LASIK Quality of Life Collaboration Project (LQOLCP)

FDA/NIH/DOD

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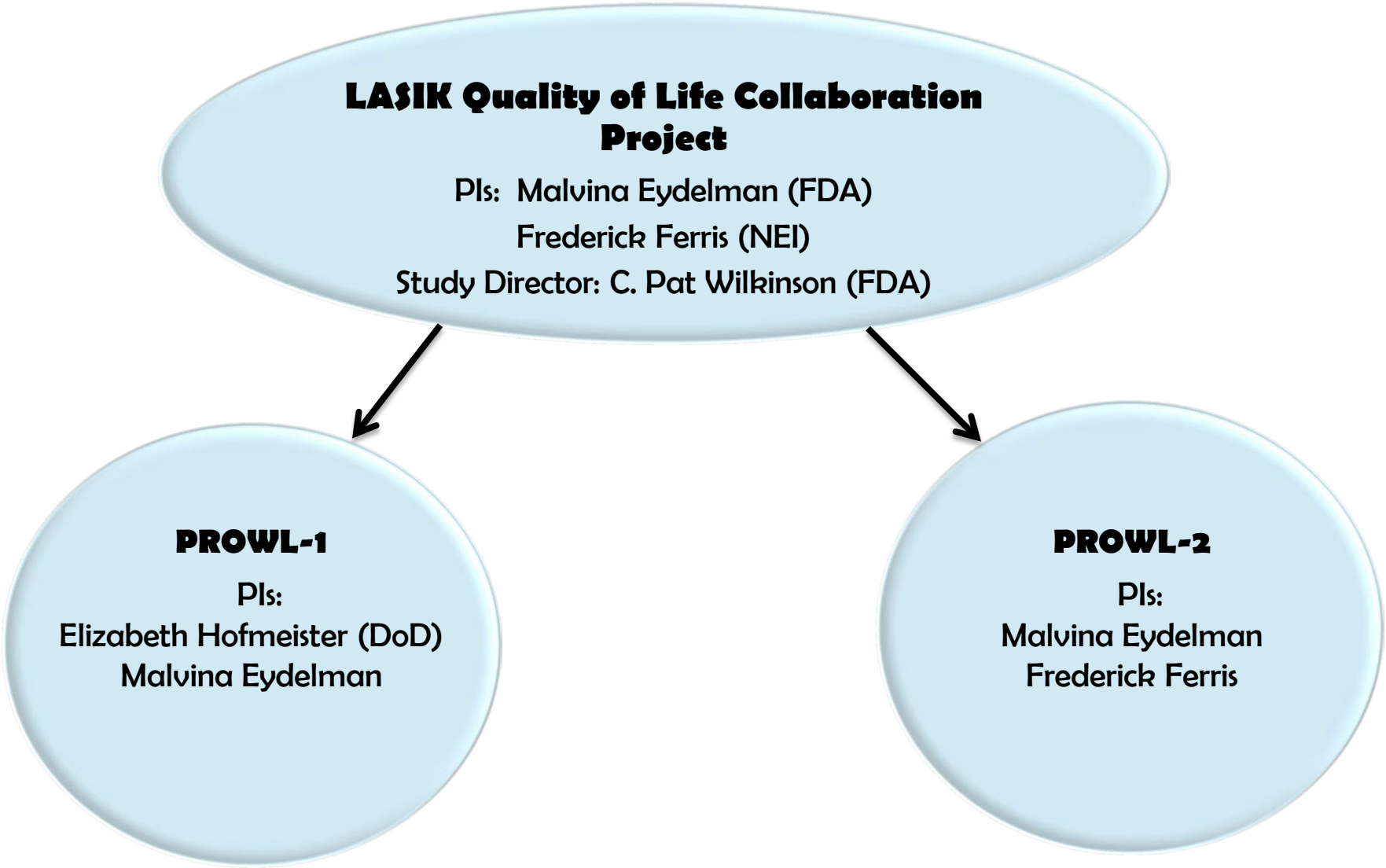
Financial Disclosures

- I do not have any financial interests or relationships to disclose.

LASIK Quality of Life Collaboration Project

Phase	Objective	Location
Pilot	To compare patient-reported outcomes (PROs) of subjects using web-based questionnaires versus paper versions of the same validated questionnaires.	Conducted at NEI
Phase I	To design a web-based instrument for assessing PROs appropriate for the evaluation of HRQOL issues in LASIK patients.	Conducted by EMMES (NEI CRO)
Phase IA	To conduct cognitive interviews to ensure ease of question understanding, user-friendly format, and comprehensive coverage of issues related to LASIK	Conducted by RAND through EMMES
Phase II (PROWL-1)	To determine an initial estimate of the prevalence of post-LASIK PROs in a select patient population of naval LASIK patients as well as a step in the validation of the questionnaire	Conducted at Navy site, San Diego
Phase III (PROWL-2)	To further validate the newly developed questionnaire in the general population	Conducted as a national multicenter NEI Intramural clinical study


LASIK Quality of Life Collaboration Project
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PROWL-1
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Current Status of LQOLCP

- Pilot - Published manuscript[1]
- Phase I - Completed, resulting in a web-based questionnaire for subsequent phases
- Phase II - Study completed, database locked, and analyses underway
- Phase III - Study completed, database locked, and analyses underway

[1]Clayton J et al. Web-based versus paper administration of common ophthalmic questionnaires: comparison of subscale scores. Ophthalmology 2013;120:2151-9.

Phase I
Questionnaire Development

- Literature, media, and citizen reports used to identify concepts and potential questionnaires
- Published questionnaires were assessed for measures of interpretability (validity) and reliability and incorporated as appropriate
  - » Obtained permission to use copyrighted items
- Concepts for which there were no available questionnaires, empiric questions and illustrative images were developed and tested in an informal and formal group of clinicians and patients

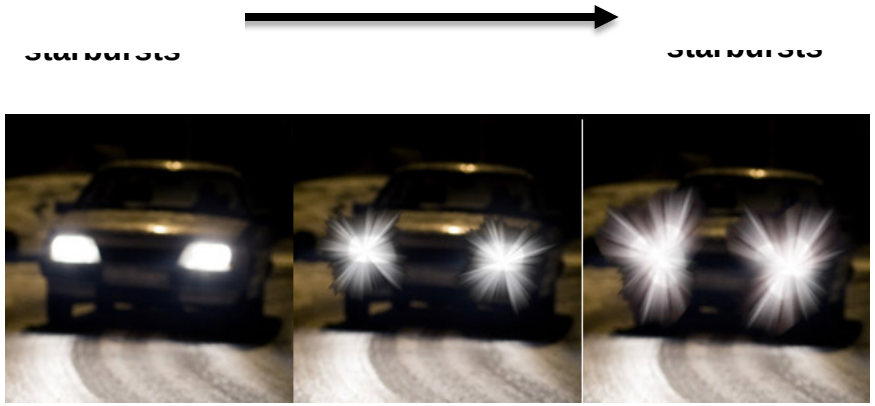
Questionnaire Components

- Vision quality
- Symptoms of aberration (glare, halos, starbursts, ghosting)*
- Work productivity
- Dry eye symptoms
- Depressive/anxiety symptoms
- Optimism
- Coping
- Expectations prior to surgery
- Satisfaction after surgery
- Social Desirability

*PROWL-2 wording slightly modified based on PROWL-1

Example of Visual Symptom Aberration Item

INSTRUCTIONS: The next few questions are about *starbursts*. By starbursts, we mean *seeing rays of light* coming out from lighted objects, such as in the car headlights in the images below. These images may not represent exactly what you see and your symptoms may be more or less severe than what is shown.



In the last 7 days, have you seen any **starbursts**?

1. Yes, but ONLY when NOT wearing glasses or contact lenses
2. Yes, but ONLY when wearing glasses or contact lenses
3. Yes, when wearing AND when not wearing glasses or contact lenses
4. No, not at all

PROWL-1

- Conducted at Navy Refractive Surgery Center San Diego
  - » Active duty military patients
  - » No cost to patients
  - » Standardized approach

PROWL-2

- Sites selected using criteria listed in NEI Request for Proposals (RFP)
  - » Infrastructure for clinical research (facilities and personnel)
  - » Certified on their laser platforms and perform at least 50 LASIK surgeries/month
  - » Experience recruiting and retaining subjects
- Conducted at 5 clinical sites across U.S.
  - » 20/20 Institute (Indiana)
  - » Durrie Vision (Kansas)
  - » Johns Hopkins University (Maryland)
  - » Stanford University (California)
  - » Vance Thompson Vision (South Dakota)

Technology utilized

- Excimer laser brands used in the study represented those with the largest market share*
  - » Wave-front guided
  - » Wave-front optimized
  - » Conventional (PROWL 2 only)

*Market share estimates provided by Market Scope, LLC based upon 2nd quarter 2014 survey data

PROWL-1 and PROWL-2

Preliminary Results

Subject Participation

	PROWL-1	PROWL-2
Total enrolled	262	312
Baseline Questionnaire	254	294
Surgery	242	292
Month 1 Questionnaire	233	265
Month 3 questionnaire	224	260
Month 6 questionnaire	217	Not Applicable

Demographics: Surgical Cohort

	PROWL-1	PROWL-2
Gender		
Woman	21%	53%
Ethnicity		
Not Hispanic or Latino	79%	90%
Hispanic or Latino	20%	4%
Unknown	1%	6%
Race		
American Indian or Alaskan Native	2%	1%
Asian	9%	11%
Black or African American	10%	2%
Native Hawaiian or Other Pacific Islander	2%	2%
White	55%	79%
Unable to specify	1%	1%
Other	21%	4%
Age		
Mean	29.1	31.5

Preoperative Clinical characteristics (Surgical Eyes)

		PROWL-1			PROWL-2	
		Myopes n=446	Hyperopes n=10	Mixed astigmats n=28	Myopes n=568	Hyperopes n=16
Sphere	Mean	-2.5	+3.1	0.6	-3.6	2.5
Cylinder	Mean	0.8	0.8	2.1	0.7	0.9
Spherical Equivalent	Mean	-2.9	+2.5	-0.5	-4.0	+2.0
	Range	-8.0 to -0.6	+1.5 to +3.6	-2.4 to +0.3	-11.6 to -0.4	+0.1 to +4.1

3-Month Visual Acuity Outcomes

	PROWL-1 N=225	PROWL-2 N=270
UCVA 20/20 or better		
OD	97%	91%
OS	98%	92%
OU	99%	96%

>95% achieved 20/20 or better binocular UCVA at 3 Months

>90% achieved 20/20 or better monocular UCVA at 3 Months

3-Month Acuity / Refractive Safety Outcomes

	PROWL-1 N=450 (eyes)	PROWL-2 N=540 (eyes)
Loss of 2 lines or more BCVA	1 (0.2%)	0 (0%)
BCVA worse than 20/40	0 (0%)	0 (0%)
Increase of greater than 2D of cylinder compared to baseline	0 (0%)	0 (0%)
BCVA worse than 20/25 if 20/20 or better pre-op	0 (0%)	0 (0%)

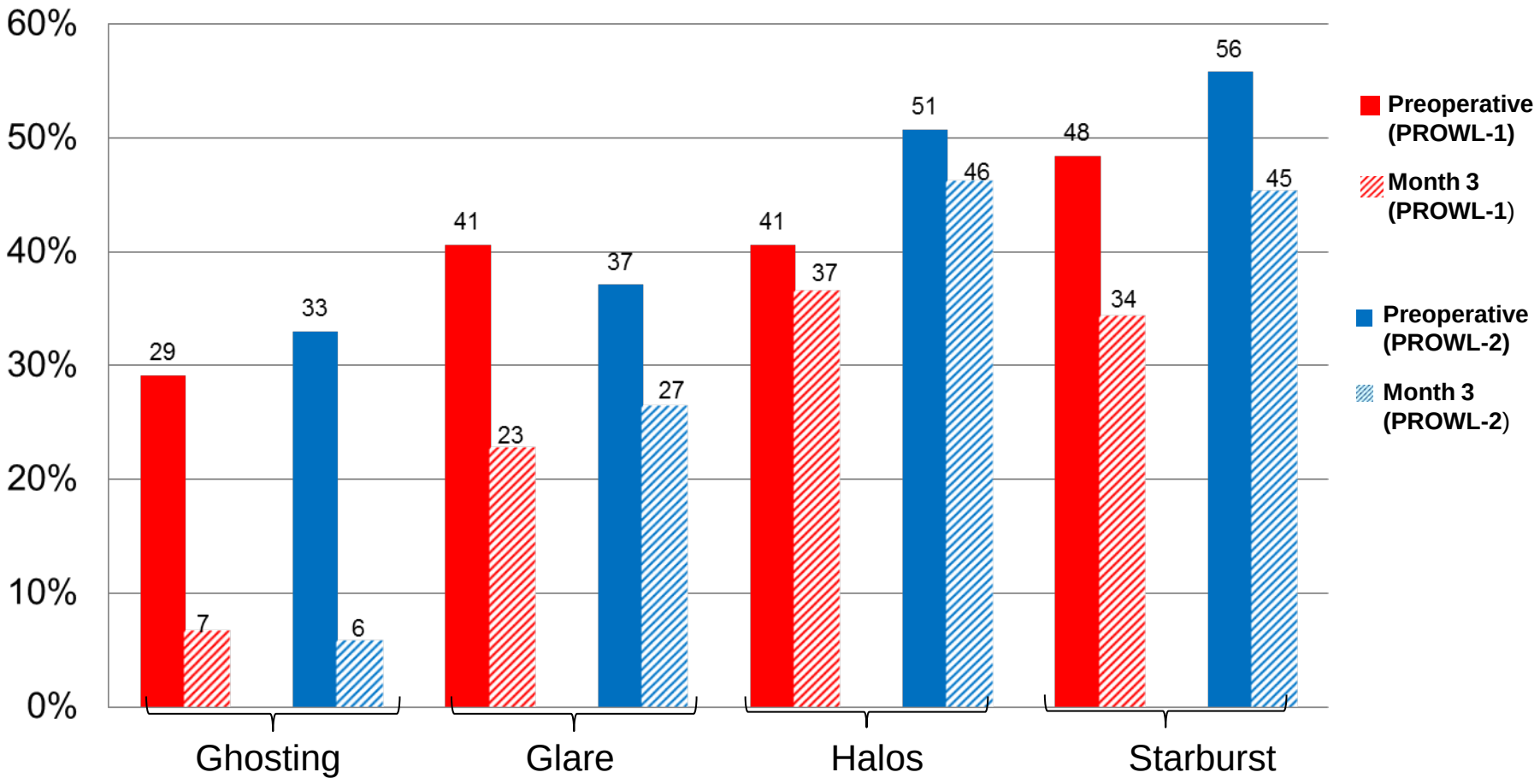
0.2% of eyes lost ≥ 2 lines of BCVA from pre-op to 3 Months

Adverse Events (Eyes) by 3 Months

- Intraoperative
  - » PROWL-1= 3 out of 484 (0.6%)
  - » PROWL-2= 1 out of 584 (0.2%)
- Postoperative[1]
  - » PROWL-1= 2[2] out of 484 (0.4%)
  - » PROWL-2= 3[3] out of 584 (0.5%)

[1] Not including Loss of 2 lines or more of BCVA or Severe Symptoms
[2] 1 event not device related
[3] 2 events not device related

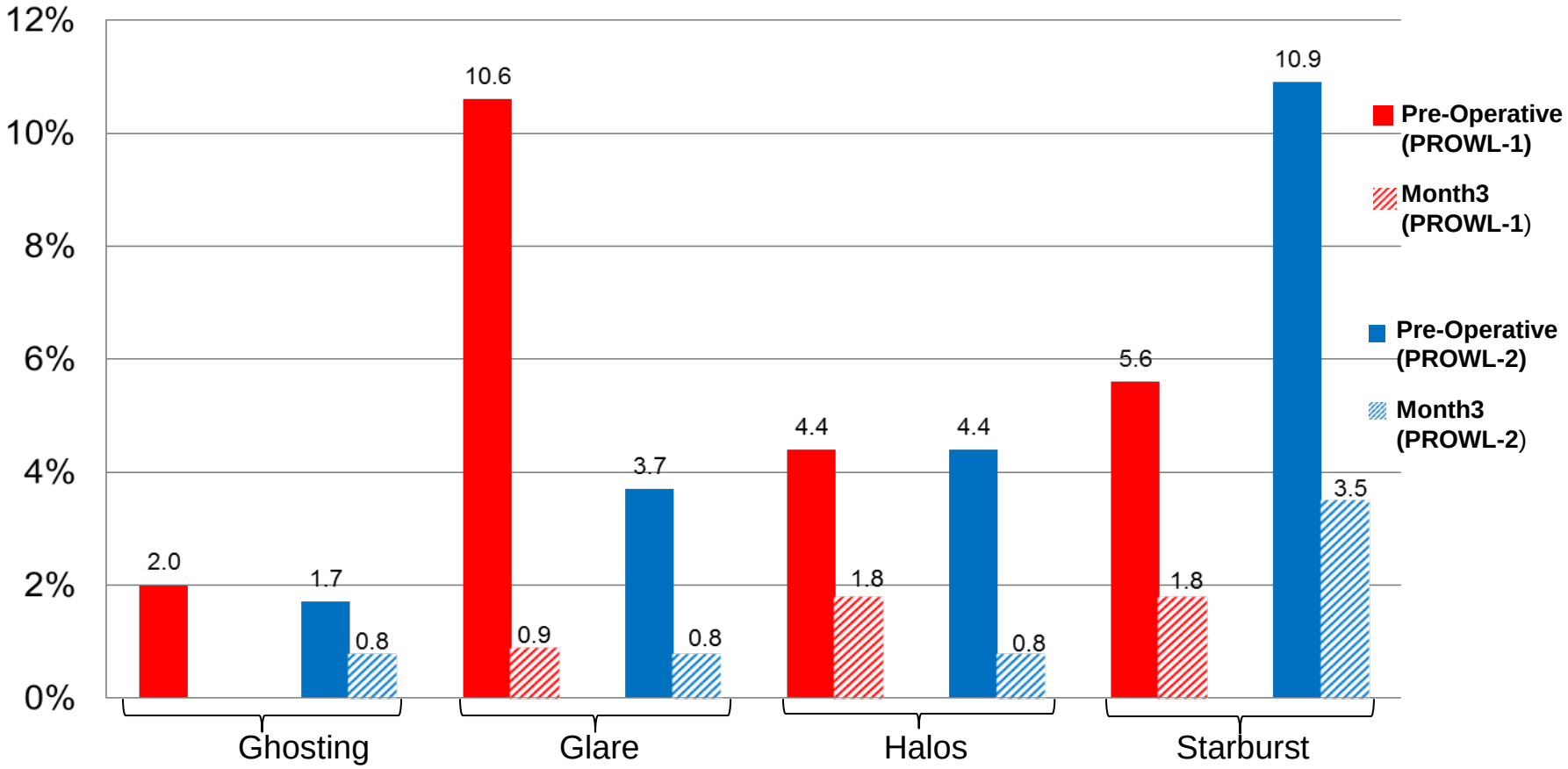
Prevalence of Symptoms: Preoperative vs. Month 3



The prevalence of visual symptoms did not increase postoperatively

Prevalence of Bothersome (Very and Extremely) Visual Symptoms

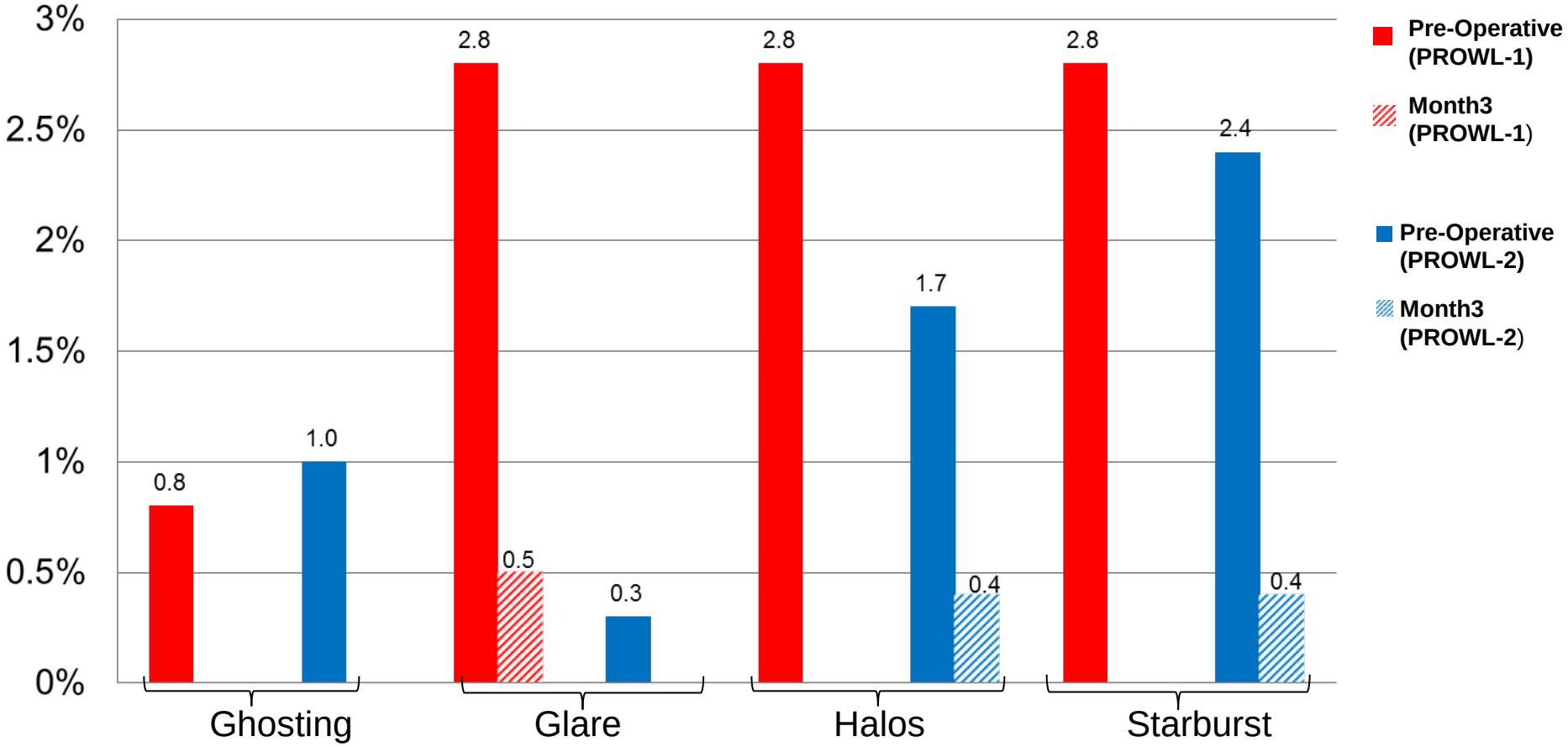
(Preop w/ correction, 3 Months – w/o correction)



Visual symptoms were very or extremely bothersome in up to 4% of subjects without correction at 3 Months

A Lot Of Difficulty With Or Inability to Perform Usual Activities Due To Visual Symptoms

(Preop w/ correction, 3 Months – w/o correction)

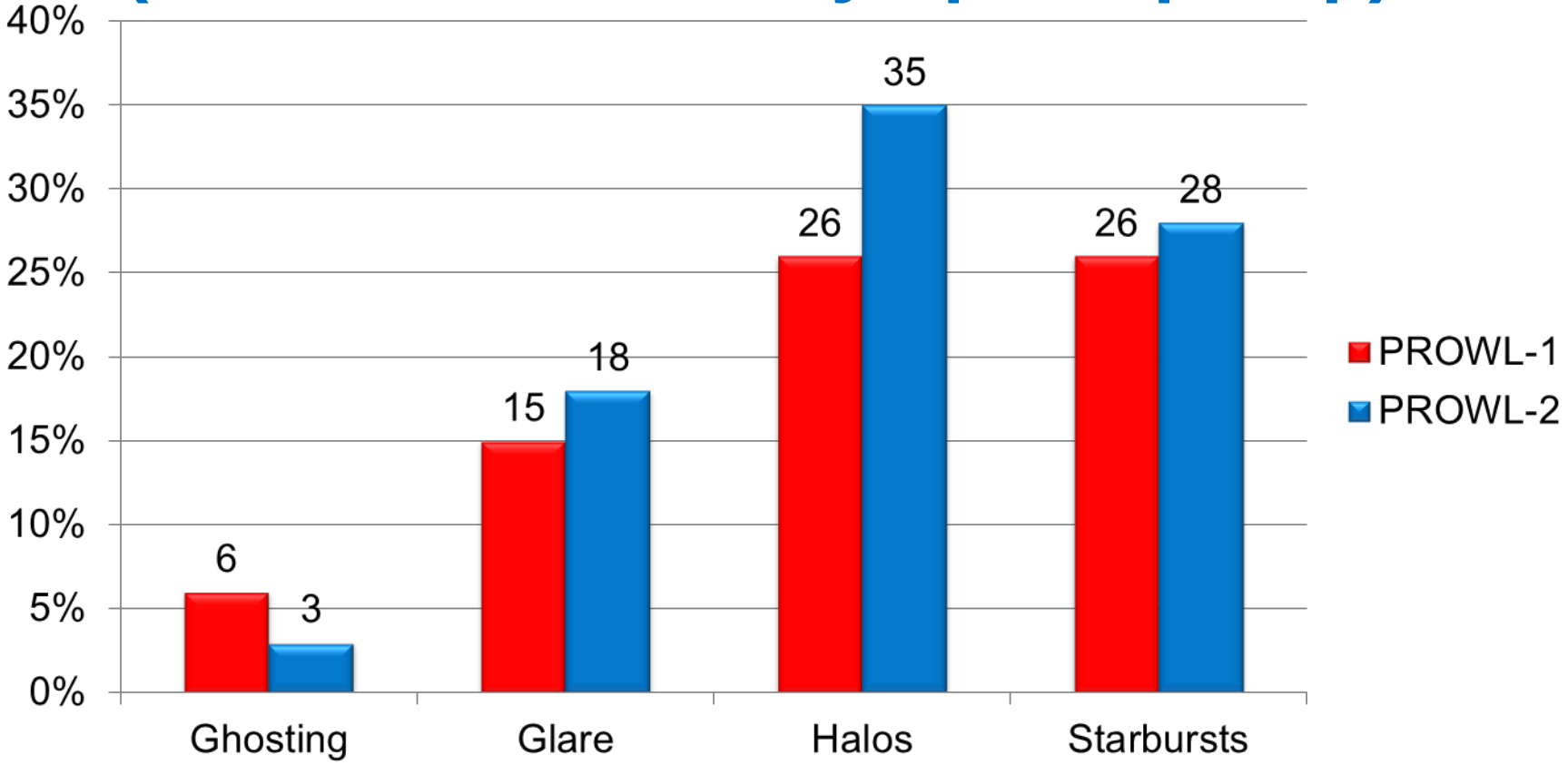


Up to 1% of subjects without correction experienced a lot of difficulty with or were unable to do usual activities due to visual symptoms at 3 Months

Subjects Developing Any New Visual Symptoms 3 Months Postop (no visual symptoms pre-op)

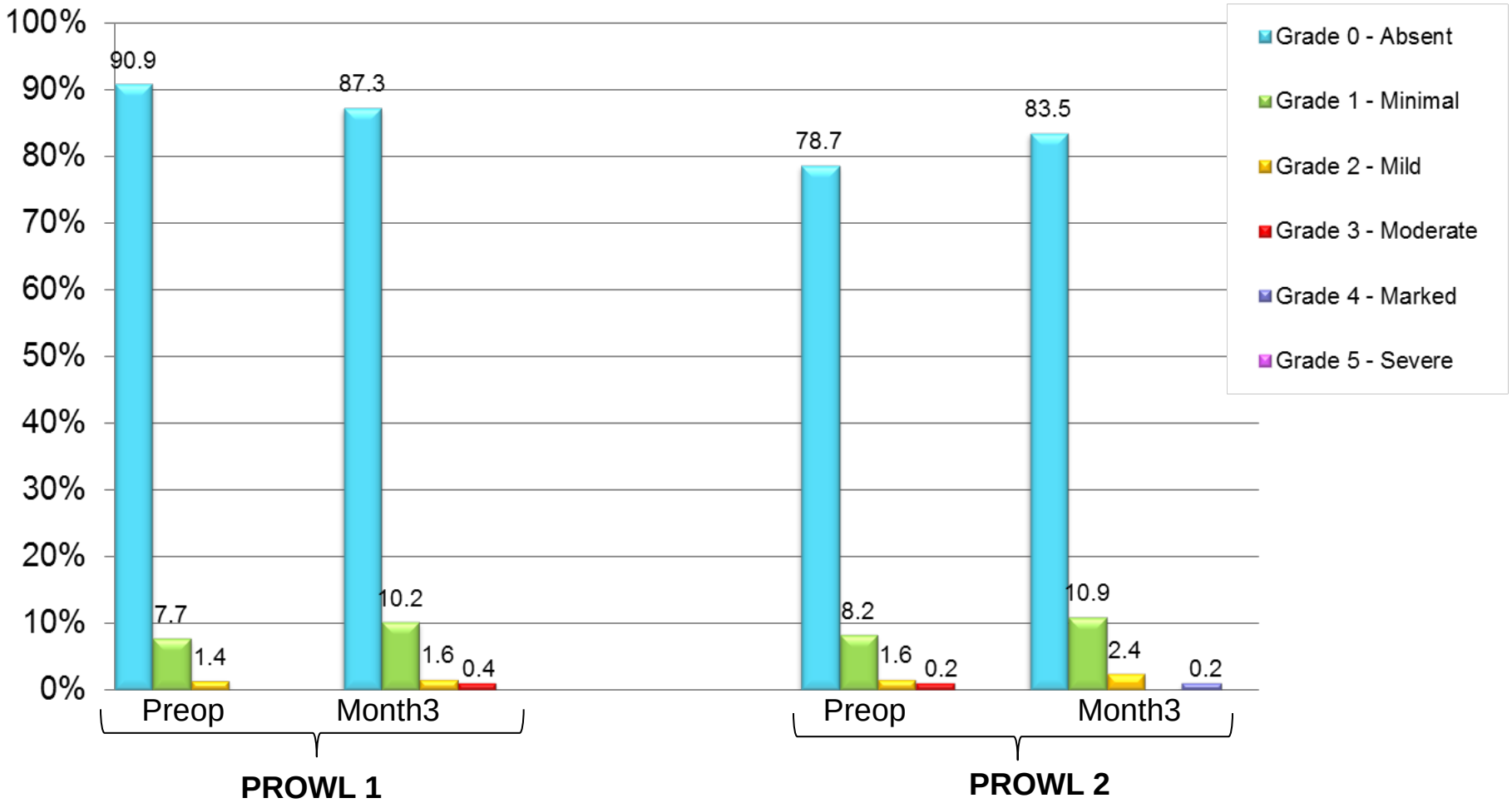
- PROWL-1: 44% (31/71)
- PROWL-2: 45% (31/69)

Subjects Developing New Visual Symptoms (did not have that symptom preop)



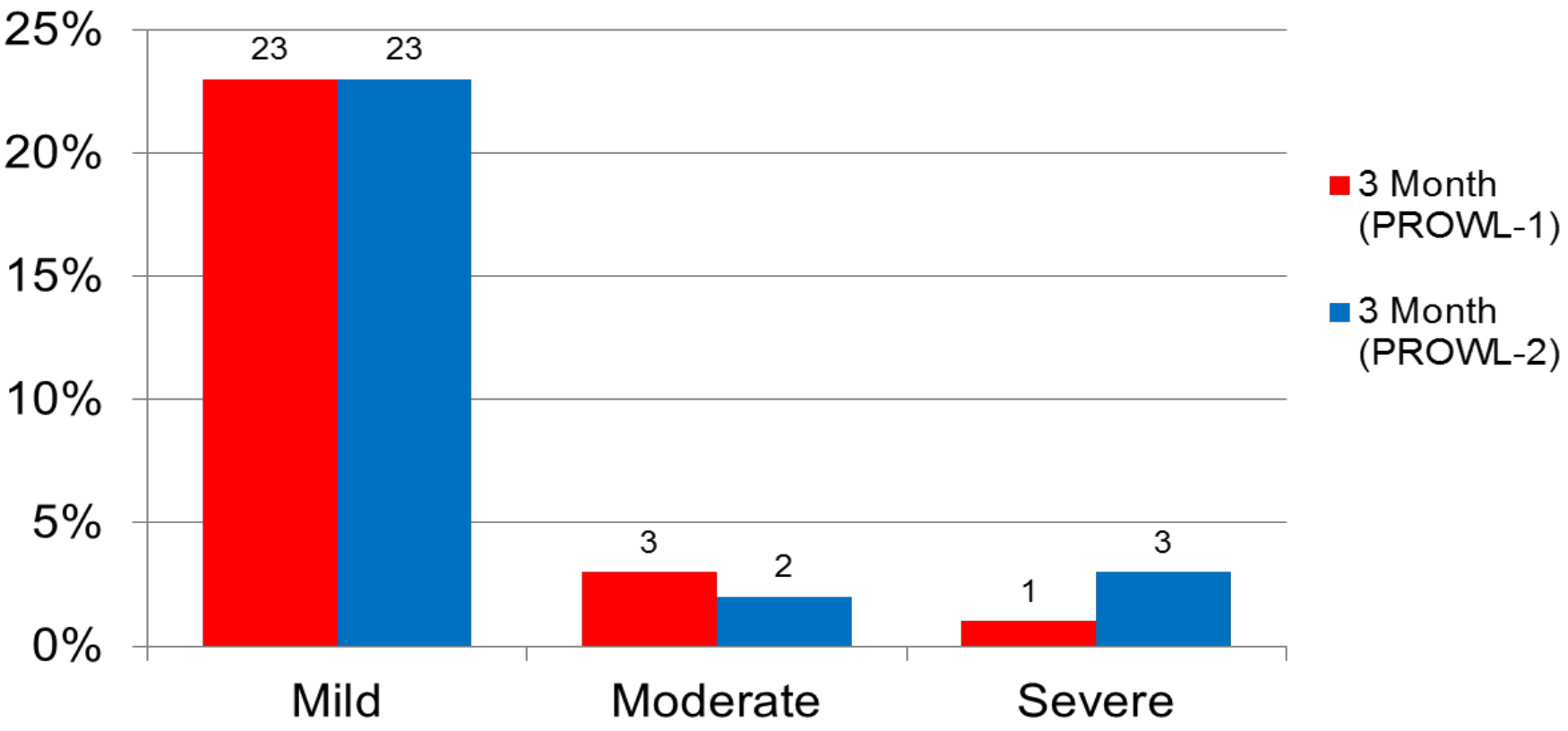
Up to 35% of subjects developed new halos

Distribution of Oxford Score staining



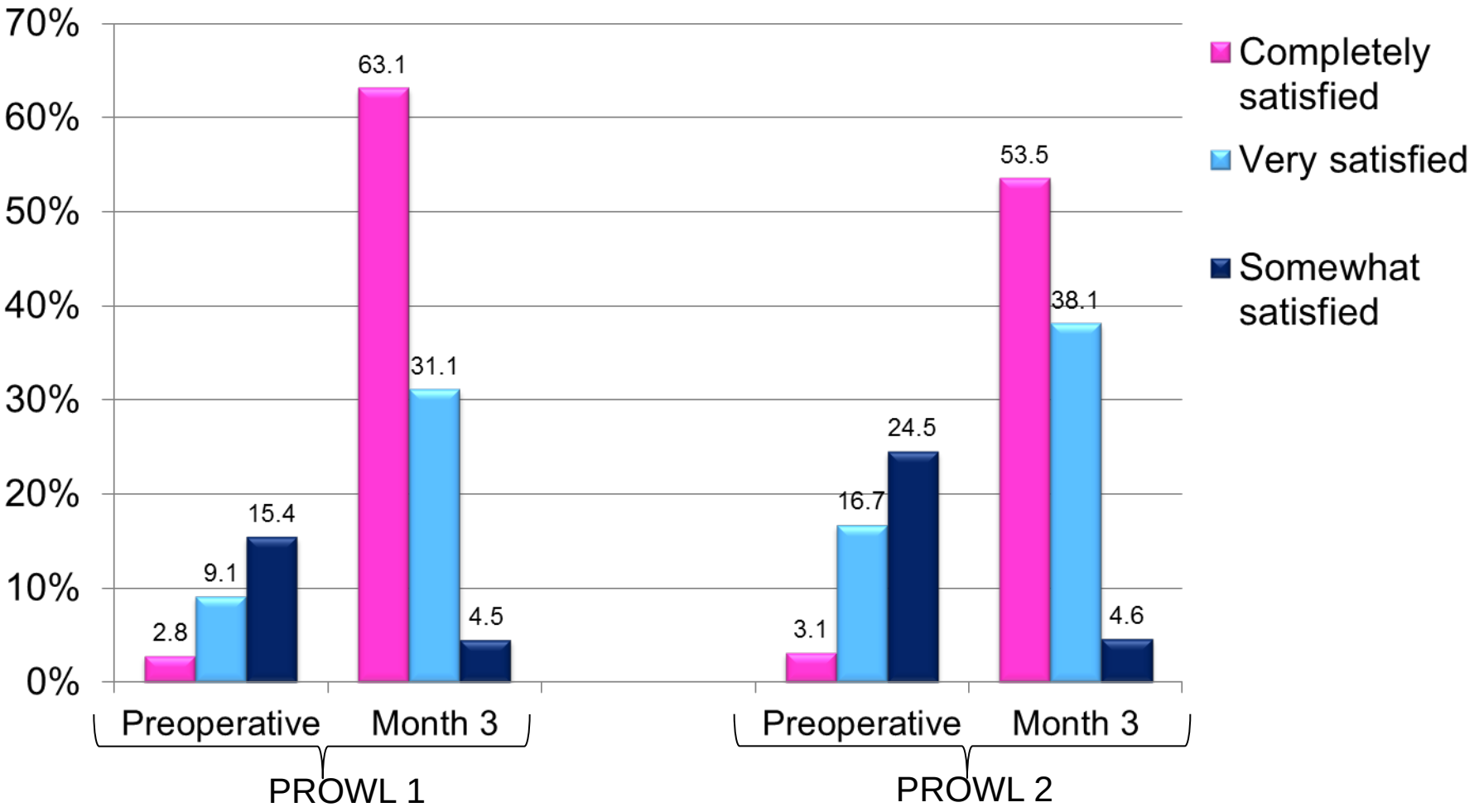
Up to 3% of eyes had staining of Oxford grade 2 or more at 3 Months

Subjects Developing New Dry Eye Symptoms (OSDI Categories) at 3 Months



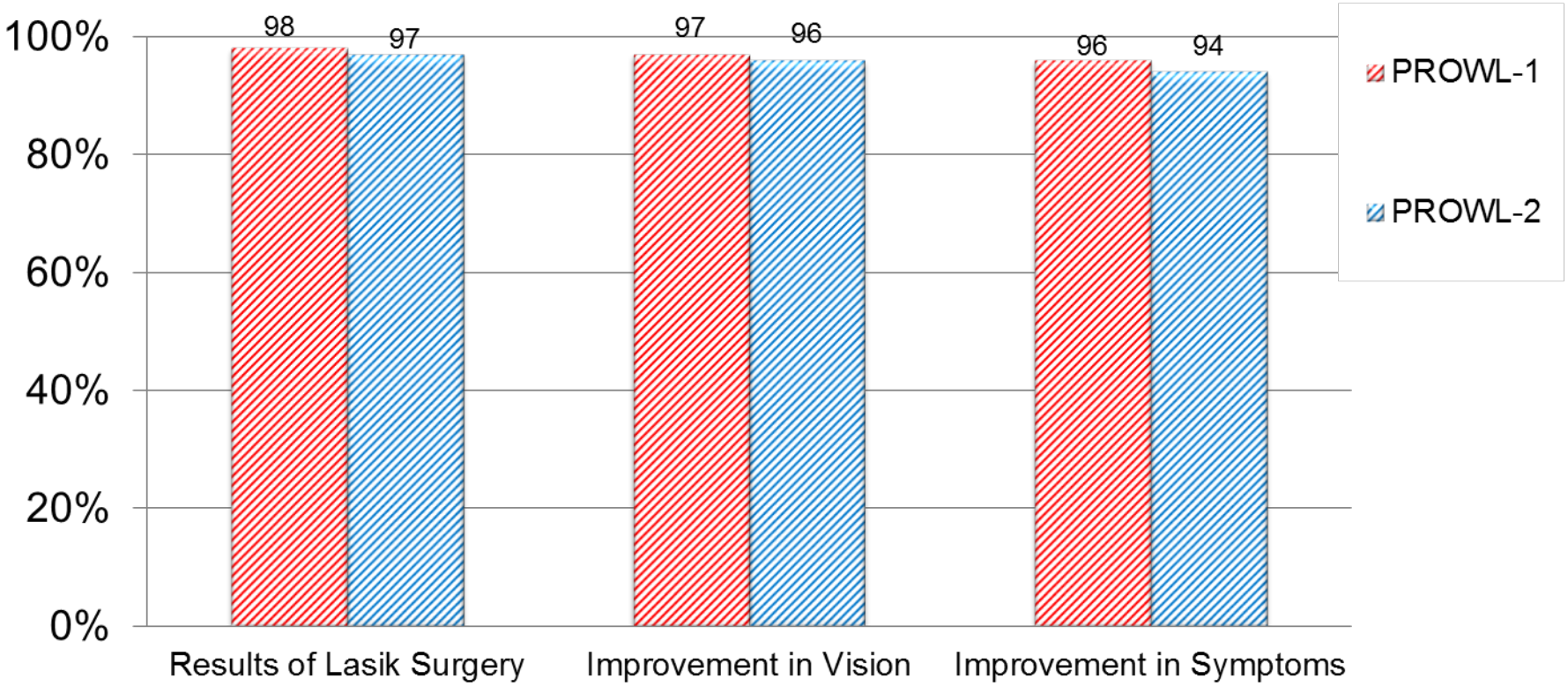
Up to 30% of subjects developed new dry eye symptoms

Overall Satisfaction with Present Vision



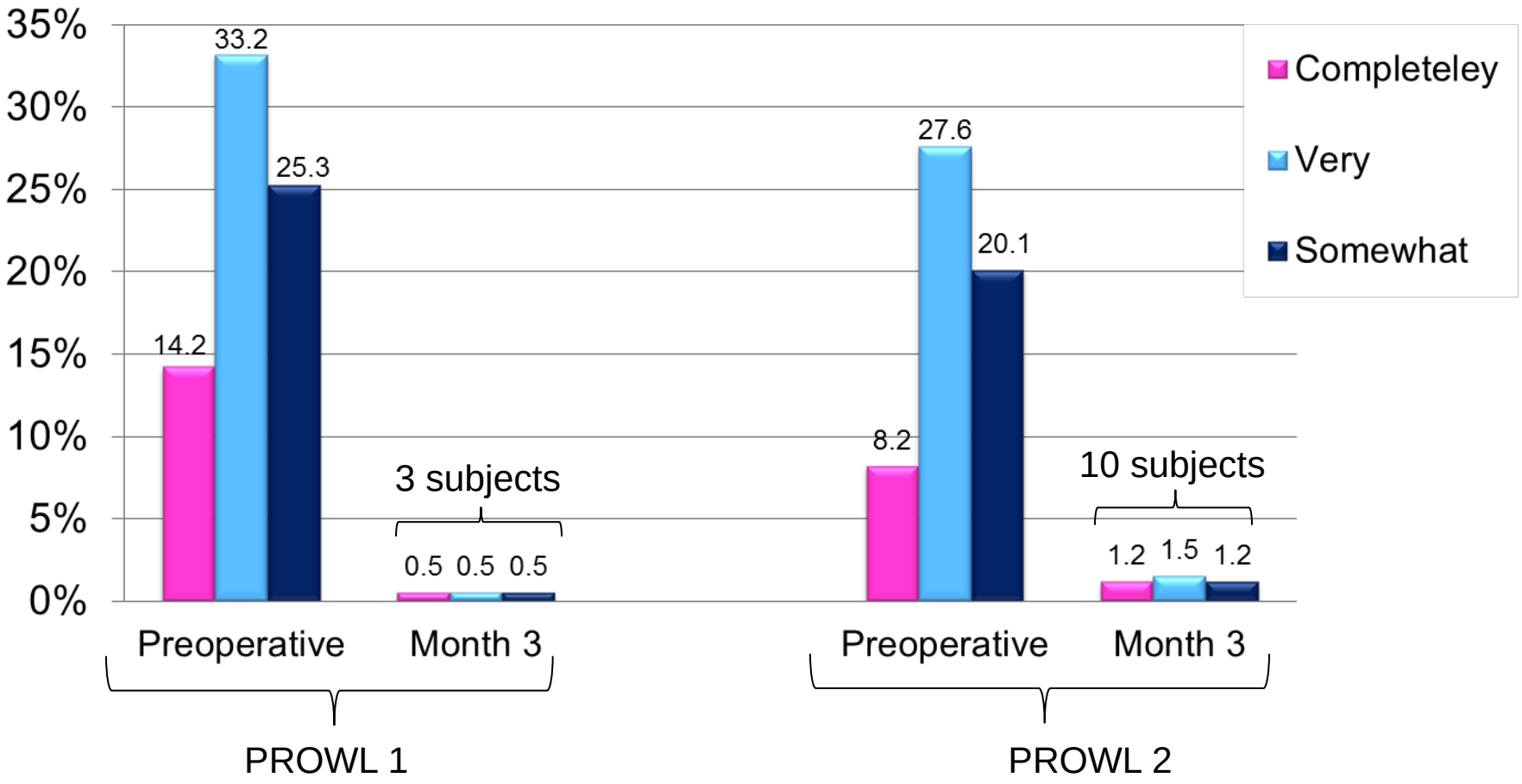
Greater than 96% of subjects were satisfied with their vision at Month 3

Additional Satisfaction Questions at Month 3



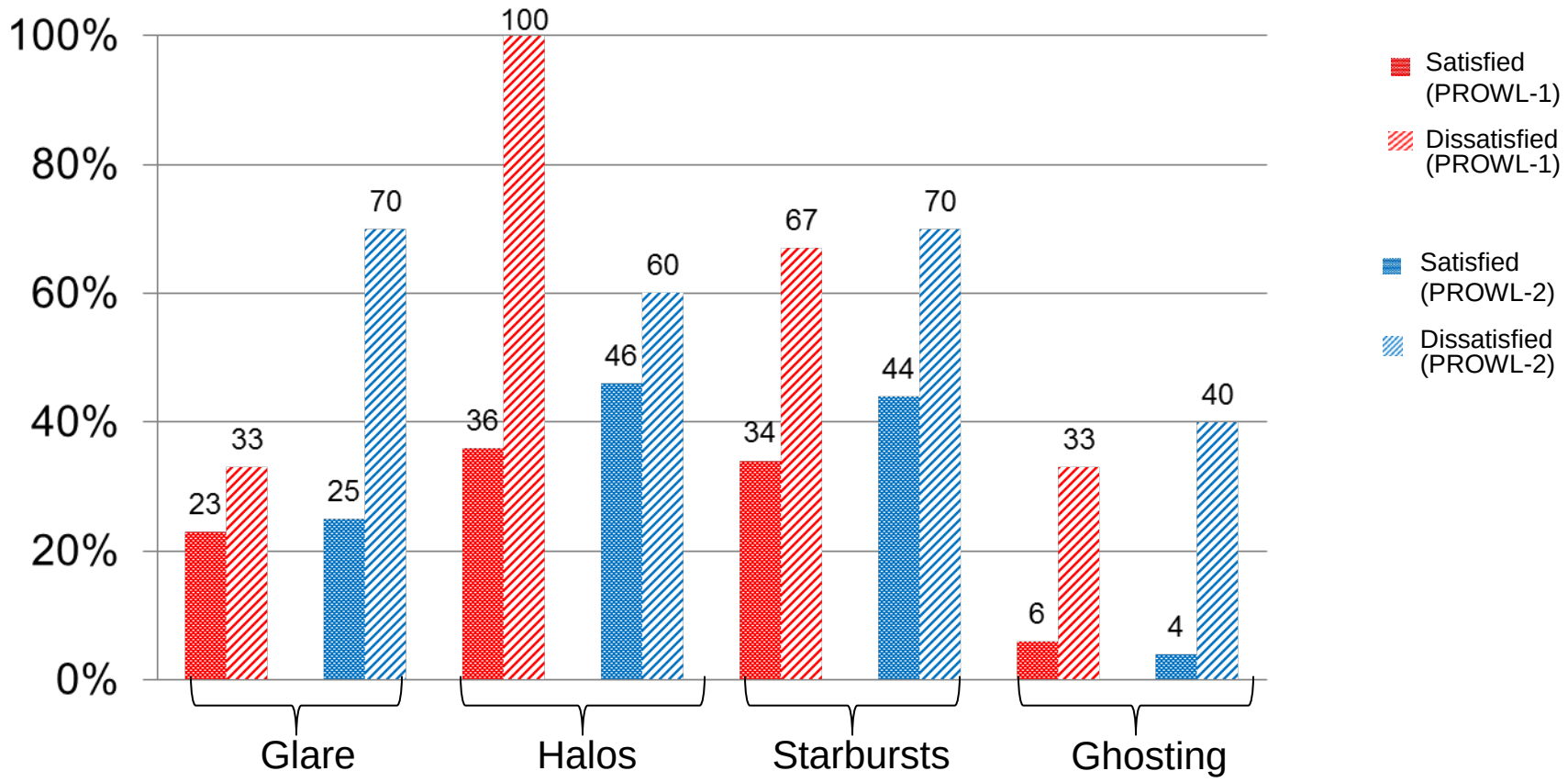
For the additional satisfaction questions, the satisfaction rate was 94% or greater

Overall Dissatisfaction with Present Vision



Up to 4% of subjects were dissatisfied with their vision at Month 3

Prevalence of Visual Symptoms at 3 Months Dissatisfied vs. Satisfied (Present Vision)



The majority of dissatisfied subjects reported visual symptoms

LQOLCP Summary

- Successful in developing a novel comprehensive questionnaire for LASIK patients
  - » Incorporates images and definitions to facilitate reporting of complex visual symptoms
  - » Captures preoperative expectations as well post-operative satisfaction
  - » Psychometrically evaluated in multiple populations

Summary (continued)

- Dry Eyes Symptoms at 3 Months
  - » Up to 30 % of subjects developed new dry eye symptoms
- Dissatisfaction at 3 Months
  - » Up to 4 % of subjects dissatisfied with vision
    - Potential association with presence of visual symptoms
    - Further analyses needed to explore additional associations

Summary (continued)

- Visual Symptoms at 3 Months
  - » Overall prevalence did not increase postoperatively
  - » Newly developed (at least one) in up to 45% of subjects who were symptom-free preoperatively
  - » Were “very” or “extremely” bothersome in up to 4% of subjects not wearing correction
  - » Caused a lot of difficulty with or resulted in inability to do usual activities in up to 1.0% of subjects not wearing correction

Public Health Impact

- Given the large number of patients undergoing LASIK annually, dissatisfaction and disabling symptoms may occur in a significant number of patients

Next Steps

- Further analysis of data
  - » PROWL-1 and PROWL-2
- FDA will explore avenues to better inform patients and physicians about LASIK risks
- Longitudinal studies
  - » Explore factors associated with and predictors of poor outcomes

Special Thanks

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