## Experiment 1- Conclusions

- This protocol gave intrasession repeatability of:

| | Mean difference ± SD | 95% Limits of Agreement | Outer 95% Confidence Intervals of Limits of Agreement | |
|---|---|---|---|---|
| | (µm) | (µm) | (µm) | (% of layer) |
| EPITHELIUM | -0.8 ± 1.5 | -3.6 to 2.1 | -5.5 to 3.9 | ± 7.6 |
| STROMA | 0.1 ± 1.6 | -3.0 to 3.2 | -5.0 to 5.2 | ± 1.0 |
| TOTAL | -0.7 ± 1.9 | -4.4 to 3.0 | -6.8 to 5.4 | ± 1.1 |

- To optimise intrasession repeatability of estimates of central corneal thickness, the following protocol was used:
  - 20 B-scans
  - 5 mm metric
  - Average of 3 line scans

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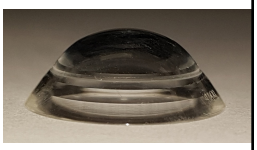
## Corneal oedema and scleral lens wear

Design
- Repeated measures approach
- Central corneal thickness measured before and after 90 minutes of lens wear
  - Lid patched for closed eye condition
- Spectralis Anterior Segment OCT- 3.9 µm axial resolution

Participants- using the one study cohort
- 10 healthy 24-37 years old with no ocular pathology
- Visual acuity of 0.00 logMAR
- No contraindications to contact lens wear

Scleral lens design
- Highly oxygen permeable material (Dk 141)
- ICD 16.5 mm total diameter
- Parameters kept constant except for variable of interest:
  - Fluid reservoir thickness
  - Central lens thickness
  - Single 0.3 mm diameter peripheral fenestration



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## Corneal oedema and scleral lens wear

| FR thickness target groups (µm) | Low | Medium | High |
|---|---|---|---|
| | 150 µm | 500 µm | 750 µm |

*Controlling for lens thickness

| Nominal Central Lens Thickness (µm) | 150 | 300 | 600 | 1200 |
|---|---|---|---|---|

*Controlling for fluid reservoir thickness

| Fenestrated vs Non-fenestrated |
|---|

*Controlling for fluid reservoir thickness and lens thickness

**Analysis: RM-ANOVA examining the effect of**
- Lens wear condition (open or closed eye)
- FR thickness
- Average central lens thickness
- Lens fenestration
- Interactions

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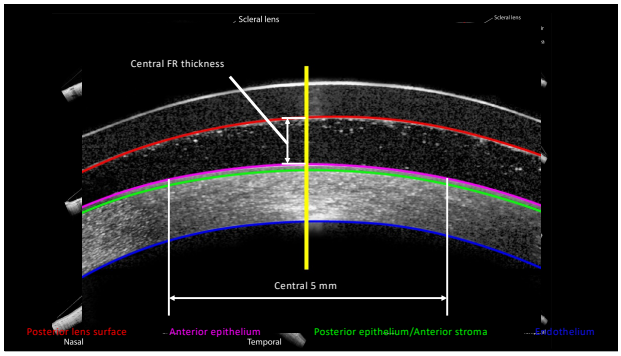


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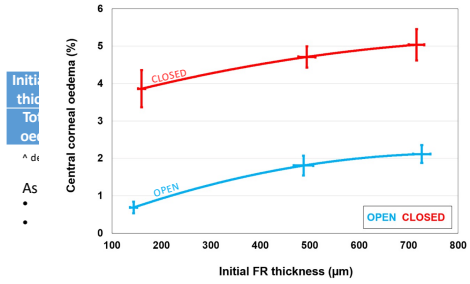
## Effect of FR thickness on corneal oedema




| RM-ANOVA |
|---|
| F10-2, p-value |
| 506, <0.001 |
| 607, <0.001 |
| 39, < 0.001 |
| 9, 0.002 |

Error bars are standard error

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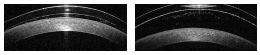
## Effect of FR thickness



Summary
- Increasing FR thickness caused a small increase in corneal oedema for both open and closed eye conditions
- Comparison to models
  - Open eye
    - Resistance in series modelling greatly over-estimated oedema for FR values > 300 µm.
    - Oxygen metabolism model gave some agreement, but slightly under-estimated levels.
  - Closed eye
    - ~3% more oedema than open eye data
    - Significantly lower levels of oedema due to the short term (90 mins) lens wear compared to overnight
    - The rate of increase in corneal oedema with increasing FR thickness is much lower than predicted

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## Effect of central lens thickness on oedema

| | | Nominal Central Lens Thickness (µm) (Mean ± SE) | | | | RM-ANOVA |
|---|---|---|---|---|---|---|
| | Lids | 150 | 300 | 600 | 1200 | F(9,3), p-value |
| Initial central FR thickness (µm) | Open | 419 ± 22 | 489 ± 18 | 528 ± 27 | 512 ± 28 | 5.84, 0.004 |
| | Closed | 431 ± 24 | 508 ± 19 | 539 ± 27 | 532 ± 25 | 5.9, 0.004 |
| Total corrected corneal oedema (µm) | Open | 1.14 ± 0.22 | 1.36 ± 0.26 | 1.74 ± 0.30 | 2.13 ± 0.24 | 3.54, 0.03 |
| | Closed | 4.31 ± 0.32 | 4.55 ± 0.42 | 4.92 ± 0.50 | 4.83 ± 0.22 | 1.66, 0.20 |

- Bonferroni corrected difference ($p < 0.05$)
- A correction was applied where a 2nd order polynomial was fitted to central corneal oedema data as a function of FR thickness for each participant
- This was used to estimate the difference in oedema due to the difference in FR thickness relative to the thinnest initial FR thickness

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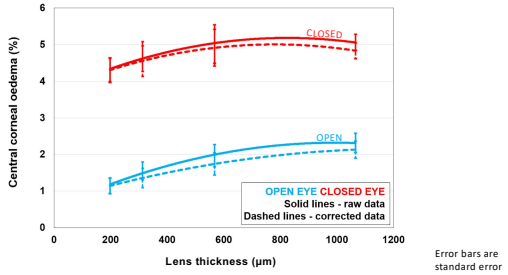
## Effect of central lens thickness

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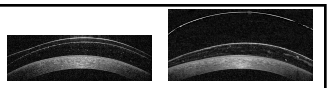
## Effect of central lens thickness



Summary

- Increasing central lens thickness caused a small increase in corneal oedema for both open and closed eye conditions
- Difference from modelling may be due to increased tear mixing or exchange with decentration or lens movement due to a thicker lens
- Comparisons
  - ❖Open eye
    - ➢Showed similar levels of oedema with studies by Pullum[1,2,3] up to 600 µm thickness
    - ➢Resistance in series modelling overestimated oedema by ~53%
    - ➢Oxygen metabolism modelling demonstrated reasonable agreement for Dk/t ~30 to 70
  - ❖Closed eye
    - ➢Rate of change deviates with Dk/t below ~30

1. Pullum, 1990. 2. Pullum, 1991 3. Pullum, 1997

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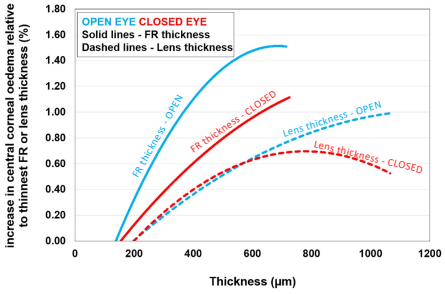
## FR thickness vs Lens thickness

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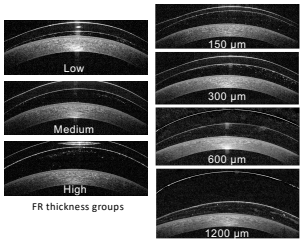
## FR thickness vs Lens thickness

Summary

- Increasing FR or central lens thickness resulted in slightly increased oedema
- Altering FR thickness has a larger effect on oedema possibly related to Dk of tears
- Oxygen metabolism modelling is consistent with open eye data but not with the rate of oedema increase shown in closed eye

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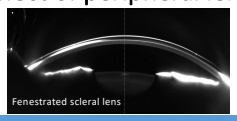
## Effect of peripheral lens fenestration




| | Fenestrated | Non-fenestrated | P-value |
|---|---|---|---|
| | Mean ± SE | | |
| Initial central FR thickness (µm) | 151 ± 14 | 146 ± 8 | 0.78 |
| Total corrected corneal oedema (µm) | 0.50 ± 0.36 | 0.62 ± 0.16 | 0.81 |

- A correction was also applied to this data for each participant
- Peripheral lens fenestration caused no significant difference in oedema levels
- While the 0.12% difference is statistically insignificant, it is a 19% relative reduction in oedema that may still be of clinical benefit when fitting a compromised cornea

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## Conclusions

- Increased FR thickness and central lens thickness results in a small increase in corneal oedema with FR thickness having the larger effect
  - ❖Oxygen metabolism modelling showed reasonable agreement with open eye data
  - ❖The rate of increase in corneal oedema with increased FR thickness or central lens thickness is lower during closed eye conditions compared to theoretical modelling
- Perhaps the increased FR alters oxygen dynamics to convection transport rather than passive diffusion resulting in increased tear exchange
- Increased lens thickness perhaps causes increased lens decentration or movement which could increase tear exchange
- A small single lens fenestration had no significant effect on corneal oedema compared to a similarly fitted non-fenestrated scleral lens

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## Clinical implications

- Limit scleral lenses to daily wear unless constant corneal protection
  - Gives a relative reduction in oedema from 54-82%
- Consider thinnest practical central FR and lens thickness to reduce oedema
  - Reducing FR thickness from 500-700 to 150 µm can give ~65% reduction
  - Reducing lens thickness from 300-1200 to 150 µm can give a 26-50% reduction
- The incorporation of a lens fenestration can achieve a further reduction
  - A potential 19% relative reduction
  - An important consideration when fitting a compromised cornea

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