A Message from the National Eye Institute

The National Eye Institute (NEI), a division of the National Institutes of Health, is proud to support the Collaborative Longitudinal Study of Keratoconus (CLEK) Study. With 16 different clinics in 12 states, the CLEK Study is the most broad-based sample of keratoconus patients ever studied. Thousands of hours in a national effort extending over a six-year period went into planning this study. During this planning period, the CLEK Executive Committee improved tests and measures, standardized procedures, and proved the feasibility of doing the study.

The CLEK Study is especially notable for setting very high goals for enrollment of keratoconus patients in the study, seeking to include 1,000 patients. As of February 1, 1996, eight months into the study’s recruitment phase, 753 keratoconus patients have already undergone their first CLEK Study visits!

Needless to say, clinical research like the CLEK Study cannot take place without the active support of patients with the condition under study. Although keratoconus is relatively rare, the National Eye Institute has chosen to fund this important project because of the profound effect keratoconus has on people’s lives. The NEI is very pleased that so many keratoconus patients across the country realize the importance of this research and have chosen to support it by participating in the study. It couldn’t be done without you!

Donald F. Everett
Acting Director
Collaborative Clinical Trials
Branch
National Eye Institute

MUM’S THE WORD!
To protect patient confidentiality, the CLEK Coordinating Center receives no patient identification information. (Story on page 2)
The Chairman’s Office at the University of California, Berkeley School of Optometry serves as the general administrative center of the CLEK Study. Karla Zadnik, OD PhD is the CLEK Study Chairman, and she heads the CLEK Executive Committee.

The CLEK Study Chairman’s Office communicates regularly with the personnel at the 16 CLEK Participating Clinics. The clinics receive their study equipment and supplies from Berkeley, including vision testing charts, contact lens trial sets, study brochures, and diskettes for storing computerized data on corneal shape.

The Chairman’s Office generated the original CLEK Operations Manual – the two-inch thick notebook that drives the project and serves as the reference for the doctors and technicians performing study protocols at the clinics. The Operations Manual will undergo updates through the Chairman’s Office, too.

Dr. Zadnik serves as the “voice of the CLEK Study” both on the telephone and on the Internet. She fields questions every day from keratoconus patients, optometrists, ophthalmologists, and patients’ family members, explaining the CLEK Study, keratoconus in general, and directing patients to the appropriate Participating Clinic for enrollment.

CLEK Coordinating Center staff – Joel Achtenberg, Mae Gordon, Ken Schectman, Michael Richman, and Teresa Roediger – will never know your name or where you live!

The Coordinating Center, directed by Mae O. Gordon, PhD and located in the Department of Ophthalmology and Visual Sciences at Washington University Medical School, provides scientific operational guidance for the CLEK Study. The goal of the Coordinating Center’s staff of statisticians, programmers, computer analysts, and research assistants is to ensure that the CLEK Study adheres to the highest scientific standards and is organizationally sound. In weekly conference calls, the Coordinating Center and CLEK Executive Committee discuss scientific and operational problems of the study. These conference calls have been held weekly for nearly 7 years. Each day the Coordinating Center receives forms from patients and investigators. Each and every form is checked for accuracy and completeness! Examining all this information from all of the CLEK Participating Clinics allows problems to be spotted and corrected as soon as possible. Each clinic is “site-visited” by a member of the Executive Committee and Coordinating Center annually. During these site visits, examination procedures and records are checked to determine if correct protocols are being used. These precautions ensure that the results from this study have the highest scientific integrity possible.
WHY ALL THOSE PHOTOGRAPHS?

We’re sure that you have wondered about all those flashing lights and pictures that your CLEK investigator has taken. The CLEK Photography Reading Center at The Ohio State University College of Optometry, directed by Joseph T. Barr, OD MS, functions as an impartial and consistent reader or “grader” of these eye and contact lens photographs.

By carefully and consistently studying the photographs of your eyes, we can measure the minor scarring that may or may not take place in your cornea. We already know that this scarring can disrupt your vision if it is large or dense enough or if it is located in the middle of your cornea. Although the word “scarring” sounds bad, most experts do not get alarmed when they see it and, therefore, you may not know about it. We are currently studying how the scarring changes and how it affects your vision. Apical (central) corneal scarring has been related to keratoconus, and it is possible, although not scientifically proven, that contact lenses – which you may need for best vision – may affect scarring. That’s one thing we are investigating. We also hope to discover ways to decrease or control this scarring. We will keep you posted regarding any findings that CLEK investigators make on this important front.

If you wear rigid gas permeable or hard contact lenses, photographs are also taken of these. We study these photographs to see how a large group of you are fitted by your doctor. We then relate this information to the photographs that are taken of the special lenses put on your eyes at the end of your CLEK examination. This test also allows us to measure the corneal curvature and its change over time. We believe that in the future this test will not only allow us to estimate how your cornea is changing, but may also help us to find a better fit for your contact lenses. The CLEK Study notifies your doctor about these results so that he or she can help you feel and see better.

When the CLEK Study started we had a hunch that all these photographs would help us to better understand your condition. Now we’re sure that they do. The CLEK Photography Reading Center keeps all of the photographs from all of your CLEK examinations on file for use now and also for many other measurements that we will be able to do in the future.
Today the Web, Tomorrow . . .

The next time you find yourself surfing the World Wide Web (WWW), check out the CLEK Study home page.

Faced with the ambitious goal of recruiting 1,000 keratoconus patients within a ten-month period, the CLEK Executive Committee decided to "catch the wave" and be the first NIH-sponsored study to recruit participants via a page on the World Wide Web. Thanks to the inspiration and technical assistance of Mark Bullimore, OD PhD, the CLEK Study WWW Page was initiated in June 1995. It provides a brief description of keratoconus and the CLEK Study as well as a list of the locations of the 16 CLEK Participating Clinics across the United States.

The CLEK home page serves as an innovative and effective means of communicating with eye care practitioners and potential study participants. Anyone unfamiliar with the CLEK Study but interested in the topic of keratoconus will find the CLEK Study Web Site simply by searching for "keratoconus."

Being terminally curious, the CLEK Executive Committee monitored interest in the new CLEK home page from September 20 to October 30, 1995 with promising results. During this forty day period, the CLEK WWW home page was visited 399 times, with an additional 168 visits to the "CLEK Clinics" page by folks wanting more information. Dr. Bullimore was also able to determine the home bases of all but 86 of CLEK’s virtual visitors. The CLEK home page inquiries fall into the following categories: 69 inquiries from universities, 21 from government-based email addresses, 8 from organizations, 153 from commercial users and 57 from home bases outside of the United States. The word is definitely getting out!

CLEK Study home page address: http://spectacle.berkeley.edu/CLEK/CLEK.html

![Locations of the 16 CLEK Participating Clinics nationwide.](chart)

CLEK Study recruitment for the first 8 months: 753 patients already enrolled as of February 1, 1996!
CLEK CROSSWORD

ACROSS
3. Thanks for participating in the Collaborative ________ Evaluation of Keratoconus Study!
5. We use _______ fluorescein dye to color your tears and to evaluate the fit of rigid contact lenses.
8. At ____ dollars per visit for incidentals, you are grossly undercompensated for your time and effort in making the CLEK Study a success.
10. It's okay to guess at the tiny letters you read 12 times in each study visit on the visual __________ charts.
12. A question asked during your exam is: "Do you have a history of hayfever or seasonal ________?"
15. We also ask if you have a history of vigorously _______ your eyes.
16. Study photographs are sent for evaluation to the CLEK Photography Reading Center located at The ________ State University in Columbus, Ohio.
17. Before you can be enrolled into the CLEK Study, you must sign an informed _______ form which describes the purpose & procedures used in the study.

DOWN
1. CLEK colors are green & _______. Hint: Barney, the dinosaur, is the same color.
2. Study data is compiled & analyzed at the CLEK Coordinating Center at _______ University in St. Louis, Missouri. Hint: this university named for 1st president.
4. Congratulations, you have completed your baseline visit and will be scheduled for an annual visit in each of the next ____ years.
6. If keratoconus progresses to a point where vision is not satisfactorily corrected with spectacles, then _______ (not soft) contact lenses are indicated.
7. The CLEK Study is funded by the National ________ Institute, a division of the National Institutes of Health.
8. One _______ keratoconus patients will be enrolled into the CLEK Study at the 16 clinical sites across the United States.
9. The color of the light we use to fluoresce the dye for the photography of the fit of the rigid contact lenses is _______.
10. Same as 10 Across.
11. After you fill out the purple Human Subject Payment Certification form, it is mailed to the Study Chairman's office at the University of _______, Berkeley.
13. The CLEK Study is the first NIH-sponsored study to recruit patients via a page on the World Wide _______.
14. Keratoconus affects the anterior-most portion of the eye, the _______.
April in Ohio – CLEK Investigators and Study Coordinators gathered in Columbus for a two-day Training Meeting to become certified in CLEK procedures and protocol.

"Say cheese..." Dr. Dave Libassi from SUNY State College of Optometry practiced corneal photography at the CLEK Training Meeting.

Back to School – Dr. Barry Eiden from the University of Illinois at Chicago graded sample corneal photographs at the CLEK Training Meeting.

IMPORTANT REMINDER

Please schedule a presurgical visit with your CLEK Participating Clinic if you decide to have a Corneal Transplant!

WANT MORE INFORMATION ABOUT KERATOCONUS?

Contact: Cathy Warren, RN CRNO
Nat’l Keratoconus Foundation
8700 Beverly Blvd. D5069
Los Angeles, CA 90048
Telephone: (310) 855-6455
e-mail: nkcl@csmc.edu

CROSSWORD SOLUTION
**Top Recruiting Team**

John Sake, Eric Sheahan, Janet Hess, Jill Nelson, and Dr. John Sterling from Gunderson Clinic in La Crosse, WI — the first CLEK Participating Clinic site to meet (and exceed!) CLEK Study recruitment goals.

Dr. Loretta Szczotka, Kimberly Supp, Bonita Darby, and Beth Ann Benetz from University Hospitals of Cleveland, Department of Ophthalmology.

Dr. Joel Silbert, Mary Jameson, and Dr. Ken Daniels from the Pennsylvania College of Optometry in Philadelphia.

Drs. Lisa Barnhart, Barry Weissman, and Melissa Chun from Jules Stein Eye Institute at the UCLA School of Medicine.
CLEK
Collaborative Longitudinal Evaluation of Keratoconus Study
is funded by the National Eye Institute, a division of the National Institutes of Health.

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Thanks for a great year!

CLEK Executive Committee:

**Karla Zadnik, OD PhD**, CLEK Study Chairman
University of California, Berkeley School of Optometry

**Joseph T. Barr, OD MS**, Director, CLEK Photography Reading Center,
The Ohio State University College of Optometry

**Mae O. Gordon, PhD**, Director, Coordinating Center, Washington University
Department of Ophthalmology & Visual Sciences and the Division of Biostatistics

**Timothy B. Edrington, OD MS**, Southern California College of Optometry

**Donald F. Everett, MA**, Project Officer, National Eye Institute