Struggle with Soft Contact Lens Wear is Addressed by Refitting with Daily Disposable Lenses: 4 Month Follow-up from the TEMPO Registry

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BACKGROUND & INTRODUCTION

•Soft contact lens (SCL) wearers often struggle to maintain comfortable wear during the entire wearing day. (1,2)

•These gaps in SCL performance often result in symptoms significant enough to cause a discontinuation of SCL wear. (3)

•There are no "standards of care", per se, for the treatment of SCL wearers who are struggling to maintain comfortable wear during their entire wearing day.

•Reusable silicone hydrogel (SiHy) and some daily disposable (DD) lenses have performed well in many studies to reduce symptoms of dryness and lengthen the comfortable wearing day.

•The 8-item Contact Lens Dry Eye Questionnaire (CLDEQ-8)(4) has been developed and validated to reflect overall opinion of habitual SCLs as subjects enter a clinical trial and to reflect change in that opinion after refitting. The CLDEQ-8 has not been tested in a large population of DD lens wearers.

PURPOSE

The primary purpose was describe which gaps in soft contact lens (SCL) performance were addressed by refitting habitual SCL wearers with silicone hydrogel (SiHyDD) or hydrogel daily disposable (HydDD) lenses in the 1.DAYACUVUE® TruEye® or 1.DAYACUVUE® MOIST® Performance Overview (TEMPO) Registry (#NCT01467557). Secondary purpose was to test the CLDEQ-8 for ability to discriminate overall opinion of SCLs before and after re-fitting this population with DD lenses.

METHODS

Registry Population

•IRB approval and informed consent completed prior to registration

•611 registered habitual SCL wearers with 2 Week and 4 Month questionnaire follow-up in an ongoing 12 Month observational Registry

CONTACT LENS QUESTIONNAIRE-8

Questions about EYE DISCOMFORT:

wearing your contact lenses?

When your eyes felt discomfort with your contact

0 1 2 3 4 5

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Questions about EYE DRYNESS:

2 Sometimes

3 Frequently

•Habitual SCL Types:

- 381 Reusable Silicone Hydrogels (SiHyd)
- 169 Daily Disposable Hydrogels (HydDD)
- 61 Reusable Hydrogels (Hyd)

•Fit within prior 2 weeks with narafilcon B DD or etafilcon A DD lenses

•Decisions on SCL fitting were completely independent of the Registry protocol

Methods

Self-administered self-branching electronic questionnaire

•8-Item Contact Lens Dry Eye Questionnaire (CLDEQ-8)

Questions on Prior Compliance with Care, Ease of Use

Average and Comfortable Wearing Time

•Within and between cohort differences analyzed by Habitual and DD study lens

Analysis

Analyzed for change over time:

- Signed Rank Test (ordinal) ANOVA for continuous variables
- Paired t-test for continuous variables

•Between Habitual CL types (DD vs. Reusable)

•By Habitual CL and DD types:

- Reusable SiHy to SiHyDD n = 187
- Reusable SiHy to HydDD n = 194
- Reusable Hyd to SiHyDD n = 30
- Reusable Hyd to HydDD n = 31
- HydDD to SiHyDD
- HydDD to HydDD

References

. Riley C, Young G, Chalmers R. Prevalence of ocular surface symptoms, signs, and uncomfortable hours of wear in contact lens wearers: the effect of refitting with daily-wear silicone hydrogel lenses

- age in young adults. Cont Lens Ant Eye 2009 32(3)113-9. . Richdale K, Sinnott LT, Skadahl E, Nichols JJ. Frequency of and factors associated with contact

3 Frequently 4 Constantly When your eyes felt dry, how intense was this (senofilcon a). Eye Contact Lens 2006 Dec;32(6):281-6. . Chalmers RL, Hunt C. Hickson-Curran S, Young G. Struggle with hydrogel CL wear increases with b. At the end of your wearing time? Never Not at All have it Intense lens dissatisfaction and discontinuation. Cornea 2007;26:168-74. 0 1 2 3 4 5 . Chalmers RL, Long B, Dillehay SD, Begley CG. Improving contact-lens related dryness symptoms with silicone hydrogel lenses. Optom Vis Sci 2008 85(8):778-84.

1 Rarely

Never Not at All

3 Frequently

2 Less than once a week

4 Several times a week

6 Several times a day

3 Weekly

5 Daily

have it Intense

2 Sometimes

When your vision was blurry, how noticeable was

0 1 2 3 4 5

During a typical day in the past 2 weeks, how often

Question about REMOVING YOUR LENSES:

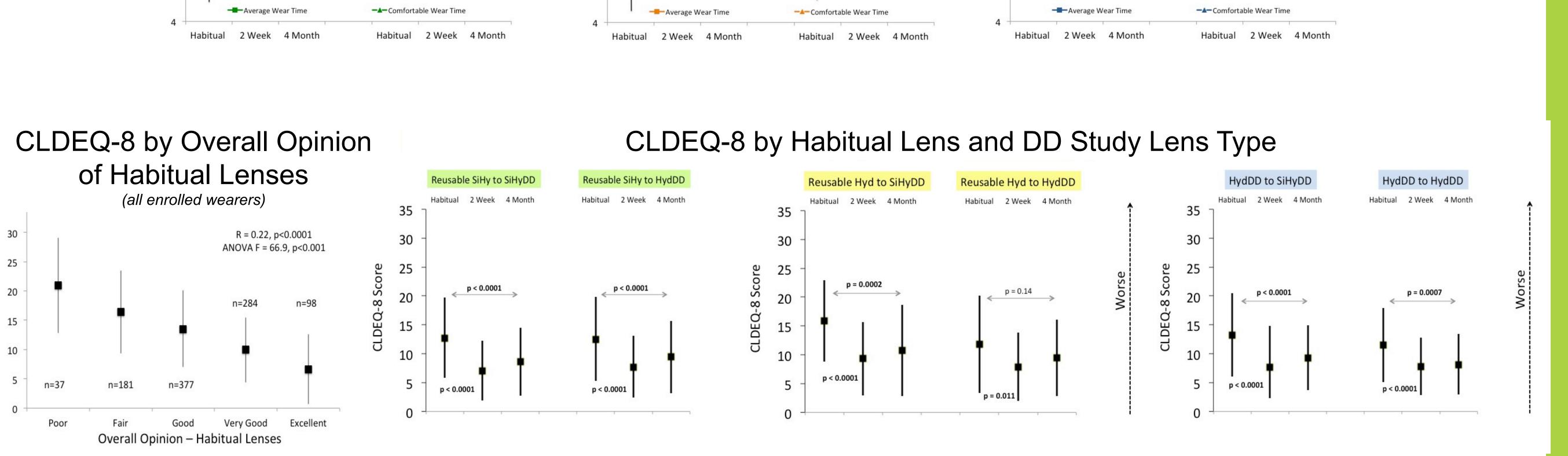
bother you so much while wearing your contact

How often during the past 2 weeks, did your eyes

lenses that you felt as if you needed to stop whatever

you were doing and take out your contact lenses?

Ease of Use by Habitual Lens Type Self-Assessed Compliance to Instructions RESULTS "Please rate how good you have been at following instructions "How easy has it been to care for your CLs." for how to care for and wear your CLs." Former Reusable CLs n=442; Former DD n=169 Former Reusable CLs n=442; Former DD n=169 Daily Disposable Daily Disposable Extremely Registration Registration ♠ Excellent Very Easy 60% Fairly Easy 40% Fairly 4 Month Visit 4 Month Visit Registration Visit Average vs. Comfortable Wearing Time Across Visits HydDD to HydDD p = 0.91p = 0.14p = 0.05p = 0.21p = 0.07p = 0.0002 p < 0.0001p = 0.13p = 0.05 p < 0.0001 p = 0.0002p = 0.45p = 0.003Average Wear Time Comfortable Wear Time ----Average Wear Time



CONCLUSIONS

Compliance to Instructions

- •At Registration, wearers of habitual DD lenses rated their compliance significantly higher than Reusable lens users.
- •More than 90% of DD wearers were "excellent" or "very good" in compliance after 4 months in DD lenses, regardless of habitual CL type •Fewer steps leads to increased confidence and compliance

Ease of Use

- •At Registration, wearers of habitual DD lenses gave significantly higher ratings for ease of use compared to wearers of Reusable lenses.
- •Ease of use rated "extremely easy" or "very easy" by 96% after 4 months, regardless of habitual CL type.

Average vs. Comfortable Wearing Time

- After refitting with DD study lenses, the amount of uncomfortable wear (average minus comfortable) was halved for most treatment arms.
- •Switching from HydDD to another HydDD brand did not change period of uncomfortable wear.

CLDEQ-8 Symptom Score

- Lower CLDEQ-8 score indicates less frequent and intense symptoms and fewer coping struggles.
- •At Registration, CLDEQ-8 scores were in the range of wearers who had an overall opinion of the habitual CLs of "good".
- •At Registration, the small group of Reusable Hyd lens wearers who were being refit with SiHyDD lenses had the highest CLDEQ-8 score with habitual lenses.
- After refitting, CLDEQ-8 scores improved significantly for all groups and remained relatively stable through the 4 months of follow-up.
- •The post-refitting range of CLDEQ-8 scores was in the "excellent" to "very good" range of overall opinion.

Acknowledgement

This study was funded by Johnson & Johnson Vision Care, Inc.

The TEMPO Registry is registered at clinicaltrials.gov as NCT#01467557.

83 Clinical Investigators in 37 Sites

