

Comparison of Two Lens Materials and their Effects on Corneal Hypoxia in Scleral Lens Wear Over Time – A Pilot Study

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Introduction

- Hypoxic stress to the cornea remains a concern when considering scleral lenses (SL) on corneas with low endothelial cell count or as the industry moves toward fitting regular corneas for refractive purposes
- To minimize corneal hypoxia during scleral lens wear, it is important to limit the fluid reservoir thickness and to maximize the lens material's Dk/t value (1)
- Previous studies (2-5) have examined the effect of varying these two parameters on corneal edema, however, since then, new materials have entered the market, namely those with hyper-Dk values (200)
- This pilot study aims to compare the clinical impact on oxygen delivery to the cornea of scleral lenses manufactured with different gas permeable materials worn on a daily wear schedule

Materials and Methods

- Investigational pilot study
- Comparison of two pairs of SL made of different material (see lens parameters in table 1)
 - Lens 1 (L1): Rofuflocon D (Dk = 100)
 - Lens 2 (L2): Tisilfocon A (Dk = 200)
- Participants were randomly assigned to wear L1 or L2 for 6 hours at Visit 1, and the other lens at Visit 2 (>72hrs from V1)
- Lenses were adjusted for each participant and were purposefully fit with a central clearance of 400 um and a lens thickness of 350 um to favor corneal swelling
- Both lens thickness and reservoir thickness were kept constant for each participant. Each lens was adjusted with toric peripheries (200 um diff) to minimize tear exchange
- Central AS-OCT measurements made at 45 mins (t1), 90 mins (t2), 2 hrs (t3), 4 hrs (t4), 6 hrs (t5) and thereafter lens removal (t6)
 - These measurements were taken at the same time of day for each participant to minimize the effect of diurnal corneal thickness variation
- Central corneal thickness (CCT), fluid reservoir thickness (FRT) and the lens Dk/t were documented and analyzed using a repeated measures ANOVA (SPSS 24)
- A paired t-test was used to analyze the difference between L1 and L2
- Only the results from OD were analyzed

Results

- Two subjects (F, 24.5 ± 0.5 years old) completed the study
- The FRT of L1 and L2 significantly decreased over time (p=0.022), by 88.50 um (L1) and 120.50 um (L2) over 6 hrs
- There is a significant difference between the CCTs of L1 and L2 (p=0.664)
 - L1 → CCT increased immediately at lens insertion (0.4% compared to baseline), reached a 3-4% increase after 45 mins and did not vary significantly thereafter (p=0.284)
 - CCT did not increase for L2 at any time point; after 6 hours, CCT showed a 0.29% decrease compared to baseline, following natural corneal deswelling
- The mean Dk/t for L1 was 25.47±0.56 and that for L2 was 53.11±1.07
 - This demonstrates that there is 108.53% (or roughly twice as much) increase in supplementary oxygen provided to the cornea with the lens made of a higher Dk material
- L2's effect regarding corneal oxygenation increases over time; as CCT increased for L1, L2's CCT remained constant and therefore the difference between the two increased with time.

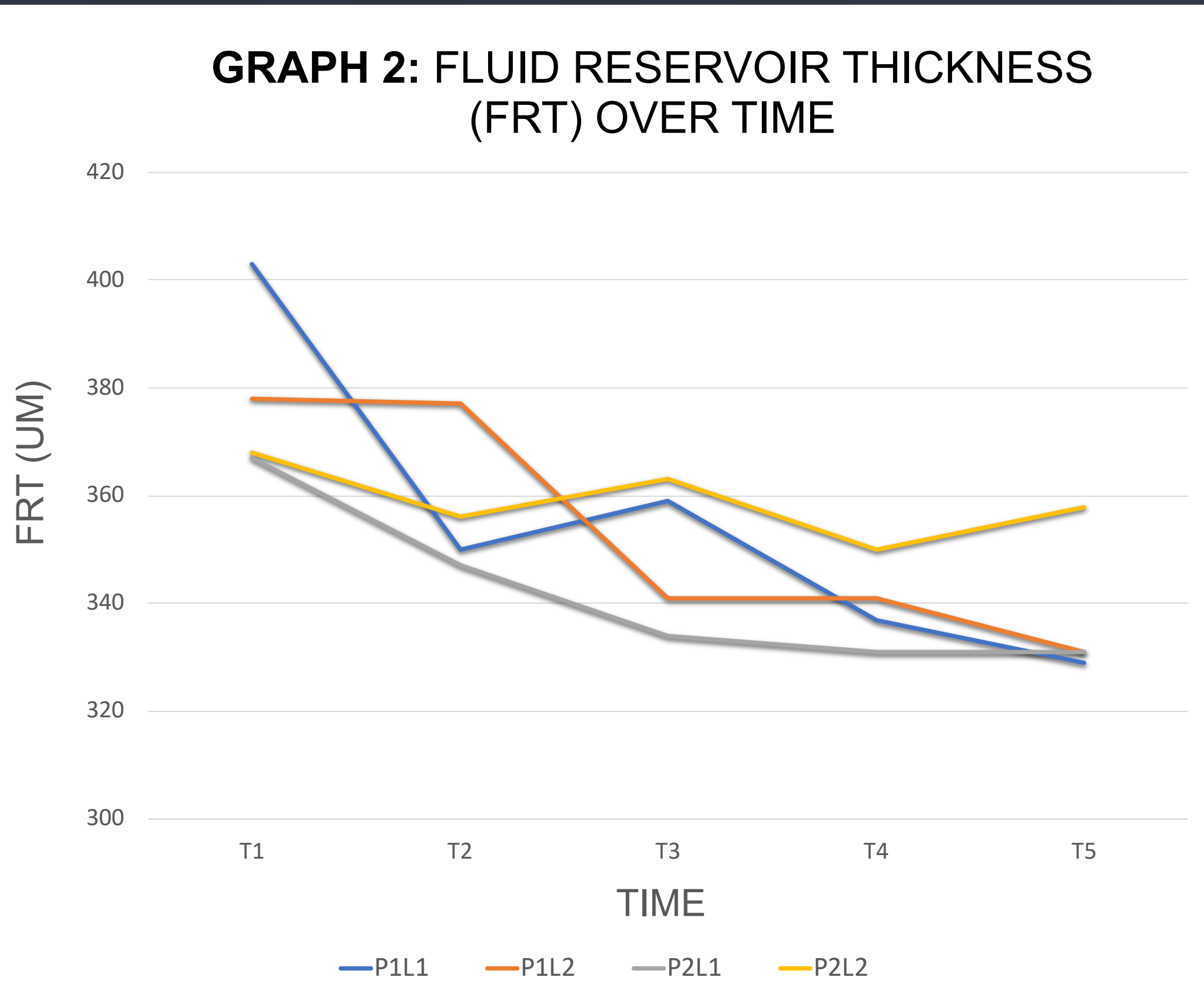
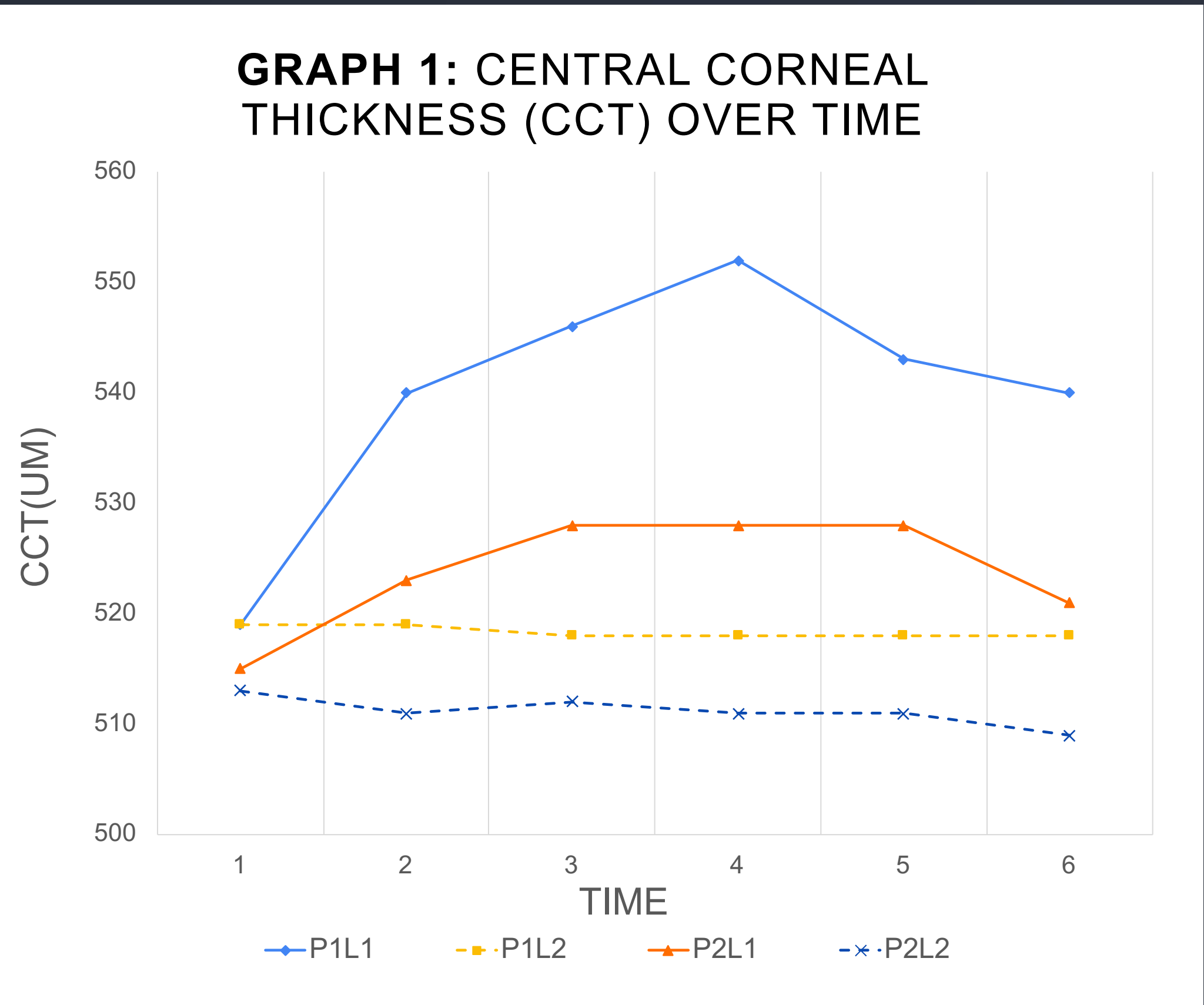


TABLE 1					
Lens parameters – OneFit MED (Laboratoires Blanchard, Sherbrooke, Canada)					
		OD		OS	
Participant 1	<i>Sag</i>	4450 µm		<i>Sag</i>	4450 µm
	<i>M</i>	-150 µm		<i>M</i>	-200 µm
	<i>L</i>	-50 µm		<i>L</i>	-50 µm
	<i>Edge</i>	+125 µm / -75 µm		<i>Edge</i>	+125 µm / -75 µm
	<i>Diam</i>	15.6 mm		<i>Diam</i>	15.6 mm
	<i>Power</i>	-6.75 D		<i>Power</i>	-7.75 D
Participant 2	<i>CT</i>	350 µm		<i>CT</i>	350 µm
	<i>Sag</i>	4600 µm		<i>Sag</i>	4600 µm
	<i>M</i>	-150 µm		<i>M</i>	-150 µm
	<i>L</i>	-50 µm		<i>L</i>	STD
	<i>Edge</i>	+125 µm / -75 µm		<i>Edge</i>	+125 µm / -75 µm
	<i>Diam</i>	15.6 mm		<i>Diam</i>	15.6 mm
	<i>Power</i>	-7.12 D		<i>Power</i>	-6.37 D
	<i>CT</i>	350 µm		<i>CT</i>	350 µm

Discussion and Conclusion

- This pilot study suggests that a higher Dk material is associated with a significant reduced hypoxic stress to the cornea, over 6 hours of scleral lens wear
- The corneas of the participants used in this study were thinner than normal – we cannot extrapolate these results for thicker corneas
- Future studies on a larger group of participants are needed to confirm if higher Dk materials may become the norm to prescribe scleral lenses whenever lowering hypoxic stress to the cornea is required

References

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