

CLEK Publications/Timeline
Current to 8/4/05

Specific Aim A:
General Description of the Course of Keratoconus

“Describe the distribution and rate of change in best corrected high and low contrast visual acuity, corneal curvature, the proportion of patients developing incident corneal scarring, and the proportion of patients progressing to surgical intervention.”

	Target <u>Submission</u> <u>Date</u>	Journal, Year
1. “Baseline findings in the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study”		IOVS, 1998
2. “A comparison of two methods of evaluating cornea-to-contact lens base curve fluorescein patterns in keratoconus”		OVS, 2001
3. “A summary of the findings from the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study”		JAOA, 2001
4. “What the CLEK Study means to you - The Collaborative Longitudinal Evaluation of Keratoconus Study is providing new insights”		Review of Optometry, 2002
5. “Between-eye asymmetry in keratoconus”		Cornea, 2002
6. “Lysosomal hydrolase staining of conjunctival impression cytology specimens in keratoconus”		Cornea, 2002
7. “A standardized rigid contact lens fitting protocol”		OVS, 2004
8. Age and disease prognosis in keratoconus	In preparation, November 2005	

Specific Aim B:

Factors Related to Vision in Keratoconus

“Characterize the association between best corrected visual acuity and visual quality of life and each of several pre-defined covariates. Best corrected and habitual visual acuity will be measured using high and low contrast Bailey-Lovie charts. Visual quality of life will be measured using the SF-36 and NEI-VFQ. The covariates of interest are corneal curvature, corneal irregularity, corneal scarring, the patient’s age, whether the patient wears spectacles or contact lenses, the type of contact lens worn, and the first definite apical clearance contact lens base curve. Determine what measure of visual acuity-high or low contrast with best correction, habitual correction, or manifest refraction and with either eye, the better eye, or both eyes-best predicts visual quality of life.”

	<u>Target Submission Date</u>	<u>Journal, Year</u>
1. “Visual acuity repeatability in keratoconus: Impact on sample size”		OVS, 1998
2. “Repeatability of refraction and corrected visual acuity in keratoconus”		OVS, 1998
3. “Repeatability of subjective refraction in myopic and keratoconic subjects: Results of vector analysis”		OPO, 2001
4. “Baseline quality of life (NEI-VFQ) in keratoconus”		AJO, 2004
5. “Longitudinal change in visual acuity: Six-year trends from the CLEK Study”		First review by IOVS complete; to be resubmitted by 8/31/05
6. Longitudinal change(s) in quality of life (NEI-VFQ)		In preparation, December 2005

Specific Aim C:
Factors Related to Disease Progression (Corneal Curvature) in Keratoconus

“Characterize the relationship between corneal curvature, as measured by keratometry, and each of several pre-defined covariates. The covariates of interest are corneal irregularity, corneal scarring, the patient’s age, whether the patient wears spectacles or contact lenses, and the type of contact lens worn.”

	Target <u>Submission</u> <u>Date</u>	<u>Journal</u> <u>Year</u>
1. “Biomicroscopic signs and disease severity in keratoconus”		Cornea, 1996
2. “A standardized rigid contact lens fitting protocol for keratoconus”		OVS, 1996
3. “Feasibility of fitting contact lenses with apical clearance in keratoconus”		OVS, 1996
4. “Repeatability and agreement of two corneal-curvature assessments in keratoconus: Keratometry and the First Definite Apical Clearance Lens (FDACL)”		Cornea, 1998
5. “Rigid contact lens fitting relationships in keratoconus”		OVS, 1999
6. “The relation between disease asymmetry & severity in keratoconus”		BJO, 2004
7. “Longitudinal changes in corneal curvature in keratoconus”		In press Cornea, 2005
8. Longitudinal asymmetry & severity	Pending	

Specific Aim D:

Factors Related to Corneal Scarring

“Determine the relationship between corneal scarring, measured by a standardized photography and reading method, and each of several pre-defined covariates. The covariates of interest are corneal curvature, the patient’s age, high and low contrast best corrected an habitual visual acuity, whether the patient wears spectacles or contact lenses, the type of contact lens worn, and the first definite apical clearance contact lens base curve.”

	<u>Target Submission Date</u>	<u>Journal, Year</u>
1. “Photodocumentation of corneal scarring”		Refractive Surgery, 1996
2. “Corneal scarring in the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study: Baseline prevalence and repeatability of detection”		Cornea, 1999
3. “Factors associated with corneal scarring in the Collaborative Longitudinal evaluation of Keratoconus (CLEK) Study”		Cornea, 2000
4. “Corneal scarring and vision in keratoconus: A baseline report from the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study”		Cornea, 2000
5. “Estimation of incidence and factors predictive of corneal scarring in the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study”		In press Cornea, 2005
6. “The safety & efficacy of rigid contact lens fitting in keratoconus”		First review received from OVS 8/17/05
7. Progression of scarring	In preparation	

Ancillary Study:**Corneal Topography Reading Center Specific Aim: Factors Related to Topographic Disease Progression in Keratoconus (PI: Tim McMahon, OD)**
- Funded by NEI U10 EY12656 started in 1997

“Compile corneal topography data from CLEK study patients in a central location, to identify the key videokeratographic variables that will be used in the analysis of the CLEK Study, and to thoroughly describe corneal topography in patients with keratoconus.”

	<u>Target Submission Date</u>	<u>Journal, Year</u>
1. “Precision of three topography instruments in keratoconus subjects”		OVS, 2001
2. “Test-retest: Repeatability of corneal topography in keratoconus w/ TMS 1”		OVS, 2005
3. “Simulation of machine specific topographic indices for use across platforms”		Submitted OVS, 2005
4. CLMI: A new keratoconus index	In preparation	
5. A new method for converting machine specific indices to a common platform	In preparation	
6. Retest of Zernike polynomials in keratoconus	Pending	
7. Clinical topographic correlates in keratoconus	Pending	
8. Cross sectional & longitudinal data on the cone location in keratoconus	Pending	

Ancillary Study: Economic Evaluation (PI: Steve Kymes, PhD) - Approved by DMOC & started in 2002

Characterize the economic burden of keratoconus from the perspective of the patient and society.

	<u>Target Submission Date</u>	<u>Journal, Year</u>
1. The cost of clinical care for keratoconus	Pending	
2. The social and patient burden in caring for keratoconus	Pending	
3. Automobile accidents, falls, & occupational injuries in persons with keratoconus	Pending	

Ancillary Study: Woman's Page - Approved by DMOC & started in 2002

Describe gender differences in the prognosis and impact of keratoconus.

	<u>Target Submission Date</u>	<u>Journal, Year</u>
1. "Differences in keratoconus as a function of gender"		In press AJO, 2005
2. Effect of menopausal status & HRT on the prognosis of keratoconus	In preparation	

Ancillary Study: Penetrating Keratoplasty - Approved by DMOC & started in 2000

Evaluate clinical, quality of life, and economic implications of penetrating keratoplasty as related to keratoconus.

	<u>Target Submission Date</u>	<u>Journal, Year</u>
1. "PK: Baseline factors predictive of incidence penetrating keratoplasty in keratoconus"		Submitted AJO, 2005
2. NEI-VFQ: Pre-post PK compared to patients who do not undergo PK	Pending	
3. Pre-post PK: Curvature, vision, staining, scarring	Pending	
4. Pre-post PK: Changes in topography	Pending	