

# Predictors for Misuse of Daily Disposable Lenses in a Large Post-Market Surveillance Registry – The TEMPO Registry

<sup>1</sup>Robin L Chalmers, OD; <sup>2</sup>Sheila Hickson-Curran, MCOptom; <sup>3</sup>Lisa Keay, PhD; and <sup>4</sup>Bill Gleason, OD

<sup>1</sup>Clinical Trial Consultant, Atlanta, GA; <sup>2</sup>Johnson & Johnson Vision Care, Inc, Jacksonville, FL; <sup>3</sup>Sydner, Australia; <sup>4</sup>Foresight Regulatory Strategies, Inc., Wilmington, MA

## BACKGROUND & INTRODUCTION

The TEMPO Registry (TruEye and Moist Performance Overview Registry) is a post-market surveillance registry designed to assess rates of corneal infiltrative events (CIEs) with two brands of Daily Disposable (DD) lenses. Annual incidence of CIEs was 0.2%/year, significantly lower than the 3-4% rate found previously with reusable soft contact lenses (SCLs). This result was despite some degree of non-compliant use of the DD lenses; namely overnight wear and storage and reuse.

## PURPOSE

To describe predictors for overnight wear (EW) and storage and reuse (re-use) of daily disposable (DD) lenses among wearers of silicone hydrogel (SiHyDD) or hydrogel daily disposable (HyDD) lenses in the 1-DAY ACUVUE® TruEye® or 1-DAY ACUVUE® MOIST® Performance Overview (TEMPO) Registry (#NCT01467557).

## METHODS

### Analyzed Registry Population

- IRB approval and informed consent completed prior to registration
- Decisions on SCL fitting were independent of the Registry protocol in 37 North American clinics
- Fit within prior 10 days with etafilcon A HydDD lenses (1-DAY ACUVUE® MOIST®) or narafilcon b SiHyDD lenses (1-DAY ACUVUE® TruEye®)
- Follow-up surveys @ 2 weeks, 4 and 12 months
- 977 habitual SCL wearers with all follow-up surveys complete

### Methods

- Eye Care Professional (ECP) rated Compliance with Instructions at Registration Visit
- After Registration, internet self-administered self-branching electronic survey
- Wearer Questions on:
  - Overnight Wear (EW)
  - DD Lens Replacement Frequency
  - Storage & Reuse of DD Lenses
  - Self-assessed Compliance with Care Instructions

### Analysis Methods

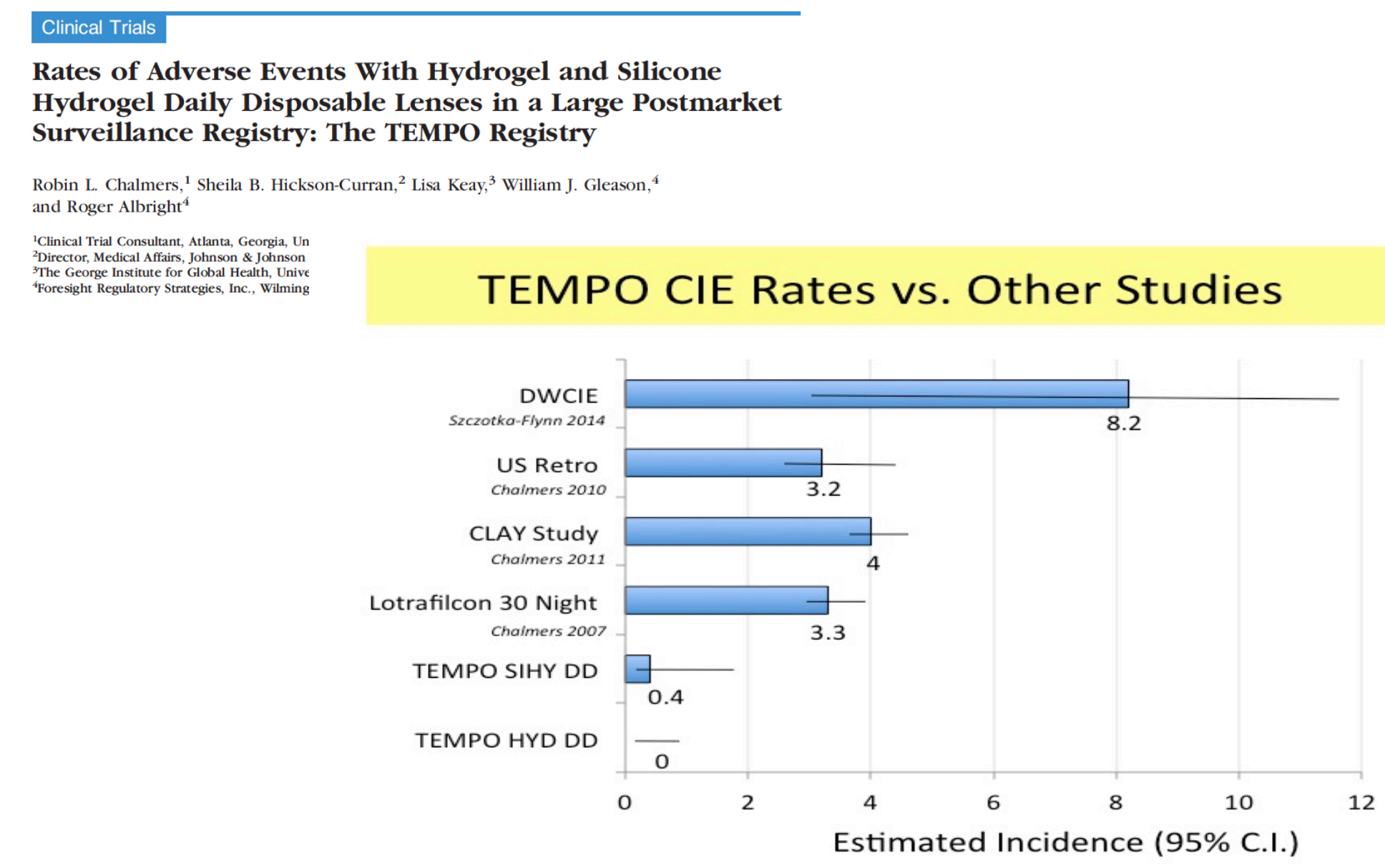
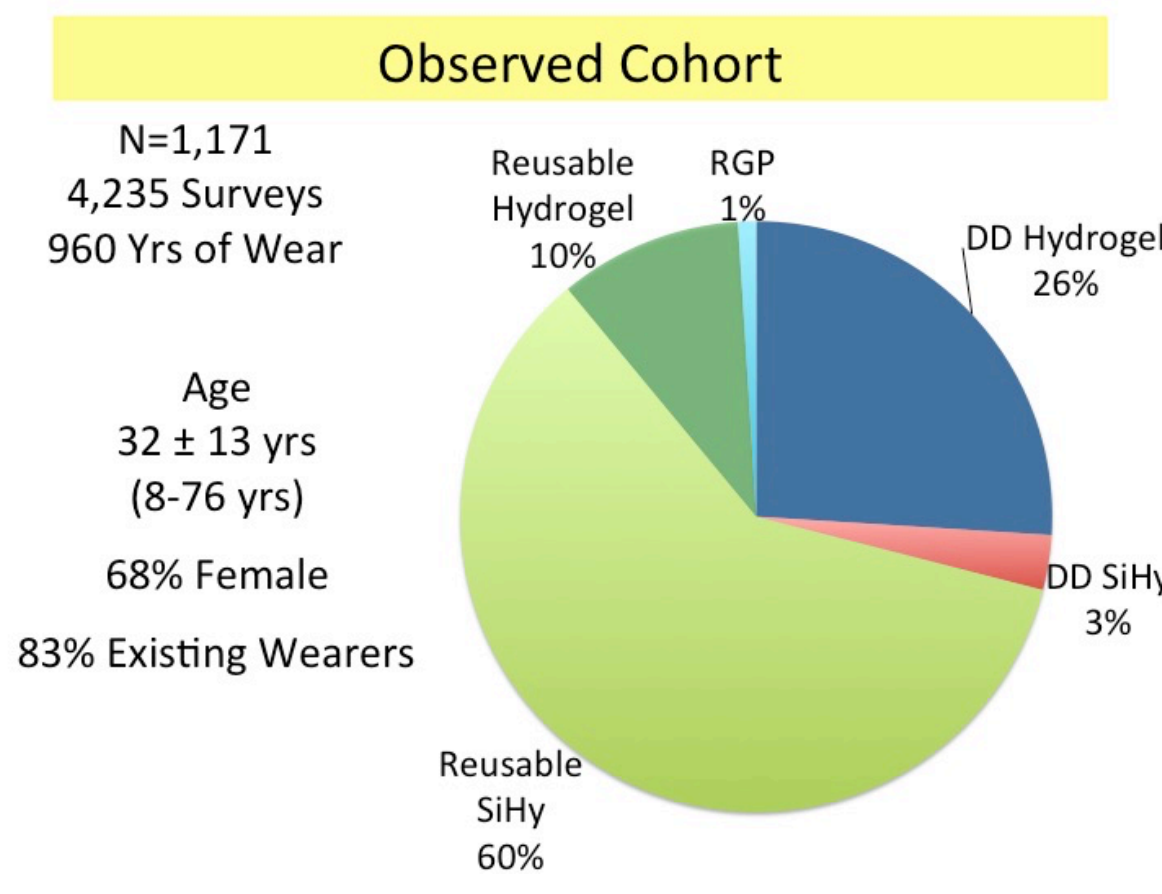
- Reports of EW or Re-Use were modelled by generalized estimating equations (GEE)
  - Survey was a repeated measure
  - Adjustment for clustering by clinical site

### Model Elements

- Age
- Gender
- ECP Compliance Rating @ Registration
- Wearer Compliance Rating @ Registration
- Wearer Report of DD Non-Compliance
  - EW with DD Lenses
  - Storage & Reuse of DD Lenses

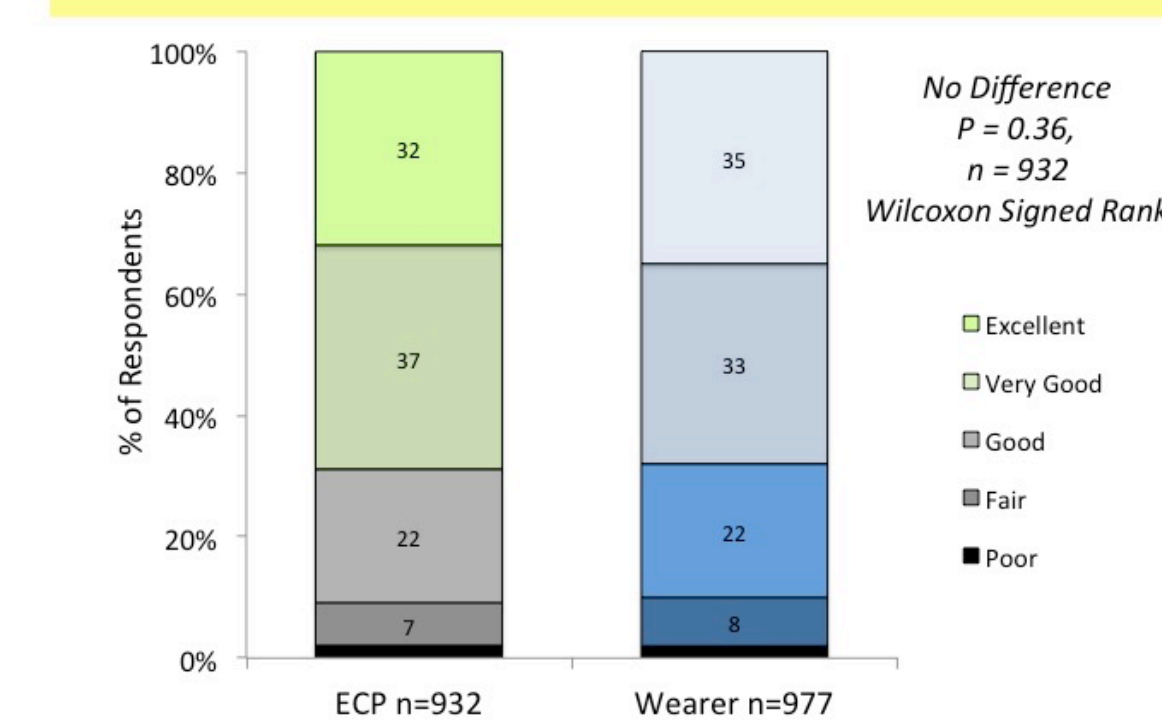
### References

- Chalmers RL, Hickson-Curran SB, Keay L, Gleason WJ, Albright R. Rates of adverse events with hydrogel and silicone hydrogel daily disposable lenses in a large postmarket surveillance registry: the TEMPO Registry. *Invest Ophthalmol Vis Sci* 2015 56:654-63.
- Szczołka-Flynn L, Jiang Y, Raghupathy S, et al. Corneal inflammatory events with daily silicone hydrogel lens wear. *Optom Vis Sci* 2014 91:3-12.
- Chalmers RL, Keay L, Long B, Bergenske P, Giles T, Bullimore M. Risk factors for contact lens complications in US clinical practices. *Optom Vis Sci* 2010 87(10):725-35.
- Chalmers RL, Wagner H, Mitchell GL, Lam DY, Kinoshita BT, Jansen ME, Richdale KL, Sorbara L, McMahon TT. Age and other risk factors for corneal infiltrative and inflammatory events in young soft contact lens wearers from the contact lens assessment in youth (CLAY) study. *Invest Ophthalmol Vis Sci* 2011 52(9):6690-6.
- Chalmers RL, McNally J, Schein OD, Katz J, Tielsch J, Alfonso, E, Bullimore M, O'Day D, Shovlin J. Risk factors for corneal infiltrates with continuous wear of contact lenses. *Optom Vis Sci* 2007 84(7):573-579.

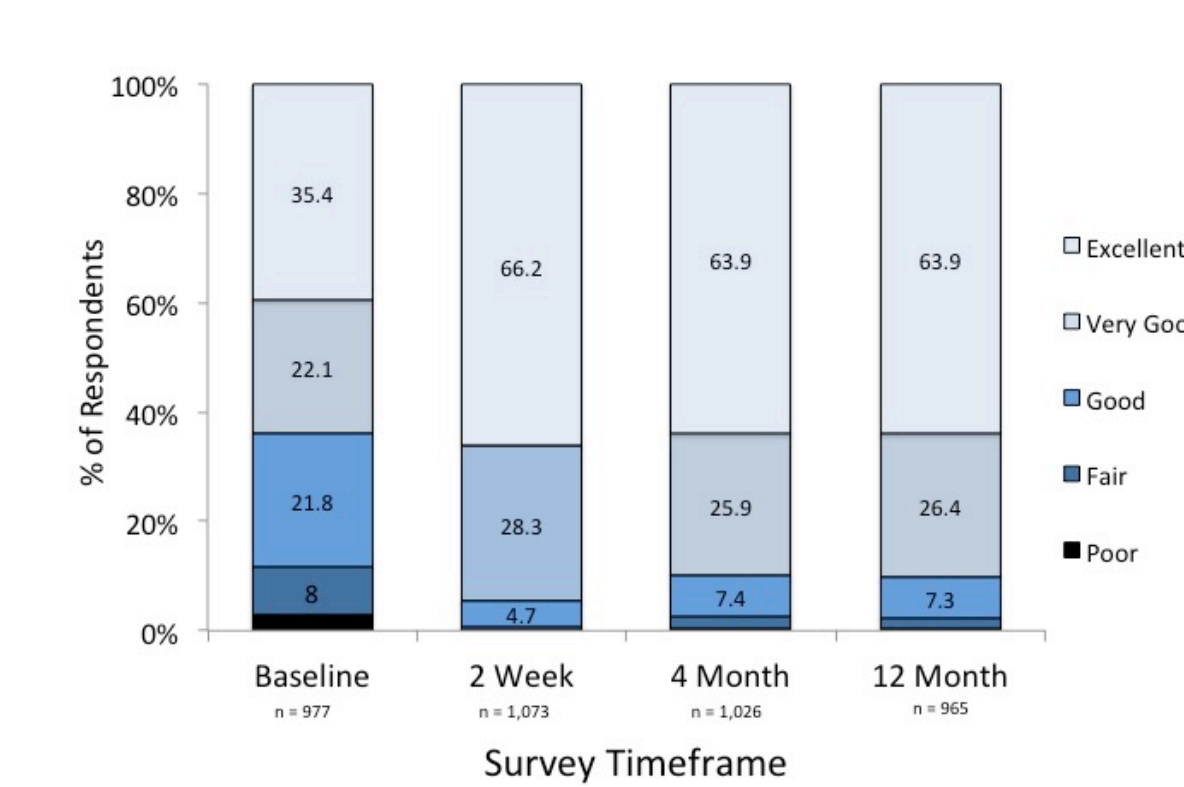


## Practitioner & Wearer Compliance Ratings

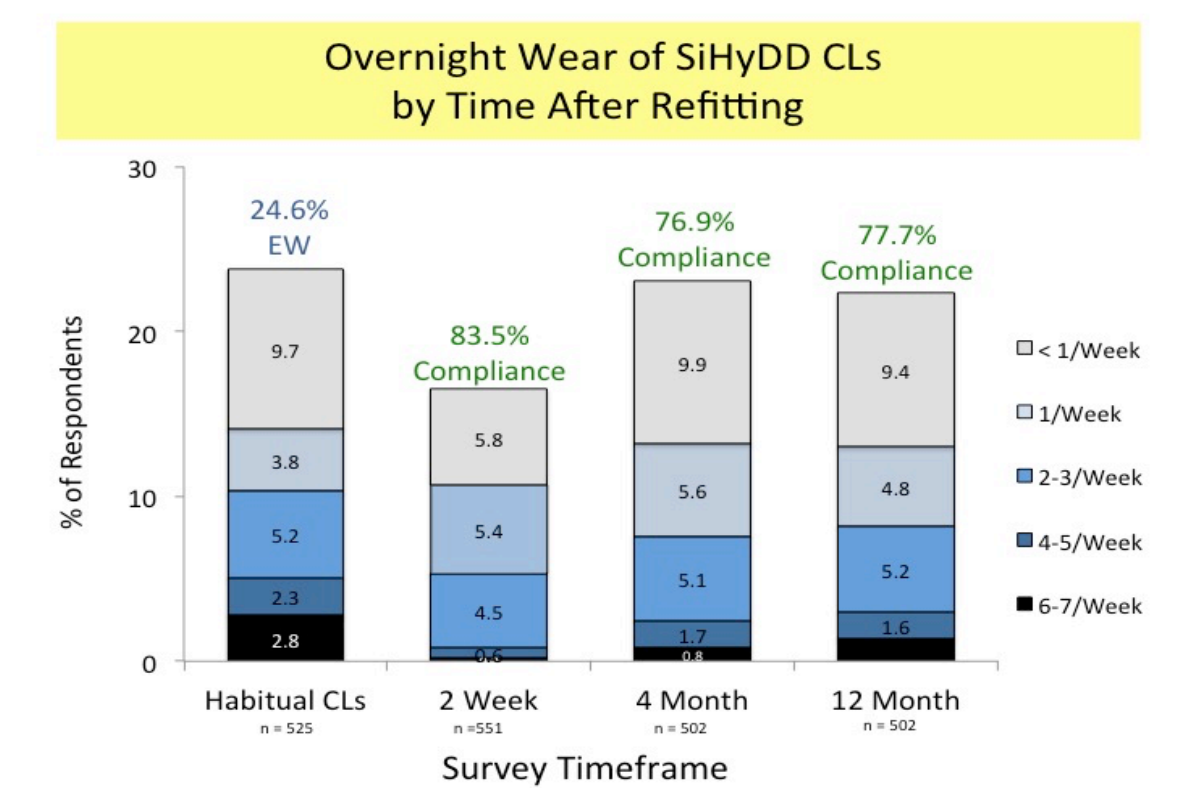
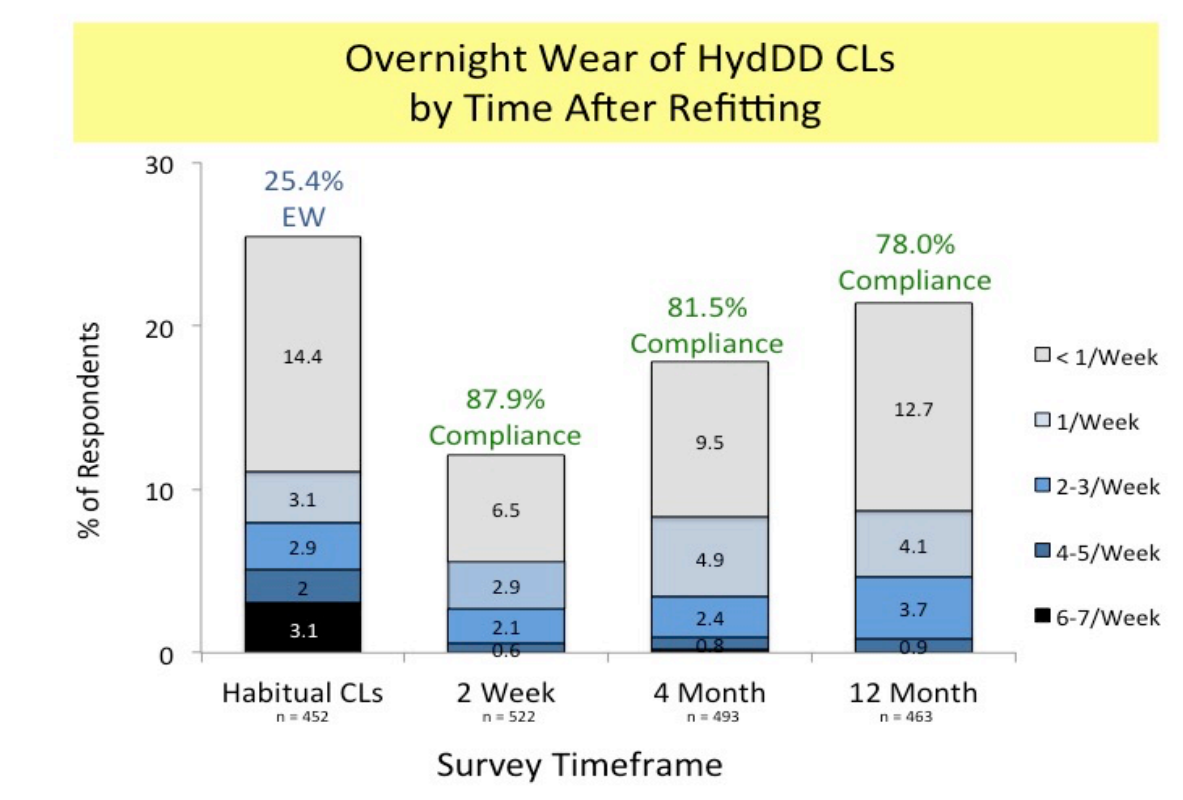
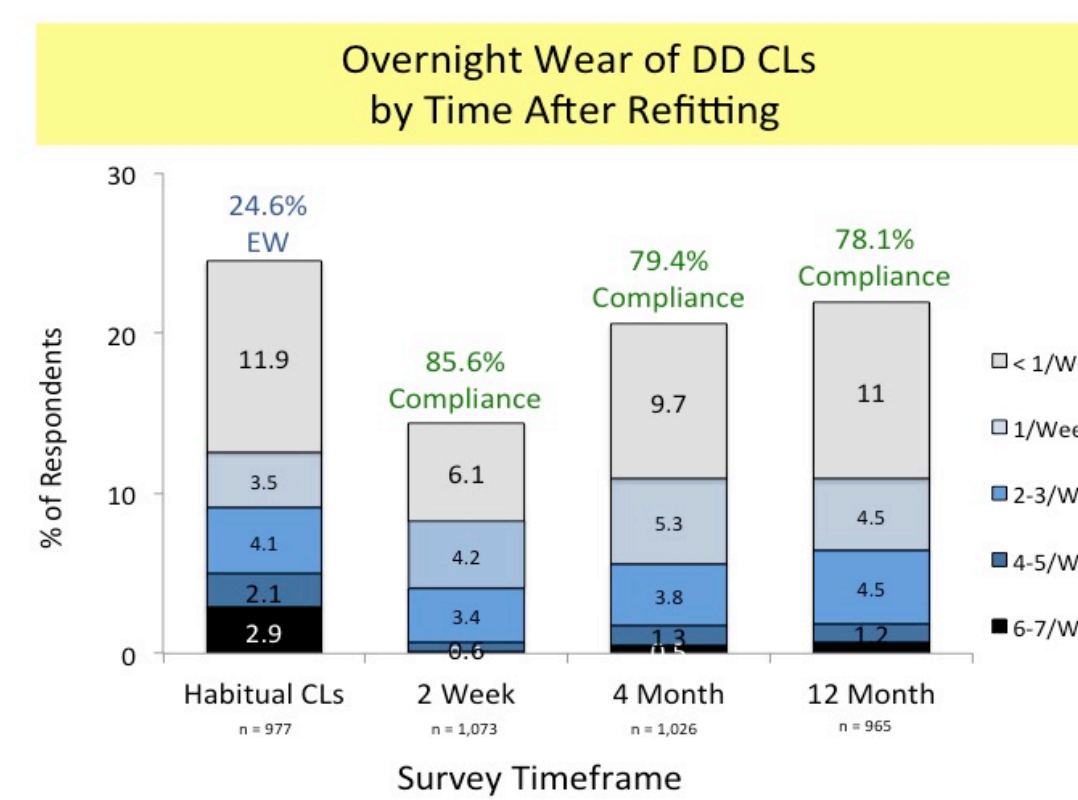
### Practitioner vs. Wearer Ratings of Compliance to Instructions at Registration Visit



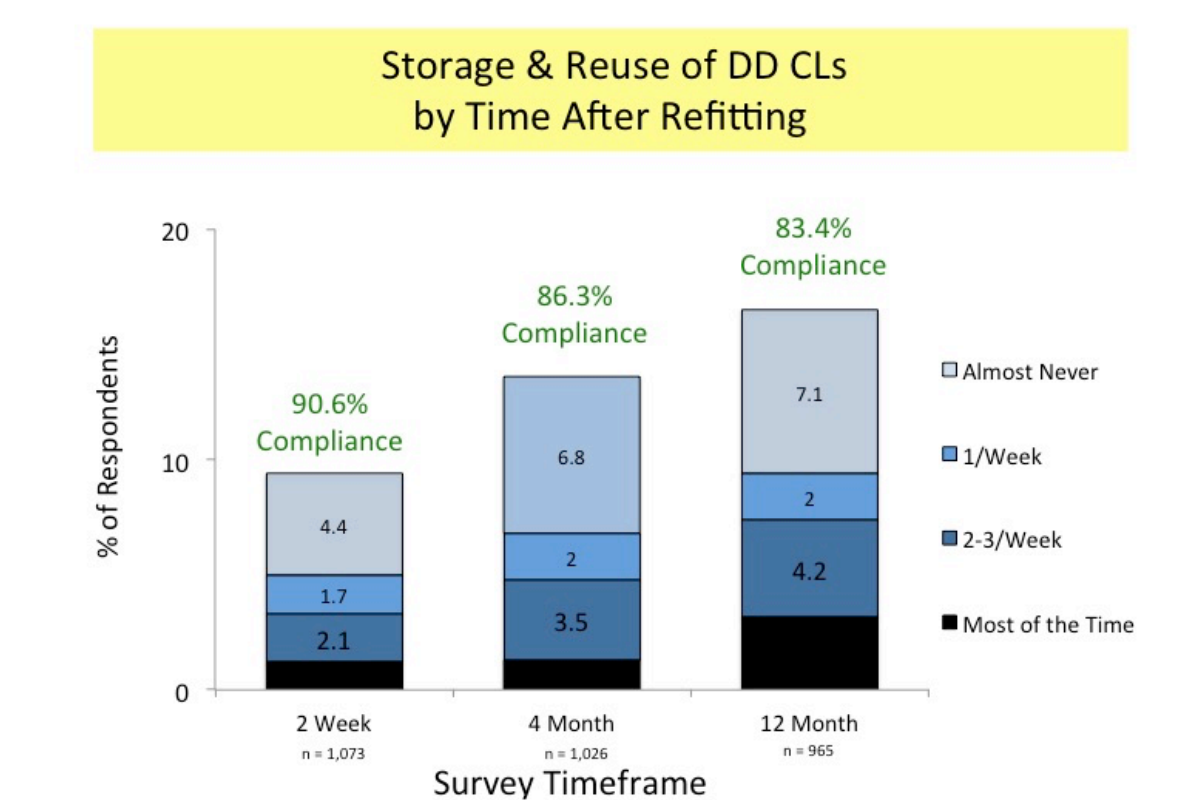
### "Please rate how good you have been at following instructions for how to care for and wear your CLs."



## Overnight Wear by Time in Study



## Storage & Reuse by Time in Study



## Models for Predicting Non-Compliant DD Use

Table 1. Effect of Time in Study on Non-Compliance with DD Lenses in TEMPO Registry

Survey	Overnight Wear			Store & Reuse DD Lenses		
	Prevalence	p-value	GEE Model Odds Ratio (95% C.I.)	Prevalence	p-value	GEE Model Odds Ratio (95% C.I.)
2 Week	154/1073 14.4%	<0.0001	OR 1.56 (1.32 – 1.84) p<0.0001	101/1073 9.4%	<0.0001	OR 1.52 (1.24 – 1.87) p<0.0001
4 Month	214/1026 20.9%	0.26		140/1026 13.6%	0.005	
12 Month	214/965 22.2%	referent		160/965 16.6%	referent	

Table 2. Predictors of Overnight Wear of DD Lenses in the TEMPO Registry

Factor	Overnight Wear of DD Lenses	
	Odds Ratio (95% C.I.)	p-value
Time from Registration (2 Week, 4 Month, 12 Month)	1.73 (1.41 – 2.12)	<0.0001
Overnight Wear at Registration	9.66 (7.37 – 12.67)	<0.0001

Table 3. Predictors of Storage & Reuse of DD Lenses in the TEMPO Registry

Factor	Store & Reuse DD Lenses	
	Odds Ratio (95% C.I.)	p-value
Time from Registration (2 Week, 4 Month, 12 Month)	1.65 (1.29 – 2.09)	<0.0001
Wearer Assessment of Compliance (Registration)	1.72 (1.14 – 2.61)	0.01
Eye Care Practitioner Compliance Rating (Registration)	1.56 (1.0009 – 2.43)	0.0496

## CONCLUSIONS

### Low Rates of Adverse Events Despite Some Non-Compliance

- Registry study design assesses performance in “real world” setting
- No protocol-driven training of DD wearers

### Self-Assessment of Compliance to Wear & Care Instructions

- Excellent agreement between ECP and wearers self-assessed compliance at Registration.
- Poor self-assessed compliance with Habitual CLs predicted non-compliant storage and reuse of DD lenses (p= 0.01)
- Poor ECP assessment of compliance with Habitual CLs predicted non-compliant storage of DD lenses (p=0.0496).

### Predictors of Overnight Wear with DD Lenses

- Overnight wear of Habitual CLs was strongest predictor (OR 9.66X)
- Overnight wear increased with time from refitting (from 14.4% at 2 Weeks to 22.2% at 12 Months)

### Predictors of Storage & Reuse of DD Lenses

- Reuse of DD lenses nearly doubled with time in study (from 9.4% at 2 Weeks to 16.6% at 12 Months)
- ECP and Wearer ratings of compliance with Habitual CLs predicted reuse of DD lenses

### Training DD Wearers

- Ask wearer to self-assess how well they have followed wear and care instructions when refitting
- Practices must emphasize habits for best use of DD lenses when refitting

## Acknowledgements

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

- |                         |                            |                                   |
|-------------------------|----------------------------|-----------------------------------|
| Helen Abdal, OD         | Ashby Jones, OD            | David Ross, OD                    |
| Linda Bennett, OD       | Christine Britscher, OD    | Michael Bloom, OD                 |
| Rebecca Maids, D.O.     | Jennifer Kao, OD           | Robert Butterwick, OD             |
| Melanie Macbeth, OD     | Grace Wong, OD             | Matthew Mast                      |
| Virginia Bonell, OD     | Trang Nguyen, OD           | Michael Rotberg, MD               |
| William Lay, OD         | Kyla Cologgi, OD           | Lisa Fox, OD                      |
| Michelle Cassell, OD    | Gregory Nilson, OD         | Judi Schaffer, OD                 |
| Sara Kilbanoff, OD      | Bradley Johnson, OD        | Jason Schwartz, OD                |
| John Todd Cornett, OD   | Stacy Louise Stulter, OD   | Lawrence Sider, OD                |
| Robert Davis, OD        | Carole Burns, OD           | Sam Silverblatt, OD               |
| Stephanie Davis, OD     | Amy Lay, OD                | Cindy Siu, OD                     |
| Aaron Evans, OD         | Steven Lowinger, OD        | Paul Super, OD                    |
| James Fickner, OD       | Michael Newman, OD         | Catherine Barker, OD              |
| Christen Flickner, OD   | William Moscovice, OD      | Loretta B. Szczołka-Flynn, OD, MS |
| Jennell Bockenstedt, OD | Sharon Berger, OD          | Thomas Stokkermans, OD            |
| Kenneth Hall, OD        | Jennifer Dattalo, OD       | Sara Schoeck, OD                  |
| Cindy Sveto, OD         | Dawn Lam, OD               | Nancy Eve Thomas, MD              |
| Maria Ha, OD            | Timothy Edgington, OD      | Peter Van Haven, OD               |
| Annie Chang, OD         | Junie Myung Lee, OD        | Nick Engle, OD                    |
| Tram Vu, OD             | Justin Kwan, OD            | Heidi Wagner, OD, MPH             |
| Bronson Hamada, OD      | Maureen O'Dwyer, OD        | Andrew Janoff, OD                 |
| Amy Dink, OD            | Lawrence Phillips, OD      | Paria Najman, OD                  |
| James Harnoff, OD       | Kathryn Richdale, M.S., OD | Eva Duchnowski, OD                |
| Blane Bruzen, OD        | Mitchell Dul, M.S., O      | Larry Wan, OD                     |
| Nadine Jamal, OD        | Bradford Rippes, OD        | Janine Tsan, OD                   |
| Jeffrey Cooper, OD      |                            | Stephanie Judkins, OD             |
| Vanesa Conenna, OD      |                            | Stephen Woo, OD                   |
|                         |                            | David Ziegler, OD                 |
|                         |                            | Chad Leftingwell, OD              |