Introduction to the LASIK Quality of Life Collaboration Project

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Financial disclosure

I have the following financial interests or relationships to disclose:

Consultant for FDA

LASIK Quality of Life Collaboration Project (LQOLCP)

"PROWL" = "Patient - Reported Outcomes With Lasik" **(web-based)**

1. U.S. Navy
2. General population

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 Organization

P. I.'s:

FDA: Dr. M. Eydelman (LQOLCP, PROWL 1 and PROWL 2)

NIH: Dr. F. Ferris (LQOLCP and PROWL 2)

DOD – Dr. E. Hofmeister (PROWL 1)

LASIK Quality of Life Collaboration Project Organization

- Study Director: C. P. Wilkinson, MD
- Study Group:

  Members = 15 (Government only)
- Steering Committee:

  Members = 10

LQOLCP Study Group (SG)

- Responsible for the development of the protocols and the questionnaire
- Comprised of federal subject matter experts in study design, clinical care, questionnaire development, and statistical analyses
  - » FDA 8
  - » NEI 5
  - » DOD 2

LQOLCP Steering Committee (SC)

- Independent review of study protocols
- Independent review of study results
- Composition:
  - » 5 Nominated members from the professional organizations with expertise in all aspects of the protocol
  - » 3 Government experts in refractive and anterior segment surgery and clinical research
  - » 2 Patient representatives who had LASIK's

LASIK Quality of Life Collaboration Project Organization

Professional organizations nominated experts but did not participate in any other component of the study:

- Society for Clinical Trials
- International Society for Quality of Life Research
- AAO
- ASCRS
- AOA

Interaction of Administrative Groups

- The SG developed and reviewed multiple iterations of the protocols
- Protocols then submitted to SC for independent review
- Recommended modifications made by SG and re-submitted to SC for final comments
- SG reviewed interim and final results of studies and discussed them with SC

Benefits of LQOLCP Structure

- A genuinely independent prospective study
- No conflicts of interest from physicians, medical organizations, patients, or industry

LQOLCP Hurdles - 1

- Execution of Inter-Agency Agreements requiring extensive legal review:
  - » FDA and DoD
  - » FDA and NEI
- Extensive process and criteria for selecting members of all the administrative groups as well as signing appropriate documents

LQOLCP Hurdles - 2

- Permission to use questions from copyrighted questionnaires
  - » Submit requests to every person, organization, and company that held copyrights to questionnaires
  - » Lawyers from all parties have negotiated terms.
- IRB Approvals
  - » Obtained from RAND and FDA for cognitive interviews
  - » Obtained from DoD for PROWL 1
  - » Obtained from Western IRB, Stanford, Hopkins, and FDA for PROWL 2

Pilot Study

- Compared the results obtained from computer with paper-and-pencil administration of components of 3 validated ophthalmic questionnaires
- Published Findings
  - » Ophthalmology 2013;120:2151-9
- Lessons learned were incorporated into the larger LQOLCP protocol

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
- For concepts for which there were no available questionnaires, empiric questions were developed and tested in an informal group of clinicians and patients as well as formal groups

Overview of PROWL-1 and PROWL-2 Study Designs

- Prospective cohort study
  - » PROWL-1: single military clinic in San Diego, CA
  - » PROWL-2: multicenter (5 sites) across US
- Measuring Instrument
  - » Web-based PROWL questionnaire
    - Administered Pre-op, 1-Month, 3-Month, 6-Months[1]
    - Surgeons – no access to questionnaire responses

[1] PROWL 1 only

Preoperative Clinical Assessments

- Uncorrected/best corrected visual acuity
- Mesopic low contrast acuity[1]
- Manifest and cycloplegic refraction
- Slit-lamp examination with Lissamine green/fluoress
- Pupil size
- Intraocular pressure
- Dilated fundus exam
- Corneal pachymetry
- Corneal topography (placido and Schiemflug image)
- Wavefront imaging

[1] PROWL 1 only

Postoperative Clinical Assessments

- Uncorrected/best corrected visual acuity
- Wavefront imaging
- Slit lamp examination
- Manifest refraction
- Mesopic low contrast acuity[1]

[1] PROWL-1 only

Current Status of LQOLCP

- Pilot - Published manuscript[1] (Susan Vitale)
- Phase I - Completed, resulting in a web-based questionnaire for subsequent phases (Ron Hays)
- Phase II - Study completed, database locked, and analyses underway (Elizabeth Hofmeister)
- Phase III - Study completed, database locked, and analyses underway (Malvina Eydelman)

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