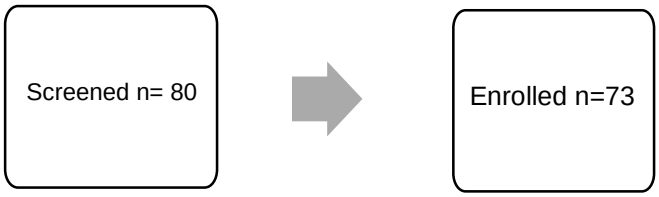
Study Title: Clinical Investigation Of Buttermere(LENS271) Soft Contact Lenses

Phase 1: Cross Over Phase

Participants



1. Baseline Characteristics

	Overall	8 to 15 years	16 to 18 years
N	70	24	46
Gender			
Female	50 (71.4%)	16 (66.7%)	34 (73.9%)
Male	20 (28.6%)	8 (33.3%)	12 (26.1%)
Age			
Mean	15.8	13.5	17.0
Median	16.0	14.0	17.0
Std-Dev	1.9	1.4	0.7

2. The Study Primary Outcome Measure the measured absolute decentration from the pupil centre after at least three (3) hours of wear at the follow-up visit

Table 1 Contact Lens Measured Absolute Decentration at Follow-up – Descriptive and Comparative Statistics

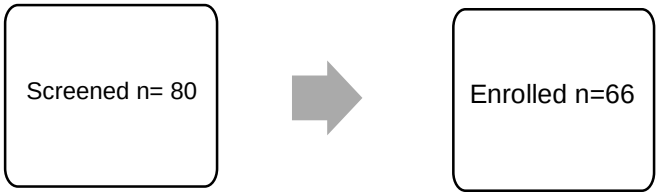
Primary Gaze	Horizontal Distance	Vertical Distance	Total Distance
CONTROL			
N	140	140	140
Mean	0.276	-0.016	0.380
Median	0.293	-0.026	0.363
Std. Dev	0.208	0.238	0.177
TEST			
N	140	140	140
Mean	0.250	0.064	0.354
Median	0.257	0.047	0.320
Std. Dev	0.201	0.219	0.169

3. Adverse Events:

There were eleven non-significant adverse events during the crossover phase. Eight adverse events were non ocular and three were ocular. All Adverse events were classified as non-serious non-significant.

Phase 2: Parallel Group

Participants



1- Baseline Characteristics

	Overall	Control	Test
N	66	33	33
Gender			
Female	49 (74.2%)	24 (72.7%)	25(75.8%)
Male	17 (25.8%)	9 (27.3%)	8 (24.2%)
Age			
Mean	15.8	15.8	15.8
Median	16.0	16.0	16.0
Std-Dev	2.0	2.0	2.0

2- The Study Primary Outcome Measure: Safety Assessment

The incidence and severity of study product related adverse events during the parallel phase study period constituted the first study safety endpoint.

There were nine non- serious non-significant adverse events. Six adverse events were non-ocular and three were ocular. One of the ocular adverse events (#51) was not study product related, whereas two (#16, #39) were associated with wearing the Control product - both were minimal events that were classified as adverse events because the contact lenses were removed temporarily that day but are usually considered as contact lens side effects (discomfort).

The review of adverse events that occurred during the study demonstrated an excellent safety profile for both the Test and Control contact lenses under the condition of the test.