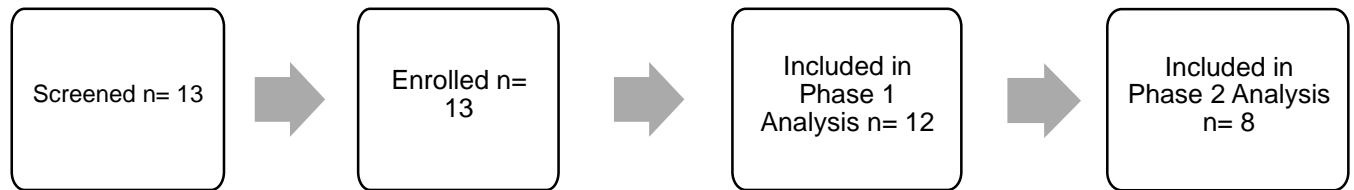


Study Title: Clinical Evaluation of Scleral Contact Lenses

Participants



Baseline Characteristics

Table 1 - Gender and Age of Study Population for Phase 01

	Overall
N	12
Gender	
Female	7 (58.3%)
Male	5 (41.7%)
Age	
Mean	55.00
Std. Dev	6.5

Table 2 - Gender and Age of Study Population for Phase 02

	Overall
N	8
Gender	
Female	5 (62.5%)
Male	3 (37.5%)
Age	
Mean	53.90
Std. Dev	6.1

Outcome Measures Phase 1

Primary Outcome Measure – Contact Lens Centration

**Table 3 – Decentration from Pupil Centre after 40 Minutes of Wear
Descriptive Statistics (distances in millimetres– angles in degree)**

		Horizontal Distance 40mins	Vertical Distance 40mins	Total Distance 40mins	Angle 40mins
Primary	N	39	39	39	39
	Mean	0.480	-0.584	0.843	283
	Std-Dev	0.284	0.376	0.282	81
Downgaze	N	36	36	36	36
	Mean	0.532	-0.054	0.703	172
	Std-Dev	0.359	0.390	0.265	146

Secondary Outcome Measure – Corneal Clearance

**Table 4 – Tear Layer Thickness at Contact Lens Apex
Descriptive Statistics (distances in µm)**

	TLT Apex 0 mins	TLT Apex 20 mins	TLT Apex 40 mins
N	43	45	44
Mean	512	470	452
Std-Dev	191	161	169

Adverse Events

Table 5 – Adverse Events

Number of participants affected	Event	Status
2	Hyperaemia	Resolved
1	Staining	Resolved

Outcome Measures Phase 2

Primary Outcome Measure – Contact Lens Centration

**Table 6 – Overall Decentration from Pupil Centre
Overall Descriptive Analysis – Phase 1 vs Phase 2**

Total Distance	Phase 1				Phase 2			
	Primary		Downgaze		Primary		Downgaze	
	20 mins	40 mins	20 mins	40 mins	20 mins	40 mins	20 mins	40 mins
N	10	10	9	10	12	10	9	8
Mean	0.790	0.864	0.700	0.683	0.988	1.014	0.836	0.667
Std-Dev	0.279	0.263	0.292	0.148	0.225	0.283	0.240	0.279

Secondary Outcome Measure – Corneal Clearance

Table 7 – TLT from Contact Lens Centre - Descriptive Statistics

	TLT Apex 0 mins (µm)	TLT Apex 20 mins (µm)	TLT Apex 40 mins (µm)
N	13	13	13
Mean	307	296	272
Std-Dev	62	54	80

Adverse Events

No adverse event, device deficiency or quality complaints were reported In Phase 2.