

Introduction

- A large percentage of patients experience contact lens discomfort, which limits their wear time and, in many instances, eventually results in discontinuation of contact lens use.¹⁻⁴
- It has been estimated that 21% to 64% of contact lens wearers permanently discontinue contact lens use because of ocular discomfort.¹⁻⁴
- The Orthokeratology and Contact Lens Quality of Life (OCL-QoL) questionnaire is a psychometrically (Rasch Analysis) validated instrument that was developed for understanding patient-reported visual quality of life for use with all forms of contact lens correction.⁵
- The impact of contact lens discomfort on a patient's quality of life has yet to be fully evaluated.

Purpose: The purpose of this study was to understand how contact lens discomfort impacts the visual quality of life of uncomfortable daily disposable contact lens wearers.

Methods

- This was a three site, randomized clinical trial that enrolled daily disposable contact lens wearers who had clinically meaningful contact lens discomfort (Contact Lens Dry Eye Questionnaire (CLDEQ)-8 scores ≥ 12).⁶
- Enrolled subjects were randomized to Systane Complete (artificial tear), Sensitive Eyes (rewetting drop), or no treatment.
- Enrolled subjects were asked to complete the OCL-QoL (0-100; 100 = best), CLDEQ-8 (0-37; 0 = best), CLDEQ-4 (0-18; 0 = best; subset of CLDEQ-8 questions that analyzes dryness trait), and Standardized Patient Evaluation of Eye Dryness (SPEED; 0-28; 0 = best) questionnaires.⁷
- Right eyes of subjects underwent a short dry eye evaluation (invasive tear break up time, Schirmer's I test without anesthetic).
- ANOVA were used to make group comparisons, paired t-tests were used to compare metrics by group to baseline values, and Pearson's correlation coefficients were used to determine associations between clinical factors and visual quality of life (OCL-QoL) scores.

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References

- Pritchard N, Fonn D, Brazeau D. Discontinuation of contact lens wear: a survey. *Int Contact Lens Clin* 1999;26:157-162.
- Young G, Veys J, Pritchard N, Coleman S. A multi-centre study of lapsed contact lens wearers. *Ophthalmic Physiol Opt* 2002;22:516-527.
- Begley CG, Chalmers RL, Mitchell GL, et al. Characterization of ocular surface symptoms from optometric practices in North America. *Cornea* 2001;20:610-618.
- Sulley A, Young G, Hunt C. Factors in the success of new contact lens wearers. *Cont Lens Anterior Eye* 2017;40:15-24.
- McAlinden C, Lipson M. Orthokeratology and Contact Lens Quality of Life Questionnaire (OCL-QoL). *Eye Contact Lens* 2018 Sep;44(5):279-285.
- Chalmers RL, Keay L, Hickson-Curran SB, Gleason WJ. Cutoff score and responsiveness of the 8-item Contact Lens Dry Eye Questionnaire (CLDEQ-8) in a large daily disposable contact lens registry. *Cont Lens Anterior Eye* 2016.
- Pucker AD, Dougherty BE, Jones-Jordan LA, Kwan JT, Kunnen CME, Srinivasan S. Psychometric Analysis of the SPEED Questionnaire and CLDEQ-8. *Invest Ophthalmol Vis Sci* 2018;59:3307-3313.

Results

Figure 1: Study Flow Diagram.

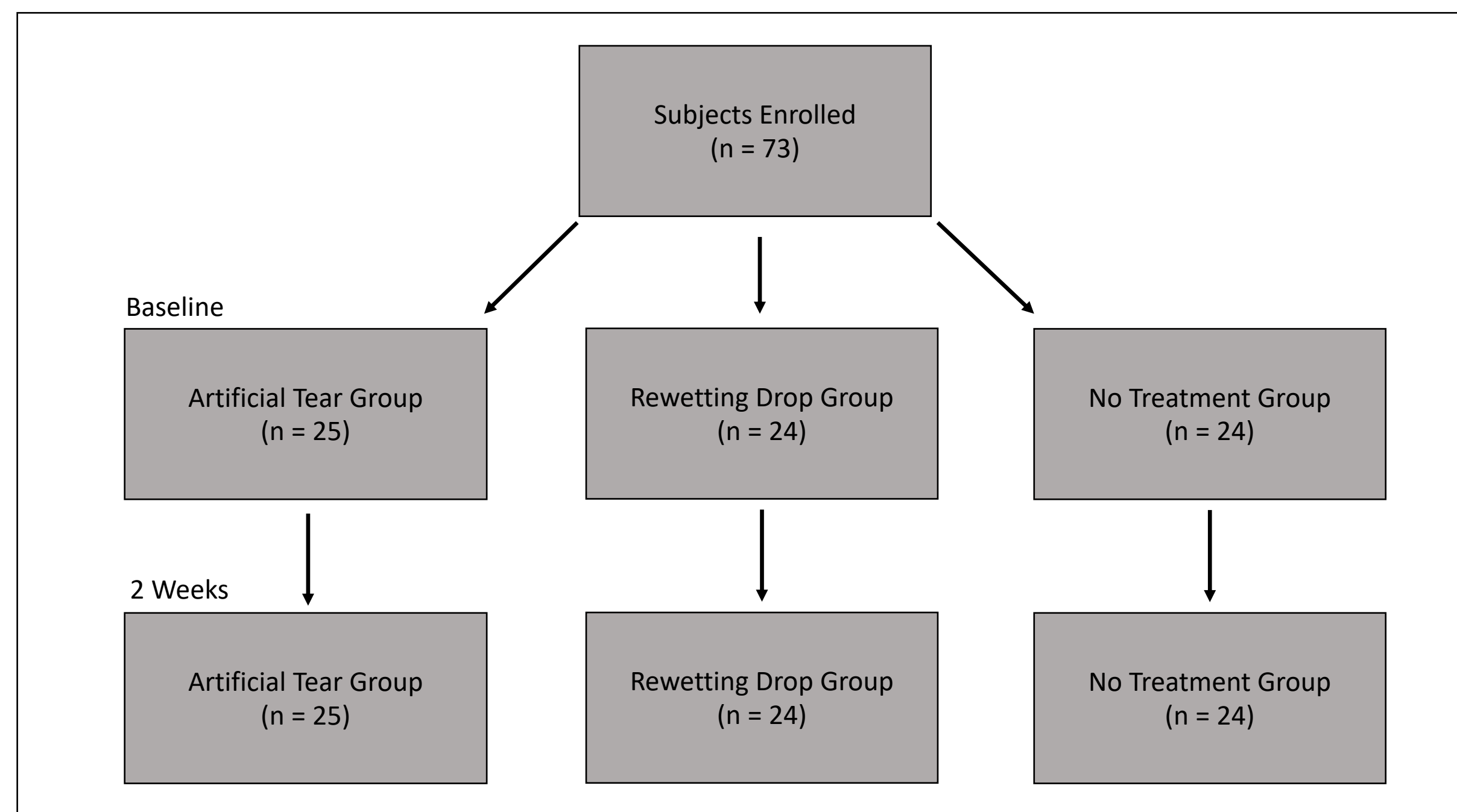


Table 1: Correlations Between Clinical Tests and Orthokeratology and Contact Lens Quality of Life (OCL-QoL) Questionnaire Scores.

Characteristic	Study Sample at Baseline (n = 73)		Study Sample at Two Weeks (n = 73)	
	r	p-value	r	p-value
Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8)	-0.54	<0.0001	-0.34	0.0032
Contact Lens Dry Eye Questionnaire-4 (CLDEQ-4)	-0.42	0.0002	-0.24	0.043
Standardized Patient Evaluation of Eye Dryness (SPEED)	-0.39	0.0007	-0.39	0.0007
Mean Sodium Fluorescein Tear Break Up Time (seconds)	-0.063	0.60	0.020	0.86
Schirmer's Test (mm)	0.14	0.22	0.16	0.18

Table 2: Clinical Characteristics by Study Group at Baseline (Right Eye).

Characteristic	Artificial Tear Group: Systane Complete (Mean \pm SD)	Rewetting Drop Group: Sensitive Eyes (Mean \pm SD)	Control Group: No Treatment (Mean \pm SD)	Group Comparisons (P-Value)
Subjects (n)	25	24	24	N/A
Age (Years) (Mean \pm SD)	29.76 \pm 10.75	29.83 \pm 11.34	31.29 \pm 12.91	0.88
Female (%)	27.40%	27.40%	27.40%	0.94
Orthokeratology and Contact Lens Quality of Life (OCL-QoL) Questionnaire	58.39 \pm 7.70	59.73 \pm 8.89	60.83 \pm 8.69	0.60
Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8)	20.64 \pm 5.25	20.54 \pm 5.47	21.75 \pm 4.95	0.67
Contact Lens Dry Eye Questionnaire-4 (CLDEQ-4)	11.32 \pm 2.44	10.88 \pm 2.36	11.58 \pm 2.19	0.57
Standardized Patient Evaluation of Eye Dryness (SPEED)	9.44 \pm 3.94	10.25 \pm 4.61	10.71 \pm 5.03	0.61
Invasive Tear Break Up Time (seconds)	9.67 \pm 4.84	9.52 \pm 4.71	7.89 \pm 3.90	0.32
Schirmer's Test (mm)	19.12 \pm 11.54	21.92 \pm 10.29	19.96 \pm 12.85	0.69

Table 3: Clinical Characteristics by Study Group at Two Weeks (Right Eye).

Characteristic	Artificial Tear Group: Systane Complete (Mean \pm SD)	Rewetting Drop Group: Sensitive Eyes (Mean \pm SD)	Control Group: No Treatment (Mean \pm SD)	Group Comparisons (P-Value)
Orthokeratology and Contact Lens Quality of Life (OCL-QoL) Questionnaire	61.20 \pm 6.81	59.66 \pm 8.35	59.83 \pm 9.07	0.77
Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8)	14.68 \pm 5.15	14.79 \pm 4.69	21.20 \pm 6.02	<0.0001
Contact Lens Dry Eye Questionnaire-4 (CLDEQ-4)	8.52 \pm 2.97	8.25 \pm 2.42	11.5 \pm 3.08	0.0002
Standardized Patient Evaluation of Eye Dryness (SPEED)	7.32 \pm 3.06	8.42 \pm 4.63	10.21 \pm 4.93	0.065
Invasive Tear Break Up Time (seconds)	10.62 \pm 4.52	9.52 \pm 5.64	8.85 \pm 3.92	0.42
Schirmer's Test (mm)	18.36 \pm 10.32	20.5 \pm 9.93	17.29 \pm 11.10	0.56

Table 4: Clinical Characteristics at Two Weeks Compared to Baseline by Study Group (Right Eye).

Characteristic	Artificial Tear Group: Systane Complete (P-Value)	Artificial Tear Group: Difference Between Visits (Difference)	Rewetting Drop Group: Sensitive Eyes (P-Value)	Rewetting Drop Group: Difference Between Visits (Difference)	Control Group: No Treatment (P-Value)	Control Group: Difference Between Visits (Difference)
Orthokeratology and Contact Lens Quality of Life (OCL-QoL) Questionnaire	0.06	2.81 \pm 7.12	0.94	1.06 \pm 5.76	0.33	-1.01 \pm 5.00
Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8)	<0.0001	-5.96 \pm 6.29	<0.0001	-4.63 \pm 4.94	0.49	-0.54 \pm 3.74
Contact Lens Dry Eye Questionnaire-4 (CLDEQ-4)	0.0002	-2.80 \pm 3.28	<0.0001	-2.15 \pm 2.80	0.85	-0.08 \pm 2.17
Standardized Patient Evaluation of Eye Dryness (SPEED)	0.02	-2.12 \pm 4.09	0.049	-1.77 \pm 4.13	0.50	-0.50 \pm 3.59
Invasive Tear Break Up Time (seconds)	0.38	0.95 \pm 5.26	1.00	-0.032 \pm 4.86	0.30	0.95 \pm 4.41
Schirmer's Test (mm)	0.65	-0.76 \pm 8.18	0.37	-0.26 \pm 7.58	0.11	-2.67 \pm 7.88

Conclusions

- Worse contact lens discomfort symptoms (CLDEQ-8, CLDEQ-4, SPEED) were consistently associated with worse visual quality of life scores at both the baseline and two-week visits.
- Visual quality of life scores were not associated with tear break up times or Schirmer's test.
- Additional work is needed to understand why improvements in comfort scores were not associated with improvements in OCL-QoL scores (e.g., minimally clinically important difference).
- Comfort drops (Systane Complete and Sensitive Eyes) significantly improved comfort scores at two weeks compared to baseline, though comfort score improvements were not significantly associated with an improvement in visual quality of life scores.
- These data are important because they provide insight into the reasons why patients may decrease contact lens wear time or permanently cease wearing contact lenses and the impact that discomfort has on patient quality of life.