CLEK ON DECK
The Official Newsletter of the Collaborative Longitudinal Evaluation of Keratoconus Study

Volume 2, Issue 1

July 1, 1995

CLEK’s Firsts

Optometry and the NEI
The project represents the first multicenter study in optometry ever funded by the NEI. It is significant in that some CLEK Clinic Principal Investigators have never before worked on this kind of project. It also represents a level of inter-institution collaboration not often observed in optometry or between optometry and ophthalmology.

Women and the Web
We believe that CLEK is the first multi-center, NEI-funded study ever chaired by a woman and the first NIH-funded study to have a home page on the World Wide Web (URL:http://ucaussie.berkeley.edu/CLEK/CLEK.html). The Chairman’s Office encourages you to stay in touch with Karla Zadnik, CLEK Study Chairman and Judy Seibert, CLEK Study Coordinator and the friendly, friendly voice on the phone, at (510) 643-0568.

CPRC Keeps Up with Slide Deluge
CLEK Photographers submitted over 80 rolls of film to the CPRC this past month, and Gloria Scott-Tibbs tracked and labeled them while Gil Pierce (our masked reader) graded them. Matt Gilbert developed the CPRC database, and certification data are now being used to test the database. CLEK Study patient slides are currently only being screened prior to formal grading to ensure adequate quality and to identify the need for repeat photography. Certification photos now have top priority. Gloria and Gil are now certified.

Robert Steffen, OD MS, who just completed his two-year contact lens residency at OSU will become the new CPRC Reader as Yvonne Johnson, OD MS, moves on to CIBA Vision. We welcome Robert and wish Yvonne all the best!

The CPRC is working on a scar density sample photograph set that will distributed soon. We can only hope to rival Tim Edrington’s fabulous FDACL sample sheet!

OSU entered the first patient.

Coordinating Center Welcome
The Coordinating Center at Washington University, Department of Ophthalmology and Visual Sciences, welcomes everyone to the CLEK Study! The Coordinating Center synchronizes efforts of investigators, monitors protocol adherence, and manages CLEK Study data which includes receiving, storing, analyzing, and preparing reports and/or publications. The Director of the Coordinating Center, Mae Gordon, has an undying reputation of always being in a good mood. Joel Achtenberg, our Senior Research Analyst, heads the CLEK Study data management effort. He loves pot stickers if you ever want to buy him lunch. Teresa Roediger, our Project Assistant, has done an outstanding job producing and organizing the CLEK Study forms. When she is not working on forms, she is usually making fun of me. I am Michael Richman, the Project Manager at the Coordinating Center. I am busy contributing to all aspects of the Coordinating Center effort. Mae, Joel, Teresa, and I look forward to getting to know each of you better in the upcoming months.

“Just Ask Esther”

Dear Esther:
I tried to do FDACL on a grafted eye last week, and it was darn near impossible. What should I do?
Sign me, Frustrated in Scranton
Dear Frustrated:
Submit a Feedback Report to the Coordinating Center, and the Executive Committee will discuss the problem and get back to you promptly.

Dear Esther:
I really liked the user-friendly protocol for calibrating with the light meters. Who should I thank?
Sign me, Gung ho in La Crosse

Dear Gung ho:
Mark Bullimore, OD PhD at UC Berkeley, who also trained visual acuity, calibrated the light meters and wrote the protocol.

Dear Esther:
Is it okay to brag? As of June 20, we have 52 patients who have agreed to participate in CLEK and are being scheduled.

Sign me, Proud in Chicago

Dear Proud:
It is more than okay to brag. We'd like nothing more than to see each and every Participating Clinic match and beat your record! Keep up the fabulous work!

Recruitment Tips

The UC Berkeley CLEK crowd found a unique source of potential study patients. Karla Zadnik and Judy Seibert invited the 10 School of Optometry Clinic front desk staff members to a bagel breakfast and gave a brief CLEK Study slide presentation to them. In the first week following the brunch, the front desk staff has referred three patients to the study. They report feeling much more a part of the clinical research efforts, too. Joe Barr suggests a similar event for your institutions clinical faculty, part-time attendings, etc.

Coordinating Center Notes

• Currently, the CLEK Study forms we receive are being reviewed manually. Computer automated edit reports will be produced within the next month.
• The Coordinating Center will begin sending notifications for Repeat Visits after you have enrolled your first eight patients.
• Please review the FDACL protocol (Chapter 9 in the CLEK Operations Manual). Several Examination Forms have been received with deviations from the FDACL protocol.
• Please remember to initial and date all corrections on CLEK Study forms: no “white-out” allowed.
• The Coordinating Center has excellent occupational classification capabilities. Please encourage your patients to be as specific as possible when classifying their current occlusion and duties on the Patient History Form (PH).
• Congratulations to all Clinics that are off and running in an exemplary fashion. Special kudos to University Hospitals of Cleveland and Loretta Szczotka’s team.

Welcome Post Training Meeting

We would like to welcome the following CLEKkies who are joining us and have accepted the challenge of post-training meeting certification:

Kate Landro, Study Coordinator, University of Utah
Carolyn Begley OD MS, Co-Investigator, Indiana University
Beth Henderson OD, Co-Investigator, University of Missouri-St. Louis School of Optometry
Lori Elliott OD, Co-Investigator, University of Missouri-St. Louis School of Optometry
Vic Malinovsky OD MS, Co-Investigator, Indiana University
Lilian Andaya, Technician, UCLA Jules Stein Eye Institute
Elisabeth Lim, Technician, UCLA Jules Stein Eye Institute
Nancy Duquette, Study Coordinator, University of Missouri-St. Louis School of Optometry
John Larson OD, Co-Investigator, Gundersen Clinic Ltd.
Jonathan Lass MD, Co-Investigator, University Hospitals of Cleveland
Protocol Refinement
The initial enrollment phase for CLEK is our first opportunity to field-test the Study forms and protocol in all their glory. Some days it seems as if each and every new patient contributes a new glitch.

Feedback from the Participating Clinics’ personnel is vitally important to the Study and needs to be processed by the Executive Committee as quickly as possible. This information can range from eligibility questions on a specific type of patient to clarification of the acuity protocol to instrument calibration and beyond.

Feedback Reports
To facilitate such feedback (and instead of or in addition to an informal phone call), please use the CLEK Study Feedback Report Form. Complete the form as completely as you can, and fax it to the appropriate Resource Center. For example, if the information relates to the photography protocol or photography data transmission, fax it to Joe Barr at (614) 688-3285. If it’s regarding forms, fax it to Mae Gordon at (314) 747-1325. If it’s a general Study protocol question or issue, send it to Karla Zadnik at (510) 643-0570. Keep on faxin’!

Slide into Columbus
The figure below is an example of one of the many CPRC reports now being generated. Soon, you will be receiving individual feedback at your Clinics regarding your slide performance, too.

This graph of non-Study data is an example of the type of report used by the CPRC to monitor cornea photography quality. Centration refers to the eye within the photograph, exposure may be high, low, acceptable, or unacceptable, focus is focus, lids refers to how wide open the eyelids are, location refers to whether or not the light beam is where it should be, and magnification is high, low, or correct. Any variable may be graded ungradable. Lids, location, and centration are graded on a scale from 1 (possible retake necessary), 2 (borderline), 3 (fair), 4 (good), to 5 (excellent). Early results are encouraging, although some retakes have been requested. Gloria, Gil, Robert, Matt, Kim, and Joe are eager to see the CPRC catch up with the backlog of photographs at the CPRC.
Coordinating Center Notes

In July, Joel Achtenberg and Teresa Roediger continued working diligently to initiate computerized edits of the CLEK Study forms. If your Participating Clinic has not received computerized edit reports by now, rest assured that they are on the way! Michael Richman has been gearing up to produce the CLEK Study’s first Data Monitoring and Oversight Committee Report. Please keep in mind that we want patient enrollment in this Report to be as strong as possible across all Clinics. We are excited that enrollment figures have already surpassed 100 patients, but not all Clinics are up to expected enrollment levels yet. Let’s all meet our expected enrollment levels together in August!

The Coordinating Center sent your Clinic the following in July:

• Newsletter and Enrollment Report
• Additional enrollment materials including Repeat Visit Forms (if applicable)
• Keratometry Calibration Log
• Light Meter Reading Log

If your Clinic has not received any of these materials, please contact the Coordinating Center.

“Just Ask Esther”

Dear Esther:
I understand CLEK is the first NIH Study to recruit patients via the Internet. Do you know what the results have been?

Sign me, Interested in Bethesda

Dear Interested:
Karla Zadnik receives on average 1-2 email messages a day from keratoconus patients or referring doctors.

Dear Esther:
I discovered just after the CLEK exam that my patient had her contact lenses reversed. I sent in my Examination Form with a note. What should I have done?

Sign me, Ambidextrous in Berkeley

Dear Ambi:
You did exactly the right thing: sending in the CLEK Forms with a note.

CLEK Babies

Born to Larry and Janice Davis on March 16, 1995: Sydni Kaye at a whopping 8 lbs, 12 ozs.

And to Barry and Carol Eiden came Lauren Alexis at 7 lbs, 15 ozs, joining brothers Jeffrey and Danny on May 23rd.

Coordinating Center Who’s Who

• Mae Gordon has been married for 27 years to Bob. She has a 7-year old son, Michael. Mae is an avid hiker and has logged over 2,500 miles in the Pacific Northwest. She also has finished three marathons and a century bicycle tour. Mae is the Director of the Coordinating Center for the Ocular Hypertension Treatment Study and a Principal Investigator for the Visual Function Questionnaire Study.

• Michael Richman moved back to the St. Louis area from Salt Lake City to join CLEK. His hobbies and interest include statistics, philosophy, fine food, music, and playing outdoors. Currently, Michael is training for a half marathon that he will run on behalf of the Leukemia Society.

• Joel Achtenberg is a long-time St. Louisan who has been in medical research and computing for 20 years. His hobbies include woodworking, gardening, and camping. Joel is completing a masters degree in Social Work in his “spare time.” He hopes to work more with children and families in the future.

• Teresa Roediger is a native St. Louisan and is married to Jeff, an undercover narcotics detective. Daughters Megan (4 years) and Trese (20 months) keep Teresa busy. Teresa enjoys peace and quiet, relaxation, music, shopping, shopping, and more shopping!

Welcome Wagon

Joining us is Laura Teutsch as a technician at the University Hospitals of Cleveland.

Now Available en español

In response to a request from Tim McMahon, and thanks to Dr. Dan Twelker of the Berkeley Ocular Biometry Study and Dr. Nina Friedman of CLEK and the Orinda Longitudinal Study of Myopia, we now have a CLEK Study information brochure in Spanish. Copies are available from Judy Seibert at the Chairman’s Office.

Now Available en español
Clinic Conference Calls a Success

Recruitment and Scheduling
The second round of conference calls with the CLEK Clinic PIs was held in late August. Patient scheduling and communication methods were reviewed, and we learned how Clinics are getting all those patients processed!

University Hospitals of Cleveland gets three patients in one day by working into the wee hours of the evening one long day per week. Gundersen Clinic personnel roller blade around their Clinic in one mammoth day of 6 patient slots per week. SUNY optometrists work as a team and process two patients simultaneously.

All Clinics are gearing up for the recruitment report to be presented to the Data Monitoring and Oversight Committee in mid-October.

FDACL
The First Definite Apical Clearance Lens protocol was a big agenda item. Various Clinicians expressed some difficulty with patients’ photophobia, differences between observations with different instruments, and were sensitive to the patients’ burden. The FDACL protocol has been revised to emphasize that the FDACL is the flattest or first lens to show apical clearance. To help with photophobia, turn down the illumination.

The Executive Committee will continue to discuss the value and specifics of the FDACL part of the protocol.

Coordinating Center Notes

Computerized Edit Report Watch
The Coordinating Center and Executive Committee have decided to cut the paper traffic on edit reports. Problems on patient-completed forms will be summarized in a monthly report. However, each clinician-completed form with problems will still get an edit report to correct missing data, inconsistent data, etc. In September, when the first edit reports on the Examination Form go out, Michael, Teresa, and Mae will go through one report, step-by-step, by telephone with each Clinic.

Is Your Light Right?
Visual acuity measures are critical to the integrity of the CLEK Study. Light meters and light meter reading logs have been provided to all Clinics. Please measure and record light meter readings weekly.

On the same note, please make sure that you are logging keratometer calibration measurements weekly as well.

Pete and Repeat
Pete will not be visiting your Clinic in the upcoming months, but representatives from the Coordinating Center and the Executive Committee will be visiting your Clinic soon. We will have a Clinic Site Visit Schedule in the October newsletter.

Repeat Visit Patients should be scheduled within a month of their Baseline Visit, if at all possible. Each Clinic is responsible for completing 10 Repeat Visits. If an assigned Repeat Visit patient is not willing to schedule an appointment, please discard that patient’s Repeat Visit forms and notify the Coordinating Center.

Keratometry, Too
Dear Esther:
Is it okay to hide Baseline Visit Forms during Repeat Visits? My Study Coordinator hides each Repeat Visit patient’s initial Examination Form so I can’t look back at it? Should I tell her to stop?

Sign me, Zorro

Dear Zorro,
Actually, she’s doing the right thing. You should be “masked” to the previous visit’s results when you perform the Repeat Visit.

Dear Esther:
How do I enter “plano” on the CLEK Examination Form?

Sign me, Zeroed Out

Dear Zeroed:
Fill in the appropriate boxes with all zeroes.

Dear Esther,
When I send film to the CPRC, should I put the film label on the outside of the plastic canister or on the metal film canister?

Sign me, Joe Photographer

Dear Joe,
All film labels should go on the outside of the metal canister. If several patients’ film rolls are sent in the same package with the labels on the outside of the plastic canister, there could be a disaster if the canisters pop open during shipment. There would be no way to identify which film belongs to which patient.

Dear Esther,
I enrolled a patient who’s scheduled for surgery in 10 days. Do I have to schedule an additional Presurgical Visit between now and then?

Sign me, Overbooked in Chicago

Dear Overbooked:
If a patient undergoes corneal surgery within 3 months of a routine CLEK Study Visit, no additional Presurgical Visit is required.

This is no rock ‘n’ roll band
It’s a unique, creative vision,
Of a small isolated group of individuals.
A group that’s skilled and dedicated,
Searching for the knowledge,
That will improve the quality of their life,
And the lives of those around them.

CLEK on the Net

Just to update you ... Karla Zadnik gets several emails each week on average from optometrists and patients who have spotted CLEK on the Worldwide Web. If someone in your Clinic’s area wants to enroll or needs information, the Chairman’s Office sends the person a brochure, gives them your name and number, and generally contacts you, too.

CLEK Photography Reading Center
Who’s Who

- Joe Barr is the Director of the CLEK Photography Reading Center. He is the editor of Contact Lens Spectrum, an associate professor at The Ohio State University, director of Clinics there, and all-around nice guy. He is married to pharmacist Janet and has two daughters, Jennifer and Beth, both avid young sportswomen.
- Gloria Scott-Tibbs has been married for 13 years to Howard A. Tibbs (aka Tony). She has two children, Wesley, age 9 and Madeleine, age 4. She has worked at The Ohio State University for 17 years, starting out in a research laboratory. For the last 10 years, she has been doing clinical research in several departments, including OB/GYN, Pediatrics, Infectious Disease, and now Optometry. Her interests include bridge, gardening, reading, counted cross-stitch, and “Days of Our Lives.”
- Robert Steffen, OD MS, amateur photographer and professional corneal and fluorescein photograph Reader is married to Lisa, who wants to be an optometrist. He is TOSU’s most experienced excimer jockey (for pig eyes) and likes good food (presumably not pork).
- Gil Pierce, OD PhD, vision scientist is involved in CLEK as a photograph Reader and conducts his own glaucoma research. He golfs, ran long distances in college, and has logged hundreds of miles for the benefit of Lions’ Eye Research. His mom was Joe Barr’s English teacher, and Janet Barr taught Gil to swim. Keep it all in the family!

New CLEKkies

Joining us are Diana Young as a technician at the University of Utah and Tom Edwards, OD at Gundersen Clinic, Ltd.

Newest CLEKkie: Kim Supp of the University Hospitals of Cleveland CLEK Clinic is proud mother to Elaina Marie Supp, born August 7
Second CLEK DMOC Meeting a Big Success

Berkeley, CA. The CLEK Data Monitoring and Oversight Committee met in Berkeley on October 13, 1995. They were impressed overall with the recruitment and enrollment of eligible CLEK patients at the 14 Participating Clinics. They urged all CLEK Study personnel to keep up the good work.

DMOC members, Gary Cutter, PhD (chair), Robin Chalmers, OD, and Bruce Barron, MD, carefully scrutinized materials produced by the three CLEK Resource Centers. They commented on such diverse Study topics as data processing, slide sorting, TMS data backup, and even beginning to think about patient retention!

The CLEK Executive Committee found the meeting very helpful and greatly appreciated the DMOC’s time and energy in helping all of us realize the Study’s scientific goals.

The December Opportunity
We anticipate that December could be a slow month for CLEK recruitment. However, Tim Edrington cleverly observed at the DMOC meeting that it’s also when your clinics and practices are likely to be slow. So, it should be a perfect time to schedule CLEK patients in the down times! We encourage you to utilize December as an “up month” for CLEK recruitment, especially after getting “fired up” at the Full Investigators Group meeting in New Orleans.

CLEK in New Orleans
The schedule for our December Full Investigators Group meeting is as follows:

• Time and Place
  630-930 pm Monday, December 11 in the Prince of Wales Room at the Riverside Hilton
  8-11 am Tuesday, December 12 in the Rosedown Room at the Riverside Hilton
  You will receive a binder of materials prior to the meeting. Remember, we will fund the PI from each Clinic or his or her representative for one night’s hotel, but if more of your Clinic staff can attend, they are welcome.

• RSVP
  Please respond by November 15 to Karla Zadnik at (510) 643-0568 as to who will be attending from your Clinic.

Coordinating Center Notes

Site Visits
The first CLEK Participating Clinic site visit will be completed during the first week of November at the University of Alabama at Birmingham School of Optometry.

Quality of Life
An interested CLEK patient suggested a new quality of life question. We think that’s great, and he or she sounds like a very interested, long-term CLEK participant. However, our quality of life questionnaire is a predetermined survey instrument with well-developed norms, but if we eventually add the NEI’s VFQ, it may cover your patient’s issues.

Edit Report Conference Calls
Joe Benjamin and Maria Voce at the University of Alabama at Birmingham School of Optometry were among the first to complete the conference call to review edit reports from the Coordinating Center on forms. Edit reports concern missing data, inconsistent data, and questionable data. The error rate on forms is very reasonable for Study start-up. Executive Committee members are reviewing the edit reports to help simplify the process and still retain rigor and high data quality.
Site Visits Improve Quality of CLEK Study

Representatives from the Executive Committee and the Coordinating Center have completed four site visits to date for the CLEK Study. The site visits have been a huge success. They have given the Executive Committee, Resource Centers, and clinics an excellent opportunity to:

**Discuss factors that affect patient recruitment, retention, and satisfaction**

These discussions were especially helpful on our site visit to the Pennsylvania College of Optometry. PCO, like many other clinics, has had problems with patients keeping appointments. Their team approach to relaying the importance of the CLEK Study to their patients seems to be turning their problem around. Keep up the good work!

**Observe how the CLEK Protocol is being interpreted**

One site visit revealed that our visual acuity protocol needed immediate attention across all CLEK Clinics. Re-establishing and tracking the visual acuity protocol will reinforce the integrity of the visual acuity outcome measures.

**Observe patient enthusiasm for the CLEK Study**

All of our site visits revealed high patient enthusiasm for CLEK Study involvement, however, Northeastern Eye Institute in Scranton, Pennsylvania really stood out. They examine up to four patients a day on two separate floors! We were impressed with Northeastern’s efforts to encourage patient enthusiasm throughout the entire “two floor shuffle.” Their patients left the clinic feeling that they were an integral part of the CLEK Study. Nice job!

**Improve the logistics of forwarding CLEK Study materials to Resource Centers**

All three site visits to date have requested that the Coordinating Center provide mailers for the CLEK Study Forms similar to the CPRC film mailers. The Coordinating Center is looking into doing so. Thank you.

**Note ingenuity within individual clinics**

The University of Alabama at Birmingham has the rare privilege of dedicating an entire examination area to the CLEK Study. At Northeastern, FDACL is confirmed by the optometrist and then, again, by the photographer. Internal quality control efforts are always encouraged. Finally, the visual acuity set-up and CLEK examination room at PCO were most impressive.

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**Follow the Protocol!**

At the Cornea Photography Reading Center, we are getting all kinds of sequences of photographs. Most of you are not making this mistake, but more than a few are.

1. Please follow the proper photography sequence.
2. Please get better instead of sloppier with time.

Thanks from the CPRC Staff: Joe Barr, Gloria Scott-Tibbs, Gil Pierce, and Robert Steffen.

**Keep Those Cards and Letters Coming!**

The Coordinating Center has received Visual Acuity Worksheets from almost all Clinics. The prompt response is appreciated. Each visual acuity measure has been reviewed to check if the correct stopping rule was used.

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**Great Work, Dr. Chun!**

Karla Zadnik received the following email: “... I should ... thank ... you for the energy and devotion to such a worthy endeavor. In particular, I take this opportunity to extend my sincere compliment to Dr. Melissa Chun, who conducted my CLEK exam. She is an excellent, caring doctor and a credit to your study. I hope that she receives the recognition that she deserves.” Duly noted, Melissa. Congratulations and thanks on behalf of all of us. You make us all look good!
Dear Esther:
My light meter is acting funny, and I think I might have accidentally messed up the light correction factor. What should I do?

Sign me, Great Idea from Scranton, PA

Dear Great Idea:
Call the Coordinating Center at (314) 362-2065 or Dr. Mark Bullimore at (510) 643-5136. One way to avoid accidentally messing up your light meter is to put a small piece of tape over the up, down, left, and right arrows on your light meter.

Dear Esther:
I saw a CLEK patient last week who had undergone an epikeratoplasty. Should I have done FDACL on her?

Sign me, FDACL-less in Cleveland

Dear FDACL-less:
No. FDACL is not required on post penetrating, lamellar, or epikeratoplasty eyes.

Dear Esther:
I received an Edit Report for putting “00” as the visual acuity score for low contrast testing at 1 m. It doesn’t seem as if “HM” or “CF” is appropriate since that’s a high contrast response. Shouldn’t “00” be okay?

Sign me, Double-0 zero in Shaker Heights

Dear Double-0 zero:
You are right. The Executive Committee discussed this, and “00” will be an acceptable score for low contrast acuity, BUT ONLY AT 1 M. If the patient cannot read anything on the low contrast acuity chart at 4 m, she must be moved closer to 1 m for continued testing.

Dear Esther:
What difference does it make if I reverse flat and steep K readings?

Sign me, Que Sera Sera

Dear Que Sera Sera:
This is not nice. You will get an edit report.

CLEK Press

• An article on the SCCO CLEK Clinic appeared in the November issue of the Orange County Optometric Society’s newsletter, Perceptions.
• Gundersen Medical Foundation’s Fall newsletter, Visions, featured an article on the Gundersen CLEK Clinic in La Crosse, Wisconsin.

University Hospitals of Cleveland CLEK Clinic
Who’s Who

• Loretta Szczotka, OD, MS, FAAO, and CLEK Principal Investigator at University of Hospitals of Cleveland graduated from The Ohio State University College of Optometry with both her OD and MS degrees. She has been a full-time faculty member and Director of the Contact Lens Service at UHC/Case Western Reserve University since 1992. She is single, fluent in Polish, enjoys traveling, cooking, skiing, the Cleveland Orchestra, the Cleveland Indians, and working with her great crew at UHC.
• Jonathan Lass, MD, CLEK Co-Investigator and Professor and Chairman of the Department of Ophthalmology at Case Western Reserve University has had a strong interest in keratoconus during his entire career as a cornea/external disease specialist. He and wife Leah are struggling with their two teenagers, ages 16 and 19. Dr. Lass’ main avocation is chamber music, and he actively plays the cello with several different physician groups at nursing homes and coordinates and directs concerts at the American Academy of Ophthalmology and ARVO meetings.
• Bonita (“Bonnie”) Darby is the CLEK Study Coordinator as well as Medical Secretary/Coordinator in the Department of Ophthalmology. She is also a certified Court Stenographer from the Academy of Court Reporting, fashion hairstylist and precision hair cutter, and professional glamour technician. Bonnie enjoys reading, travel, contemporary jazz, piano/keyboard, dancing, baton twirling, workout videos, bowling, movies - and generally likes to have fun.
• BethAnn Benetz, CRA is the CLEK Photographer and Ophthalmic Photographer for UHC/Case Western Reserve University. She received a BS degree in Biomedical Photography from the Rochester Institute of Technology, an MA in Liberal Studies from Duke University, and a graduate certificate in Women’s Studies. Her newest sport is rowing in the Cuyahoga River. She and her team work hard to stay on the water and not in it.
• Kimberly Supp, NCLC, is an Ophthalmic Assistant and Technician for the CLEK Study. She joined the UHC’s Department of Ophthalmology in 1992. She and husband Joey are the proud parents of 4-month old Elaina Marie and enjoy raising their daughter and working on their new home.
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Full Investigators Group Meeting in New Orleans

All 16 CLEK Participating Clinics were ably represented by a Principal or Co-Investigator at the second CLEK Full Investigators Group meeting held in conjunction with the American Academy of Optometry meeting in New Orleans. The six hours of meeting time covered a full agenda, including recruitment, baseline data, and visual acuity protocols, and an informative roundtable discussion on recruitment successes at some of the top recruiting Clinics.

Data, We Have Data ...

One of the highlights of the meeting was the NEI’s Don Everett’s perspective on CLEK recruitment efforts to date. Don compared CLEK recruitment to the other 16 studies he supervises, and he characterized our recruitment schedule and goals as “ambitious.” He observed that, “if you ignore June 1995 on the recruitment plot as a startup month, you are at 100% of recruitment through the end of November!” He compared that to other NEI-funded studies with recruitment rates in the 30-60% range.

Data on the demographics and clinical characteristics of the patients enrolled through October 31, 1995 were presented. The male to female ratio is 1.3:1; 34%, 54%, and 12% of the patients were categorized as mild, moderate, and advanced based on the flat keratometric reading, almost 15% of the patients had corneal scarring in both eyes, and 78% of the patients are contact lens wearers.

Visual Acuity

We learned that 17% of the visual acuity data that Clinics have submitted worksheets on through December 5 did not observe the visual acuity stopping rule and could not be rescored. The visual acuity protocol was reviewed in detail.

Patient Enrollment Tips

The top recruiting Clinics make their patients feel special. They send birthday cards, specially designed reminder postcards, give them free contact lens solutions, and generally make them think they’re the most important person in the place. (And they are!)

Ethnic and age distributions for CLEK Study patients enrolled between May 31 and October 31, 1995.
“Just Ask Esther”

Dear Esther:
Sometimes CLEK Study patients ask to switch their care from their current doctors to my Clinic. What should I do?

Sign me, My cup runneth over

Dear Cup,
Tim McMahon at the University of Illinois-Chicago Department of Ophthalmology has a very diplomatic answer for this one. He points out that to take a patient away from a referring doctor would create a conflict of interest for him personally but offers to give the patient a list of other doctors he would recommend.

Dear Esther:
I’ve noticed that our Principal Investigator doesn’t always reset the keratometer between successive readings on an eye.

Sign me, Super-observant

Dear Super-Observant,
He or she should definitely reset the power wheels in both meridians between measures on an eye.

Dear Esther:
When I’m doing FDACL on a cornea with a “proud nebula,” do I try to vault the apex of the cone or the elevated area of scarring?

Sign me, Out there in Wisconsin

Dear Out There,
Apply FDACL trial lenses to vault the apex of the cone.

Dear Esther:
How much fluorescein is best for habitual and FDACL photography?

Sign me, Orange Fingers

Dear Orange Fingers,
We find it’s best to instill just a bit of fluorescein with each application since it provides good fluorescence without having too much fluorescein flowing over the front of the lens. Joel Silbert’s recipe is to just touch the tip of the wetted strip to the conjunctiva.

Dear Esther,
Can I have someone else record CLEK examination results while I call them out?

Sign me, Efficient at the Rock & Roll Hall of Fame

Dear Efficient,
Yes, as long as the person is certified in some aspect of the CLEK Study.

FDACL is the Goal
You can now apply lenses on your way to FDACL in bigger than one lens jumps. That is, if you observe a lens that looks really flat, you can skip to a lens quite a bit steeper, but you must apply all lenses in 0.05 mm steps as you approach FDACL to make sure you have the very flattest lens that clears the corneal apex.

Laundry, Anyone?
Attendees at the FIG meeting received the new CLEK Study t-shirts hot off the presses. These laundering instructions for them are hot off the presses:
(1) Turn the shirt inside out.
(2) Wash in cold water.
(3) Don’t use bleach.
(4) Iron inside out.

Please call the Chairman’s Office to specify your Clinic’s t-shirt sizes (large or extra large) and order, and we’ll send them along.

CLEK in the Abstract
The Executive Committee has submitted the following scientific abstracts:
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CLEKkies in New Orleans
In addition to the CLEK Study Group’s presentation on the training meeting, CLEK personnel were well-represented individually in all aspects of the American Academy of Optometry in New Orleans. Loretta Szczotka ably moderated and presented in a stimulating session on corneal topography. DMOC Chairman, Gary Cutter, presented a laptop-based session on the use of graphics. CPRC Director Joe Barr developed both special symposia put on by the Cornea and Contact Lens Section. SUNY Clinic Co-Investigators Dave Libassi and Ralph Gundel presented a poster on the use of aspheric lenses in keratoconus. Executive Committee member Tim Edrington presented posters on case reports, contact lens disinfection, and the California Chapter of the Academy. Indiana Clinic Principal Investigator Jerry Lowther is president-elect of the Academy. An active, involved group!
Science in Salt Lake

Dateline Salt Lake City, Utah. The CLEK Executive Committee plus Coordinating Center personnel Ken Schechtman and Michael Richman met in Salt Lake City, Utah on January 29, 1996 to review initial Baseline and Repeat Visit data and to begin planning the first phase CLEK Study publications.

We reviewed test-retest data on your keratometry, visual acuity, and manifest refraction measures. We looked at intriguing trends in clinical-reported scarring and staining. These data were very preliminary, will undergo DMOC review in April, and will be part of extensive discussions at the Full Investigators Group meeting at ARVO.

Data on patient-reported variables like systemic diseases, family history of keratoconus, and eye rubbing were reviewed.

Publication policies for the CLEK Study were discussed briefly, and a call for proposals for manuscripts will go out to all Principal Investigators and Co-Investigators in March. So, put on your thinking caps!

The Gushue Report

In a recent conversation with Steve Gushue of Northeastern Eye Institute, the CPRC learned some secrets of his photographic success:
• Treat all your patients like your livelihood depends on it.
• Be careful not to photograph with too much or too little fluorescein.
• Always review the protocol as you do photography, and never assume you have the protocol memorized.
• Record any variations in the photography immediately; don’t rely on your memory to record them later.
• Center the eye (pupil) in the frame
• Vertical positioning is graded more critically than horizontal
• Photograph the lens when it is positioned over the apex if possible, we realize that this may not be possible always since the lens may settle in a low position after the lids are out of the way with a blink or if you have to hold the lids away with your or your assistant's fingers, but the goal is to photograph the lens as it is positioned over the corneal apex.

Thanks, Steve, for these suggestions, and also special thanks to John Sake and Eric Sheahan of Gundersen Clinic for their help with the Nikon FS-3 protocols.

Penmanship Counts

Just a reminder from the Coordinating Center: Please write clearly the initials of the patient and your certification initials. Data entry is having a tough time deciphering these lately.

When you do a manifest or over-refraction and do not find cylinder, record the cylinder as 00.00, and leave the axis boxes blank.

Site Visits Continue

Four site visits have been conducted in January, at Gundersen Clinic in La Crosse, Wisconsin (5°F), The Ohio State University College of Optometry (during the Blizzard of ‘96), Southern California College of Optometry, and Jules Stein Eye Institute (75°F). Michael Richman, Teresa Roediger, and Karla Zadnik were impressed with the Clinics’ enthusiasm, efficiency, and energy.

Overheard from the Site Visit patient at SCCO (who was seen by Julie Shin): “You can just tell when you’re in the hands of a caring healer.”

It’s our impression that all the CLEK Study patients are in those healing hands.
“Just Ask Esther”

**Dear Esther,**

Which of the rigid gas permeable lens-wearing related protocols apply to piggyback and Softperm wearers?

Sign me, Hybrid

**Dear Hybrid,**

You should **not** perform habitual fluorescein photographs. You should perform over-refraction and visual acuity with over-refraction and should measure the rigid lens parameters.

**Dear Esther,**

I read in the January 1, 1996 edition of “CLEK on Deck” that I am supposed to apply FDACL lenses in 0.05 mm steps when I get close to FDACL nirvana. Please Fedex me the other half of my CLEK diagnostic set.

Sign me, Confused in Fullerton

**Dear Tim,**

Typo! CLEK diagnostic lenses are distributed in 0.10 mm increments. If you employ clinical judgment and apply lenses in greater than 0.10 mm steps, it is imperative that you verify that the lens 0.10 mm flatter than FDACL is not apical clearance.

**Dear Esther,**

As we exhaust our supply of in-house patients, I find I’m evaluating more ineligible patients. Do I really need to send in Eligibility Forms on these patients, too?

Sign me, Up for Eligibility

**Dear Up,**

Yes. Our only estimate of the “denominator” of keratoconus patients in our Clinics’ catchment areas is based on both eligible and ineligible patients, so take a minute to complete the form, even if the patient is ineligible. Thanks.

**Dear Esther,**

Some of my CLEK Study patients respond to the “serious eye injury” question on the CLEK Examination Form by describing their most recent abrasion? Does this really count?

Sign me, Eroded in Berkeley

**Dear Eroded,**

No. A serious eye injury is meant to denote trauma like a corneal laceration, lid laceration, gunshot wound, etc., not a routine corneal abrasion—however painful—related to keratoconus and contact lens wear.

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**Who’s Who**

Ralph Gundel, OD, CLEK Co-Investigator, is a 1981 graduate of SUNY State College of Optometry. Ralph spent nearly seven years in industry as Director of Clinical Research for Allergan/American Hydron before returning to the College in 1989. Along with wife Bonnie and sons Matthew (11) and Jeremy (8), he is a “true” New Yorker, having always lived within the five boroughs of our great city of New York.

Dave Libassi has been a SUNY faculty member for the past 13 years and a CLEK member since 1989. Dave has fulfilled several roles within the Contact Lens Service, including Chief and, presently, Director of Contact Lens Education.

Beyond his professional life, Dave is husband to Deborah and the father of three energetic children: Paul (8 years), Matthew (6 years), and Laura (4 years). The Libassi family weekends are jam-packed with work for Deborah, a nurse and lactation consultant, soccer, and Boy Scouts for the boys and dancing school for Laura.

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**CLEK News**

“CLEKkies Invade SCCO” was an article in SCCO’s weekly newsletter, announcing the SCCO site visit.

CLEK was listed among the Jules Stein Current Clinical Trials in 1995.

The CLEK recruitment news release on recruitment was featured in the January 22, 1996 issue of the AOA News. The Chairman’s Office’s phone has been ringing off the hook, and those teal and purple brochures are winging their way to optometrists all over the country.

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**Another CLEK Baby**

Born to Drs. John and Filomena Larson of the Gundersen Clinic: Kathryn Mathea Larson, 7 lbs, 13 oz., 20” long on January 4, 1996 at 9:00 P.M. This was the day after Gundersen’s CLEK site visit. Thanks for waiting, Kathryn!

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**Abstracts Accepted**

The CLEK Executive Committee has just been notified that abstracts submitted to the Society for Clinical Trials on the use of Feedback Reports and on CLEK patient recruitment via the Internet have been accepted. The papers will be presented at the Society’s annual meeting, May 5-8, 1996 in Pittsburgh.
How much fluorescein is best for habitual and FDACL photography?

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**Gundersen and Cleveland Get to 80**

On January 24, 1996, the CLEK team at the Gundersen Clinic, Ltd. in La Crosse Wisconsin became the first CLEK Participating Clinic to see their 80th CLEK Study patient. They have had patients come from as far away as Duluth, Minnesota (where it was -30° the day the patient happily drove to La Crosse) and have seen as many as 6 patients in a single day! John Sterling, Janet Hess, and Jill Nelson form the core of the Gundersen team effort, ably assisted by Eric Sheahan, John Sake, Tom Edwards, and John Larson. Not wishing to rest on their laurels, their 83rd patient’s data was just received at the Coordinating Center.

Likewise, on February 15, 1996, Loretta Szczotka, et al. enrolled their 80th patient. Her cohort of Bonnie Darby, Kimberly Supp, Beth Ann Benetz, Laura Teutsch, and Jonathan Lass have seen patients into the wee hours of the evening week after week. Way to go, Case Western Reserve!

**CLEK: A Week in the Life**

At the Chairman’s Office, we get a unique overview of the multi-center nature of the CLEK Study. During the week of January 29, 1996:

- On Monday, three patients were seen in La Crosse (one from Iowa!), and the Clinics at Indiana University School of Optometry, Northeastern Eye Institute, and NOVA Southeastern University College of Optometry all saw patients.
- On Tuesday, Northeastern, Indiana, the University of Utah Department of Ophthalmology, and one of the southern California Clinics all saw patients (Utah seeing 3 on the same day).
- On Wednesday, Berkeley saw a patient commuting 80 miles from Sacramento, and Indiana, Cleveland, one of the southern California clinics, and the Pennsylvania College of Optometry all enrolled eligible patients.
- On Thursday, Berkeley, NOVA, and Ohio State all enrolled CLEK Study patients.
- On Friday, the UMSL-School of Optometry Clinic was busy.
- On Saturday, again, either Jules Stein or SCCO and Gundersen Clinic worked hard and enrolled patients.
- Sunday was a day of rest.

So, the next time you’re FDACL-ling, photographing, or refracting that CLEK patient, it’s very likely someone else across the country is, too.

**New Clinics Initiate Enrollment**

The CLEK Clinics added in late 1995 to increase our geographic coverage enrolled their first patients in January and February. Heidi Wagner and her co-workers, Andrea Janoff, Karla Rumsey, and Arnie Patrick are off to the races with lots of Softperm-wearing patients.

**Hooray! Hooray! We’re Postage Paid**

Most clinics are now using the Business Reply Labels for mailing their hard copies of data to the Coordinating Center. If you are not aware of this, please try to locate the new labels. All clinics have been mailed these new Business Reply Labels. If you have any questions, please call Teresa Roediger at the CLEK Coordinating Center (314) 362-4377.

**Ft. Lauderdale-Bound**

The third CLEK Full Investigators Group meeting will be held April 20, 1996 at the Marina Marriott in Ft. Lauderdale, Florida from 9:00 a.m. to 5:00 p.m. in the Marlin Room. The Clinic Principal Investigators have all received information on making housing arrangements through ARVO. The Chairman’s Office has received queries about air travel arrangements.

Please go ahead and make your air reservations and pay for your tickets in advance. (Sorry!) Then submit your airfare (and other receipts) to the Chairman’s
Office after travel, and we will expedite your reimbursement.
“Just Ask Esther”

Dear Esther,
I’ve recently encountered a few potential CLEK patients who have responded to the three-hour examination time with an “Are you kidding?” rapidly followed by a dial tone. What can I do?

Sign me, Desperate in Fullerton

Dear Desperate,
Instead of saying it is a three-hour examination, I recommend a marketing strategy that has worked for me. With a smile on your face and a song in your heart say “Since we only see you one time a year the exam is extensive and takes about three hours.” Or, “The bad news is that the examination takes three hours; the good news is that we only have to examine you once a year.”

Dear Esther,
I was a little worried by the memorandum (CO-0014) about not needing to do funduscopy at the Repeat Visits.

Sign me, Savvy at the Coordinating Center

Dear Savvy,
Only funduscopy is to be deleted from Repeat Visits, but it will still be performed at all other CLEK Study Visits. Likewise, patients at Repeat Visits do still need to be dilated so that oblique corneal photographs can be performed.

Dear Esther,
I know the CPRC can’t grade photographs when the eyelids are in the way, but how can I ensure good lid position to produce gradable photographs?

Sign me, Blinking in Columbus

Dear Blinking,
If your Study Coordinator, Technician, or other warm body are around, ask one of them to hold the patient’s lids open without exerting pressure on the globe. We have found this to be particularly helpful during FDACL.

CLEK News

Dr. Nina Friedman of the University of California, Berkeley School of Optometry CLEK Clinic is first author on a paper published in the January-February 1996 issue of the Journal of Refractive Surgery entitled “Quantifying corneal toricity from videokeratography with Fourier analysis.”

Drs. Larry Davis and Ed Bennett, both of University of Missouri, St. Louis School of Optometry, taught workshops at the Heart of America Contact Lens Society Annual Meeting, held in February, in Kansas City.
University of Illinois at Chicago
Department of Ophthalmology
CLEK Participating Clinic
Who’s Who

Timothy T. McMahon, OD, FAAO has been the director of the Contact Lens Service at the University of Illinois at Chicago Department of Ophthalmology since 1981 and serves as the clinic PI for the CLEK study. He is currently an Assistant Professor. A 1980 graduate of ICO, Tim followed this with a VA Hospital residency in Kansas City before moving back to Chicago. After joining CLEK, he is survived by his wife Kay (ageless) and two sons Ryan (11) and Kyle (8). When not at work he is actively involved with his family in indian guides, scouting, little league, and soccer. Occasionally, he even finds time for skiing and orienteering.

S. Barry Eiden, OD, FAAO received his OD degree from SUNY in 1982 followed by a residency in primary care at ICO. He then returned to New York and served on the SUNY faculty until 1988 when he moved to Chicago and entered private practice (North Suburban Vision Consultants). He serves as Co-Investigator for the CLEK study where he volunteers his time and effort. He is a Clinical Assistant Professor at the University of Illinois at Chicago. Additional activities include being Director of the Optometric Service, Rush Eye Laser Centers and President, United Vision Associates, a continuing education organization. In his other life he shares time with wife Carol Barron-Eiden, OD, sons Jeffrey (5), Danny (3), and daughter Lauren (9 months). Hobbies include guitar, tennis, golf, and enjoying rare moments of peace and quiet.

Jamie L. Putz, COMT, NCLC is the Study Coordinator, Technician, and Photographer for the CLEK Study at UIC. She is the Manager of the Contact Lens Service and has worked for Dr. McMahon for the past 8 years. Her commitment is to patient care, training, and research. She has been involved with teaching student technicians on clinical rotation, technicians at the AAO meetings, and ophthalmology residents. She has been past Secretary and Vice-President for the Society of Ophthalmic Medical Assistants in Chicago and currently sits on its Board of Directors. She has taught Retinoscopy Workshops for the past 7 years and has lectured and co-authored publications. Besides enjoying her career, she enjoys traveling, dancing, spending time with family and friends, going out, and having fun!
Recruitment Goal Met and Surpassed

On March 25, 1996, one week ahead of schedule, the CLEK Coordinating Center announced that it had processed Baseline Visit data for 1,003 Study-eligible CLEK patients. This represents a landmark accomplishment, made more significant by the fact that very few of the CLEK Clinic Principal Investigators had previous experience with multi-center studies like CLEK.

Four CLEK Participating Clinics have reached—and surpassed—their individual goal of enrolling 80 patients in 10 months. Now joining Gundersen Clinic and the University Hospitals of Cleveland CLEK Clinic in the “80” Club are SUNY State College of Optometry, under the direction of Drs. Dave Libassi and Ralph Gundel, and the University of Illinois-Chicago Department of Ophthalmology with Drs. Tim McMahon and Barry Eiden.

Recruitment will continue through April 30, 1996. Patients beyond the 1,000 mark will provide assurance that at least 1,000 patients will complete the entire Study and that the Study’s scientific objectives will be achieved.

Chairman’s Office to Relocate

Effective July 1, 1996, CLEK Study Chairman, Karla Zadnik, will become an Assistant Professor at The Ohio State University College of Optometry. The CLEK Chairman’s Office will change locations with her. Year 2 TMS diskettes will be sent there. You will be notified of the updated address, phone and fax numbers, and email address when they take effect.

Dr. Nina Friedman will take on the responsibility of Clinic Principal Investigator at UC Berkeley, along with Co-Investigator Dr. Dennis Burger. Pamela Qualley of the Orinda Longitudinal Study of Myopia will serve as the Berkeley Clinic’s Study Coordinator.

Keratoconus Patients are Everywhere

We have it on good authority that UMSL Clinic PI, Dr. Larry Davis, found a CLEK-eligible patient in a most unlikely location. Larry was having his photograph taken for a CLEK PR spot. The photographer mentioned he was wearing some “special bitoric contact lenses,” so Larry sat him down at the slit lamp. Lo and behold, Vogt’s striae OU! The moral of the story: listen to your patients.

DMOC Meeting

On April 5th, in a pleasant room in the Women’s Faculty Club on the Berkeley campus, the CLEK Data Monitoring and Oversight Committee will be reviewing the scientific and operational health of the CLEK study. All members of the Executive Committee will be in attendance. Some of the questions discussed include “How is the study doing?” “What needs attention?” “What should be the study’s next priorities?” To prepare for this meeting, a binder with 130 pages of text, tables and graphs has been prepared. The decisions and recommendations of DMOC can affect what any and all aspects of the study. We will keep you informed on a time critical basis via numbered memoranda and via the monthly newsletter.

Attention: TMS Clinics

(And you know who you are). Please be sure you are labeling TMS data diskettes with the following information (ONLY):
• Patient’s complete ID number,
• Date of examination, and
• Eye (OD or OS).
Your initials, the type of visit, and the patient’s mother’s maiden name are not necessary. And don’t forget those write protect labels!
“Just Ask Esther”

Dear Esther,

We had a patient whose cornea was way too steep for the steepest (5.00 mm base curve) trial lens. When we tried to do steep-K VA with this lens, the lens kept popping out, but we stabilized it long enough to get the VA measurement by inserting a disposable soft lens underneath. Is that okay?

Sign us, The Dream Team in Fullerton

Dear DT,

Not only is it okay, it’s a very clever way of getting the measurement!

Feedback Forms Talk
CLEK has only one single page form completed by investigators and coordinators. Think about it! Which form is this? It is the Feedback Report Form. But the Feedback Report Form may be among the most important forms in the study. These forms keep the Executive Committee informed of problems and tracks their resolution. During study start-up, some comments on the Feedback Form resulted in protocol changes within weeks. We know that other studies would profit by our experience. To document the usefulness of the Feedback Report Form, Mae Gordon and Don Everett will audit the response to each Feedback Report Form through Executive Committee conference calls, monthly newsletters, and study memoranda. These results will be presented at the Annual Meeting of the Society for Clinical Trials in Pittsburgh in May. This meeting attracts researchers from all major studies (cardiovascular, AIDS, cancer, etc.) sponsored by the National Institutes of Health. It will be a great forum for our presentation. Keep those Feedback Report Forms coming in!

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The Ohio State University
College of Optometry
CLEK Participating Clinic
Who’s Who

Barbara A. Fink, OD PhD is the Principal Investigator for the CLEK Participating Clinic at The Ohio State University College of Optometry. She did her undergraduate work at the University of Notre Dame, earned her OD at Indiana University in 1981, taught at Inter-American University of Puerto Rico from 1981 to 1984, and earned her PhD in physiological optics from The Ohio State University in 1987. Her husband, Eric O. Pineiro Carrero, is an environmental scientist who works for the Ohio EPA in the division of surface water and does computer modeling of rivers and streams. They have a 7-year-old daughter, Angela, and a 2-year-old son, Joseph. They have been renovating (and living in) a century-old house near the University for the past 4 years.

Lisa Badowski, OD MS is the Back-Up Examiner. She was born and raised in Cleveland, Ohio, is single, and has no children. She earned her BA from Miami University in 1985 and her OD and MS degrees from The Ohio State University in 1988 and 1990, respectively. She is an Assistant Professor of Clinical Optometry and Associate Chief of the Contact Lens Clinic. She teaches geometric optics and courses in contact lenses. Her interests include snow and water skiing and traveling.

Sue Sabers is the Clinic Coordinator. She’s originally from Buffalo, NY, where she received her BS in Medical Technology from SUNY in 1988. She worked in the field of medical research for 4 years before seeing the light and returning to optometry school. Throughout optometry school, she has remained active in research by serving as the Study Coordinator for several clinical trials. Sue is currently a fourth year student at Ohio State and enjoys counting the days down to graduation!!

Skylar Burns is the Back-Up Study Coordinator. She has worked in the optical field for the past 12 years and as worked as a Contact Lens Technician at The Ohio State University for the past 5 years. Her husband, Gary, works in plumbing wholesale. They have two children, Adam (10 years) and Kylie (7 years). She enjoys playing second base in softball, and she is team mother for her daughter’s T-ball team.

If you any CLEK personnel who still need t-shirts, please let Karla Zadnik know, and specify large or extra large.
CLEK Patients Migrate to Wisconsin

The CLEK Study Chairman’s Office has made an astonishing discovery. Upon processing address changes from the recent newsletter mailing, it appears that almost 800 of the enrolled CLEK patients have moved to La Crosse, Wisconsin. When one was asked the reason for the big move, she answered, “Because we want to get our next CLEK Study Visit from the fun team at the Gundersen Clinic!” An overwhelmed Dr. John Sterling was unavailable for comment.

CLEK on Deck Wins Pulitzer

In a surprise announcement, the 1995 volume of CLEK on Deck, the official publication of the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study, has been awarded a Special Pulitzer Prize. Pulitzer Committee Chairman, I.M. Looney, said, “The publication is just so consistently of such high quality. And I love that Esther column.”

FDACL: Everyone’s Favorite Measure

In a recently conducted Gallup poll, CLEK Clinic investigators reported a 73% approval rating for FDACL. Quoting Dr. Tim Edrington of the Southern California College of Optometry, “Everyone loves FDACL! At SCCO, we consider it a rite of passage for first year optometry students and require that all faculty members, whether affiliated with CLEK or not, demonstrate their FDACL proficiency.”

Kodak Stock Soars

Blue-chip stocks ended higher yesterday. Although most technology stocks slumped, one—Kodak of Rochester, New York—soared along with the blue-chip eagles. Kodak spokespeople credit the volume of Ektachrome film used in the well-known CLEK Study of keratoconus patients. In a related story, McAlister’s Camera and Video of Columbus, Ohio just went public, making its proprietors instant multimillionaires.

Topography Companies to Merge

In a bold move, sure to be known for its blatant flaunting of anti-trust statute, Tomey, Humphrey, Alcon, and EyeSys are merging their videokeratography divisions into one company that will manufacture the Visi-TMS-SYS corneal topographer. The new device will continue to utilize a wacky analysis algorithm that no one understands. The companies cite pressure from the world renowned CLEK Study as a significant factor leading to this landmark decision.

New Visual Acuity Measure

The CLEK Executive Committee has decided to add an additional set of visual acuity measures to the CLEK Study protocol. High and low contrast Bailey-Lovie visual acuity in each eye will now be measured with the patient doing a headstand while wearing the previous CLEK patient’s rigid contact lenses. Comments can be directed to Mr. Michael Richman at the Coordinating Center, who especially loves the whole concept of visual acuity.

Quote for the day: “Never retract, never explain, never apologize—get the thing done and let them howl.”

—Nellie McClung
April FIG Meeting a Big Success

On April 20, 1996, 49 CLEK personnel met at the Marina Marriott in Ft. Lauderdale for a day of spirited discussion and enthusiasm. Don Everett of the National Eye Institute congratulated the CLEK Study on achieving its recruitment goals last month with a week to spare. He also announced that the NEI would be doubling the reimbursement to Clinics from the point of each Clinic’s recruitment of its 60th patient on.

Test-retest data from the beloved Repeat Visits and Baseline Visit data from the first 600-700 patients was presented to the group, and preliminary Publications Committees were formed.

Pam Qualley of UC Berkeley presented tips for retention of patients, including her “attitude of gratitude” that should influence every interaction between CLEK Study personnel and patients. The assemblage took the “100% retention” oath throughout the day.

Many of the people there who have been affiliated with other multi-center studies commented on the high level of involvement by CLEK Investigators and Coordinators. Here’s to the future!

A Warm Thank You from the Coordinating Center

As the enrollment period comes to a close, the Coordinating Center would like to extend my appreciation to everyone. Mae, Ken, Teresa, Michael, and Joel feel privileged to work with the professionalism and enthusiasm that exists across the entire CLEK Study. They hope that everyone is as excited as the Coordinating Center is as retention begins, and the CLEK Study’s science begins to unfold. Here’s to another successful year, and thanks to everyone!

Way to Go, Dr. Libassi!

On Wednesday, May 1, Karla Zadnik received the following email from a keratoconus patient: “The terrific news is I was able to act fast and enroll just “under the wire” with Dr. Libassi (a very professional, courteous, and competent man). I drove down ... to NYC and was probably the last patient to enroll in the entire study. I’m delighted to participate, and I thank you for your timely email (isn’t Internet fantastic)? Anyway, keep up the good work. And may God, and funding (!), bless you, all the CLEK people, the NIH, and the NEI.”

DMOC Meeting Held

On April 5, 1996, the CLEK Data Monitoring and Oversight Committee met with the CLEK Executive Committee and key Coordinating Center staff. The CLEK Study to date was reviewed stem to stern, and the DMOC congratulates the entire Study Group on its fabulous retention performance.

CPRC Readers’ Top Ten List of Reasons for Poor Quality Slides

Note: Any reflections of real life situations are purely coincidental.

#10 “Have you seen these filters? (You know, the blue and yellow ones.)
#9 Half-empty/over-filled patterns.
#8 Not reaching the zenith (apex, that is).
#7 Non-approved positions - light source!
#6 Extreme over-magnification.
#5 Centration, centration, centration.
#4 Focus.
#3 Combos - High magnification, poor focus, and lids closed.
#2 Eastwood lids in squinty-eyed patients.
#1 Indecent exposure: both under- and over-.
“Just Ask Esther”

Dear Esther,

We had a patient that showed a big bubble under the lens applied for the steep-K acuity reading. We believe this limited the best corrected visual acuity with this lens. What should we have done?

Sign us, Bubbly in La Crossen

Dear Bubbly,

In the future, apply progressive flatter CLEK Study trial lenses until the bubble disappears, then over-refract and measure visual acuity per the protocol.

Congratulations to Colleagues

Many CLEKkies were represented in the contact lens topical issues of two prominent optometric journals.

Kudos to:

Barb Fink: Contact lens transmissibility: effects on delivery of oxygen to the cornea
Barry Weissman: Oxygen transmissibility at various locations in hydrogel toric prism ballasted contact lenses
Tim McMahon: Recovery from induced corneal edema and endothelial morphology after long-term PMMA contact lens wear
Carolyn Begley, Joe Barr, Tim Edrington, and Robin Chalmers: Characteristics of corneal staining in hydrogel contact lens wearers
Ralph Gundel: Anterior hydrogel lens deposits: polished vs. unpolished surfaces
(all in the March, 1996 issue of Optometry and Vision Science)

and to:

Carolyn Begley: The effectiveness of soft contact lens disinfection systems against acanthamoeba on the lens surface
Joe Barr: Corneal response and vision with the Softperm lens in simulated aircraft conditions
Joel Silbert: A review of therapeutic agents and contact lens wear

CLEK Recipe Corner:

Karla’s Corn and Papaya Salsa for 50

2 large bags frozen corn, thawed
2 large ripe, papayas, peeled and diced
3 ripe avocados, peeled and diced
1 bunch cilantro, chopped juice of 2 lemons
Combine ingredients. Serve in aluminum foil-type roasting pans around the pool.

University of Alabama at Birmingham School of Optometry
CLEK Participating Clinic
Who’s Who

William “Joe” Benjamin, OD PhD is the Principal Investigator for the CLEK Study at “The” UAB School of Optometry. He is a graduate of Ohio State. Joe came to UAB in 1988 with his wife, Dr. Patricia Benjamin. Joe enjoys outdoor activities like golf, hunting, and shooting, and intently observes, with Pat, the academic progress and baseball prowess of 9-year-old son Daniel. At home, he thinks he is beginning to sound too much like his parents and, at work, too much like his mentors. Currently a Professor of Optometry and Director of Clinical Research, his wife also wears pants in the family, and his real boss at UAB is Ms. Maria Voce.

Carol Rosenstiel, OD is a CLEK Co-Investigator at the UAB School of Optometry. Her primary appointment is in the Department of Ophthalmology at The Eye Foundation Hospital as the Director of the Contact Lens Service. She enjoys biking, skiing, fishing, and well ... just about everything.

Denise Pensyl, OD MS, CLEK Co-Investigator at The University of Alabama at Birmingham, is a graduate of The Ohio State University. She completed a residency in hospital-based optometry at the Cleveland VA Medical Center and is currently an Assistant Professor at the UAB School of Optometry. She likes to combine her interest in ocular disease with her love of travel and, in the past year, has ventured to Costa Rica, Mexico, and a South Dakota Indian Reservation for eye care missions. When she isn’t exerting her liberal Yankee influence on her CLEK cohorts (including the redneck wannabe Joe Benjamin), she enjoys water skiing, white water rafting, hiking and reading.

Maria Voce is the CLEK Study Coordinator as well as the Clinical Research Coordinator at The UAB School of Optometry. Maria graduated from UAB’s Optometric Technician Program in 1980. Her obsessions are with fine fragrances and Castles, Castles, Castles. She enjoys strolling through parks and wooded areas, music (classical, contemporary jazz, and pop—no country!!), watching The Alabama Crimson Tide, reading, attempting crafts, but most of all, having fun with her family and friends. She has also enjoyed working on the CLEK Study and meeting with the Investigators and Coordinators. It’s been a rewarding and demanding study, especially since she has to keep up with Dr. Denise Pensyl (Jinx), Dr. Carol Rosenstiel (Barbie), and most troublesome, Dr. Joe Benjamin (Big Ben).
CPRC Given a Clean Bill of Health

On May 23, 1996, three members of the CLEK Executive Committee joined Larry Hubbard from the Fundus Photograph Reading Center at the University of Wisconsin, Madison in conducting a site visit of the CLEK Photography Reading Center.

Mr. Hubbard put Joe Barr, Gloria Scott-Tibbs, Gil Pierce, Robert Steffen, and computer programmer Matt Gilbert through their paces. He asked questions about topics ranging from Ektachrome film type to documentation of CPRC database programming and everything in between. His expertise was far-ranging, and his questions and comments were thought-provoking. Overall, it appeared that Mr. Hubbard, with over a decade of experience in photograph grading and reading center administration, was most impressed with the work of Barr et al. Congratulations to everyone at the CPRC!

Fourth Quarter Clinic Payments

In an effort to make the move of the Chairman’s Office from UC Berkeley to Ohio State University as smooth as possible, the fourth quarter (March-April-May 1996) payments will be made to the Participating Clinics out of the UC Berkeley offices. The Coordinating Center will submit a list of patients seen in those months at the Clinics, and payment will be processed as early in June as possible.

Remember, the amounts will be doubled for all visits after the 60th patient was enrolled, and your deans/presidents/department chairmen have been informed of this change.

As usual, each Clinic Principal Investigator will receive a letter confirming that payment has gone to Disbursements in UC Berkeley with a list of the patients and their visits for this quarter attached.

Year 1 Examinations Underway

Forms for Year 1 Follow-up Visits have been mailed and examinations have begun. To stress again: Retention is more important than recruitment. The Coordinating Center will help you monitor late and missed visits to help you achieve our goal of 100% retention.

UAB Investigator Escapes IRB’s Death Sentence

“Don’t get caught with your pants down” is the advice given by Joe Benjamin of the University of Alabama at Birmingham CLEK Participating Clinic when speaking about annual IRB protocol renewals. Due in part to staff turnover at the Chairman’s Office, UAB’s CLEK IRB renewal date came and went, and 12 CLEK patients were enrolled between the expiration date and when renewal correspondence was initiated. After appealing to the Chairman of the Institutional Review Board with supporting correspondence from the CLEK Executive Committee, the UAB Clinic was granted a “stay of execution,” and the patients will be allowed to participate in the CLEK Study.

Both Joe and Karla Zadnik want all the other Clinics to use this as a pointed reminder that IRB protocols are very serious business, and that the date one month before their annual expiration should be circled in red on Principal Investigators’ calendars. And watch that mail for timely reminders from the Chairman’s Office.

As Joe put it, “this error did not lead to any unearned runs in this instance because the rest of the team helped snuff out the rally.” In other words, your patients can’t be involved if your IRB approval isn’t current. Check your annual approval date today!
Dear Esther,

The other day I was the only person in our CLEK Clinic not felled by the flu. The scheduled CLEK patient had come from 3,000 miles away, and I did everything (even things I wasn’t certified for!). What should I put in the certification initials boxes for the tasks for which I’m not certified (including photography)?

Sign me, Still Well in Madison

Dear Well,

You should be honest. Although performing key tasks for which you’re not certified constitutes a protocol violation in the CLEK Study, the Coordinating Center and the CPRC would prefer to know that a non-certified person had performed clinical tests. In short, you should never sign another person’s initials.

Dear Esther,

Rigid contact lenses: they’re warped, I’ll tell ya. What’s a guy to do?

Sign me, Bimeridional in So Cal

Dear Bi,

Often, a patient’s habitual contact lenses are warped. Radioscope readings will reveal different in-focus endpoints. Record the two major meridian values in the two base curve spaces on the bottom of page 7 of the CLEK Examination Form. Lensometry power for mildly warped lenses will be spherical; if not, suspect a bitoric or base curve toric design. To differentiate rigid lens designs, the Coordinating Center will assume a warped lens if two base curve readings and one power are recorded. If two base curve radii and two contact lens powers (without an axis notation) are recorded, it will be assumed that the lens is a bitoric design. If two powers, an axis relative to the base down position, and one base curve are recorded, it is highly suspect that the lens is a prism-ballasted, front surface toric design. Okay, so it’s none of the above. Fill out a Feedback Report, and call Tim Edrington.

Dear Esther,

We’ve had a couple of questions come up already about patients’ addresses. Should we assume that the Chairman’s Office will let the Clinic know if a patient’s address has changed, according to returned items from a mass mailing? The Chairman’s Office will also let the Clinics know if a piece of central mail is undeliverable, even if there’s not a new address. In the future, the Chairman’s Office will list each mass mailing in CLEK on Deck after it happens. The last such mailing was the first issue of Insight, which went out bulk mail in early March.

Sign us, Address Correction Requested in New York

Southern California College of Optometry
CLEK Participating Clinic
Who’s Who

Tim (Bernie) Edrington is a 1974 graduate of Indiana University School of Optometry. He is Chief of the Cornea and Contact Lens Services at SCCO. Teresa, a worker’s compensation defense attorney, and Tim are the parents of 5-1/2 year old Jeffrey. Tim enjoys playing golf, watching IU destroy TOSU in football, FDACLing (when weather permits), and sporting trendy new hairstyles. The Edringtons are pleased to announce Jeffrey’s engagement to Joe and Janet Barr’s daughter, Jennifer.

Julie A. Shin serves as CLEK Co-Investigator and Study Coordinator at SCCO. She received her undergraduate degree from UC Riverside and her OD degree from SCCO. After completing her residency in Cornea and Contact Lenses at SCCO, Julie joined the faculty in 1994. She enjoys outdoor sports, beachgoing, and is a volleyball fanatic. Julie is currently vacationing in Korea, Hong Kong, and Hawaii. She is the polite, well-mannered member of the SCCO CLEK team.

Julie Schornack, OD MEd is a CLEK Co-Investigator at the Southern California College of Optometry. She is a graduate of the Illinois College of Optometry and received her Masters degree from Pacific University College of Optometry. She is currently an assistant professor and serves as the Director of Clinical Education at SCCO. She is married to an optometrist in private practice, Doug Stephey, and they have two girls: Emily, 4 years old, and Amanda, 2 years old. For enjoyment, Julie quilts, sews, and spends a lot of time in the garden, priding herself on her prizewinning compost heap. Constantly striving for the “Martha Stewartian” home, she fears she ultimately lacks the gentility and grace to pull it off, as she is prone to speaking in a loud voice and smoking cigars.
Retention, Retention, Retention

Prior to my departure for Ohio State, I began scheduling the first 20 Year 1 follow-up visits for CLEK patients seen at the UC Berkeley CLEK Clinic Clinic. Here are my impressions and advice “from the trenches.”

First, tackle this task in small pieces. Don’t expect that you can sit down for a couple of hours and get a whole list of patients scheduled. I used a spreadsheet in my word processing program with column headings like patient’s name, phone number, address, visit window dates, doctor to be seen, action taken, and final dispensation. I added patients to the spreadsheet upon notification from the Coordinating Center. I open the file at the beginning of each day and “call away” at it during the day, making notations when I leave a message, speak with a roommate, get a new phone listing, etc. I tried to initiate calls when I knew the patient could call back and speak to me in person that day or over the next several days. those of you who are not always near your phone may want to suggest appointment times so that the patient can simply call you back and confirm one of them. Once I have the patient actually scheduled, I noted it in the “final dispensation” column, sent them a confirming letter and directions to the Clinic, and shaded out their row in the table. I called them the day before to confirm their appointments again.

I was amazed at the number of “bad work phone numbers” after a year. I also found that co-workers are often willing to confirm information you’ve gotten from another source about where a patient has ended up. I’ve also left my phone number because a co-worker was willing to pass the message along to a former colleague.

The UC Berkeley Clinic staff is still in the process of tracking down one person: bad work phone, bad home phone with no forwarding number, a lead on an address in another state from his UC Berkeley General Clinic record. Even his mother, listed as his closest relative/friend not living with him on the Patient Tracking Form, claims not to know where he’s moved to. We’ll see if the magic “address correction requested” works on the letter sent to his out-of-California address.

My overall impression is: scheduling patients takes at least as much time as finding them and enrolling them did—maybe more. Don’t underestimate the time required, and be tenacious. The science we all produce stands only to gain from your efforts.

Year 1 Site Visits Near Completion

The University of Illinois-Chicago site visit was completed June 12th and the site visit for the Indiana University School of Optometry and Indianapolis Eye Care Center is scheduled for July 22nd and 23rd. All clinics will have been site visited at least once by the end of July. Remember also that anyone at any Participating Clinic can request a site visit at any time.

Writing Committees Hard at Work

The writing committees have emerged. It is not too late to get involved on a writing committee of a topic that interests you. Please contact Karla to become included.

Quality Control Group Meets

The quality control group met on 5/16/96 by way of conference call under the leadership of Dr. Julie Shin. Other members include: Ms. Bonita Darby, Ms. Janet Hess, and Dr. David Libassi.


“Just Ask Esther”

Dear Esther,

It seems like ancient history now, but when I got my revised copy of the Operations Manual, I wasn’t sure where the really important protocol changes were.

Sign me, Bedtime Reader in Ohio

Dear Bedtime,

In general, the really important protocol changes find their way into a numbered memorandum from the Chairman’s Office, faxed to all CLEK personnel. Loreta Szczotka f the University Hospitals of Cleveland CLEK Participating Clinic went through the new OM painstakingly, and she found that the only major change she wasn’t aware of was Section 6.3, “Alternative Refraction Technique,” on pages 6-6 to 6-7.

CPRC: Early Data Analysis

The following tables show agreement data from the CPRC, depicting both agreement within a measurement method (test-retest) and comparison between methods. The Kappa statistic denotes agreement, accounting for that based on chance alone. A “good” Kappa value is about 0.70.

Baseline-Repeat Visit Data from Clinicians on Habitual Lens Fluorescein Pattern

<table>
<thead>
<tr>
<th></th>
<th>Touch</th>
<th>Clearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Touch</td>
<td>33</td>
<td>1</td>
</tr>
<tr>
<td>Clearance</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

Kappa statistic = 0.381. Despite the low Kappa, these data show good agreement.

Baseline-Repeat Data from CPRC Readers on Habitual Lens Fluorescein Pattern

<table>
<thead>
<tr>
<th></th>
<th>Touch</th>
<th>Clearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Touch</td>
<td>53</td>
<td>5</td>
</tr>
<tr>
<td>Clearance</td>
<td>7</td>
<td>14</td>
</tr>
</tbody>
</table>

Kappa statistic = 0.509. The Kappa is not high, but most of the disagreements are due to “alignment” patterns that are hard for Readers to judge as touch or clearance.

Clinician vs. CPRC Readers on Habitual Lens Fluorescein Pattern

<table>
<thead>
<tr>
<th></th>
<th>CPRC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician</td>
<td>Touch</td>
</tr>
<tr>
<td>Touch</td>
<td>329</td>
</tr>
<tr>
<td>Clearance</td>
<td>20</td>
</tr>
</tbody>
</table>

Kappa = 0.345. Again, not a high Kappa, but remember, the Readers are masked. Note the high proportion of central touch fits.

Indiana University School of Optometry
CLEK Participating Clinic
Who’s Who

Gerald E. Lowther, OD, PhD is Professor of Optometry and Co-director of The Borish Center for Ophthalmic Research at the School of Optometry, Indiana University. He is Immediate Past-President of the International Society for Contact Lens Research and President-Elect of the American Academy of Optometry. He is Co-editor of International Contact Lens Clinics. He has an active clinical research program in the areas of contact lens materials, contact lens design, aftercare problems, care systems, and dry eye. He has received the John Neill Medal from the Pennsylvania College of Optometry, an Award for Distinguished Research on the Cornea and Contact Lenses from the University of Houston College of Optometry, the Distinguished Faculty Award from the Michigan Association of Governing Boards, and gave the Max Schapero Memorial Lecture at the American Academy of Optometry meeting in 1995. He has authored two books, many chapters for other books and has over 100 published papers. He has lectured extensively nationally and internationally.

Lee Wagoner, MHA, CLEK Study Coordinator at the IU School of Optometry, is the Center Coordinator for the school’s Borish Center for Ophthalmic Research. Originally from Bloomington, she received her undergraduate degree from the University of Iowa and her MHA from the University of South Florida College of Public Health. Her research experience includes a US Public Health Traineeship and a Research Associateship with the Florida Mental Health Institute. Lee’s interests include ballet, music, playing cello, reading, national affairs, and spending time with family and friends.

Carolyn Begley, OD, CLEK Co-investigator, is an Associate Professor at the Indiana University School of Optometry. She received her MS and OD degrees from the IU School of Optometry, and completed a postdoctoral year at the University of Illinois in immunology and biochemistry. Her research interests include cellular biology of the cornea and conjunctiva, monovision and bifocal contact lenses, and ocular immunology. She enjoys traveling, hiking, bird watching, reading, and spending time with her husband, Jiri, a mathematics professor at IU, and their children.
Late Visit Reports

Just to let you know how you’re doing...

As of August 6, 1996, 23 Late Visit Reports have been sent to seven Participating Clinics. Of those 23, only two patients’ whereabouts are unknown, and one patient appears reluctant to return. Two patients have been located somewhat far away from their Baseline Clinic and will be seen at a different site.

Thirteen of the 23 patients prompting a Late Visit Report to date have been seen or scheduled; the rest of the Late Visit Reports’ results are still pending from the Clinic.

In short, you are doing a superb job! The Late Visit Report system is helping the CLEK Study track retention of patients, and the early returns look good.

If you need a letter from the Chairman’s Office—prompting a patient to return to the Study and customized to his or her scheduling difficulties—just call, fax, or email Karla at Ohio State. So far, we’ve sent such letters to patients at Jules Stein and at the University of Illinois, so we’ll see how we do. Remember, patients want to fulfill their obligation to the Study; they’re just busy people.

Welcome New Staff

The CPRC has a new photograph Reader: Marjorie Jeandervin, OD. Marjie describes herself as “a Buckeye any way you look at it.” She grew up in the small town of Tuscarawas, Ohio and has been at The Ohio State University in some capacity ever since graduating from high school. She has both a B.S. in Physiological Optics and her O.D. from Ohio State. She is currently completing a residency in cornea and contact lenses while finishing her M.S. degree at Ohio State. Longer-term plans include a Ph.D. degree and further research. In her spare time, Marjie enjoys sewing and other such “crafty” pastimes.

Jodi Malone has joined the Chairman’s Office at Ohio State as overall Study Coordinator. Jodi comes to CLEK from the Women’s Health Initiative at Ohio State. She brings a wealth of experience from other clinical studies in which she has been involved. Jodi’s particular challenge is that Karla has yet to obtain either furniture or file cabinets, so all CLEK materials are in boxes, stacks, or can’t be found. Jodi is also enrolled in nursing school, has two teenage daughters, and, according to Gloria, “loves to hang out by the pool.”

CPRC Reminder

The comments on the CPRC Photo Log are invaluable. Imagine you’re Gloria Scott-Tibbs, sorting over 112,000 slides to date, trying to figure out which pictures are FDACL shots and which are habitual, whether the patient had a graft or not, and why a set of obliques is missing. Gloria provides the following insights about comments on the Photo Log:

<table>
<thead>
<tr>
<th>Helpful comments</th>
<th>Not helpful comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piggyback lenses OU</td>
<td>Patient had lunch at the Clinic today</td>
</tr>
<tr>
<td>No FDACL OS: shot taken of 8 mm base curve lens</td>
<td>I’m sick of the CLEK Study!</td>
</tr>
<tr>
<td>No habituals OD</td>
<td>The humidity’s really low here today.</td>
</tr>
<tr>
<td>Transplant OS</td>
<td>We used our CLEK film for our family vacation last week. Sorry.</td>
</tr>
</tbody>
</table>

Seriously, the CPRC reports that you’re using the Photo Logs very effectively and that the organizational flow of slides is very smooth. As usual, keep up the good work, and follow the protocol.
Dear Esther,

I noticed that when some people get frightened that the lighter complected people have very large pupils and the darker complected people don’t. Would this make a difference in corneal photography in the CLEK Study?

Sign me, Frightened in Ohio

Dear Frightened,

Yes, darker irises do not dilate as well. Although patient safety is always our first consideration, it would be helpful to use two drops of tropicamide and/or add a drop of 2.5% phenylephrine when dilating these patients for optimal oblique photography outcomes.

Dear Esther,

I saw a patient this week who had undergone what sounded like a superficial keratectomy for a proud nebula. Should he have come in for a Presurgical Visit?

Sign me, Proud in Berkeley

Dear Proud,

No, that kind of minor procedure does not qualify as corneal surgery in terms of needing a Presurgical Visit for the CLEK Study. Thanks for asking, though.

University of Utah
Department of Ophthalmology
CLEK Participating Clinic
Who’s Who

Harald E. Olafsson, OD was the first member of his family that was born in the United States; his parents and sister are from Norway. Harald did his undergraduate work at Brigham Young University and optometry degree at the Southern California College of Optometry. He is married with three teenage children that are driving him crazy. He likes mountain biking, hiking, skiing, and basketball, although he feels he is getting too old for the basketball. He has no problem keeping busy with his family, working, and volunteering as an LDS bishop.

Libbi A. Tracy, OD is from Springfield, Missouri. She is the middle child who likes to be diplomatic. Libbi graduated from Southern Missouri State University in biology and went on to the UMSL School of Optometry. She now lives in Centerville with her wonderful husband, Reid, and one daughter, Kara.

Her hobbies include scuba diving, water skiing, softball, and she is learning to snow ski. She is also the pianist at the Grace Baptist Church.

Kate Landro, CLEK Study Coordinator, is from Salt Lake City and graduated from Utah Valley State College with a business degree. She just recently bought a home and feels “very broke.” She enjoys spending time with her husband, Thom, and son, Bryan, and likes to camp, hike, swim, and platform dive. She has worked at the John Moran Eye Center for three years and especially enjoys working with all the Eye Center’s volunteers.

Marie Cason, LPN, CLEK Study Technician is a Utah native. She and her mother proudly graduated from nursing school in Kansas, and Marie enjoys biking, dating, traveling, the symphony, and the ballet. She has been at the John Moran Eye Center for almost three years and works on CLEK as well as studies on post-cataract anti-inflammatory drugs and uveitis.

Paula Morris, CLEK Photographer, has been with the John Moran Eye Center for 13 years. She brings tremendous skill and experience to the CLEK Study, is easygoing, and will talk to anybody! She has a wonderful husband, Mike, and three fun-loving kids. Paula is a member of the Ophthalmic Photography Society and is currently its Education Chairman. She is slated to attend a photographers’ conference in Scotland. Paula loves skiing and has been spotted on the slopes 9 months pregnant!

Doug Blanchard, CLEK Photographer, is from Ogden, Utah. His ophthalmic photography training came in the Navy, where he served for five years. He has an e-year-old daughter, Chantell. Doug is truly cosmopolitan, having lived in Japan, Maryland, California, Korea, and Mexico. His pastimes include fishing, extreme snow skiing, boating, traveling, rock climbing, and partying. Doug has just joined the CLEK Study, and is the only guy we know who had a Snow White cake for his 25th birthday (picked out by Chantell, presumably). Welcome, Doug!

Deborah Harrison, Director of Clinical research at John Moran Eye Center, was born and raised in Pennsylvania. She received her BS in Biology from Bucknell University and her MS in Genetics at the Medical College of Virginia. Deborah likes to cycle and pump iron to offset her passion for good food and wine. Jazz and shopping at Nordstrom also pique her interest. The most gratifying part of Deborah’s job is “to see all the individuals who volunteer themselves as patients to help us do research.” And she lives with one very spoiled cat.
New Schedule for December 1996

The CLEK Executive Committee has decided that there will not be a Full Investigators Group meeting in conjunction with the American Academy of Optometry meeting this December in Orlando. Instead, various CLEK working groups will meet to move forward on topography analysis and manuscript production.

The schedule and CLEK personnel affected are as follows.

<table>
<thead>
<tr>
<th>VA/Refraction Writing Committee</th>
<th>Monday, December 9, 1996</th>
<th>5:30 - 9:00 P.M.</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDACL Writing Committee</td>
<td>Monday, December 9, 1996</td>
<td>5:30 - 9:00 P.M.</td>
</tr>
<tr>
<td>Baseline Writing Committee</td>
<td>Tuesday, December 10, 1996</td>
<td>8:30 - 11:00 A.M.</td>
</tr>
<tr>
<td>CLEK Topography Analysis Group</td>
<td>Tuesday, December 10, 1996</td>
<td>8:30 - 11:00 A.M.</td>
</tr>
</tbody>
</table>

The Visual Acuity/Refraction Writing Committee includes Larry Davis, Tim McMahon, Julie Schornack, and Karla Zadnik. The Baseline Writing Committee is comprised of John Sterling, Heidi Wagner, Julie Shin, Don Everett, Mary Jameson, and Karla Zadnik, and the FDACL Writing Committee is Tim Edrington, Denny Burger, Loretta Szczotka, and Carolyn Begley. CLEK-TAG includes Tim McMahon, Loretta Szczotka, Larry Davis, Nina Friedman, and Tim Edrington. Everyone, please adjust your Academy travel schedules appropriately.

UAB—A Job Well Done

This email was sent to Maria Voce, Study Coordinator, at UAB by a year 1 follow-up patient from Atlanta who had car trouble on the way to his CLEK appointment:

“Just a quick note to let you and the doctor know how pleasant you made our visit, particularly after the weird car brake problems.

It looks like tomorrow afternoon we will once again travel to Birmingham and pick up my car (with working brakes).

We did go up the hill to that very nice bar & grill the doctor recommended and had a great dinner. It was an excellent recommendation.

Thanks again for being such friendly people; it sure makes all the poking and prodding at the eyes more tolerable.”

Welcome to New CLEKkies

Nikole Himebaugh, OD at Indiana University School of Optometry and Indianapolis Eye Care Center

Chris Woodruff, OD at Nova Southeastern University College of Optometry

Aminah Guy, COT at the University of Illinois-Chicago, Department of Ophthalmology

Jason Nichols at The Ohio State University College of Optometry

Two tips from Richard A. Moran in *Never Confuse a Memo with Reality and Other Business Lessons Too Simple Not to Know*: Tip #350: Be loyal to your career, your interests, and yourself. Tip #361: When someone tells you these are the best years of your life, believe it and act accordingly. They are.
“Just Ask Esther”

Dear Esther,
What is appropriate to enter in K reading when we are unable to see any mires due to a proud nebula? The cornea is not too steep, so we didn’t think that "H" would be acceptable. I’ll wait for your response before I send this report in to St. Louis.

Sign me, Not off-the-scale

Dear Not,

Just record “unable” across the keratometry measurement boxes on the CLEK Examination Form, and write a note in the margin explaining the specific circumstances. Although the computer will generate an Edit Report, your handwritten note will be read by Teresa Roediger at the Coordinating Center, and you will not receive an official Edit Report at your end.

Sign me, Conscientious in Salt Lake

Dear Esther,

One of our patient’s two-month target window for his year 01 visit is August 25, 1996 through October 25, 1996. He has undergone a corneal transplant in the left eye (and was appropriately seen for his Presurgical Visit), but his surgeon does not want him to have his CLEK follow-up examination until November or December. Are we in trouble?

Sign me, Please Advise in Ohio

Dear Please Advise,

We would not go against the surgeon’s wishes. Please schedule this patient as soon as his surgeon releases him to have the CLEK examination. And thanks for your diligence on this one.

Dear Esther,

Unfortunately one of our CLEK patients has passed on. Do I need to supply the Coordinating Center with any documentation other than the Confirmation of Death (DT) Form?

Sign me, Meticulous in So Cal

Dear Meticulous (and we like you that way),

Very good observation. Please make a note of the exam date which corresponds to the correction in the upper right hand corner.

Dear Esther,

I have recently seen a patient transferred from his enrolled clinic. What ID am I supposed to use?

Sign me, On the Move in Alabama

Dear On the Move,
The ID (numeric number and initials) always stays the same. The clinic at which the patient is being seen, even if different from the enrolled clinic, should be listed. The clinic at which the patient was last seen should forward a copy of the patient’s entire file and any follow-up visit patient forms which it may have. You may always call the Coordinating Center for additional forms if you do not receive them from the prior clinic.

SCCO and UAB Earn Bragging Rights

The CLEK Study was featured in the Summer ‘96 issue of SCCO’s Alumniscope, stating: “Alumni were instrumental in assisting SCCO researchers achieve their target goal of 80 eligible keratoconus patients for the CLEK Study.” The article went on to list all the SCCO alumni who have referred patients to the CLEK Study, quoting and acknowledging Tim Edrington, Julie Shin, and Julie Schornack.

Likewise, the University of Alabama at Birmingham-School of Optometry’s newsletter, Clinical Research at the UAB School of Optometry, listed their CLEK referring doctors and summarized the Study, including UAB’s specific recruitment and NEI’s increased financial commitment to the project.

OSU Students Know CLEK

The O-Eye-O, a publication of the Beta Chapter of Epsilon Psi Epsilon at Ohio State, reported on CLEK’s recruitment and OSU personnel in its Spring 1996 issue. The article was surrounded by student party photos, so Joe Barr thought, “Esther must not have been available.”

Who’s Esther?
Anyone who knows who Esther refers to should drop Karla Zadnik a line via e- or snail-mail.
Writing Committee Progress

The three CLEK Study Writing Committees are very hard at work. The FDACL and Keratometry Test-Retest Committee has met several times by conference call and are collaborating on a very reasonable working draft. The Visual Acuity/Manifest Refraction Test-Retest Committee just had its second conference call. This group is taking an interesting tack. Not content to simply present data meaningful for the study of keratoconus patients, the group is presenting the visual acuity data in the context of the effect of measurement repeatability on sample size. It is being targeted to appeal to both clinical and epidemiological/biostatistical audiences. Lastly, the Baseline Committee has just convened by telephone to discuss a manuscript outline and will initiate its writing frenzy between now and the December Writing Committee meetings.

To all of you participating, thank you. To those of you on Writing Committees yet to be officially convened (and you know who you are; if you don’t, contact Karla Zadnik), get ready for hard but very rewarding work!

Wise Words from the CPRC

All Clinicians certified in slit lamp examination should review the slit lamp examination protocol in the Operations Manual (Chapter 7) and the scar density photographic standards (laminated sheet).

All Clinicians certified in fluorescein photography and the FDACL procedure should apply this protocol with care and follow the protocol (Chapter 9 of the CLEK Operations Manual).

Inquiring Minds Want to Know

Now that we’re into the first year of follow-up examinations for the CLEK Study, patients being examined may want to know what results are emerging from the CLEK Study. Remember, these patients have to be examined for another three years. Please take care not to influence their future responses on patient-reported information. You can tell them that we are learning new things about fitting contact lenses in keratoconus (FDACL), that our photographic data are being compared to our clinician examination data to determine the frequency of scarring in keratoconus, and that we are currently working very hard on compiling the test-retest data and baseline data for publication.

CLEK Data Belong to ...

Please remember that all CLEK patient data—patient-reported, examination-based, video-keratography files, etc.—belong to the CLEK Study as a whole. You cannot analyze or publish your individual Participating Clinic’s data. In fact, an individual Clinic’s data might show different results when compared to the entire CLEK data set. CLEK Study data, in whole or part, cannot be released to another person or entity. CLEK patients cannot be enrolled in other studies at your institution without the express permission of the CLEK Executive Committee.

Goin’ to the Chapel

Congrats to Jill Nelson of the Gundersen Clinic on her recent marriage! She plans on “early retirement” in lieu of a honeymoon. Nice work if you can get it!

This Just In

Just too late for September’s question about Esther: “That’s easy. She’s G-L-O-R-I-A!” — Joe Benjamin
Dear Esther,
I just saw one of our CLEK patients as an urgent appointment with an acute corneal hydrops. She is scheduled for her one year CLEK exam tomorrow. What should we do?

Sign me, Edematous in La Crosse

Dear Edematous,
Either see her tomorrow or sometime within her target window. If you elect tomorrow (or sometime before the hydrops is significantly resolved), just do whatever parts of the protocol you can accomplish and she can tolerate. Hydrops is part of the natural history of keratoconus, and we certainly expect to see some occurrences of it in the CLEK Study.

Dear Esther,
On page 4 of the CLEK Examination form, question #20 asks, “Which type of contact lens have you been prescribed (check all that apply)? Does that mean all the lens types they’ve ever worn or all those that they wear at the time of the examination?

Sign me, Conscientious in St. Louis

Dear Conscientious (and you are!),
The question should be answered by checking all the boxes that the patient says represent lens types they are currently prescribed.

Lisa Barnhart, OD is an Assistant Clinical Professor of Ophthalmology and Associate Chief of the Contact Lens Service at Jules Stein. Her role includes taking care of many talented UCLA athletes (including 5 Olympians!) as contact lens consultant to the athletic department. However, as a graduate of UC Berkeley, she still roots for Cal at UCLA-Cal games. She enjoys running and rollerblading at the beach to stay in shape for skiing, Scuba, and other travel adventures, like white water rafting in Chile.

Melissa Chun, OD has been practicing at the Jules Stein Eye Institute for the past 11 years. She is currently an Assistant Clinical Professor. Her other job is being a mother of two young children, Timothy, 4-1/2 years, and Katrina, 2 years. Timothy just started preschool and is interested in dinosaurs and karate. Katrina is a fun-loving chatterbox who is already proficient in her verbal skills to direct the whole family. Along with husband, Alein, who is director of Health Services Research Core at Cedars-Sinai, the family stays active and busy.

Elisabeth Lim was born and raised in Manila, Philippines and moved to the U.S. in 1976. She is ABO, NCLE, and COA certified and has been working in private practice the past 15 years before joining the ophthalmology group at Jules Stein Eye Institute in 1994. In her spare time, she enjoys shopping and traveling.

Lilian L. Andaya, NCLC, is a certified Ophthalmic Assistant and serves as CLEK Study Coordinator and Technician at Jules Stein Eye Institute. She was originally from Manila, Philippines, where she received her OD degree. She enjoys traveling, craftmaking, reading, decorating, music, working out in the gym, and, most of all, dancing.

Ronit A. Englanoff, OD is a CLEK Co-Investigator at Jules Stein. She served a contact lens fellowship there with Dr. Weissman after receiving her OD degree at SUNY State College of Optometry in 1993. Her professional areas of interest include contact lenses, refractive surgery, and low vision.

Louis Rosenberg, OD was raised in New York City. Dr. Rosenberg served as a radio operator in Germany during World War II. He graduated from the Los Angeles College of Optometry, having been supported during optometry school by his wife, Anne, a social worker. Following 43 years of private optometric practice in Alhambra, California, Dr. Rosenberg retired in 1995. He is very proud of his two sons and young grandson. Dr. Rosenberg enjoys playing golf weekly, traveling whenever possible, and attending the theater and opera.
Report Card Update

In response to your feedback regarding our first CLEK Clinic Report Card, the Coordinating Center has reviewed the “scoring” for patient-completed forms and has detected an error that has seriously over-reported queries from each of your Clinics. This has been corrected for future report cards.

We certainly apologize for this error, and we appreciate your feedback.

Meanwhile, for your records, here’s the revised and corrected tabulation of “Percent Patient-Completed Forms with No Queries”:

<table>
<thead>
<tr>
<th>Institution</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Alabama at Birmingham</td>
<td>83%</td>
</tr>
<tr>
<td>UC Berkeley</td>
<td>68%</td>
</tr>
<tr>
<td>University Hospitals of Cleveland</td>
<td>84%</td>
</tr>
<tr>
<td>NOVA Southeastern University</td>
<td>89%</td>
</tr>
<tr>
<td>Gundersen Clinics, Ltd.</td>
<td>91%</td>
</tr>
<tr>
<td>Indiana University</td>
<td>54%</td>
</tr>
<tr>
<td>University of Illinois at Chicago</td>
<td>97%</td>
</tr>
<tr>
<td>Jules Stein Eye Institute-UCLA</td>
<td>77%</td>
</tr>
<tr>
<td>University of Missouri-St. Louis</td>
<td>89%</td>
</tr>
<tr>
<td>Northeastern Eye Institute</td>
<td>90%</td>
</tr>
<tr>
<td>Ohio State University</td>
<td>86%</td>
</tr>
<tr>
<td>Pennsylvania College of Optometry</td>
<td>83%</td>
</tr>
<tr>
<td>Southern California College of Optometry</td>
<td>84%</td>
</tr>
<tr>
<td>University of Utah</td>
<td>95%</td>
</tr>
<tr>
<td>SUNY State College of Optometry</td>
<td>74%</td>
</tr>
<tr>
<td>For All Clinics</td>
<td>83%</td>
</tr>
</tbody>
</table>

Coordinating Center Kudos

The Coordinating Center recently recognized Dr. Larry J. Davis for the first monthly CLEK “AR Award”. As part of the Visual Acuity Test-Retest Writing Committee, Larry detected an inconsistency in a table of visual acuity data. The Coordinating Center wrote to Larry, “...your valuable time and efforts have not gone unnoticed... As always, it is a pleasure to work with you on this pathbreaking study.”

CLEK in the News

The Fall 1996 newsletter of the California Chapter of the American Academy of Optometry published a lead story on the CLEK Study. CLEKkies Denny Burger, Tim Edrington, and Karla Zadnik are all current or previous Chapter leaders.

ARVO Abstracts

The CLEK Study Group has submitted two abstracts for the upcoming ARVO 1997 meeting: one on CPRC Reader and Clinician agreement on scarring status and one on test-retest reliability on visual acuity.
“Just Ask Esther”

Dear Esther,

When a CLEK patient transfers from one CLEK Participating Clinic to another, what happens to their informed consent?

Sign me, Uninformed across the Country

Dear Everyone,
The original, signed informed consent document should be retained at the original Clinic, and a copy of that should be sent to the Clinic to which the patient is transferring. When the patient is seen for the first time at the new Clinic, he or she will have to sign an informed consent document for that institution as well.

Dear Esther,
If a patient transfers to another CLEK Clinic, who takes responsibility for the patient’s retention in the Study? Who receives the Late Visit Report if one is needed?

Sign me, Not Really Late in New York

Dear Not Really,
The Clinic to which the patient has transferred becomes responsible for retention, and, if necessary, a Late Visit Report will go to the patient’s new Clinic.

Dear Esther,
We had a patient last year that began her Baseline examination on one date and completed it a month or so later. Which date should be her “anniversary date” for future follow-up visits?

Sign me, Bipolar in Ohio

Dear Bipolar,
The date on which the patient completed her CLEK Baseline Visit examination should serve as her target date for future visits.

Who’s Who
Pennsylvania College of Optometry
CLEK Participating Clinic

Joel A. Silbert, OD, FAAO is a graduate of the Pennsylvania College of Optometry (Class of 1973). Joel is the Director of the Cornea and Specialty Contact Lens Service at The Eye Institute and Professor of Optometry at PCO. In his role as Director of Contact Lens Programs at PCO, he has overall responsibility for the didactic, clinical, and research activities involving contact lenses for the college. A Diplomate of the Section on Cornea and Contact Lenses of the American Academy of Optometry, Joel is also Director of Contact Lens Services at Allegheny University of the Health Sciences (Hahnemann Medical School, Department of Ophthalmology), where he is an Assistant Professor of Ophthalmology.

Joel is the editor of Anterior Segment Complications of Contact Lens Wear (Butterworth-Heinemann) and has authored numerous articles plus 10 chapters in 0 textbooks concerning contact lenses and anterior segment eye disease. Joel is the Principal Investigator at PCO for the CLEK Study, where he “FDACLs” with Mary Jameson and Ken Daniels. Note: Joel assures me that FDACL has been accepted as a verb in the Funk and Wagnall’s dictionary but that it defies a lay definition. – Ed.

Kenneth M. Daniels, OD is a graduate of the New England College of Optometry (Class of 1987). After completing his degree, he joined the Morrison Associates of Harrisburg, PA, where he specialized in contact lens and low vision care and participated in several research projects for various contact lens manufacturers.

In 1990, Ken joined Allergan-American Hydron, Inc. as Manager of Clinical Research in their Woodbury, NY facility, where he was responsible for the clinical assessment of cast-molded and spin-cast lens products. In 1991, he visited the CCLRU in Sydney, Australia to collaborate in Allergan-sponsored research projects.

Ken is currently an Assistant Clinical Professor at Pennsylvania College of Optometry and Director of the Contact Lens Research Program. When not reminiscing about how much he enjoyed Australia, Ken enjoys his role as Co-Investigator for the CLEK Study at The Eye Institute of PCO.

Mary Jameson, AS, OptTR, COA, NCLC is the CLEK Study Coordinator at PCO. Originally from Indiana, she received her AS degree in Optometric Technology from the Indiana University School of Optometry. She is currently serving as Chair of the AOA’s Paraoptometric Section and is the editor of the soon-to-be-released Self-Study Course for Optometric Assisting. Mary has written articles for a number of journals and has lectured nationally and internationally. In her spare time, she enjoys horseback riding, vintage auto racing, and hanging out with her husband, Andrew, and their two Rhodesian Ridgebacks.

Mark Your Calendars

The 1997 CLEK Full Investigators Group meeting—to include a Principal or Co-Investigator and a Study Coordinator from each Clinic—will be held in Ft. Lauderdale on Saturday, May 10, 1997.
DMOC Meeting Upcoming
The CLEK Data Monitoring and Oversight Committee is scheduled to meet Friday, January 17, 1997 by conference call. The Coordinating Center has been hard at work compiling quality control information, baseline data summaries, lists of ancillary studies, and retention data into a comprehensive DMOC binder that goes out this week. The Executive Committee looks forward, as always, to the DMOC’s input on Study conduct and data.

Manuscripts on Deck
Several Writing Committees met in conjunction with the American Academy of Optometry meeting in Orlando. The Visual Acuity Test-Retest Committee, the Baseline Committee, and the FDACL and Keratometry Test-Retest Committee are all aiming for March 1, 1997 manuscript submission dates. Every CLEK Study Group member will receive a draft manuscript two weeks prior to submission in case he or she wants to provide specific feedback.

CLEK Travel Reimbursement
The Ohio State University Foundation (unfortunately) requires original travel documents—airfare receipt, hotel receipt, etc.—to properly reimburse you for CLEK-related travel. If the CLEK Study only reimburses you for part of your travel to a given meeting, your institution may require originals as well. To take care of this problem, plan ahead of time on asking for duplicate originals from airlines, hotels, cab drivers, rental car companies, etc. so that both institutions will be happy with our procedures.

Quality of Life!
Martin Wax, MD, a colleague of Mae Gordon’s, opines, “I always thought quality of life meant having more money than you need, less money than you want, and the health to enjoy it with the people you love.”

Utah’s Holiday Spirit
The staff at the University of Utah CLEK Participating Clinic sent out a holiday letter to all their enrolled patients thanking them for keeping their appointments and acknowledging the often significant obstacles (babysitting, several hundred mile drives) to keep their CLEK appointments. Way to go: Harald, Libbi, Kate, Paula, Doug, Marie and Deborah!

KZ Thank You (I Think!)
Joe Barr, Tim Edrington, and Mae Gordon presented Karla Zadnik with a very useful holiday gift—a snow shovel. Actually, Joe presented it to Kurt Zadnik, Karla’s husband, which is probably more appropriate. Mae observed, “It’s to shovel snow and other stuff, too.” Thanks, guys!
Dear Esther,

How should we score visual acuity when the patient can’t read all the letters on the top line of the chart at a distance of 1m?

Signed, Testing Up Close in California

Dear Up Close,

If a patient can’t read all the acuity letters on the top line at 1m, record the actual number read on that line. If he or she reads 3 or more on that top line, you have to continue down the chart at 1m until he or she misses at least 3 on a line on which an attempt has been made to read all 5 letters.

Mark Your Calendars

The 1997 CLEK Full Investigators Group meeting—to include a Principal or Co-Investigator and a Study Coordinator from each Clinic—will be held in Ft. Lauderdale on Saturday, May 10, 1997.

Who’s Who

Nova Southeastern University College of Optometry
CLEK Participating Clinic

Heidi Wagner, OD, FAAO is the Principal Investigator for the CLEK Participating Clinic at Nova Southeastern University College of Optometry. She is a 1986 graduate of The Ohio State University College of Optometry. Heidi joined the Nova faculty in 1993 after seven years in private practice with her husband, Chris Woodruff, OD. She has also served as a part-time clinical preceptor at Ohio State and as a part-time staff doctor in a multi-disciplinary setting. Her teaching responsibilities at Nova are primarily in the didactic and clinical cornea and contact lens program. In her free time, she enjoys decorating with CLEK colors and spending time with her husband and daughter, Alexandra, a lovable (and sometimes terrible) two. Heidi would like to issue an invitation to the CLEK Study Group to visit the University while attending the CLEK Full Investigators Group meeting in Ft. Lauderdale in May.

Andrea Janoff, OD is the CLEK Co-Investigator at Nova, where she recently joined the faculty as an Assistant Professor. It was her desire to be involved in clinical research and education, as well as the appeal of a warmer climate and close proximity to her family, that lured Andrea away from her practice in suburban Boston, just eighteen months ago. As Academic Director of the Contact Lens Externship Program and Interim Chief of the Cornea and Contact Lens Service, she finds her free time limited but still enjoys ballroom dancing (from swing to two-step), musical events (Blues rules!), walking on the beach near her home, or just being a tourist. Currently a single “thirty-something,” she was raised in Philly, lived in L.A., and moved to Boston to attend NEWENCO (Class of 1986). She was first introduced to keratoconus while working as a technician for Drs. Korb and Finnemore and became more interested in it while at NEWENCO in a VA Residency program (Brockton, MA) and at the Strauss Clinic, Haddassah Hospital, Jerusalem, Israel. Being involved with CLEK is one of the highlights of her job, and she looks forward to the busy years ahead.

Arnie Patrick, OD, FNAO is the CLEK Study Coordinator. He is a 1994 graduate of Nova Southeastern University College of Optometry and spent a year honing his skills in contact lens fitting during a residency at the University of Houston College of Optometry. Arnie currently serves as an Instructor of Optometry at Nova Southeastern University where he teaches ophthalmic optics and contact lens laboratories and serves as a clinical preceptor in the College’s Cornea and Contact Lens Service. Arnie’s colleagues claim that he was the perfect choice for Study Coordinator because he suffers from Obsessive Compulsive Disorder, a fact that Teresa Roediger can attest to. This is Arnie’s second career, having been an ophthalmic dispenser for 13 years prior to entering optometry school. His classmates still kid him about the fact that he’ll probably be paying off his student loans with his Medicare checks. In his free time, Arnie enjoys playing racquetball and listening to his extensive record collection. He’s still single, so if there are any single female ODs out there reading this....

Chris Woodruff, OD is the CLEK Photographer at Nova Southeastern University. He is a 1986 graduate of The Ohio State University. He and his wife, Heidi Wagner, relocated to south Florida to enjoy the sun and surf after seven years of private practice in Mansfield, Ohio. He is an Assistant Professor with teaching responsibilities in contact lenses, public health, optometric theory and methods, practice management, and primary care. Chris is pursuing graduate education in Public Health with an emphasis in Epidemiology. He enjoys water sports and spending time with his family.
Second Round of Site Visits Initiated

Three CLEK Participating Clinic site visits were completed in January 1997. Karla Zadnik trekked to the University of Alabama at Birmingham School of Optometry and the University of Utah John Moran Eye Center, and Tim Edrington visited the Jules Stein Eye Institute, UCLA. Karla and Tim were uniformly impressed with the caliber of facilities and personnel continuing to be allocated to the CLEK Study. All three Clinics are performing exceedingly well in terms of retention of CLEK patients, and protocols were only in need of some fine-tuning.

Maria Voce Honored

Dr. Sam Galloway, Executive Director of the Southern Council of Optometry, has announced that Maria Voce of the University of Alabama at Birmingham School of Optometry will be named the 1997 Paraoptometric of the South. Maria will be recognized at the annual meeting of the Southern Council of Optometry and will personally receive the award from the President of that organization at the end of February in Atlanta. Maria is specifically cited for her devotion to duty in the recruitment of subjects, retention of subjects, and accomplishment of the many clinical research studies performed in UAB’s Clinical Research Facility.

Maria is the CLEK Study Coordinator and has simultaneously coordinated the enrollment of 250 elderly female patients in Dr. Robert Kleinstein’s Eye Health Segment of the Women's Health Initiative at UAB.

Joe Benjamin, UAB CLEK PI, writes, “Maria is a graduate of Les Caplan's Optometric Technician program and is in her sixth year on the staff of the UABSO, all of that time working to expand the clinical research performed here. She is a vital member of the Clinical Research Advisory Committee and our team of clinical researchers here at the UABSO. [Her award is] especially suitable and well deserved.

New University Hospitals of Cleveland Study Coordinator—Welcome!

Stephanie Schach is a young and vibrant new addition to the Department of Ophthalmology at the University Hospitals of Cleveland CLEK Participating Clinic as Study Coordinator, officially starting January 20th. She is finishing her Masters degree in psychology, and is coming to us from another major study at Case Western Reserve University where she was involved in the patient and caregiver aspects of a study of Alzheimer’s disease.

Ideas, Anyone?

While Karla Zadnik was at the UAB site visit, an interesting question came up? Has anyone discovered a better way (than scotch tape) to attach the Wratten filter to the slit lamp camera?

Congratulations!

Early-on CLEK consultant, Israel Goldberg, PhD of Health Research Associates in Rockville, MD, forwards this bit from the Washington Post: “Jason Goldberg [Izzy’s son] ... moves over to be a special assistant to [Clinton’s] chief of staff Erskine B. Bowles.”

Kudos to AAO Section on Cornea and Contact Lenses Diplomates

At the Annual Meeting of the American Academy of Optometry, held in Orlando Florida in December, 1996, Loretta Szczotka of the University of Hospitals of Cleveland and Tim McMahon of the University of Illinois at Chicago became Diplomates of the Academy’s Section on Cornea and Contact Lenses. Loretta and Tim completed slide, written, practical, and oral examinations in the area of cornea and contact lenses and had successfully completed 10 case reports in the area. Congrats to both!
"Just Ask Esther"

Dear Esther,
What measurements should be performed specific to Softperm and piggyback lens wearers enrolled in the CLEK Study?

Signed, Hybrid in Ft. Lauderdale

Dear Hybrid,
Softperm and piggyback lens wearers should have their contact lens parameters measured (rigid lens only for piggyback patients) and best-corrected visual acuity measured with an over-refraction. No fluorescein pattern interpretation or habitual fluorescein photographs should be performed.

Dear Esther,
Can I apply the lenses to achieve FDACL while the patient’s pupils dilate?

Signed, Efficient Across the Country

Dear Efficient,
Unfortunately, your excellent time management skills will have to be applied elsewhere. It is imperative that oblique corneal photographs be taken before FDACL lenses are applied to avoid inducing positive photographic findings in the cornea via the application of so many trial lenses.

As of January 31, 1997, the following people have volunteered to participate in CLEK Writing Committees. Please contact Karla Zadnik at the Chairman’s Office if you are interested in joining any of these existing Committees or if you have ideas for future analyses and would like to form a new Writing Committee. Coordinating Center resources for analyses for manuscripts will be allocated according to manuscript priorities set by the CLEK Executive Committee.

<table>
<thead>
<tr>
<th>Manuscript topic</th>
<th>Committee members</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeatability of visual acuity</td>
<td>Zadnik, Davis, McMahon, Schornack, Schechtman</td>
<td>Additional analyses by 2/10/97; next draft 2/19/97</td>
</tr>
<tr>
<td>FDACL &amp; keratometry</td>
<td>Edrington, Burger, Szczotka, Begley, Gordon, Wilson</td>
<td>Will schedule conference call in early 2/97</td>
</tr>
<tr>
<td>Baseline: demographics, clinical characteristics</td>
<td>Zadnik, Sterling, Wagner, Shin, Everett, Jameson, Gordon</td>
<td>First text draft out by 2/10/96</td>
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<tr>
<td>Photography reading: scarring, test-retest</td>
<td>Barr, Fink, Pierce, Pensyl</td>
<td>To be submitted 3/1/97</td>
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<tr>
<td>Manifest refraction and visual acuity: test-retest</td>
<td>Davis, Shin, Zadnik, Schechtman</td>
<td>To be initiated after 3/1/97</td>
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<tr>
<td>Baseline: how flat they’re fitted</td>
<td>Edrington, Burger, Szczotka, Chun</td>
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<td>Repeatability: patient report</td>
<td>Gordon</td>
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<td>Risk factors for scarring</td>
<td>Barr, Everett, Edrington, Gordon, Zadnik</td>
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<tr>
<td>Fluorescein grading: habitual</td>
<td>Edrington, Gundel, and Libassi</td>
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<tr>
<td>Baseline: visual acuity and over-refraction</td>
<td>Barr, Davis, Shin, Pensyl</td>
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<tr>
<td>Topography in nonkeratoconic fellow eyes</td>
<td>Shin, McMahon, Szczotka</td>
<td></td>
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<tr>
<td>Quality of life in keratoconus</td>
<td>Gordon, Schornack, Pensyl, Barnhart</td>
<td></td>
</tr>
</tbody>
</table>
Ft. Lauderdale Plans

Plans are shaping up for the Full Investigators Group meeting in Ft. Lauderdale on May 10, 1997. The meeting will be at the Ft. Lauderdale Marina Marriott from 8:00 a.m. to 2:30 p.m., followed by Writing Committee meetings from 2:30 p.m. to 5:00 p.m. A poolside dinner at The Sea Lord, Lauderdale-by-the-Sea will be held that evening at 7:00 p.m.

Each CLEK Participating Clinic is to send one Investigator and one Study Coordinator to the meeting. Please RSVP to Karla Zadnik (614-292-6603 or zadnik.4@osu.edu) to let the Chairman’s Office know who will be attending from your Clinic.

The Writing Committees that will be meeting are: Scarring: Test-Retest (Joe Barr, Gil Pierce, Barb Fink, and Denise Pensyl), CLEK Topography Analysis Group (Loretta Szczotka, Tim McMahon, Nina Friedman, Tom Raasch, Larry Davis, and Ken Daniels), Manifest Refraction Test-Retest (Larry Davis, Julie Shin, Ken Schechter, and Karla Zadnik), and Quality of Life (Mae Gordon, Julie Schornack, Denise Pensyl, Lisa Barnhart, and Karla Zadnik), and How Flat They’re Fitted (Tim Edgington, Denny Burger, Loretta Szczotka, and Melissa Chun). If you are a member of one of these Writing Committees and you are not planning on attending as a representative of your Clinic, please contact Karla as soon as possible to arrange for you to attend the meeting.

Wratten Filter “Security”

Last month, we asked whether anyone had novel ideas for attaching the Wratten filter to the slit lamp camera and got the following responses:

“You can buy a two-part filter at camera shops which has one portion you glue onto the front of the slit lamp. It is a square frame with a large, round opening for the objective. The second part is a frame in which you place the filter. The part with the filter slips into the part on the slit lamp and just slides out when you do not want the yellow filter in place. (Kodak makes it, although I had our shop make up several, and we have them on all the biomicroscopes.)”

—Jerry Lowther, Indiana University

For more information and/or a photograph of this device, call Jerry at (812) 855-0132 or email him at glowther@indiana.edu.

“We use the velcro that comes with the Boston Wratten yellow filter kit to attach the filters to both the slit lamps and to the camera. We use two sets of attachments, one over the objective and the other on the body somewhere to hold the filter when not in use.”

—Barry Weissman, Jules Stein Eye Institute

Coordinating Center Happy with VFQ

The Coordinating Center has recently begun processing the Visual Function Questionnaire, a step that was delayed, pending receipt of the official scoring rules from the VFQ’s creators.

Congratulations!! Nearly all of the VFQ forms are free of queries; in fact, 95% are query-free, and less than 2% have more than one query. Congratulations!

Of those forms that do have problems, almost half of all the errors are in the section about driving. The patients appear to be confused by the “skip logic,” and they either answered questions that should have been skipped (because they don’t drive), or they skipped questions that they should have answered.

All the remaining problems are due to patients leaving one or more items blank. Question 14 seems to be a particular culprit. This question should be answered whether or not the patient is wearing glasses.

As with all patient-completed forms, please review these forms before the patient leaves your office, so that errors or omissions can be corrected.
“Just Ask Esther”

Dear Esther,
We have had patients where a CLEK trial lens will not stay on a grafted cornea long enough for a steep K over-refraction and visual acuity. Can we use other lenses available in our Clinic to obtain this best-corrected visual acuity measurement?

Signed, Popping Out in New York

Dear Poping Out,
Please continue to try to use CLEK trial lenses first, even going with a slightly steeper lens than the steep K lens. If all else fails, you can use a lens that you have available in the office that will stay in place, with appropriate over-refraction, to obtain the measurement.

Dear Esther,
What are the Executive Committee’s plans at the moment in terms of future studies of keratoconus? (I know you’re privy to them.)

Signed, Enthusiastic in Ohio

Dear Enthusiastic,
This is a very timely question. The Executive Committee is meeting by conference call March 5, 1997 to discuss this very issue and has a full-day meeting in Columbus scheduled for early June.

Manuscript Update

The goals of the currently active Writing Committees are rather lofty. The FDACL Test-Retest paper is in its final stages, and the Visual Acuity Test-Retest Committee is reviewing a near final draft. The Baseline Committee is eagerly anticipating a first draft with initial data analysis already completed by the Coordinating Center, and the Scarring Test-Retest Committee has circulated an initial outline and draft.

Everyone in the CLEK Study will receive a copy of each manuscript two weeks before it is scheduled for submission with instructions on who to contact with comments.

ARVO Acceptances

The CLEK Study had three presentations accepted as posters for the 1997 Association in Research and Vision in Ophthalmology (ARVO) meeting. They are:

• VISUAL ACUITY REPEATABILITY IN KERATOCONUS (K. Zadnik, M.O. Gordon, Ken Schechtman, Larry J. Davis, Timothy T. McMahon, Julie A. Schornack, and the CLEK Study Group, scheduled for presentation on Wednesday, May 14

• BASELINE TEST-RETTEST FINDINGS OF CORNEAL SCARRING IN THE CLEK STUDY, J.T. Barr, G.E. Pierce, T.B. Edrington, K. Zadnik, M.O. Gordon, and the CLEK Study Group, scheduled for presentation on Sunday, May 11

• VIDEOKERATOGRAPHIC DATA QUALITY AND DISEASE SEVERITY IN KERATOCONUS, [L.B. Szczotka, N.E. Friedman, L.J. Davis, T.T. McMahon, and the CLEK STUDY GROUP, scheduled for presentation on Thursday, May 15.
CLEK Study Applauds Personnel—No Foolin’!

It’s astounding sometimes to reflect back on where the CLEK Study came from and how we got to the point of having over 1,200 patients to round up and account for. Thanks to everyone—from Jodi Malone’s efforts to wade through the Ohio State University Research Foundation’s requirements for Participating Clinic subcontracts to Gloria Scott-Tibbs’s religious recycling of film canisters to keep our film development costs down, from Kate Landro’s tracking down a CLEK patient in her neighborhood to Janet Hess’s and Jill Nelson’s efficiency suggestions, from investigators and coordinators who drive patients to and from appointments to personnel who make sure the patients’ favorite foods and beverages are available at appointments, from the Coordinating Center’s Edit Reports to the CLEK-TAG’s considerable efforts to wade their way into the topography data—the CLEK Study is on track to achieve its scientific goals. It’s the part of epidemiological research that no one thinks of that the CLEK Study personnel accomplish on a daily basis and that have made the CLEK Study a success. Thanks to one and all!

Coordinating Center Director Apprehends Thief

During a CLEK conference call, Mae Gordon suddenly was missing from the conversation and returned to the phone breathless. In her absence, she had not run a marathon, but had, in fact, apprehended a purse-snatcher by chasing him down her hallway, containing him, and calling the Washington University campus police. The perpetrator was heard to mutter, “Those darn CLEK women; they can do anything!”

OSU Group Sings with Esther

On March 15, 1997, an impromptu CLEK training meeting was held to certify new Ohio State-based CLEKbies Tom Raasch and Roanne Flom in Esther-ing. Now performing at Schmidt’s in German Village, Esther was clad all in green (right down to her patent leather kelly green sandals!) and led the OSU College of Optometry table in a rousing chorus of “Head, Shoulders, Knees, and Toes.”

Dog Chews Film Canister

The CPRC recently received a film cartridge that looked like it had been a dog’s chew toy. The film was intact, the photographs were beautiful, and it’s obvious that our CLEK film can “take a lickin’ and keep on tickin’”!

A Close Shave

It is expected that the CLEK-by-the-Pool Annual Dinner following the Full Investigators Group Meeting at ARVO, to be held May 10, 1997, will once again culminate in buzz-cuts for all. Joe Barr and Tim Edrington were unavailable for comment because they were too busy booking appointments prior to ARVO with their own barbers.

Quote for the day: “Keep a journal, but not one in which you begin each page with ‘Dear Diary.’ Use a simple notebook where you make entries when something significant, interesting, or surprising happens. Someday it will help you answer the question, ‘Where did all those years go?’”

—Richard A. Moran
Year One Done

The Chairman’s Office has it on good authority that two CLEK Participating Clinics have completed their first year’s follow-up visits. Gundersen Lutheran, with John Sterling, Janet Hess, Jill Nelson, Eric Sheahan, John Sake, John Larsen, and Tom Edwards have completed all their visits with just two patients “missing in action.” The Buckeye CLEK team at Ohio State, Barbara Fink, Jason Nichols, and Lisa Badowski, are all done with 100% retention! These are fantastic accomplishments. Any longitudinal study lives or dies by its retention, and John and co-workers and Barb et al. are to be sincerely congratulated by one and all. Now on to Year Two!!

Shin and Benetz: Above and Beyond

In early April, Julie Shin from the Southern California College of Optometry, and Beth Ann Benetz of the University Hospitals of Cleveland traveled to San Antonio to see the Texas-based CLEK patients for their year 1 visits. Julie scheduled the patients long-distance from California before their arrival, and they saw 14 patients in four days. Julie and Beth were greeted with flowers from the Coordinating Center upon their arrival.

It turns out the TMS at the San Antonio clinic was out, so patients were transported to a research laboratory for topography. Gloria Scott-Tibbs at the CPRC reported receiving 29 rolls of film on April 8. Thanks, Julie and Beth, for a job well done!

Daughter of CLEK

Joe Barr, Tim Edrington, Mae Gordon, and Karla Zadnik held a conference call in March to discuss future CLEK studies. They will meet again, in person, in Columbus on June 3 for an all-day brainstorming session to outline the important questions that will remain unanswered after the current CLEK Study.

Congratulations, Roanne and Tom!

The Ohio State University College of Optometry welcomed newest addition, Alexa Bernice Raasch, on April 1, 1997. Alexa’s proud parents are Roanne Flom, newest CPRC Reader, and Tom Raasch, CLEK-TAG member. We bet Alexa will show up in the CPRC reading room, and she already has a teal and purple stroller perfect for the job!

Writing Committees Moving Forward

Two of the CLEK Writing Committees are nearing manuscript submission. The manuscripts on test-retest of FDACL and keratometry and on test-retest of visual acuity are in their final stages of production. The entire CLEK Study Group should expect to receive the visual acuity manuscript just after ARVO, and the FDACL manuscript just after that. Upon receipt, each member of the CLEK Study Group and the CLEK Data Monitoring and Oversight Committee will have two weeks within which to give feedback to Karla Zadnik (visual acuity) or Tim Edrington (FDACL). After that, the manuscripts will be submitted for publication. Other Writing Committees actively working include the Baseline Writing Committee and the Scarring Test-Retest Committee.

As always, if you have interest in joining any of the current or planned Writing Committees, contact Karla Zadnik at the Chairman’s Office.

Slides for Presentation

Three sets of slides, one on visual acuity test-retest data, another on preliminary baseline data, and one on FDACL test-retest, will be distributed to CLEK personnel attending the FIG meeting May 10, 1997 just before ARVO. If anyone else would like a copy of these slides for local use, please contact Karla Zadnik (visual acuity and baseline) or Tim Edrington (FDACL). If you use the slides in presenting to students or local doctors, do drop Karla an email to that effect.
Dear Esther,

A patient was prescribed contact lenses but had lost a lens at the time of his CLEK visit. I completed both pages 4 and 5 of the Examination Form relating to currently prescribed lenses and not currently prescribed lenses. Was this the right approach?

Sign me, Paged Out in Timbuktu

Dear Paged,

No, please collect only the data that would be applicable to the patient. In this case, all that had to be collected was the information pertaining to the prescribed contact lens wear. A note stating that the contact lens was lost would be sufficient to the Coordinating Center for information that could not be collected.

Dear Esther,

My colleague saw a patient that was not prescribed a contact lens in her right eye. He over-refracted the FDACL + 0.2 lens and corrected her to 20/30 in that eye. Should we write a letter to the referring doctor suggesting that she fit the eye with a contact lens?

Sign me, Diligent in California

Dear Diligent,

Because the CLEK Study is an observational study, we are not supposed to interfere in the ongoing care of the patient in any way. Obviously, if the patient has a corneal abrasion or another urgent eye problem, he or she must be cared for (see just below), but in this case, the fitting of the right eye is up to the patient and her doctor, without CLEK input.

Dear Esther,

I had a patient come in this week for her year 1 CLEK Study Visit. She habitually wears RGP lenses, but she was not wearing them because her right eye became irritated the day before at work. We completed the CLEK examination up through slit lamp, promptly diagnosed infiltrative keratitis, prescribed for it, and sent her home. When she returned, recovered, I began the CLEK examination from where I'd left off. Is that right?

Sign me, Interrupted in Indianapolis

Dear Interrupted,

You did exactly the right thing. You should just make certain that the minimum amount of time elapses between the two visits.

Site Visit Planned

The first site visit of the Coordinating Center is planned for June 19, 1997. Maureen Maguire from Scheie Eye Institute and a well-known figure in multicenter vision studies will conduct it. Mae Gordon and her staff will roll out the red (or is that purple?) carpet for the event.

The call for abstracts for the Annual Meeting of the American Academy of Optometry in San Antonio in December 1997 is out. Abstracts are due via email August 18, 1997. If you have ideas for Academy presentations, please transmit them to Karla Zadnik at the Chairman’s Office.

Tag, You’re It

The CLEK Topography Analysis Group (Tim McMahon, Loretta Szczotka, Bob Anderson of the University of Illinois at Chicago, Larry Davis, Nina Friedman, Tom Raasch, and Ken Daniels) have been active this spring. They have been outlining plans for a Reading Center, conference calling, and plan to meet at ARVO.

Just Wondering

Joe Barr wonders whether anyone has ever heard of an animal model for keratoconus. CLEKkies?

Let Us Hear from You

If anything exciting, interesting, novel, or just plain fun is going on in your life, let us know at the Chairman’s Office. One of the most difficult things about a multicenter study like the CLEK Study is maintaining a sense of community. Although we all know we’re involved in this joint endeavor, we’d love to tell you more about each other. Keep us posted.

Only the initiated know and honor those whose patient integrity and devotion to exact observation have made the last step possible.

—Hans Zinsser, 1940
FIG Meeting Went Off Without a Hitch

The second annual CLEK Full Investigators’ Group Meeting at ARVO went well. Although Joe Barr was missing from the meeting, Gil Pierce filled in for him admirably with the CPRC Report. Presentations of study data by Larry Davis, Tim McMahon, Brad Wilson, and Karla Zadnik resulted in lively discussions that positive influenced Writing Committees’ work later in the day. New-since-last-year CLEK Study members Jodi Malone, Nikole Himebaugh, and Donna Carter attended. NEI Project Officer, Don Everett, had high praise for the recruitment, retention, and high quality data that characterize the CLEK Study.

More Clinics Cross First Finish Line

It was announced at the FIG Meeting that two more Clinics have joined Gundersen and Ohio State in finishing their year 1 CLEK Visits. The University of California, Berkeley School of Optometry completed all their year 1 visits without losing a patient, and Jules Stein Eye Institute, UCLA has completed all their year 1 visits with just two patients missing. Fabulous job, all!

Gundel and Libassi Appreciated

The Chairman's Office received the following email on May 20, 1997:

“Dr. Zadnik,

Just wanted to thank you for the CLEK Study and show appreciation for all the meticulous work being done on behalf of keratoconus.

“I had my second annual appointment with Drs. Libassi and Gundel on May 15 at SUNY, and they were wonderful. Once again I was impressed with their professionalism and sturdy competence. It was a very pleasant visit. My wife and I are enjoying the coffee mugs too. Nice touch.

“I wish you and the CLEK professionals continued success as you unravel the mysteries of keratoconus.”

Congratulations, Dave and Ralph!

Presurgical Visits Not Needed

Remember, the Executive Committee has decided not to pursue the issue of Presurgical Visits any longer. That means that if any of your stock correspondence to patients or their referring doctors includes reminders of the need for Presurgical Visits, they should be revised.

Congratulations, Heidi and Chris!

Nova Southeastern University College of Optometry CLEKkers, Heidi Wagner and Chris Woodruff, welcomed their newest addition, Alyssa Gabrielle Woodruff, on May 19, 1997. Alyssa was born at 8:03 a.m., weighing 7 pounds, 3 ounces, and measuring 19-3/4 inches. Big sister Alexandra is “a little jealous,” according to Mom.

VA Test-Retest Manuscript on the Launching Pad

Final edits from members of the CLEK Study Group on the Visual Acuity Test-Retest manuscript were due in the Chairman’s Office by June 2, 1997. Final touches are being put on the figures for the manuscript, and it will be submitted to Archives of Ophthalmology in early June. Keep your fingers crossed that the reviewers love us!

Congrats to Authors

University of Illinois-based CLEKites, Tim McMahon and Jamie Putz, had a paper published in a recent issue of the Journal of the American Optometric Association (Volume 68, pages 215-224. The title of the paper is “Contact Lens Use after Corneal Trauma.”

Likewise, Larry Davis authored a clinical review, “Keratoconus: Current Understanding of Diagnosis and Management” for Clinical Eye and Vision Care in its volume 9, pages 13-22.
“Just Ask Esther”

Dear Esther,
I loved the fruit salsa at the CLEK dinner at ARVO. Does someone have the recipe?

Sign me, CLEK Spouse in Salt Lake City

Dear Spouse,
Glad you liked it! The recipe is at the bottom of the next column.

Dear Esther,
We had a patient that needed to stay overnight in Columbus during his appointment for his year 1 visit. Now he wants the same courtesy extended for year 2. We’re proud of our 100% retention and want to keep him. What should we do?

Sign me, Dedicated in Ohio

Dear Dedicated,
Any special arrangements like this have to be approved by the Chairman’s Office. Call Jodi Malone or Karla Zadnik, explain your dilemma, and see what can be accomplished.

Dear Esther,
I had a patient who went to see her regular ophthalmologist for a corneal problem a couple of weeks after her CLEK Visit. What needs to be reported to the CLEK Study?

Sign me, Potentially Abraded in St. Louis

Dear Abraded,
You should file an Adverse Event Form with the Coordinating Center. If you have any questions about the specifics, call Karla Zadnik, the CLEK Study Chairman.

Dear Esther,
I didn’t get a CLEK baseball cap at the FIG meeting and am desperately coveting the one my Principal Investigator came home wearing. Is there any hope of getting one? Also, I lost my CLEK T-shirt and would like another one. Are there any more of those available?

Signed, Undressed in Utica

Dear Undressed,
More caps are on order, and Jodi Malone at the Chairman’s Office has T-shirts available in large and extra large.

Let Us Hear from You

If anything exciting, interesting, novel, or just plain fun is going on in your life, let us know at the Chairman’s Office. One of the most difficult things about a multicenter study like the CLEK Study is maintaining a sense of community. Although we all know we’re involved in this joint endeavor, we’d love to tell you more about each other. Keep us posted.

CLEK at ARVO Fruit Salsa

1 ripe pineapple
1 ripe cantaloupe
4 fresh jalapeno peppers
1 bunch fresh cilantro
4 cloves garlic

Dice the pineapple and cantaloupe finely (1/4 inch dice). Finely mince the garlic, jalapenos, and cilantro. (Tom Raasch advises wearing gloves for the peppers, especially if you’re a contact lens wearer!). Combine all ingredients. Serves lots.

ARVO 1997 Citations

The CLEK Study Group was a co-author on the following three abstracts at the 1997 ARVO meeting. Please update your cvs appropriately:


The call for abstracts for the Annual Meeting of the American Academy of Optometry in San Antonio in December 1997 is out. Abstracts are due via email August 18, 1997. If you have ideas for Academy presentations, please transmit them to Karla Zadnik at the Chairman’s Office.
Coordinating Center Gets Clean Bill of Health

The CLEK Coordinating Center was site-visited on June 19, 1997 by Maureen Maguire, PhD of Scheie Eye Institute, University of Pennsylvania. Dr. Karla Zadnik traveled to St. Louis for the site visit of the Coordinating Center conducted by Dr. Maureen Maguire. Site visits are conducted at the CLEK Photography Reading Center and Coordinating Center in much the same spirit as clinic site visits. The site visits are intended to be helpful, to identify problem areas and to strengthen the operation of organization. Dr. Maureen Maguire has extensive experience as biostatistician at the Coordinating Center at Johns Hopkins University for the Macular Photocoagulation Studies, Collaborative Ocular Melanoma Study and Collaborative Corneal Transplantation Studies. She has also served on the Data and Safety Monitoring Committees for the Glaucoma Laser Trial, Central Vein Occlusion Study and Krypton-Argon Regression of Neovascularization Study. Although the formal site visit report has not yet been received by the Coordinating Center, Dr. Maguire’s informal comments were very positive. She cited the high degree of data quality in the CLEK Study, the obviously positive working environment, and the dedication of the Coordinating Center staff as particularly impressive.

Don’t Let Patients Take Forms

Although we want to accommodate CLEK patients’ schedules as much as possible, you should not allow patients to take CLEK Patient-Completed Forms with them with the promise that they will mail them back. Please insist that they take the few minutes required to complete them in-office.

Thanks, Kate!

Kate Landro of the University of Utah expressed appreciation to the Resource Centers of CLEK following ARVO:
“Just a note to say thanks for all the work you did to make our CLEK meeting a smashing success!” and “I’ve worked on several clinical studies and this one is by far the most organized and fun to work on.... Thanks for letting me be a part of it.”

More Clinics Finish

Hot off the presses: University Hospitals of Cleveland, University of Illinois at Chicago, Department of Ophthalmology, University of Missouri-St. Louis School of Optometry, and Northeastern Eye Institute have all completed their year 01 visits. They are still locating 4, 3, 3, and 3 patients respectively. Congratulations to Loretta Szczotka’s, Tim McMahon’s, Larry Davis’s, and Joe Shovlin’s teams for all their hard work.

Missed Visits Generally Not Repeats

Of the 21 patients for whom Missed Visit Forms have been sent for year 01 visits, only three were Repeat Visit patients at last report.

Famous Keratoconus Patients

CLEK paparazzi report: Tim Edrington sent a clipping from USA Today that Mandy Patinkin, Tony-award winning actor, recently of Chicago Hope, did indeed have a corneal transplant for keratoconus. Loretta Szczotka sends a clipping that Jerry Stackhouse of the Philadelphia 76ers has keratoconus, described as “a cone-shaped cornea[!] disease that “probably is hereditary.”
Help from the Chairman’s Office
At the July 1, 1997 Executive Committee conference call, the Executive Committee decided to implement a program of Chairman’s Office support of CLEK manuscript production. As each CLEK Study manuscript proceeds to its penultimate draft, the Chairman of the Writing Committee will manage the Writing Committee, correspond with the Coordinating Center, pull together different people’s drafts, arrange and chair conference calls, and produce materials to circulate to the Writing Committee members for comment.

When the manuscript is at the point where the Writing Committee members are being invited to provide their final comments before submission, the manuscript and figures should be submitted to the Chairman’s Office for final production and submission to the journal that the Writing Committee has chosen. The Study Chairman will serve as the corresponding author.

This system will relieve Writing Committee members of the tedium of final edits and manuscript production, checking of references, and manuscript submission. The Chairman’s Office will produce the final version of the manuscript, will circulate the manuscript to the CLEK Study Group for invited comments, will obtain appropriate copyright transfer information from Writing Committee members, will attach the current CLEK Study Group list, and will provide copies of the submitted manuscript to the Writing Committee, the Executive Committee, and the Data Monitoring and Oversight Committee.

The Chairman’s Office will track the review of the manuscript contacting the journal as necessary. When the Chairman’s Office receives feedback from the journal editor, the Writing Committee will be contacted via conference all to address reviewers’ comments. The post-review revisions will be implemented through the Chairman’s Office with input from the Writing Committee, and the manuscript will be resubmitted by the Chairman’s Office.

Hopefully, by providing this support, we can facilitate actual submission of CLEK Study papers. Remember, unless we get our results out to our scientific and clinical communities, the impact of all your hard work will be limited.

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<tr>
<th>Manuscript topic</th>
<th>Committee members</th>
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<td>Repeatability of visual acuity</td>
<td>Gordon, Zadnik, Davis, McMahon, Schornack, Schechtman</td>
<td>Submitted 6/24/97</td>
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<td>FDACL &amp; keratometry</td>
<td>Edrington, Burger, Szczotka, Begley, Gordon, Wilson</td>
<td>Draft due back to Edrington 6/30/97</td>
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<tr>
<td>Baseline: demographics, clinical characteristics</td>
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<td>Data received by Zadnik 6/27/97</td>
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<tr>
<td>Photography reading: scarring, test-retest</td>
<td>Barr, Fink, Pierce, Pensyl, Schechtman</td>
<td>Barr and Schechtman to discuss 6/17/97</td>
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<tr>
<td>Manifest refraction and visual acuity: test-retest</td>
<td>Davis, Shin, Zadnik, Schechtman, Begley, Gordon</td>
<td>Had conference call 6/11/97</td>
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<td>Baseline: how flat they’re fitted</td>
<td>Edrington, Burger, Szczotka, Chun, Janoff</td>
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<td>Risk factors for scarring</td>
<td>Barr, Everett, Edrington, Gordon, Weissman, Zadnik, Siegmund</td>
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<td>Fluorescein grading: habitual</td>
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<td>Baseline: visual acuity and over-refraction</td>
<td>Barr, Davis, Shin, Pensyl</td>
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<tr>
<td>Topography in nonkeratoconic fellow eyes</td>
<td>Shin, McMahon, Szczotka</td>
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<tr>
<td>Quality of life in keratoconus</td>
<td>Gordon, Schornack, Pensyl, Barnhart, Zadnik, McMahon, Roediger</td>
<td>Met 5/10/97</td>
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Writing Committees
July 1, 1997
Please Keep Up the Hard Work

In general, we are most impressed with the efforts you are putting forth in the Participating Clinics to retain CLEK patients. However, as Karla Zadnik compiled results of the Late Visit Report system for tracking patient visits, the patients marked “unable to locate” or “scheduling difficulties” add up.

Of the 1,209 enrolled CLEK patients, four have died. Of the remaining 1,205 patients, 19 cannot be located, and 39 are having difficulty being scheduled.

We know that your Clinic’s individual losses to follow-up are small, but it adds up over 15 Clinics and across three years.

So, if there are patients you haven’t tried to locate in a while, try again! If you as a Study Coordinator have tried to confirm them for their fifth missed visit in a row, see if one of your Investigators will make the confirming phone calls this time.

Coordinating Center Kudos Continue

Gary Cutter, Chairman of the CLEK Data Monitoring and Oversight Committee writes, “Thanks for the copy of the [Coordinating Center] Site Visit Report. I usually don’t say much about the site visit reports we get, but I did want to congratulate you on such a positive and enthusiastic endorsement of your work. I agree that the suggestions are good ones, but also note that the compliments sprinkled throughout should not go unnoticed.” Way to go, Mae, Ken, Joel, Brad, Teresa, and Pat.

Publications Congratulations

To Denise Pensyl at UAB for her (first author) article, “Distribution of astigmatism among Sioux Indians in South Dakota” in the July 1997 issue of the Journal of the American Optometric Association. Great work, Denise!

Overheard on the ‘Net

From Mae Gordon to Larry Davis: “Thank you, thank you, thank you for your detailed fax explaining why deviations from randomized selection of patient and/or eye were made for the refraction paper. ... I hereby wish to welcome you to the select membership of [the] ‘compulsively careful’ club (CCC).

From Larry Davis to Mae Gordon: “Gee, is that good?”

From Mae to Larry: “Membership in the compulsively careful club is by invitation only. Eligibility is established only by good works, not by reputation. In my experience, it is only by walking that extra mile does one stumble over the rock that reveals secrets. ... I wish all my collaborators were as careful as you!!”

From Larry to Mae: “Thanks for your kind comments. In order to assess the interest of other members of the CCC I would offer the following argument for a club name change. Webster defines compulsion as ‘an irresistible ... arousing of the mind and spirit to action.’ This suggests that one has no choice for [his] direction; not to mention the pie in the face when others learn that we have a ‘compulsion.’ On the other hand conscientious is defined as ‘guided by one’s own sense of right and wrong,’ an admirable quality without the baggage of a compulsion. Splitting hairs? Yes, but that’s what makes us conscientious. The acronym CCC could remain as is.”
Dear Esther,
I just had a patient whose cornea was too flat for the CLEK Trial Lens Set. Is it possible to extend the range of the trial set?

Sign me, Flattened in Alabama

Dear Flattened,
Joel Achtenberg of the Coordinating Center writes, “Since we began asking whether the trial lens set was inadequate, we’ve assessed 2,381 eyes. Forty-six (1.9%) were too flat for the 8.00 mm lens, and 37 (1.6%) were too steep for the 5.00 mm lens. Any trial set will always have a “ceiling” and a “floor.” Excluding \( \approx 3\% \) of the sample seems acceptable, so we think the current trial set is adequate.

Dear Esther,
We received an Edit Report asking for contact lens parameters for an eye wearing a Softperm lens. We think it was in error.

Sign us, Soft Skirts in CLEK

Dear Soft Skirts,
Actually, the CLEK Study protocol does require you to measure the rigid lens base curve, diameter (recorded as the optic zone diameter), power, and overall diameter of the lens for Softperm lenses.

That Teresa!
Last month at the Society for Clinical Trials meeting in Boston, an entire morning session was devoted to honoring Nathan Mantel (statistical giant, named as part of the well-known Mantel-Haenszel chi-squared test. Dr. Mantel was in the front row, and Teresa Roediger of the Coordinating Center sat next to him, not knowing who he was. She proceeded to talk with him, tell him about CLEK and her role in it, and (probably) delight him no end. Only at the end of the session, when Dr. Mantel stood to acknowledge the room’s applause, did Teresa find out his identity!

From the CPRC
FDACLers of the month: Jerry Lowther and Julie Shin
Most consistently great photography over time: BethAnn Benetz
Most improved photographer: Nikole Himebaugh
Most consistent photographers: Steve Gushue, Eric Sheahan, John Sake
Most enduring reader: Gil Pierce
Most outstanding side handler: Gloria Scott-Tibbs
Toughest reader: Marjorie Jeandervin
Most improved reader: Roanne Flom

Clinical Trials Aphorisms
(by Curtis L. Meinert in Clinical Trials Dictionary, reviewed by Simon Day in the ISCB Newsletter)

The way to be sure is not to check.
So three cheers (sorry, one cheer) for doing away with double data entry.

Definitive is a label affixed 30 years after the fact. By which time it’s too late to take the glory (but not too late to make money).

The difference between a good and a bad paper is 15 iterations.
The good paper is usually the second iteration, and things go downhill after that.

Put too many pigs under a blanket and they all get away.
And that we really, really don’t understand? Anyway, how does he know!? (something about portfolio management perhaps?)

For the actual number of people to be enrolled into a trial, divide the number promised by 4 and multiply the time stated for getting them by 2.
Note that this rule is recursive. (Mae Gordon notes that CLEK has defied this principle.)

Data and wine should be aged.
Sadly not the wine we can afford.

When you are up to your rear end in alligators, it’s hard to remember you started out to drain the swamp.
No comment, OK!? Just no comment.

Get Well Soon
Pat Nugent of the Coordinating Center received her donor kidney on July 28 at 3:00 a.m. We wish her a speedy recovery!

Congrats, Loretta!
The June/July 1997 issue of the Ohio Optometric Association’s Perspectives profiles Loretta Szczotka as the Association’s 1997 recipient of the Jack T. Keith Young Young Optometrist of the Year Award “for her commitment to the profession of optometry and community involvement.” It cites her involvement as a CLEK Participating Clinic.
Ancillary Study Approved
The CLEK Data Monitoring and Oversight Committee approved the ancillary study, “Lysosomal Enzyme Staining in Conjunctival Epithelium of Patients with Keratoconus,” proposed by Tim McMahon and Carolyn Begley. DMOC Chairman Gary Cutter writes, “wishing you the best of success in this endeavor.”

Leave Your Message at the Tone
Jason Nichols, CLEK Study Coordinator at The Ohio State University College of Optometry Participating Clinic reports a successful year 2 visit of a CLEK patient on Friday, August 22. Jason logged 32 individual phone calls to get the patient scheduled and seen!

Publish, Publish, Publish
Congrats to OSU Clinic PI, Barbara Fink, for her lead article in the August 1997 of the Journal of the American Optometric Association entitled “Corneal Responses to Lens Transmissibility”. It includes the new nomenclature, oxygen shortfall units, or “osus” for short. Get it?

Just Ask Esther
Dear Esther,
Will you remind me what we do when we don’t have a lens steep enough or flat enough in the CLEK Study trial lens set for FDACL or FDACL + 0.2 mm and their photographs?

Sign me, Al Goodthingsmustcometoanend
Dear Al,
If you use a 7.90 mm lens for FDACL, use the 8.00 mm lens for FDACL + 0.2 mm and photograph both. If the 8.00 mm lens is too steep, photograph it. If the 5.00 mm lens is too flat, photograph it. Always document all of this on the CPRC Film Fax Log.

Dear Esther,
Sometimes when a CLEK patient’s pupil doesn’t dilate fast enough, we go ahead and do FDACL first, then take the obliques at the very end. Is that okay?

Sign me, Well Dilated in Lots of Clinics
Dear Well Dilated,
No. The protocol specifies that oblique corneal photographs must be taken before FDACL is performed. The concern is that the FDACL lens series will induce new corneal staining that will confound the oblique photographs.

Writing Committee Schedule in San Antonio
The following Writing Committees are slated to meet just after the American Academy of Optometry meeting in San Antonio in December. As usual, the CLEK Chairman’s Office will fund an additional night’s hotel for anyone involved in these meetings (plus feeding you!). CLEK-TAG will most likely meet, too.

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<tr>
<th>Topic</th>
<th>Committee Members</th>
<th>Date and Time</th>
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<tbody>
<tr>
<td>Manifest refraction: test-retest</td>
<td>Davis, Shin, Schechtman, Begley, Gordon, and Zadnik</td>
<td>Monday, December 15, 5:30 pm to 9:30 pm</td>
</tr>
<tr>
<td>Habitual fluorescein grading</td>
<td>Edrington, Gundel, Libassi, and Wagner</td>
<td>Monday, December 15, 5:30 pm to 9:30 pm</td>
</tr>
<tr>
<td>Risk factors for scarring</td>
<td>Barr, Edrington, Gordon, Weissman, Zadnik, and Everett</td>
<td>Tuesday, December 16, 8:00 am to 11:00 am</td>
</tr>
<tr>
<td>Quality of life</td>
<td>Gordon, Schornack, Pensyl, Barnhart, McMahon, Zadnik, and Roediger</td>
<td>Tuesday, December 16, 8:00 am to 11:00 am</td>
</tr>
</tbody>
</table>
CLEK-TAG Is “It”
The nascent CLEK Topography Reading Center has its start. **Tim McMahon** was awarded a subcontract through the CLEK Chairman’s Grant for a two-year period to establish a reading center to evaluate corneal topography in patients with keratoconus. In collaboration with **Loretta Szczotka**, **Thomas Raasch**, **Larry Davis**, OD, **Nina Friedman**, and **Robert Anderson**, comprising the CLEK Topography Analysis Group, the CLEK Topography Reading Center will establish a comprehensive protocol for evaluating and correlating corneal topography measures with historical, quality of life and clinical measures of disease progress. Way to go Tim, et al.!

Take Good Care of My Baby
In the “What’s Really Important in Life Department,” we welcome two more CLEK babies. Rachel Zina Englanoff-Hulkower was both to **Ronit Englanoff** of Jules Stein Eye Institute at UCLA and her husband on August 14, 1997. Rachel weighed in at 10 lbs, 3 oz. CLEK exams won’t seem like much after that, Ronit! And **Nikole Himebaugh** of Indiana University School of Optometry and husband Bruce welcomed Blake Alexander Himebaugh on September 22, 1997, weighing in at 6 pounds. Best wishes to everyone!

Heard It Through the Grapevine
A young keratoconus patient and his family were referred to **Joel Silbert** at Pennsylvania College of Optometry through the National Keratoconus Foundation. Here’s how they felt about their care and Dr. Silbert: “... On the hour ride home from the doctor’s office, [our son] kept talking about all the things he couldn’t wait to do again that he hasn’t done in years—now that he could see again. We understand that this will be a lifelong process, but at least now he knows that there are actually people out there that can help him and understand what he’s been going through.”

More on Tim
**Tim McMahon** has been named to the board of directors of the Wesley Jessen Special Eyes Foundation, which will combine the operations of the Narcissus Eye Research Foundation and W-J’s own prosthetic contact lens program. The Foundation will operate as a not-for-profit organization that develops and produces prosthetic contact lenses to mask ocular disfigurement.

Some People Will Do Anything for a Patient
Continuing to confirm our belief that CLEK investigators will do anything for a follow-up visit, we received a copy of a letter from none other than **Joe Benjamin** of the University of Alabama at Birmingham School of Optometry inviting a patient to return for his overdue CLEK visit: “We really need you to have you come back and go through another examination in order to complete this year’s data for the study. Maybe Maria could turn the stereo on so we can listen to music during the CLEK exam? I’d even listen to Earl Pitts on FM 99.5 if you’ll come in for your visit!” We don’t know who Earl is, Joe, but it sounds like fun.

Just Ask Esther

Dear Esther,
One of our CLEK patients has informed us that she will be unavailable for her upcoming year 2 CLEK Study Visit. This patient will her entire window of opportunity to spend a fun-filled afternoon with us. Can we examine this patient several months early as opposed to eight months late?

Sign us, Every Clinic in the Study

Dear Every Clinic,
It depends on the timing. If you can see the patient at least six months after her baseline anniversary date, then it will count as year 2. If it’s less than or equal to six months, there’s no point, assuming you already have a year 1 visit.
Writing Committee Schedule in San Antonio

<table>
<thead>
<tr>
<th>Topic</th>
<th>Speakers</th>
<th>Time and Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manifest refraction: test-retest</td>
<td>Davis, Shin, Schechtman, Begley, Gordon, and Zadnik</td>
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</tr>
<tr>
<td>Habitual fluorescein grading</td>
<td>Edrington, Gundel, Libassi, and Wagner</td>
<td>Monday, December 15, 5:30–9:30 pm; Marriott Rivercenter Room 6</td>
</tr>
<tr>
<td>Quality of life</td>
<td>Gordon, Schornack, Pensyl, Barnhart, McMahon, Zadnik, and Roediger</td>
<td>Monday, December 15, 5:30–9:30 pm; Marriott Rivercenter Room 7</td>
</tr>
<tr>
<td>Baseline correlates of corneal scarring</td>
<td>Barr, Edrington, Gordon, Weissman, Zadnik, Everett, and Fink</td>
<td>Tuesday, December 16, 8:00–11:00 am; Marriott Rivercenter Room 7</td>
</tr>
<tr>
<td>CLEK-TAG</td>
<td>Szczotka, McMahon, Davis, Friedman, Raasch, Anderson</td>
<td>Tuesday, December 16, 8:00–11:00 am; Room 10</td>
</tr>
</tbody>
</table>

Everything You Always Wanted To Know About the CLEK Clinic Report Card But Were Afraid To Ask

The Quarterly Report Card summarizes activity for a designated calendar quarter, for each clinic individually, and the average for all clinics. Reporting includes only that information received and processed at the Coordinating Center or CLEK Photography Reading Center (CPRC) prior to the end of the quarter. Forms received at the Coordinating Center prior to the end of the quarter but still in “suspense”, due to pending edit queries, may not be reflected in the Report Card.

% of Visits Within Target Window
% of Missed Visits
These two columns summarize the timeliness of visit completion for only those visits whose 6-month window ended during the quarter covered by the report. Annual visits are targeted for completion within 6 weeks of the anniversary of the original Baseline visit, and must be done no later than 6 months after the anniversary date or they are considered “missed”. The timeliness of each such visit, accordingly, is classifiable as one of the following:
Within Target: Within ± 6 weeks of the anniversary of the Baseline Visit.
Missed Visit: Visit not done within 6 months, or not yet received and processed at the Coordinating Center.
Done, But Outside the Target: More than ± 6 weeks but less than 6 months before/after the anniversary date.

% of Patient Completed Forms with No Queries
% of Exam Forms with No Queries
Mean Number of Queries on Exam Forms
These three columns summarize the results of computerized checking of forms edited at the Coordinating Center during the reporting period, regardless of the actual visit date. Forms are edited generally within 3 working days of receipt.

The number of “queries” refers to the number of individual form fields for whom messages were issued by the computer program, and may be greater than the number of “edits” (printed at the bottom of the edit report sent to clinics) since some edits raise queries about more than one field on the form. Column 3, the percent of patient completed forms with no queries, summarizes the editing of the Patient History, Quality of Life, and Visual Function questionnaire. Since edit queries are not issued for errors made by the patient, queries for these forms usually represent problems with the date on the form, or (form PH only) with the initials of the staff member who reviewed the form or time to completion.

% VA Stopping Rule Followed
This column reports the clinic’s adherence to the Stopping Rule mandated by the Manual of Procedures for measuring visual acuities. You’ve all been doing so well generally that (since January, 1997) only a random sample of VA Worksheets received each quarter is reviewed for compliance.

% Adequately Dilated Pupils Photographed
% Cornea Photography Slides Gradable
% Fluorescein Photography Slides Gradable
Each of these report card items is based on slides read (graded) at the CPRC during the quarter, regardless of the date the photos were taken or when they were received at the CPRC. Percentages may vary considerably due to small numbers of slides from a particular clinic that were graded during the reporting period.
Update Your CVs

The following presentations were given (with pride) at the American Academy of Optometry Annual Meeting in San Antonio in December. These published abstracts can now be included in your resumes:


Congrats, Jodi!

CLEK Study Coordinator, Jodi Malone, of the Chairman’s Office. After seven long years of hard work, part-time classes, and clinic rotations in her spare(!) time, Jodi received her R.N. degree from Columbus Community College this month. Wish her a hearty congratulations the next time you talk to her!

Benjamin Does Borish

Many CLEKkies have participated in the soon-to-be-published *Borish’s Clinical Refraction*, edited by our own Joe Benjamin and Irv Borish. CLEK contributors include Lisa Barnhart, Melissa Chun, Ronit Englanoff, and Barry Weissman, all of UCLA’s Jules Stein Eye Institute for the chapter on “Patients with High Refractive Errors.” Jerry Lowther of Indiana University School of Optometry wrote “Patients with Irregular Corneal Astigmatism.” Denise Pensyl of UAB School of Optometry authored the chapter on “Ocular Motility” and Karla Zadnik wrote on “Incidence and Distribution of Refractive Anomalies.” Joe Benjamin himself, believing the old adage about doing things right, authored chapters on “Objective Refraction,” “Retinoscopy, Autorefraction, and Phorofraction,” “Monocular and Binocular Subjective Refraction,” “Prescription of Multifocal Spectacle Lenses,” “Contact Lenses: Visual Function and Practical Optics,” and “Correction of Presbyopia with Contact Lenses.” Way to go, Joe!

Above and Beyond

Teresa Roediger of the Coordinating Center reports that Kate Landro at the University of Utah has gone the extra mile for a CLEK follow-up. The patient is experiencing a great many personal difficulties (sounds like an episode of Melrose Place, actually), and Kate rented a car, went and got the family from 3-4 hours away, and babysat the children during the examination!

ARVO Date

The FIG Meeting will be held Saturday, May 9, 1998 in Ft. Lauderdale.
Manuscript Accepted
The first manuscript from the full-scale CLEK Study has been accepted for publication in *Optometry and Vision Science*. The appropriate citation at this time for your curriculum vitae is:


It is scheduled to appear in the April or May, 1998 issue of *OVS*. When available, reprints will be distributed to the CLEK Study Group and to our patient and doctor database.

Get Well Soon
Jodi Malone, CLEK Study Coordinator at the Chairman’s Office, underwent non-life threatening surgery last week. She will be back in the office in mid-March, and we wish her a speedy recovery. In the meantime, Jodi’s key tasks are being ably covered by Dione Allen.

CLEK II on the Horizon
Joe Barr, Tim Edrington, Mae Gordon, and Karla Zadnik held another in a series of meetings and conference calls to discuss future plans for a follow-on CLEK Study. Currently, we are designing a randomized clinical trial with three treatment arms—flat, steep, and piggyback contact lens fits—with outcome measures visual acuity, contact lens comfort, corneal scarring, and quality of life. We will present the study design and details to the Data Monitoring and Oversight Committee in mid-June and plan to submit Resource Center and Clinic proposals October 1, 1998.

CLEK at ARVO
The CLEK Full Investigators Meeting is scheduled for Saturday, May 9, 1998 at the Marina Marriott, Ft. Lauderdale. As in the past, each Clinic will be covered for travel and related expenses for two representatives: one Investigator and one Study Coordinator. Selected Writing Committees will also meet that day (to be announced).

<table>
<thead>
<tr>
<th>Manuscript topic</th>
<th>Committee members</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline: demographics, clinical characteristics</td>
<td>Zadnik, Sterling, Wagner, Shin, Everett, Jameson, Gordon</td>
<td>Submitted to <em>Archives of Ophthalmology</em> 11/6/97</td>
</tr>
<tr>
<td>Photography reading: scarring, test-retest</td>
<td>Barr, Fink, Pierce, Pensyl, Schechtman</td>
<td>New draft 1/5/98</td>
</tr>
<tr>
<td>Manifest refraction and visual acuity: test-retest</td>
<td>Davis, Shin, Zadnik, Schechtman, Begley, Gordon</td>
<td>Met 12/15/97</td>
</tr>
<tr>
<td>How flat they’re fitted</td>
<td>Edrington, Burger, Szczotka, Chun, Janoff, Boyle, Gordon, Wilson</td>
<td>Rough draft written</td>
</tr>
<tr>
<td>Baseline correlates of scarring</td>
<td>Barr, Everett, Edrington, Gordon, Weissman, Shovlin, Zadnik, Siegmund</td>
<td>Met 12/16/97</td>
</tr>
<tr>
<td>Impact of scarring</td>
<td>Zadnik, Gordon, Wilson</td>
<td>Met 12/17/97</td>
</tr>
<tr>
<td>Contact lens comfort</td>
<td>Edrington, Gundel, Libassi, Wagner, Pierce</td>
<td>Met 12/15/97</td>
</tr>
<tr>
<td>Quality of life in keratoconus</td>
<td>Gordon, Schornack, Pensyl, Barnhart, Zadnik, McMahon, Roediger, Beiser, Walline</td>
<td>Met 12/15/97</td>
</tr>
</tbody>
</table>
Another Manuscript Accepted!
The second manuscript from the full-scale CLEK Study (and the second in 1998 to date) has been accepted for publication in *Cornea*. The appropriate citation at this time for your curriculum vitae is:


When available, reprints will be distributed to the CLEK Study Group and to our patient and doctor database.

The Baseline manuscript is still out for review.

To Commute or Not to Commute
Pam Qualley and Nina Friedman of UC Berkeley remind us that little gestures can mean a lot to patients. For example, one Berkeley-based CLEK patient recently came to a Saturday appointment with her CLEK commuter cup in hand. When Nina commented on it, the patient said that she loved it and used it all the time—except when her husband gets to it first! In the interest of family harmony, Nina gave the patient a new cup which sweetened the experience for both her and her husband (who drove her to the appointment).

Let the Chairman’s Office know if you would like a renewed supply of commuter cups.

Publish (Not Perish!)
Loretta Szczotka of University Hospitals of Cleveland has an article in the January 1998 issue of *The CLAO Journal*: Comparison of axial and instantaneous videokeratographic data in keratoconus and utility in contact lens curvature prediction in volume 12, pages 22-28. Let the Chairman’s Office know if you’d like a copy.


CLEK at ARVO
The CLEK Full Investigators Meeting is scheduled for Saturday, May 9, 1998 at the Marina Marriott, Ft. Lauderdale. As in the past, each Clinic will be covered for travel and related expenses for two representatives: one Investigator and one Study Coordinator. Selected Writing Committees will also meet that day (to be announced).

CLEK Study Group Under Review
All Clinic Principal Investigators recently received a current copy of the CLEK Study Group listing to review and revise. Remember to update the Chairman’s Office if your personnel’s status changes or if you add someone to your Clinic officially. This is the list that goes along with publications, remember!
Better Luck This Time
The CLEK baseline manuscript was rejected by Archives of Ophthalmology recently and was submitted to the section on Clinical and Epidemiologic Research of Investigative Ophthalmology & Visual Science on February 20, 1998.

Wedding Bells
Elisabeth Lim of the Jules Stein Eye Institute, UCLA married Ben Yu on January 31.

Farewell and Good Luck
Kate Landro of the University of Utah left the CLEK Study on February 26. She is pregnant with her second child (purported to be a girl), due mid-March. Her husband, Thom, a chemical engineer, is choosing a graduate school for his MBA degree, so the family will end up either in North Carolina, Michigan, or Pennsylvania later this year. She writes, “I am going to deeply miss all my fellow ‘CLEKkies’ and patients.... It has been so refreshing working such upbeat people. I sincerely hope our paths will cross again. Good luck with CLEK and CLEK II.” We will miss you, Kate. Good luck to all of you!

Volunteers Sought
It’s been (rightly) observed that the CLEK web page is what’s termed a “cobweb” (a site that is out of date and doesn’t change). Karla Zadnik is seeking someone from the CLEK Study Group who would be interested in generating copy to update the site on a regular basis. The actual updating of the site will be taken care of through the Chairman’s Office, so don’t panic if you don’t “speak Internet.” Call the Chairman’s Office to offer your help.

Check It Out!
The CLEK Study is described in a new feature on the National Eye Institute’s web site. There is a clinical trials database of all past and ongoing large-scale clinical studies at the NEI. You can view it at http://www.nei.nih.gov.
Your task this month is to determine which of these stories are real and which are April Fool’s!

Industrial Accident Reported
After three weeks of processing 188 rolls of film (developing and mounting roughly 5,600 slides) for the CLEK study, Doug Cress, the developing technician at McAlister Camera, set fire to the developing machine and ran from the building on Wednesday, March 18. In between incoherent mumbling the words “Enough, I’ve had enough” could be heard. Fortunately, there were no CLEK slides in the processor at the time. Doug has assured Gloria that after appropriate medical intervention he will be able to resume his duties at McAlister’s. We wish him well.

Keratoconus-Link Topical?
Topics covered in keratoconus-link in 1998 include the use of shredded raw potato to ease ocular irritation, EOTDS (End of the Day Syndrome) in rigid contact lens wearers, and the cost of eye drops and ointments.

The Color Police
How do they decide these things? It appears that teal and purple are out (what’s in: that lime green?) as the CLEK stationery supplier is discontinuing our paper line. Send your teal and purple crayons to Jodi Malone at the Chairman’s Office, as we may be creating our own paper soon.

Esther Errata
Last month we published the following observation in CLEK on Deck:

“Dear Esther, I wish you were still at Deibel’s. I love those cute blue shoes and, or course, your glorious voice.... Sign me, ‘Hungry in Columbus’”

This week we received the following “anonymous” message:

Dear “Hungry in Columbus”, Esther wore a turquoise blue sheath with red patent leather life stride, open toed shoes, NOT BLUE shoes -- (those were worn by some other dude).

Signed, “Imprinted”

and this reply:

Dear “Imprinted”,
Thank you for this clarification. Anal[retentive] is good! I think something must have clouded my memory of that night.

As always, “Hungry in Columbus”
First Paper Published


**From the Coordinating Center: Good News!**

Thanks to all of your efforts in keeping a timely response to edit queries! There has consistently been a low number of edit queries in suspense—currently there are 3! This takes a large effort on your part as well as the Coordinating Center to keep up-to-date data for the many publications being prepared. Congratulations!

**Addition to the Executive Committee**

Tim McMahon, Director of the CLEK Topography Reading Center at the University of Illinois at Chicago Department of Ophthalmology, joined the CLEK Executive Committee as of April 1, 1998. Welcome, Tim, and we just know you’ll love those weekly conference calls!

**All Our Exes Seen in Texas**

Once again, CLEKkies extraordinaire, Julie Shin and Beth Ann Benetz, traveled to San Antonio to see the Texas patients for their year 02 visits. They celebrated Fiesta, ate their way through a CLEK fruit basket, and returned with the data and photographs. Way to go, ladies!

**Announcing the Arrival of ...**

Jessica Lizzie Landro, born March 16, 1998 to proud parents Tom and Kate Landro, weighing in at 8 pounds 9 ounces.

**Fun Fact**

The average person consumes approximately 17 gallons of coffee each year.

**Just Ask Esther**

Dear Esther,

I have been searching the Operations Manual in vain looking for a clue as to how to record low contrast visual acuity when the patient can’t read anything on the chart. What should I be doing?

Signed, Counting Fingers in California

Dear CF,

If the patient cannot read any letters on the low contrast chart, even at the 1-m distance, you record 0.00. CF and HM are not appropriate for low contrast acuity.

Dear Esther,

I enjoyed the most recent CLEK on Deck offering. Someone at the stationery supplier should not remain stationary and should inform Disney that the Mighty Ducks hockey jerseys are now passé in color. Next thing you know, they will discontinue red patent leather life stride, open-toed shoes.

Signed, Bernie

**Appreciative Berkeley Patient**

A University of California, Berkeley-based patient wrote the following email to Nina Friedman:

“I just wanted to thank you for the pleasant clinic visit yesterday. As clinic visits go, a visit to the CLEK Study, is up there on top. The two of you [he means Nina and Pam Qualley] make the drive, and the time, worthwhile. I hope that my eye conditions help, in some way, to make the study a success.”

Keep up the fabulous effort out there!
Papers Published
The CLEK Study Group will receive reprints of our first paper as soon as they are available. In the meantime, here are the citations:


CLEK Around the World
Dear Karla—
Finding the CLEK Insight vol 2.1 reminded me to send you a note. In the last 9 months I may have seen more keratoconus patients, but I have fitted fewer of them. After your presentation at the New Zealand Contact Lens Practitioners conference in Auckland, I gave some thoughts to whether I had been in too much rush to force some patients into HGP lenses and I would usually inflict such unnecessary discomfort on a person to whom I may never have otherwise suggested even hydrophilic, occasional (disposable) wear, considering their atopy, itchy eyes and irritable disposition. It was all too easy to coerce the client into suffering the 'shock' of hard contact lenses when all the costs are covered by Social Security funding. My approach is now much the same as I would take with any other spectacle wearer whose refractive error was a 'little out of the ordinary'. "It is possible to present you with better around vision. When you decide you would like to proceed I will prescribe contact lenses appropriate to your specific needs". Not surprisingly, I have many happier K fits this year! Now the new challenge is presbyopes and bifocal contact lenses. (Not for my own personal wear) Those teenagers I fitted 25 years ago are returning, still as vain as before and still refusing to be seen dead in glasses. Fortunately they are blessed with a greater disposable income to their conventional lens requirements.

—Frederick Swain, Optometrist, Auckland, NZ

And Marco Bellacci, from Italy, asked about someone who could perform the CLEK “procedure” in Italy. Karla wrote him back that CLEK is a study, not a treatment, and invited him to join our mailing list.

Raise the Roof
Teresa Roediger from the Coordinating Center writes: “100% adherence to the VA stopping rule per random sampling” for the first time to the best of our knowledge. Congratulations to all!

Did You Know ...
That the CLEK web page receives 400 hits or so each day?

Thanks, Lou!
Lou Rosenberg of the Jules Stein Eye Institute CLEK Participating Clinic writes, “It was real nice seeing you again at the CLEK meeting in Florida. I enjoyed the fact that I got to meet the people, who until then, have just been a name without a face, like Joe Barr, Gloria Scott-Tibbs, Teresa, Loretta, and the others like Don Everett. I found the ARVO meeting an enlightening experience…. I’m very proud to be part of this effort.”

Quote of the Day
“I may be unpopular, but I’m not wrong” from Allan Roses, controversial Alzheimer’s genetic researcher.
The Next Frontier

On June 15, 1998 the CLEK Executive Committee met with the CLEK Data Monitoring and Oversight Committee to discuss the future of CLEK-based studies in keratoconus. We are excited at the DMOC’s enthusiastic endorsement to continue to follow CLEK patients. It is felt that we have a chance to learn a great deal about the natural history of this slowly progressing disease and that our continued, intensive follow-up is an opportunity that may never again present to another research group working in keratoconus.

We plan to submit a competitive renewal (November 1, 1998 deadline) for five more years (9/30/99 to 9/29/04) to follow CLEK patients annually during that time out to a total of eight years of follow-up (nine annual visits, including baseline).

We plan to submit a new grant (February 1, 1999 deadline) to fund a clinical trial. Eligible patients (no transplants, “keratoconus” patients who wear contact lenses already) from CLEK (and others, if necessary) will be randomized to steep, piggyback, or “standard of care” (ie, flat). Outcome measures might be low contrast visual acuity, contact lens comfort, corneal scarring (new or progressing), and vision-specific quality of life. All patients would be followed through year 08 (grant to run from 12/1/99 to 11/30/04).

We feel that all of us—the CLEK team—are invested with enormous potential to learn more and more about the natural history and management of keratoconus.

CLEK in Five-Year Plan
The CLEK Study is specifically mentioned as part of the Corneal Diseases Program in the Executive Summary of Vision Research, A National Plan: 199-2003, A Report of the National Advisory Eye Council.

Thanks, Thanks, Thanks
To the entire CLEK Study Group—
I would like to take this opportunity to thank you all for your hard work and dedication to the CLEK Study. Without your diligence, my Master’s thesis, Quality of Life in Keratoconus, would not have been possible. I collected about half of the data you collect at each CLEK examination on normal subjects, and I found even that relatively easy work to be challenging. I bow to you all!
—Jeff Walline, OD MS, The Ohio State University

Congrats to Authors
Be sure and check out Loretta Szczotka’s article in the June 1998 issue of Contact Lens Spectrum, “Contact Lenses for the Irregular Cornea.”

Insight Out
The 1998 issue of the CLEK Study patient newsletter, Insight, is available on newsstands now. Actually, it’s being mailed to all CLEK Study personnel, CLEK Study patients, and an extensive mailing list of interested patients and eye care practitioners. Kudos to Jodi Malone for a job excellently done. Her “Frequently Asked Questions” section should be especially appreciated by patients and doctors alike.

Congrats to Me
Karla Zadnik received the Galileo Award “for research excellence in children’s vision and learning” from the American Foundation for Vision Awareness at the American Optometric Association meeting in June. Her award is a lovely glass trophy, but it looks like she could do serious damage with it (Miss Scarlet in the Library with the Galileo Award instead of the candlestick!).

Quote of the Day
You can always find happiness at work on a Friday. — A Fortune Cookie
A Banner Week

All our hard work from the winter has paid off. Last week, we had the baseline CLEK paper accepted by *Investigative Ophthalmology & Visual Science*, the scarring test-retest paper accepted with minor revisions by *Cornea*, and have resubmitted a revised version of the manifest refraction test-retest paper to *Optometry and Vision Science*. For now, you may add the baseline paper to your cv as follows: The CLEK Study Group. Baseline findings in the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study. *Investigative Ophthalmology & Visual Science*. In press. Congratulations to us!

Meet and Greet

Early on, we introduced CLEK clinic personnel, site by site, with biographical sketches authored by each person. Since we last did that, we have had several people become CLEKkies.

**Craig Fehr, University of Utah, Department of Ophthalmology**
I'm certified by the American Board of Opticianry as a Dispensing Optician and by the National Contact Lens Examiners as a contact lens technician. I started working in the family Optical business (retail stores and wholesale ophthalmic laboratory) during summers starting at age 13. I have a beautiful wife, Melissa, with whom I share 5 children. I enjoy cooking, computers, and camping in my spare time. The children range in ages from 5 - 12: three girls, two boys.

**Stephanie Walter Cooper, CLEK Topography Reading Center**
I am an undergraduate biology major at the University of Illinois at Chicago. I hope to attend optometry school eventually. I have been married 3 years. I am a Colorado native, and I have only lived in Illinois for three years. I enjoy participating in triathlons, mountain biking, skiing, and hiking. I also love watching football. Go Broncos!

**Mark Thomas Wright, CLEK Topography Reading Center**
A man of few words: hobby: golf, married to Nancy, with two children: Lainie (age 3); Thomas (age 1).

Kimberley Wegner, University of Utah, Department of Ophthalmology
I worked as a Study Coordinator for 6 years in genetic studies before I came here, five years of in diabetes and one year was in breast cancer. I have never worked in ophthalmology before and am looking forward to the challenge of learning new information and coordinating new studies. I am single, have no children, but do have a cocker spaniel named Raz that is my baby. I love to be outside, in the mountains if possible. I like to go whitewater rafting, hiking, and camping. I also love to read. Eventually, I would like to go back to school and further my education.

Update from Jodi Malone

The July 1998 CLEK Insight was mailed to 2,019 study participants, clinical sta ff and interested persons. Needless to say, without staff help in the Chairman’s Office, this could not have been accomplished in such an expedient manner. Rachel Watson has worked for us for two summers and is to be commended for her exemplary efforts in working with the databases as she did. (That means she had to think along Jodi’s brain waves! Dione Allen is to be commended for her “labelmania” (she retyped all those with address changes). Last Jodi heard, after the last label she headed out of town and was last seen at an altitude 30,000 miles above Louisville, Kentucky.

In summary, address changes we don’t know about present a unique challenge. The clinics can contact Jodi for address updates if need be; we are still missing 68 updates currently.
Another Banner Week

All our hard work from the winter has paid off. The paper on manifest refraction repeatability has been accepted by *Optometry and Vision Science* for publication. The citation is: Davis LJ, Schechtman KB, Begley CG, Shin JA, Zadnik K, and the CLEK Study Group. Repeatability of refraction and corrected visual acuity in keratoconus. *Optometry and Vision Science*. In press.

We also submitted a record 7 CLEK abstracts for the American Academy of Optometry meeting in San Francisco. We’ll keep you posted on their outcomes.

Busy Bees

The following publications by CLEKkies were located this summer:


Just Ask Esther

Dear Esther, We’ve occasionally encountered a bubble under the optic zone when performing the Steep K overrefraction and visual acuity protocol. This results in poor overrefraction endpoints and reduced visual acuity. We desperately need your wisdom.

Signed, Bubbles and Annoyed by Bubbles

Dear Bernie and Annoyed by Bubbles,

After applying a Steep K CLEK trial lens, quickly observe whether a bubble is present under the optic zone. If a bubble is present, apply a trial lens with a flatter (by 0.10 or 0.20 mm) base curve and verify that the bubble is absent. Then cheerfully proceed with the Steep K overrefraction and visual acuity testing. Love, Esther

Dear Esther: Is it important to record the location and other aspects of scarring and staining even though I’ve drawn a picture on the form?

Signed, Documenting Doc

Dear Doc: It is important to record all items for all scars and all stains. Complete the form. This is very important to the critical study outcomes and their possible etiologies.

Forwarding Address

Even when we can’t keep track of our patients, we keep track of our “alumni.” Kate Landro, former Study Coordinator at the University of Utah has landed in Ann Arbor of all places! She sends a postcard of Michigan Stadium and her new address at 2434 Stone Rd., Ann Arbor, MI 48105.
CLEK and Cable Cars

Remember, the CLEK Executive Committee and Principal Investigators will be meeting in San Francisco on Monday, December 14th from 5:00 to 9:00 p.m. and on Tuesday, December 15th from 8:00 to 11:00 a.m. (rooms to be announced). There will be two purposes to this meeting. The first will be to discuss the future of the existing observational study, which has provisionally received a five-year administrative extension from the National Eye Institute. This means our current patients will continued to be followed annually through 2004, for a total of eight years of follow-up. We will discuss the rationale for this decision as well as present alternatives for clinic funding during the next five years (beginning September 30, 1999). The second, and more ambitious, goal of the meeting is to discuss specifics regarding a future clinical trial.

Welcome to New CPRC Staff

The CPRC staff has increased by one. Cynthia (Cindy) Taylor has joined the motley crew known in CLEKkie land as the CLEK CPRC. Cindy has finished her graduate school course work in Human and Community Resource Development. She and her husband, Joe, have a daughter, Allie. We are pleased to have her working with us. Welcome, Cindy!

On Teamwork

This is no rock ‘n’ roll band.-------
It’s a unique, creative vision,
Of a small isolated group of individuals.
A group that’s skilled and dedicated,
Searching for the knowledge,
That will enable them to improve the quality of their life,
And the lives of those around them.

Piggyback Pilots Launched

In order to evaluate the usefulness of piggyback fitting as a therapy for keratoconus, Dr. Mo Merchea at Ohio State has fitted 10 patients with piggyback lenses as part of his Master’s thesis. (Check out his poster at the Academy on the topic.) The preliminary results were just intriguing enough to motivate the Executive Committee to want to see more patients fitted with this modality by more practitioners. Loretta Szczotka, Larry Davis, and Heidi Wagner have agreed to each fit 10 patients according to Mo’s protocol. Stay tuned.

NSAID, She Said

In another pilot project at OSU, Dr. Brad Giedd is designing a study evaluating the use of topical non-steroidal anti-inflammatory agents in keratoconus patients for pain relief.

Why Do We Measure Low Contrast Visual Acuity, Anyway?

As part of OSU’s T35 National Eye Institute training grant, second year optometry student, Melissa Bailey, has expanded on Dr. Jeff Walline’s work on vision and quality of life in RGP wearers by assessing vision and quality of life in 100 spectacle wearers and soft contact lens wearers. Look for her paper presentation at the AAO meeting in San Francisco.

Mark Your Calendars

The annual CLEK Full Investigators Group meeting will take place before the ARVO meeting on Saturday, May 8, 1999 at the Marina Marriott in Ft. Lauderdale, Florida.

Papers, We Have Papers

The high level of productivity exhibited by the CLEK Study of late continues. The baseline paper is slated for publication in the December 1998 issue of Investigative Ophthalmology & Visual Science, and the manifest refraction test-retest paper is on deck for Optometry and Vision Science. The “how flat they’re fitted” manuscript is in the hands of the CLEK Study Group for final review, and the two scarring Writing Committees are working on the two baseline scarring papers. Whew!
I Left My CLEK in San Francisco

The CLEK Executive Committee and Principal Investigators will be meeting in San Francisco on Monday, December 14th from 5:00 to 9:00 p.m. and on Tuesday, December 15th from 8:00 to 11:00 a.m. (at the San Francisco Hilton and Towers, most probably in the Mason Room, but check the hotel monitors that day). Dinner will be served Monday and breakfast Tuesday. We will discuss the future of the existing observational study, which has provisionally received a five-year administrative extension from the National Eye Institute. This means our current patients will continued to be followed annually through 2004, for a total of eight years of follow-up. We will discuss the rationale for this decision as well as present alternatives for clinic funding during the next five years (beginning September 30, 1999). The second, and more ambitious, goal of the meeting is to discuss specifics regarding a future clinical trial. We will discuss: (1) Outcome measures. Candidates: corneal curvature (keratometry, FDACL, topography), corneal scarring (incidence and progression), high and low contrast visual acuity, quality of life, corneal staining, contact lens comfort, patient care costs, burden of the disease. (2) Treatment/intervention. Candidates: steep rigid lenses, no change for some patients, flat rigid lenses, piggyback, nonsteroidal antiinflammatories, Rose-K lenses, aspherics, “alignment” fit, penetrating keratoplasty. (3) Entry criteria. Candidates: current, successful contact lens wearers, unsuccessful contact lens wearers, no transplant in either eye, scarring in only one eye at most, at least one irregular cornea, slit lamp signs. Can we identify a “high risk” sample? (4) Can existing CLEK patients participate if they want to? (5) Sample size considerations. (6) Ethics of randomization. Is every clinic willing to randomize? (7) Follow-up schedule. (8) Specific protocol.

Congrats to Our Own

The November 1998 issue of Optometry and Vision Science is chock-full of CLEKkies. Check out Joe Barr and Marjorie Jeandervin writing about ortho-keratology in a guest editorial (where they cite OSU Study Coordinator Jason Nichols) and Joe, Marjie, and Ed Bennett’s article, “Effect of topical anesthetic use on initial patient satisfaction and overall success with rigid gas permeable contact lenses.” Karla Zadnik also writes on “Inter-clinician agreement on clinical data abstracted from patients’ medical charts.”

On Leadership

A leader’s role is to raise people’s aspirations for what they can become and to release their energies so they will try to get there.

—David Gergen in US News & World Report

Mark Your Calendars

The annual CLEK Full Investigators Group meeting will take place before the ARVO meeting on Saturday, May 8, 1999 at the Marina Marriott in Ft. Lauderdale, Florida.
CLEK ON DECK
The Official Newsletter of the Collaborative Longitudinal Evaluation of Keratoconus Study

Volume 6, Issue 1 January 5, 1999

CLEK in the New Millennium
As announced by Donald F. Everett, MA of the National Eye Institute at our December 14, 1998 CLEK Full Investigator Group meeting, the CLEK Study has been administratively extended through September 29, 2004. This extension gives us the opportunity to capitalize on this cohort of keratoconus patients and learn more about what turns out to be a slowly progressive disease.

This means that CLEK patients will continue to be followed annually through their eight-year follow-up visit. They will receive a letter shortly telling them the good news.

We are proposing to increase clinic payments to $800 per patient, to be paid each year in quarterly installments. Each year’s clinic budget of patient care costs will be based on the number of patients the clinic saw in the previous year.

It would be appropriate for you to notify the appropriate administrative officials at your institution of this terrific news. Also, your Institutional Review Board should be advised that the study has been extended and that patients will continue to be followed through 2004. Also, we hope to revise the budget such that patients will be reimbursed annually in the amount of $50 for their participation.

This extension represents the NEI’s and the National Advisory Eye Council’s acknowledgment of our hard, high quality work and very productive study. Congratulations to all!

Chalk Up Another Two
The December 1998 issue of Optometry and Vision Science is features the following CLEK manuscript:


All CLEK personnel will receive reprints of both these articles in the near future.

You can always find happiness at work on Friday.
—Found in a fortune cookie

Just Ask Esther
Dear Esther,
We had a patient ask us for a copy of all of his CLEK forms to date. He is thinking of having a corneal transplant and wants to give them to his surgeon. What should we do?
Signed, Tired of Xeroxing in California

Dear Tired,
The patient is certainly entitled to the information. I would have him provide his request in writing. You might want to offer a summary letter that would distill the most important information for him, either instead of or in addition to the copy of the actual forms.

TGIF
CLEK in Seattle: Will There be a Curfew?

The CLEK Agenda for our meetings after the American Academy of Optometry meeting is as follows:

**Monday, December 13, 1999**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>4:00 - 5:00 pm</td>
<td>Executive Committee meeting</td>
<td>Zadnik’s room in the Sheraton (room # TBA)</td>
</tr>
<tr>
<td>5:00 - 5:15 pm</td>
<td>Welcome</td>
<td>Zadnik</td>
</tr>
<tr>
<td>5:15 - 5:30 pm</td>
<td>Extension update</td>
<td>Zadnik</td>
</tr>
<tr>
<td>5:30 - 6:15 pm</td>
<td>CTRC update</td>
<td>McMahon</td>
</tr>
<tr>
<td>6:15 - 6:30 pm</td>
<td>CPRC update</td>
<td>Barr</td>
</tr>
<tr>
<td>6:30 - 7:15 pm</td>
<td>Dinner</td>
<td>Gordon</td>
</tr>
<tr>
<td>7:15 - 7:30 pm</td>
<td>Coordinating Center update</td>
<td>Gordon</td>
</tr>
<tr>
<td>7:30 - 7:45 pm</td>
<td>Corneal surgery forms</td>
<td>Wagner, Shin, Zadnik</td>
</tr>
<tr>
<td>7:45 - 8:00 pm</td>
<td>Clinical trial introduction</td>
<td>Zadnik</td>
</tr>
<tr>
<td>8:00 - 9:00 pm</td>
<td>Contact lens fitting methods</td>
<td>Edrington</td>
</tr>
</tbody>
</table>

**Tuesday, December 14, 1999**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location  TBA</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00 - 8:15 am</td>
<td>Breakfast</td>
<td></td>
</tr>
<tr>
<td>8:15 - 10:00 am</td>
<td>Writing Committees:</td>
<td></td>
</tr>
<tr>
<td>10:00 am - 12:00 pm</td>
<td>Clinics’ grant writing</td>
<td></td>
</tr>
</tbody>
</table>

**Lions Roar at PCO**

The Pennsylvania College of Optometry's Lions Club has provided eyeglasses for a CLEK patient unable to afford them otherwise. The patient was extremely appreciative to the CLEK staff and Director of Research at PCO as well as to the Lions Club for their efforts in providing what would have otherwise been impossible.

In addition, the Honesdale Lions Club has provided a $500.00 research grant to PCO's Eye Institute for the past ten years. This year's grant was designated to the CLEK study and will be used to facilitate research in that area.

**See Yourself in “Print”**

The CLEK presentations in Seattle are:
• McMahon et al., USE OF IMPRESSION CYTOLOGY IN KERATOCONUS RESEARCH. Sunday, December 12, Poster #73, Hall 4C.
• Edrington et al., THE EFFECT OF RIGID CONTACT LENS PERIPHERAL CLEARANCE ON PATIENT …. Monday, December 13, Paper presentation, 1:00 p.m., Rooms 608-609.
• Barr et al., ESTIMATING INCIDENT CORNEAL SCARRING …. Monday, December 13, Paper presentation, 2:40 p.m., rooms 608-609.
Executive Committee To Plan Clinical Trial

The CLEK Executive Committee (minus Don Everett) will meet in St. Louis, Missouri on January 31st to discuss critical issues for the submission of the clinical trial grant application. Topics to be discussed include the utility of topography, the impact of scarring, entry criteria, the Data Safety and Monitoring Committee, the relation between scarring, visual acuity, and FDACL, grading staining, and how to stay sane while we embark on this new adventure together. Stay tuned for updates that will assist the Clinic Investigators in their Participating Clinic grant proposal preparation.

Congrats to “The Professor”

Effective July 1, 2000, we get to refer to Joe Barr as “The Professor.” He received notice last week from The Ohio State University’s Office of Academic Affairs that his promotion had been approved. Well deserved! In related news, Gil Pierce of the CLEK Photography Reading Center has received notice that he will be promoted to the rank of Associate Professor of Clinical Optometry. Congratulations, Gil!

It’s a Rompin’ Stompin’ Boy

Greg Nixon, CLEKkie at Ohio State, and wife Vondolee welcomed Jackson James Nixon at 9:57 p.m. on January 6, 2000. He weighed in at 7 lbs, 2 oz and was heard to gurgle “Go Buckeyes.”

Just Ask Esther

Dear Esther—
Is there an official CLEK Study Policy on the release of spectacle prescriptions to patients, whether or not they are the regular patient of a CLEK investigator.
Signed, Glassy-Eyed in Ohio

Dear Glassy—
The release of spectacle prescriptions to CLEK patients is at the discretion of the examining CLEK investigator.

Plan for ARVO

The usual CLEK schedule will apply this spring. A meeting will be held on Saturday, April 29, 2000 at the Marina Marriott in Ft. Lauderdale, Florida. Dinner will follow poolside at The Sea Lord in Lauderdale-by-the-Sea. (Note that the ARVO meeting runs from May 1-5, 2000.) Each Clinic will be funded by the Chairman’s Office to send an Investigator and a Coordinator. Each person will be funded for airfare, two nights’ hotel stay, two days’ per diem, and appropriate ground transportation.

“Bedtime”

Mom and Dad were watching TV when Mom said, "I'm tired, and it's getting late. I think I'll go to bed." She went to the kitchen to make sandwiches for the next day's lunches, rinsed out the popcorn bowls, took meat out of the freezer for supper the following evening, filled the sugar container, put spoons and bowls on the table, and started the coffee pot for brewing the next morning. She put some wet clothes into the dryer, put a load of clothes into the washer, ironed a shirt, and secured a loose button. She picked up the newspapers strewn on the floor, picked up the game pieces left on the table, and put the phone book back into the drawer. She watered the plants, emptied a wastebasket, and hung up a towel to dry. She stopped by the desk and wrote a note to the teacher, counted out some cash for the field trip, and pulled a schoolbook out from under a chair. She signed a birthday card for a friend, addressed and stamped the envelope, and wrote a quick list for the grocery store. She, then, washed her face and brushed and flossed her teeth. Hubby called, "I thought you were going to bed." "I'm on my way," she said. She looked in on each of the kids. She turned off a bedside lamp, hung up a shirt, threw some dirty socks in the hamper, and had a brief conversation with the one child who was still awake, doing homework. In her own room, she set the alarm and laid out clothing for the next day. She added three things to her list of things to do for tomorrow. About that time, hubby turned off the TV and announced, to no one in particular, "I'm going to bed," and he did.
CLEK Meetings in Orlando

Monday December 11, 2000 5:00 to 9:00 pm Australia 3 Room
Tuesday December 12, 2000 8:00 to 11:00 am Europe I Room (Writing Committees as follows)

- Asymmetry (Zadnik, Tyler, Fink, Nichols, Schechtman, Steger-May, Rosenstiel, Joslin, Shin)
- Contact lens comfort (Edrington, Gundel, Libassi, Wagner, Pierce, Walline, Olafsson, Achtenberg)
- Incident scarring (Barr, Zadnik, Riley, Jeandervin, Wilson, Gordon)
- TAG (McMahon, Szczotka, Friedman, Davis, Raasch, Roberts, Anderson)

Dinner provided 5:30 pm Monday evening
Continental Breakfast provided 8:00 am Tuesday morning

If you are attending and haven’t let us know, contact Jodi Malone, RN at malone.6@osu.edu.

Just Ask Esther

Dear Esther,

At the bottom of page 7 of the Patient History Form, it says that females only complete page 8. Men get to stop at the end of page 7. Do I, as the Coordinator, still need to review page 9 and sign my initials on it for male patients?

Sign me, Confused by Sex

Dear Confused,

Although this can be confusing (and perhaps sounds unnecessary), please initial the bottom of page 8 for all patients, regardless of gender. By signing your initials and noting how long it took the patient to complete the form, you are verifying that you reviewed the entire Patient History Form—including page 8—for thoroughness.

CLEK and Mickey Mouse

There are three CLEK presentations scheduled for the American Academy of Optometry meeting in Orlando:


CL-228 A TECHNIQUE TO IMPROVE THE AGREEMENT BETWEEN TWO METHODS OF EVALUATING CORNEA-TO-CONTACT LENS BASE CURVE FLUORESCIN PATTERNS IN THE COLLABORATIVE LONGITUDINAL EVALUATION OF KERATOCONUS (CLEK) STUDY. Gilbert E. Pierce, Joseph T. Barr, Timothy B. Edrington, Mae O. Gordon, Marjorie Jeandervin, Roanne E. Flom, Barbara A. Fink, Karla Zadnik, CLEK Study Group. Mon. Dec. 11, 2000, Poster 37 in Northern Hemisphere C-D.


Eligible Bachelorette Finds Wedded Bliss

CLEK Clinic Investigator at SCCO, Julie Yu (nee Shin) wedded Howard Yu on September 9, 2000 in southern California. Photos of the couple provided masked evidence of extreme happiness. Wish them well!
Publish, Not Perish!

Update those cvs! The CLEK Study has two new publications—one in print and one in press. All CLEK Study Group members (and CLEK patients) will receive reprints of the article in *Cornea* as soon as the reprints are available. Note that the publication on the repeatability of refraction is in *Ophthalmic and Physiological Optics*. This is the first paper we’ve published in this British journal.


Cats on a Hot Tin Roof!

Stephanie Shaffer of Case Western Reserve and husband Alan announce the birth of twins. They were born on October 12, 2000: Hannah Gene Shaffer (weighing in at 6 lbs, 13 ozs) and Jacob Edward Shaffer (8 lbs, 13 ozs). They join proud big sister Grace. Stephanie writes, “We’re having a blast! Perhaps I’ve become delirious from lack of sleep and constant chaos, but I really am having fun, enjoying every minute of it! I feel completely blessed.” Our best wishes for happiness and sleep to all.

Where Are We Now?

You may wonder what has happened to those clinical trial grants we submitted back in June 2000. Well, they are set to be reviewed sometime just before or just after the first of the year. First, the proposals will undergo scientific, peer review in an NEI Special Emphasis Panel. That group of reviewers is typically very skilled, very knowledgeable about clinical research, and very tough. We should receive feedback on that review shortly after it happens and will be able to tell you more then. If that review does not go well or if we receive constructive comments that need to be addressed by resubmitting all the grants, we will let you know ASAP. If that happens, we could be looking at a March 1, 2001 resubmission date. So, if you can avoid taking that long-deserved ski vacation the last weekend in February, it might be advisable!

Lions Roar

For the second consecutive year the Lions Club of the Pennsylvania College of Optometry has assisted a CLEK Study patient in purchasing spectacles. The Lions’ continued support makes it possible for patients, who would otherwise be unable to afford them, purchase their eyewear.

CLEK at AAO

CLEKkies are not just represented at the Academy meeting on the dance floor at the Australia Party. Here’s the lowdown on who’s doing what as a volunteer for the AAO in 2001-02.

Tom Raasch: Awards Committee and Chair, Scientific Program Committee
Roanne Flom: Ellerbrock Committee
Marjorie Rah: Ellerbrock Committee
Tim McMahon: Chair, Research Committee
Joe Shovlin: Chair, Section on Cornea and Contact Lenses
Joe Barr: Vice-Chair, Section on Cornea and Contact Lenses
Larry Davis: Program Committee
Loretta Szczotka: Scientific Program Committee
Karla Zadnik: Executive Council
Publish, Not Perish!

Update those cvs! The CLEK Study has two new publications—one in print and one in press. All CLEK Study Group members (and CLEK patients) will receive reprints of the article in *Cornea* as soon as the reprints are available. Note that the publication on the repeatability of refraction is in *Ophthalmic and Physiological Optics*. This is the first paper we’ve published in this British journal.


We’re Not Worthy

Open your November 2000 issue of *Optometry and Vision Science* to catch Loretta Szczotka’s scientific article, “Decay-accelerating factor in tears of contact lens wearers and patients with contact lens-associated complications.”
First Paper Published
The CLEK Study Group will receive reprints of our first paper as soon as they are available. In the meantime, here’s the citation: Gordon MO, Schechtman KB, Davis LJ, McMahon TT, Schornack J, Zadnik K, and Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study Group (1998). Optometry and Vision Science 75:249-257.

From the Coordinating Center:
*Good News!*
Thanks to all of your efforts in keeping a timely response to edit queries! There has consistently been a low number of edit queries in suspense—currently there are 3! This takes a large effort on your part as well as the Coordinating Center to keep up-to-date data for the many publications being prepared. Congratulations!

Addition to the Executive Committee
Tim McMahon, Director of the CLEK Topography Reading Center at the University of Illinois at Chicago Department of Ophthalmology, joined the CLEK Executive Committee as of April 1, 1998. Welcome, Tim, and we just know you’ll love those weekly conference calls!

All Our Exes Seen in Texas
Once again, CLEKkies extraordinaire, Julie Shin and Beth Ann Benetz, traveled to San Antonio to see the Texas patients for their year 02 visits. They celebrated Fiesta, ate their way through a CLEK fruit basket, and returned with the data and photographs. Way to go, ladies!

Announcing the Arrival of...
Jessica Lizzie Landro, born March 16, 1998 to proud parents Tom and Kate Landro, weighing in at 8 pounds 9 ounces.

Just Ask Esther
Dear Esther,
I have been searching the Operations Manual in vain looking for a clue as to how to record low contrast visual acuity when the patient can’t read anything on the chart. What should I be doing?
Signed, Counting Fingers in California

Dear CF,
If the patient cannot read any letters on the low contrast chart, even at the 1-m distance, you record 0.00. CF and HM are not appropriate for low contrast acuity.

Dear Esther,
I enjoyed the most recent CLEK on Deck offering. Someone at the stationery supplier should not remain stationary and should inform Disney that the Mighty Ducks hockey jerseys are now passé in color. Next thing you know, they will discontinue red patent leather life stride, open -toed shoes.
Signed, Bernie

Appreciative Berkeley Patient
A University of California, Berkeley-based patient wrote the following email to Nina Friedman:

“I just wanted to thank you for the pleasant clinic visit yesterday. As clinic visits go, a visit to the CLEK Study, is up there on top. The two of you [he means Nina and Pam Qualley] make the drive, and the time, worthwhile. I hope that my eye conditions help, in some way, to make the study a success.”

Keep up the fabulous effort out there!

Fun Fact
The average person consumes approximately 17 gallons of coffee each year.
Papers Published

The CLEK Study Group will receive reprints of our first paper as soon as they are available. In the meantime, here are the citations:


CLEK Around the World

Dear Karla—

Finding the CLEK Insight vol 2.1 reminded me to send you a note. In the last 9 months I may have seen more keratoconus patients, but I have fitted fewer of them. After your presentation at the New Zealand Contact Lens Practitioners conference in Auckland, I gave some thoughts to whether I had been in too much rush to force some patients into HGP lenses and I would usually inflict such unnecessary discomfort on a person to whom I may never have otherwise suggested even hydrophilic, occasional (disposable) wear, considering their atopy, itchy eyes and irritable disposition. It was all too easy to coerce the client into suffering the 'shock' of hard contact lenses when all the costs are covered by Social Security funding. My approach is now much the same as I would take with any other spectacle wearer whose refractive error was a 'little out of the ordinary'. "It is possible to present you with better around vision. When you decide you would like to proceed I will prescribe contact lenses appropriate to your specific needs". Not surprisingly, I have many happier K fits this year! NOw the new challenge is presbyopes and bifocal contact lenses. (Not for my own personal wear) Those teenagers I fitted 25 years ago are returning, still as vain as before and still refusing to be seen dead in glasses. Fortunately they are blessed with a greater disposable income to their conventional lens requirements.

—Frederick Swain, Optometrist, Auckland, NZ

And Marco Bellacci, from Italy, asked about someone who could perform the CLEK “procedure” in Italy. Karla wrote him back that CLEK is a study, not a treatment, and invited him to join our mailing list.

Raise the Roof

Teresa Roediger from the Coordinating Center writes: “100% adherence to the VA stopping rule per random sampling” for the first time to the best of our knowledge. Congratulations to all!

Did You Know ...

That the CLEK web page receives 400 hits or so each day?

Thanks, Lou!

Lou Rosenberg of the Jules Stein Eye Institute CLEK Participating Clinic writes, “It was real nice seeing you again at the CLEK meeting in Florida. I enjoyed the fact that I got to meet the people, who until then, have just been a name without a face, like Joe Barr, Gloria Scott-Tibbs, Teresa, Loretta, and the others like Don Everett. I found the ARVO meeting an enlightening experience…. I’m very proud to be part of this effort.”

Quote of the Day

“I may be unpopular, but I’m not wrong” from Allan Roses, controversial Alzheimer’s genetic researcher.
On June 15, 1998 the CLEK Executive Committee met with the CLEK Data Monitoring and Oversight Committee to discuss the future of CLEK-based studies in keratoconus. We are excited at the DMOC’s enthusiastic endorsement to continue to follow CLEK patients. It is felt that we have a chance to learn a great deal about the natural history of this slowly progressing disease and that our continued, intensive follow-up is an opportunity that may never again present to another research group working in keratoconus.

We plan to submit a competitive renewal (November 1, 1998 deadline) for five more years (9/30/99 to 9/29/04) to follow CLEK patients annually during that time out to a total of eight years of follow-up (nine annual visits, including baseline).

We plan to submit a new grant (February 1, 1999 deadline) to fund a clinical trial. Eligible patients (no transplants, “keratoconus” patients who wear contact lenses already) from CLEK (and others, if necessary) will be randomized to steep, piggyback, or “standard of care” (ie, flat). Outcome measures might be low contrast visual acuity, contact lens comfort, corneal scarring (new or progressing), and vision-specific quality of life. All patients would be followed through year 08 (grant to run from 12/1/99 to 11/30/04).

We feel that all of us—the CLEK team—are invested with enormous potential to learn more and more about the natural history and management of keratoconus.

CLEK in Five-Year Plan
The CLEK Study is specifically mentioned as part of the Corneal Diseases Program in the Executive Summary of Vision Research, A National Plan: 199-2003, A Report of the National Advisory Eye Council.

Thanks, Thanks, Thanks
To the entire CLEK Study Group—
I would like to take this opportunity to thank you all for your hard work and dedication to the CLEK Study. Without your diligence, my Master’s thesis, Quality of Life in Keratoconus, would not have been possible. I collected about half of the data you collect at each CLEK examination on normal subjects, and I found even that relatively easy work to be challenging. I bow to you all!
—Jeff Walline, OD MS, The Ohio State University

Congrats to Authors
Be sure and check out Loretta Szczotka’s article in the June 1998 issue of Contact Lens Spectrum, “Contact Lenses for the Irregular Cornea.”

Insight Out
The 1998 issue of the CLEK Study patient newsletter, Insight, is available on newsstands now. Actually, it’s being mailed to all CLEK Study personnel, CLEK Study patients, and an extensive mailing list of interested patients and eye care practitioners. Kudos to Jodi Malone for a job excellently done. Her “Frequently Asked Questions” section should be especially appreciated by patients and doctors alike.

Congrats to Me
Karla Zadnik received the Galileo Award “for research excellence in children’s vision and learning” from the American Foundation for Vision Awareness at the American Optometric Association meeting in June. Her award is a lovely glass trophy, but it looks like she could do serious damage with it (Miss Scarlet in the Library with the Galileo Award instead of the candlestick!).

Quote of the Day
You can always find happiness at work on a Friday. — A Fortune Cookie
A Banner Week

All our hard work from the winter has paid off. Last week, we had the baseline CLEK paper accepted by *Investigative Ophthalmology & Visual Science*, the scarring test-retest paper accepted with minor revisions by *Cornea*, and have resubmitted a revised version of the manifest refraction test-retest paper to *Optometry and Vision Science*. For now, you may add the baseline paper to your cv as follows: The CLEK Study Group. Baseline findings in the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study. *Investigative Ophthalmology & Visual Science*. In press. Congratulations to us!

Meet and Greet

Early on, we introduced CLEK clinic personnel, site by site, with biographical sketches authored by each person. Since we last did that, we have had several people become CLEKkies.

Craig Fehr, University of Utah, Department of Ophthalmology

I’m certified by the American Board of Opticianry as a Dispensing Optician and by the National Contact Lens Examiners as a contact lens technician. I started working in the family Optical business (retail stores and wholesale ophthalmic laboratory) during summers starting at age 13. I have a beautiful wife, Melissa, with whom I share 5 children. I enjoy cooking, computers, and camping in my spare time. The children range in ages from 5 - 12: three girls, two boys.

Stephanie Walter Cooper, CLEK Topography Reading Center

I am an undergraduate biology major at the University of Illinois at Chicago. I hope to attend optometry school eventually. I have been married 3 years. I am a Colorado native, and I have only lived in Illinois for three years. I enjoy participating in triathlons, mountain, biking, skiing, and hiking. I also love watching football. Go Broncos!

Mark Thomas Wright, CLEK Topography Reading Center

A man of few words: hobby: golf, married to Nancy, with two children: Lainie (age 3); Thomas (age 1).

Kimberley Wegner, University of Utah, Department of Ophthalmology

I worked as a Study Coordinator for 6 years in genetic studies before I came here, five years of in diabetes and one year was in breast cancer. I have never worked in ophthalmology before and am looking forward to the challenge of learning new information and coordinating new studies. I am single, have no children, but do have a cocker spaniel named Raz that is my baby. I love to be outside, in the mountains if possible. I like to go whitewater rafting, hiking, and camping. I also love to read. Eventually, I would like to go back to school and further my education.

Update from Jodi Malone

The July 1998 CLEK Insight was mailed to 2,019 study participants, clinical staff and interested persons. Needless to say, without staff help in the Chairman’s Office, this could not have been accomplished in such an expedient manner. Rachel Watson has worked for us for two summers and is to be commended for her exemplary efforts in working with the databases as she did. (That means she had to think along Jodi’s brain waves! Dione Allen is to be commended for her “labelmania” (she retyped all those with address changes). Last Jodi heard, after the last label she headed out of town and was last seen at an altitude 30,000 miles above Louisville, Kentucky.

In summary, address changes we don’t know about present a unique challenge. The clinics can contact Jodi for address updates if need be; we are still missing 68 updates currently.
Another Banner Week

All our hard work from the winter has paid off. The paper on manifest refraction repeatability has been accepted by Optometry and Vision Science for publication. The citation is: Davis LJ, Schechtman KB, Begley CG, Shin JA, Zadnik K, and the CLEK Study Group. Repeatability of refraction and corrected visual acuity in keratoconus. Optometry and Vision Science. In press.

We also submitted a record 7 CLEK abstracts for the American Academy of Optometry meeting in San Francisco. We’ll keep you posted on their outcomes.

Busy Bees
The following publications by CLEKkies were located this summer:

Just Ask Esther
Dear Esther, We’ve occasionally encountered a bubble under the optic zone when performing the Steep K overrefraction and visual acuity protocol. This results in poor overrefraction endpoints and reduced visual acuity. We desperately need your wisdom.
Signed, Bubbles and Annoyed by Bubbles

Dear Bernie and Annoyed by Bubbles,
After applying a Steep K CLEK trial lens, quickly observe whether a bubble is present under the optic zone. If a bubble is present, apply a trial lens with a flatter (by 0.10 or 0.20 mm) base curve and verify that the bubble is absent. Then cheerfully proceed with the Steep K overrefraction and visual acuity testing. Love,
Esther

Dear Esther:
Is it important to record the location and other aspects of scarring and staining even though I’ve drawn a picture on the form?
Signed, Documenting Doc

Tenure, Shmenure
The juvenile sea squirt wanders through the sea searching for a suitable rock or hunk of coral to cling to and make its home for life. For this task it has a rudimentary nervous system. When it finds its spot and takes root, it doesn’t need its brain any more so it eats it. It’s rather like getting tenure.
—Consciousness Explained by Daniel C. Dennett

Forwarding Address
Even when we can’t keep track of our patients, we keep track of our “alumni.” Kate Landro, former Study Coordinator at the University of Utah has landed in Ann Arbor of all places! She sends a postcard of Michigan Stadium and her new address at 2434 Stone Rd., Ann Arbor, MI 48105.
CLEK and Cable Cars

Remember, the CLEK Executive Committee and Principal Investigators will be meeting in San Francisco on Monday, December 14th from 5:00 to 9:00 p.m. and on Tuesday, December 15th from 8:00 to 11:00 a.m. (rooms to be announced). There will be two purposes to this meeting. The first will be to discuss the future of the existing observational study, which has provisionally received a five-year administrative extension from the National Eye Institute. This means our current patients will continued to be followed annually through 2004, for a total of eight years of follow-up. We will discuss the rationale for this decision as well as present alternatives for clinic funding during the next five years (beginning September 30, 1999). The second, and more ambitious, goal of the meeting is to discuss specifics regarding a future clinical trial.

Welcome to New CPRC Staff

The CPRC staff has increased by one. Cynthia (Cindy) Taylor has joined the motley crew known in CLEKkie land as the CLEK CPRC. Cindy has finished her graduate school course work in Human and Community Resource Development. She and her husband, Joe, have a daughter, Allie. We are pleased to have her working with us. Welcome, Cindy!

On Teamwork

This is no rock ‘n’ roll band.............
It’s a unique, creative vision,
Of a small isolated group of individuals.
A group that’s skilled and dedicated,
Searching for the knowledge,
That will enable them to improve the quality of their life,
And the lives of those around them.

Piggyback Pilots Launched

In order to evaluate the usefulness of piggyback fitting as a therapy for keratoconus, Dr. Mo Merchea at Ohio State has fitted 10 patients with piggyback lenses as part of his Master’s thesis. (Check out his poster at the Academy on the topic.) The preliminary results were just intriguing enough to motivate the Executive Committee to want to see more patients fitted with this modality by more practitioners. Loretta Szczotka, Larry Davis, and Heidi Wagner have agreed to each fit 10 patients according to Mo’s protocol. Stay tuned.

NSAID, She Said

In another pilot project at OSU, Dr. Brad Giedd is designing a study evaluating the use of topical non-steroidal anti-inflammatory agents in keratoconus patients for pain relief.

Why Do We Measure Low Contrast Visual Acuity, Anyway?

As part of OSU’s T35 National Eye Institute training grant, second year optometry student, Melissa Bailey, has expanded on Dr. Jeff Walline’s work on vision and quality of life in RGP wearers by assessing vision and quality of life in 100 spectacle wearers and soft contact lens wearers. Look for her paper presentation at the AAO meeting in San Francisco.

Mark Your Calendars

The annual CLEK Full Investigators Group meeting will take place before the ARVO meeting on Saturday, May 8, 1999 at the Marina Marriott in Ft. Lauderdale, Florida.

Papers, We Have Papers

The high level of productivity exhibited by the CLEK Study of late continues. The baseline paper is slated for publication in the December 1998 issue of Investigative Ophthalmology & Visual Science, and the manifest refraction test-retest paper is on deck for Optometry and Vision Science. The “how flat they’re fitted” manuscript is in the hands of the CLEK Study Group for final review, and the two scarring Writing Committees are working on the two baseline scarring papers. Whew!
CLEK in the New Millennium

As announced by Donald F. Everett, MA of the National Eye Institute at our December 14, 1998 CLEK Full Investigator Group meeting, the CLEK Study has been administratively extended through September 29, 2004. This extension gives us the opportunity to capitalize on this cohort of keratoconus patients and learn more about what turns out to be a slowly progressive disease.

This means that CLEK patients will continue to be followed annually through their eight-year follow-up visit. They will receive a letter shortly telling them the good news.

We are proposing to increase clinic payments to $800 per patient, to be paid each year in quarterly installments. Each year’s clinic budget of patient care costs will be based on the number of patients the clinic saw in the previous year.

It would be appropriate for you to notify the appropriate administrative officials at your institution of this terrific news. Also, your Institutional Review Board should be advised that the study has been extended and that patients will continue to be followed through 2004. Also, we hope to revise the budget such that patients will be reimbursed annually in the amount of $50 for their participation.

This extension represents the NEI’s and the National Advisory Eye Council’s acknowledgment of our hard, high quality work and very productive study. Congratulations to all!

Chalk Up Another Two


All CLEK personnel will receive reprints of both these articles in the near future.

TGIF

You can always find happiness at work on Friday.
—Found in a fortune cookie

Just Ask Esther

Dear Esther,
We had a patient ask us for a copy of all of his CLEK forms to date. He is thinking of having a corneal transplant and wants to give them to his surgeon. What should we do?
Signed, Tired of Xeroxing in California

Dear Tired,

The patient is certainly entitled to the information. I would have him provide his request in writing. You might want to offer a summary letter that would distill the most important information for him, either instead of or in addition to the copy of the actual forms.
CLEK Publications

Sometimes winter/spring is annual review time at academic institutions. Here is a list of CLEK publications to date for the full-scale study, as compiled by the Chairman’s Office. If you want a copy emailed to you, please contact Karla Zadnik.


Busy Bees

The December 1998 issue of the *Journal of the American Optometric Association* includes an article, “Contact lenses after LASIK” by Loretta Szczotka and her colleague, Michael Aronsky.

In the January 1999 issue of *Contact Lens Spectrum*, look for the articles, “Hydrops Results in Visual Acuity Improvement” by David Friedman and Ralph Gundel, “Dk/L: Into the Ultra-High Zone” by Bradley J. Smith, Barbara A. Fink, and Richard M. Hill, and “Diagnosis and Management of Corneal Surface Irregularity” by newest OSU CLEKkie, Gregory J. Nixon.

Here’s Looking at You, Kid

Stephanie and Alan Shaffer (nee Schach, Study Coordinator at Case Western Reserve CLEK Clinic) welcomed their daughter Grace Loretta. (No, she’s not named after Loretta Szczotka; Loretta is after Alan’s grandmother) on December 28, 1998.

Steph was two weeks overdue, and Grace weighed 10 lbs, 2.6 oz and measured 20-1/2 inches!!!

Top Ten Thoughtless Things People Say to Me about me Keratoconus!

1. Stop paying your doctor so much for your lenses, you can just use a mail order service.
2. You don’t have to use wetting solution to insert your lenses; I use saliva to insert mine.
3. I think you are using too many eye drops!
4. Oh, my eyes hurt sometimes too, just like yours do.
5. Will your eyeballs fall out as you get older?
6. What did you do to cause your disease?
7. Can’t you see ________? (Fill in the blank from everything to a sunset to a road sign!)
8. You shouldn’t squint because it will make lines in your forehead!
9. You don’t need to wear sunglasses indoors!
10. Why don’t you just wear glasses!

—From a patient on the keratoconus-link network
Everybody’s Eligible
There appears to be some confusion on the administrative extension of the CLEK Study, recently announced by the National Eye Institute. Patients received a letter about the extension and their continued participation in it in February 1999.

Please note that ALL patients originally enrolled in the CLEK Study in 1995-1996 are eligible for the continuation. The original CLEK Study entry criteria will NOT be re-applied for continuation. So, patients who have corneal transplants in both eyes, those who have developed cataract, those who have developed retinal disease, etc. are all still eligible and should continue to be followed. Patients who have missed a visit in the past should be actively contacted and recruited for continuation. Only those patients who have died and for whom the Coordinating Center has received appropriate documentation on will not be followed.

Praise from the Coordinating Center
The CLEK Study group has consistently performed well on their edit query to resolution response time. It is remarkable however that there are only 4 forms needing query resolution in the suspense database. This represents your consciousness efforts in maintaining the highest degree of "clean" data. Congratulations to all of you for making the Coordinating Center's job easier. Teresa challenges all of you to help fulfill the ultimate goal of "0" number of edits in suspense. Keep up the good work!

Testimonial
Just in case you feel discouraged that this CLEK deal is too much of a burden for our patients, read this email received (unsolicited) by Karla Zadnik:

“I have been in the CLEK Study since it started 4 years ago. I am a patient at the University of Illinois at Chicago under Dr. McMahon and Study Coordinator Jamie Putz. I wanted to let you know that during the past 4 years the study has been anything other than a burden. Both Dr. McMahon and Ms. Putz have been informative and professional throughout. I am going to continue in the study and look forward to helping find out more about keratoconus.”

Lost Contact Lens Sagas
Patients on the email network, keratoconus-link, are sharing their lost contact lens stories. It’s good to remember what they go through:

“Ever spend an hour dismantling the plumbing beneath the sink in the bathroom late at night, because you lost your lens down the drain? Ever have to stop a floor hockey game in a split second and have all players on both teams get down on their hands and knees to search for your lens? Have you ever been reading a newscast live on the radio, and all of a sudden, for no apparent reason, just pop a lens? Ever been in a crowd in a public place, and yell ‘Stop! Don’t anyone move!!!’ and actually live to tell about it?

I think my best lost lens story was a couple of years ago shoveling snow after a storm. The starry night and the newly fallen snow looked like a billion contact lenses everywhere. Of course, the drawstring on the hood of my jacket flicked in my eye, and you know the rest. Ever search for a contact lens at night, outdoors, on fresh snow, with a full moon, half-blind?

In every one of these cases, I found the lens, believe it or not. However, sitting in my living room one peaceful quiet Sunday afternoon watching TV, my lens popped, and fell on the floor, just a simple floor, carpet, nothing else. You guessed it. Never found it. Go figure.

Maria’s Marriage
Maria Suzette Voece married Stephen Franklin Stephens on March 6, 1999 in Natural Bridge, Alabama. Our best wishes to both!
Sometimes winter/spring is annual review time at academic institutions. Here is a list of CLEK publications to date for the full-scale study, as compiled by the Chairman’s Office. If you want a copy emailed to you, please contact Karla Zadnik.


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### Getting’ It Done

In the March 1999 issue of *Contact Lens Spectrum*, the CPRC Reader, Marjorie Jeandervin, writes “A Review of Current Ocular Research,” Ed Bennett authors “RGP’s and soft torics: making the right decision,” and Carolyn Begley poses the question, “Rose bengal or lissamine green?”

### Love Keratoconus Style

My most memorable lens loss, and I had many, was during my wedding back in 1983. When the minister said "you may kiss the bride", I turned, and my contact popped out as I looked at my new bride. She thought it was a tear travelling down my cheek, and smiled rather sweetly.

My brother/best man could tell what had really happened, and watched in horror as I turned and stepped right on the lens. After we walked back down the aisle, he went back and found the lens still intact in the deep pile carpeting. Good thing too, since we were headed to Aspen, Colorado for our honeymoon, and I had no backup lenses.

That was my wife's introduction to a dozen years of watching me struggle with lenses, and she still smiles sweetly. After 2 successful transplants, I only wear glasses today, and don't miss the tenuous nature of contacts.

### Tim, Tim, He’s Our Man!

The University of Illinois at Chicago publication, *This Week*, featured an article on Tim McMahon and the CLEK extension through 2004 as its lead story in its February 22, 1999 issue. The publication provided a nice summary of the study to date, and Tim’s quotes on what we’re trying to achieve were positively brilliant.
A lively time was had by all at the CLEK Full Investigator Group Meeting in Ft. Lauderdale on May 8, 1999. Tim McMahon, Joe Barr, Mae Gordon, and Tim Edrington presented results from recent CLEK analyses, including two paper presentations to be given later in the week at ARVO. Discussions ensued regarding the future of the CLEK (Observational) Study and about plans for a future clinical trial. Heidi Wagner hosted a lively discussion centered around designing forms to assess patients postsurgical experiences, and Karla Zadnik announced the addition of a “Woman’s Page” to the CLEK Patient History Form for year 5 follow-up visits.

The crowd convened for dinner at the infamous Sea Lord and dined on shrimp and chicken tacos, pineapple and cataloupe salsa, black beans, and key lime pie.

Out and About

Love Keratoconus Style
From the annals of keratoconus-link: “My most memorable lens loss, and I had many, was during my wedding back in 1983. When the minister said 'you may kiss the bride', I turned, and my contact popped out as I looked at my new bride. She thought it was a tear travelling down my cheek, and smiled rather sweetly. My brother/best man could tell what had really happened, and watched in horror as I turned and stepped right on the lens. After we walked back down the aisle, he went back and found the lens still intact in the deep pile carpeting. Good thing too, since we were headed to Aspen, Colorado for our honeymoon, and I had no backup lenses. That was my wife's introduction to a dozen years of watching me struggle with lenses, and she still smiles sweetly. After 2 successful transplants, I only wear glasses today, and don't miss the tenuous nature of contacts.

Update Your CV …


After Hours at ARVO
What Coordinating Center director and prominent West Coast CLEK Study Coordinator were seen in Ft. Lauderdale dancing the night away (to the blues, no less!) until 3:30 in the morning on May 14?
CLEK Extension Is Official!
The Ohio State University College of Optometry announced today that the National Eye Institute is extending funding of the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study through 2004. The CLEK Study is based at three core institutions: The Ohio State University College of Optometry, Washington University, Department of Ophthalmology and Visual Science and the Division of Biostatistics, St. Louis, MO, and the University of Illinois at Chicago Department of Ophthalmology and Visual Sciences. The project is the first multicenter clinical research project ever conducted in optometry under federal funding and is scheduled to receive $13 million from the National Eye Institute over five years.

Subcontracts to the CLEK Clinics are in the works. Jodi M. Malone and the Ohio State University Research Foundation will be corresponding with your grants and contracts offices in the near future.

CTRC Is a Go
The University of Illinois at Chicago announced last week that the National Eye Institute is funding the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study Corneal Topography Reading Center. The Center will be part of the Department of Ophthalmology & Visual Sciences in the University’s College of Medicine. Timothy McMahon, OD (Associate Professor, Department of Ophthalmology and Visual Sciences) will serve as the Director of the center, and Robert Anderson, PhD (Associate Professor, Division of Epidemiology & Biostatistics, School of Public Health) will serve as the Center Biostatistician, which is scheduled to receive $1.97 million over a five-year period. The Center will assemble, process, and analyze corneal topographic map data collected at 15 CLEK Study Clinics across the US.

CLEK in Seattle
Although the American Academy of Optometry abstract deadline crept up on us, an interesting new analysis was formulated by Tim Edrington and implemented by the Coordinating Center. CLEK pilot studies on piggyback lens fitting and the use of non-steroidal anti-inflammatory agents were submitted by Joe Barr’s graduate students, Mo Merchea and Brad Giedd.

Loretta Just Keeps Going and Going
Look for “Fitting RGP lenses in pellucid marginal degeneration patients” by Loretta Szczotka in the August 1999 issue of Contact Lens Spectrum.


CLEKkie Is Neighborhood Activist
Theresa Sanogo, of the Pennsylvania College of Optometry CLEK Clinic was featured on local television in Philadelphia recently. It turns out she was instrumental in getting a sidewalk installed in an area where there was not one previously!

Welcome, Welcome
Proud Alabama mom, Carol Rosenstiel, welcomed William Thomas on June 23. Carol took the summer off to be a new mom and is now back at work, FDACLing right and left.
**CLEK in Seattle: Will There be a Curfew?**

The CLEK Agenda for our meetings after the American Academy of Optometry meeting is as follows:

<table>
<thead>
<tr>
<th>Monday, December 13, 1999</th>
<th>Cedar Room</th>
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<tr>
<td>4:00 - 5:00 pm</td>
<td>Executive Committee meeting</td>
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<tr>
<td>5:00 - 5:15 pm</td>
<td>Welcome</td>
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<tr>
<td>5:15 - 5:30 pm</td>
<td>Extension update</td>
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<td>5:30 - 6:15 pm</td>
<td>CTRC update</td>
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<tr>
<td>6:15 - 6:30 pm</td>
<td>CPRC update</td>
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<td>6:30 - 7:15 pm</td>
<td>Dinner</td>
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<td>7:15 - 7:30 pm</td>
<td>Coordinating Center update</td>
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<td>7:30 - 7:45 pm</td>
<td>Corneal surgery forms</td>
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<td>7:45 - 8:00 pm</td>
<td>Clinical trial introduction</td>
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<td>8:00 - 9:00 pm</td>
<td>Contact lens fitting methods</td>
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<tr>
<th>Tuesday, December 14, 1999</th>
<th>Location TBA</th>
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<tr>
<td>8:00 - 8:15 am</td>
<td>Breakfast</td>
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<td>8:15 - 10:00 am</td>
<td>Writing Committees:</td>
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<td>Quality of life</td>
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<td>Fluorescein test-retest</td>
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<td>CLEK-TAG</td>
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<td>Contact lens comfort</td>
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<td>Asymmetry</td>
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<tr>
<td>10:00 am - 12:00 pm</td>
<td>Clinics’ grant writing</td>
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**Lions Roar at PCO**

The Pennsylvania College of Optometry's Lions Club has provided eyeglasses for a CLEK patient unable to afford them otherwise. The patient was extremely appreciative to the CLEK staff and Director of Research at PCO as well as to the Lions Club for their efforts in providing what would have otherwise been impossible.

In addition, the Honesdale Lions Club has provided a $500.00 research grant to PCO's Eye Institute for the past ten years. This year's grant was designated to the CLEK study and will be used to facilitate research in that area.

**See Yourself in “Print”**

The CLEK presentations in Seattle are:
- McMahon et al., USE OF IMPRESSION CYTOLOGY IN KERATOCONUS RESEARCH. Sunday, December 12, Poster #73, Hall 4C.
- Edrington et al., THE EFFECT OF RIGID CONTACT LENS PERIPHERAL CLEARANCE ON PATIENT …. Monday, December 13, Paper presentation, 1:00 p.m., Rooms 608-609.
- Barr et al. ESTIMATING INCIDENT CORNEAL SCARRING … Monday, December 13, Paper presentation, 2:40 p.m., rooms 608-609.
Executive Committee To Plan Clinical Trial

The CLEK Executive Committee (minus Don Everett) will meet in St. Louis, Missouri on January 31st to discuss critical issues for the submission of the clinical trial grant application. Topics to be discussed include the utility of topography, the impact of scarring, entry criteria, the Data Safety and Monitoring Committee, the relation between scarring, visual acuity, and FDACL, grading staining, and how to stay sane while we embark on this new adventure together. Stay tuned for updates that will assist the Clinic Investigators in their Participating Clinic grant proposal preparation.

Congrats to “The Professor”

Effective July 1, 2000, we get to refer to Joe Barr as “The Professor.” He received notice last week from The Ohio State University’s Office of Academic Affairs that his promotion had been approved. Well deserved! In related news, Gil Pierce of the CLEK Photography Reading Center has received notice that he will be promoted to the rank of Associate Professor of Clinical Optometry. Congratulations, Gil!

It’s a Rompin’ Stompin’ Boy

Greg Nixon, CLEKkie at Ohio State, and wife Vondolee welcomed Jackson James Nixon at 9:57 p.m. on January 6, 2000. He weighed in at 7 lbs, 2 oz and was heard to gurgle “Go Buckeyes.”

Just Ask Esther

Dear Esther—

Is there an official CLEK Study Policy on the release of spectacle prescriptions to patients, whether or not they are the regular patient of a CLEK investigator.

Signed, Glassy-Eyed in Ohio

Dear Glassy—

The release of spectacle prescriptions to CLEK patients is at the discretion of the examining CLEK investigator.

Plan for ARVO

The usual CLEK schedule will apply this spring. A meeting will be held on Saturday, April 29, 2000 at the Marina Marriott in Ft. Lauderdale, Florida. Dinner will follow poolside at The Sea Lord in Lauderdale-by-the-Sea. (Note that the ARVO meeting runs from May 1-5, 2000.) Each Clinic will be funded by the Chairman’s Office to send an Investigator and a Coordinator. Each person will be funded for airfare, two nights’ hotel stay, two days’ per diem, and appropriate ground transportation.

“Bedtime”

Mom and Dad were watching TV when Mom said, "I'm tired, and it's getting late. I think I'll go to bed." She went to the kitchen to make sandwiches for the next day's lunches, rinsed out the popcorn bowls, took meat out of the freezer for supper the following evening, filled the sugar container, put spoons and bowls on the table, and started the coffee pot for brewing the next morning. She, put some wet clothes into the dryer, put a load of clothes into the washer, ironed a shirt, and secured a loose button. She picked up the newspapers strewn on the floor, picked up the game pieces left on the table, and put the phone book back into the drawer. She watered the plants, emptied a wastebasket, and hung up a towel to dry. She stopped by the desk and wrote a note to the teacher, counted out some cash for the field trip, and pulled a schoolbook out from hiding under a chair. She signed a birthday card for a friend, addressed and stamped the envelope, and wrote a quick list for the grocery store. She, then, washed her face and brushed and flossed her teeth. Hubby called, "I thought you were going to bed." "I'm on my way," she said. She looked in on each of the kids. She turned off a bedside lamp, hung up a towel to dry. She stopped by the desk and wrote a note to the teacher, counted out some cash for the field trip, and pulled a schoolbook out from hiding under a chair. She signed a birthday card for a friend, addressed and stamped the envelope, and wrote a quick list for the grocery store. She, then, washed her face and brushed and flossed her teeth. Hubby called, "I thought you were going to bed." "I'm on my way," she said. She looked in on each of the kids. She turned off a bedside lamp, hung up a shirt, threw some dirty socks in the hamper, and tied a brief conversation with the one child who was still awake, doing homework. In her own room, she set the alarm and laid out clothing for the next day. She added three things to her list of things to do for tomorrow. About that time, hubby turned off the TV and announced, to no one in particular, "I'm going to bed," and he did.
Publish, Publish!

Update your resumés with the following citation:

Congratulations to all!

FDAACL, FDAACL?

One of the CLEK patients at UCLA is the sheriff of a nearby town. During the sheriff’s recent CLEK visit, Lou Rosenberg, OD, a CLEK examiner at UCLA, described a traffic "indiscretion" dating back 50 years. The Sheriff, in proper form, forgave him (as per the statute of limitations..) and instead awarded him the "Finest Definer of Automobile Crusing Speed in Los Angeles" (FDAACL) Award.

Just Ask Esther

Dear Esther,
When can we expect to get a new set of Bailey-Lovie charts? My CLEK patients are convinced they are memorizing the charts.

Signed, FNPRU in PA

Dear FNPRU, (or is it PRNFU),
The CLEK Study protocol calls for use of Bailey-Lovie visual acuity charts 4, 5, 6, and 7. It is pretty unlikely that your patients are remembering the letters from year-to-year. And, remember, the protocol calls for you to change the charts with each individual visual acuity measure. It may be that all the letters seem similar to them (the charts were designed that way specifically). Do let the Chairman’s Office know, though, if you need a new set of charts because yours have gotten dirty or marred, and be sure you’re following the protocol correctly in terms of switching charts.

Author, Author!


The January 2000 version of *Optometry and Vision Science* features “Responses of Contact Lens Wearers to a Dry Eye Survey” by IU’s own Carolyn Begley, and Dr. Begley’s group is featured in an article in the December 1999 issue of OVS entitled “Symptoms of Ocular Irritation in Patients Diagnosed with Dry Eye.”

Look for Barry Weissman’s “Keratoconus with good unaided visual acuities: two case reports in the *Journal of the American Optometric Association* in December 1999..
Publish, Publish!

Update your resumés with the following citation:

Congratulations to all!

Well Deserved and Overdue

Congratulations to Mae Gordon. Her promotion to full Professor at Washington University has been approved. She’ll finally be at the rank we CLEKkies have had her at forever!

FDACL, FDACL?

One of the CLEK patients at UCLA is the sheriff of a nearby town. During the sheriff’s recent CLEK visit, Lou Rosenberg, OD, a CLEK examiner at UCLA, described a traffic "indiscretion" dating back 50 years. The Sheriff, in proper form, forgave him (as per the statute of limitations..) and instead awarded him the "Finest Definer of Automobile Cruising Speed in Los Angeles" (FDACL) Award.

So, which of these is April Fool’s? None! Truth is stranger than fiction!

Just Ask Esther

Dear Esther,
When can we expect to get a new set of Bailey-Lovie charts? My CLEK patients are convinced they are memorizing the charts.

Signed, FNPRU

Dear FNPRU, (or is it PRNU),
The CLEK Study protocol calls for use of Bailey-Lovie visual acuity charts 4, 5, 6, and 7. It is pretty unlikely that your patients are remembering the letters from year-to-year. And, remember, the protocol calls for you to change the charts with each individual visual acuity measure. It may be that all the letters seem similar to them (the charts were designed that way specifically). Do let the Chairman’s Office know, though, if you need a new set of charts because yours have gotten dirty or marred, and be sure you’re following the protocol correctly in terms of switching charts.
CLEK: The Sequel

On June 1, 2000, an unbelievably high stack of paper left The Ohio State University College of Optometry and walked itself across the street to the Ohio State University Research Foundation. OSURF shipped it to the National Institutes of Health’s Center for Scientific Review. Thanks to everyone who participated in the work that went into the 14 NIH grant proposals that describe the CLEK Clinical Trial.

Special thanks to Jodi Malone and Nora McFadden who facilitated the final copying and shipping. Thanks here at Ohio State to Beth Oglevee, Gloria Scott-Tibbs, Gil Pierce, Mo Merchea, Mark Bullimore, Melissa Bailey, Roanne Flom, Marjie Jeandervin, Tom Raasch, Kelly Nichols, and Don Mutti, who participated in a CLEK “Read-in” on May 30 and helped ensure consistency across the proposals.

The grant proposals will be reviewed in December or January, so now it’s back to working on CLEK Observational Study manuscripts!

From the Coordinating Center

Just a reminder to make sure you fill in a date on the Missed Visit Forms. There have been a lot of Missed Visit Forms recently without dates. All the Missed Visit Forms (going back to year 1) are being reviewed for missing data and/or missing forms. Soon you will be getting requests to provide information to the Coordinating Center.

Just Ask Esther

Dear Esther,

If a patient presents wearing soft contact lenses, should an over-refraction be done?

Signed, Hydrogeling in PA

Dear Hydro,

An over-refraction over the soft lens isn’t necessary. But, the patient should undergo the “Steep K-VA” protocol, where a CLEK trial contact lens with base curve the same as the steep keratometry reading is placed on the cornea, over-refracted, and the visual acuity is measured according to protocol.

Dear Esther,

Our CLEK patient was originally a patient of our clinic but is now seeing an outside doctor. Is she considered an outside referral now on the Examination Form?

Signed, Just asking

Dear Just Asking,

Consider the patient as what she was when she started the CLEK Study, i.e., your patient, for the purposes of completing the Exam Form.

White Chocolate Chip and Toffee Cookies from Kerry Kordet, OD

4-1/2 cups flour
2 tsp baking soda
1 tsp salt
1 cup margarine, softened
1-1/2 cups granulated sugar
1-1/2 cups packed light brown sugar
2 tsp vanilla extract
4 eggs
8 oz. toffee bits (Skor brand)
1 bag white chocolate chips

Heat oven to 350 degrees. Lightly grease cookie sheet. Stir together flour, baking soda, and salt. In a large bowl, beat the margarine, granulated sugar, brown sugar, and vanilla until well blended. Add eggs; beat well. Gradually add flour mixture, beating until well blended. Stir in toffee and white chocolate chips. Drop by rounded teaspoons onto prepared cookie sheet. Bake 9-11 minutes or until VERY LIGHTLY browned. Cool slightly; remove from cookie sheet. Makes about 8 dozen cookies.
CLEK: The Sequel

On June 1, 2000, an unbelievably high stack of paper left The Ohio State University College of Optometry and walked itself across the street to the Ohio State University Research Foundation. OSURF shipped it to the National Institutes of Health's Center for Scientific Review. Thanks to everyone who participated in the work that went into the 14 NIH grant proposals that describe the CLEK Clinical Trial.

Special thanks to Jodi Malone and Nora McFadden who facilitated the final copying and shipping. Thanks here at Ohio State to Beth Oglevee, Gloria Scott-Tibbs, Gil Pierce, Mo Merchea, Mark Bullimore, Melissa Bailey, Roanne Flom, Marjie Jeandervin, Tom Raasch, Kelly Nichols, and Don Mutti, who participated in a CLEK “Read-in” on May 30 and helped ensure consistency across the proposals.

The grant proposals will be reviewed in December or January, so now it’s back to working on CLEK Observational Study manuscripts!

Above and Beyond

We estimate that OSU Clinic PI Barbara Fink has spent three weeks of full-time work maintaining the CLEK exam space at Ohio State during recent renovations there. Thanks so much, Barbara!

Wedding Bells Chime

CLEK Photography Reading Center reader extraordinaire, Marjorie Jeandervin, wed Michael Rah on August 12 in Columbus. She has accepted a faculty position at the New England College of Optometry as of this fall but plans to continue her CLEK involvement remotely. Congratulations, Marjie and Mike!

Baby Boomers, Then and Now

Then: Long hair
Now: Longing for hair

Then: Acid rock
Now: Acid reflux

Then: Watching John Glenn's historic flight with your parents
Now: Watching John Glenn's historic flight with your kids

Update those CVs


Data Monitoring and Oversight Committee Provides Feedback

The Executive Committee met with the CLEK Data Monitoring and Oversight Committee on August 24, 2000 via conference call. The Coordinating Center had prepared a comprehensive binder for the DMOC’s review on such topics as retention, publications, performance of the reading centers, etc. Recommendations that came out of the call were: (1) Karla Zadnik will work with the clinics to maximize retaining the patients that have missed their last two consecutive CLEK visits; (2) The Coordinating Center and Executive Committee will discuss strategies for longitudinal data analyses; and (3) data on reasons for surgery will be formally collected from patients and their surgeons.

Above and Beyond

In an attempt to obtain the very latest in information regarding keratoconus, Joe Benjamin ran across the following sentence written by William Rowley, M.D., on page 153 of his Treatise on the Principal Diseases of the Eyes in 1773. "A person lately applied to me who had a convexity of the cornea, which formed a conic point, that no glasses could remedy. This remarkable case happened from the force of crying aloud during hard labour. It appears to me that, although the cause was ‘misconceived,’ Dr. Rowley described a case of keratoconus!

Necessity is the Mother of Invention

From Jill Nelson of Gundersen Lutheran in LaCrosse, Wisconsin: Thanks to Jodi Malone and Gloria Scott-Tibbs for your help when we had no camera for the study. Our photographer, John Sake, saved the day by finding a camera back that belongs to one of our in-house dentists. He shot a couple of pictures, took them to get developed in our med. media department, and within an hour he was able to tell us that it had worked. Whew! We were able to complete all data that day on all patients.
CLEK Meetings in Orlando

Monday December 11, 2000 5:00 to 9:00 pm Australia 3 Room
Tuesday December 12, 2000 8:00 to 11:00 am Europe I Room (Writing Committees as follows)

- **Asymmetry** (Zadnik, Tyler, Fink, Nichols, Schechtman, Steger-May, Rosenstiel, Joslin, Shin)
- **Contact lens comfort** (Edrington, Gundel, Libassi, Wagner, Pierce, Walline, Olafsson, Achtenberg)
- **Incident scarring** (Barr, Zadnik, Riley, Jeandervin, Wilson, Gordon)
- **TAG** (McMahon, Szczotka, Friedman, Davis, Raasch, Roberts, Anderson)

Dinner provided 5:30 pm Monday evening
Continental Breakfast provided 8:00 am Tuesday morning

If you are attending and haven’t let us know, contact Jodi Malone, RN at malone.6@osu.edu.

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**Just Ask Esther**

*Dear Esther,*
*At the bottom of page 7 of the Patient History Form, it says that females only complete page 8. Men get to stop at the end of page 7. Do I, as the Coordinator, still need to review page 9 and sign my initials on it for male patients?*

_Sign me, Confused by Sex_

*Dear Confused,*
*Although this can be confusing (and perhaps sounds unnecessary), please initial the bottom of page 8 for all patients, regardless of gender. By signing your initials and noting how long it took the patient to complete the form, you are verifying that you reviewed the entire Patient History Form—including page 8—for thoroughness.*

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**Eligible Bachelorette Finds Wedded Bliss**

CLEK Clinic Investigator at SCCO, Julie Yu (nee Shin) wedded Howard Yu on September 9, 2000 in southern California. Photos of the couple provided masked evidence of extreme happiness. Wish them well!

*"If we knew what we were doing, it wouldn’t be research."
-Albert Einstein*
Publish, Not Perish!

Update those cvs! The CLEK Study has two new publications—one in print and one in press. All CLEK Study Group members (and CLEK patients) will receive reprints of the article in *Cornea* as soon as the reprints are available. Note that the publication on the repeatability of refraction is in *Ophthalmic and Physiological Optics*. This is the first paper we’ve published in this British journal.


Cats on a Hot Tin Roof!

*Stephanie Shaffer* of Case Western Reserve and husband Alan announce the birth of twins. They were born on October 12, 2000: Hannah Gene Shaffer (weighing in at 6 lbs, 13 ozs) and Jacob Edward Shaffer (8 lbs, 13 ozs). They join proud big sister Grace. Stephanie writes, “We’re having a blast! Perhaps I’ve become delirious from lack of sleep and constant chaos, but I really am having fun, enjoying every minute of it! I feel completely blessed.” Our best wishes for happiness and sleep to all.

Where Are We Now?

You may wonder what has happened to those clinical trial grants we submitted back in June 2000. Well, they are set to be reviewed sometime just before or just after the first of the year. First, the proposals will undergo scientific, peer review in an NEI Special Emphasis Panel. That group of reviewers is typically very skilled, very knowledgeable about clinical research, and very tough. We should receive feedback on that review shortly after it happens and will be able to tell you more then. If that review does not go well or if we receive constructive comments that need to be addressed by resubmitting all the grants, we will let you know ASAP. If that happens, we could be looking at a March 1, 2001 resubmission date. So, if you can avoid taking that long-deserved ski vacation the last weekend in February, it might be advisable!

Lions Roar

For the second consecutive year the Lions Club of the Pennsylvania College of Optometry has assisted a CLEK Study patient in purchasing spectacles. The Lions’ continued support makes it possible for patients, who would otherwise be unable to afford them, purchase their eyewear.

CLEK at AAO

CLEKkies are not just represented at the Academy meeting on the dance floor at the Australia Party. Here’s the lowdown on who’s doing what as a volunteer for the AAO in 2001-02.

**Tom Raasch:** Awards Committee and Chair, Scientific Program Committee

**Roanne Flom:** Ellerbrock Committee

**Marjorie Rah:** Ellerbrock Committee

**Tim McMahon:** Chair, Research Committee

**Joe Shovlin:** Chair, Section on Cornea and Contact Lenses

**Joe Barr:** Vice-Chair, Section on Cornea and Contact Lenses

**Larry Davis:** Program Committee

**Loretta Szczotka:** Scientific Program Committee

**Karla Zadnik:** Executive Council

“If we knew what we were doing, it wouldn't be research.”

-Albert Einstein
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Update those cvs! The CLEK Study has two new publications—one in print and one in press. All CLEK Study Group members (and CLEK patients) will receive reprints of the article in Cornea as soon as the reprints are available. Note that the publication on the repeatability of refraction is in Ophthalmic and Physiological Optics. This is the first paper we’ve published in this British journal.


We’re Not Worthy

Open your November 2000 issue of Optometry and Vision Science to catch Loretta Szczotka’s scientific article, “Decay-accelerating factor in tears of contact lens wearers and patients with contact lens-associated complications.”
So, Are We Doing a Clinical Trial?
Seventeen CLEK Clinical Trial grant proposals were reviewed in Washington, DC on January 4, 2001. The Chairman’s grant and three Resource Centers did not receive priority scores. The reviewers raised many good points and encouraged us to use more CLEK Observational Study data to build the rationale for the clinical trial. Each of the clinical sites received a priority score, and they ranged from 130 to 400. Our plan is to resubmit all the grant proposals, either July 1, 2001 or November 1, 2001. We have asked the clinical sites to revise their proposals aiming for the July submission date. That way, even if the Chairman’s grant and Resource Centers’ grants are not ready until November, I (KZ, that is) can spend some time helping the clinics tune up their proposals before turning to work hard on the Chairman’s grant. There will be extensive discussions of this at ARVO, and each clinic will receive communication from me about their specific review and how to address the identified problems. Nothing in the review of the study overall has derailed our intent to accomplish this clinical trial, and the Executive Committee will meet April 10 in Columbus to outline our plans for resubmission.

We’re Not Worthy
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And, in more Ohio State news, look for newest CPRC reader, Kelly Nichols’ s, review of Abelson’s Allergic Diseases of the Eye, Jason Nichols’s article, “Daily disposable vs. disposable extended wear: a contact lens clinical trial” and Jeff Walline’s “Vision-specific quality of life and modes of refractive error correction.”

Writers’ Block (Not!)
Several Writing Committees are toiling away as we speak. The paper on baseline asymmetry just went out to the Writing Committee, and Mae Gordon is hard at work on the quality of life paper. Joe Barr and Coordinating Center staff are analyzing data for the incident corneal scarring paper, and the Fluorescein Test-Retest paper is about to be revised and resubmitted to Optometry and Vision Science.

Outreach at PCO
Congratulations to Mary Jameson, BHS, CPOT, COA, NCLC, Back-up Study Coordinator at the Pennsylvania College of Optometry.

Mary will be teaching a course for the Middle Bucks Institute of Technology in Optometric Assisting Certification. Women in transition will learn basic skills necessary for a career as an Optometric Assistant. Students will prepare for the Certified Paraoptometric examination. Upon successful completion of the examination, candidates will receive the title of Certified Paraoptometric Technician (CPOT).

Ask Esther
Dear Esther,
A CLEK patient recently experienced a spontaneous expulsion of the globe from the socket during her CLEK exam. What should I have done?”

—Pressed in Berkeley

Dear Pressed,
Put the eye back in.

—Esther
New Office Terminology

BLAMESTORMING - Sitting around in a group discussing why a deadline was missed or a project failed and who is responsible.

404 - Someone who's clueless. From the World Wide Web error message "404 Not Found," meaning that the requested document could not be located. Used as in: "Don't bother asking him ... he's 404, man."

CUBE FARM: An office filled with cubicles.

IDEA HAMSTERS: People who always seem to have their idea generators running.

MOUSE POTATO: The on-line, wired generation's answer to the Couch Potato.

PRAIRIE DOGGING: When someone yells or drops something loudly in a cube farm, and people's heads pop up over the walls to see what's going on.

Eyes of March

Truth or fiction? A Columbus, Ohio-area radio station is giving away a pair of LASIK procedures from Dr. Baran, the Laser Man. Contestants dial in and tell why they desperately need the surgery. One entrant described how his contact lenses fall out during skydiving.

It's Raining Cats and Dogs

Truth or fiction? This headline appeared in the Metro Section of the San Francisco Chronicle earlier this year: "Berkeley Debates Pet Empowerment: [City] Council Ready to Elevate Domestic Animals from Kept Status."

What's the Buzz?

Truth or fiction? Karla Zadnik and her team of Ohio State College of Optometry colleagues placed second in the Worthington, Ohio Adult Spelling Bee, successfully spelling such words as cerise and uncoquettish before losing on cantonment.
So, Are We Doing a Clinical Trial?
Seventeen CLEK Clinical Trial grant proposals were reviewed in Washington, DC on January 4, 2001. The Chairman’s grant and three Resource Centers did not receive priority scores. The reviewers raised many good points and encouraged us to use more CLEK Observational Study data to build the rationale for the clinical trial. Each of the clinical sites received a priority score, and they ranged from 130 to 400. Our plan is to resubmit all the grant proposals, either July 1, 2001 or November 1, 2001. We have asked the clinical sites to revise their proposals aiming for the July submission date. That way, even if the Chairman’s grant and Resource Centers’ grants are not ready until November, I (KZ, that is) can spend some time helping the clinics tune up their proposals before turning to work hard on the Chairman’s grant. There will be extensive discussions of this at ARVO, and each clinic will receive communication from me about their specific review and how to address the identified problems. Nothing in the review of the study overall has derailed our intent to accomplish this clinical trial, and the Executive Committee will meet April 10 in Columbus to outline our plans for resubmission.

Joel Achtenberg, MSW LCSW
Joel Achtenberg of the Coordinating Center in St. Louis writes, "Note the new initials (LCSW) after my name. After almost eight years of study and supervised clinical practice, I am now fully licensed in Clinical Social Work." Congratulations, Joel!

Ask Esther
Dear Esther,
As a Coordinator I have noticed that there are two different dated versions of the Patient History (PH) form—one version dated 4/1/99 and one version dated 3/1/00. How do I decide which is the correct version/date to use?

Sign me, Still Stumped by Date
Dear Still Stumped by Date,
This is not as complicated as it seems. Both dates for the PH form version 03 are okay with the exception of page 8. All PH page 8 ("the woman's page") should be dated 3/1/00. Please have all female patients complete this page. Coordinators should review completeness of the entire PH form, including page 8, for both male and female patients. By signing their initials at the bottom of page 8, the coordinator is verifying that you reviewed the entire PH form.
So, Are We Doing a Clinical Trial?
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CLEK at ARVO
CLEK Clinic Principal Investigators and Study Coordinators met in Ft. Lauderdale on April 28, 2001. The arrangements were superb, thanks to Jodi Malone. The discussions about the Observational Study were lively, including brainstorming about retention of patients, corneal photography, and corneal topography.

John Sterling presented interesting assumptions underlying work he’s doing for a Master’s degree on the costs of keratoconus incurred by patients with the condition.

Four Writing Committees met to discuss topography papers, the asymmetry paper, a paper on contact lens comfort, and a paper on incident scarring. Look for them to cross your desk in 2001.

Joel Achtenberg, MSW LCSW
Joel Achtenberg of the Coordinating Center in St. Louis writes, “Note the new initials (LCSW) after my name. After almost eight years of study and supervised clinical practice, I am now fully licensed in Clinical Social Work.” Congratulations, Joel!

Patent Received
Dr. William J. “Joe” Benjamin’s patent for “Improved Conjunctival Inserts for Topical Delivery of Medication or Lubrication” was issued on April 17, 2001 by the United States Patent Office. U.S. Patent # 6,217,896 is one result of basic eye research conducted in his laboratory from 1989 to 1993 that was applied to the design of inserts for placement in the upper and lower cul-de-sacs.

Further development of Dr. Benjamin’s idea is being conducted in a proprietary manner and will no longer surface in the public domain—until such products become available to eye care practitioners from companies now investing resources into this technology. Dr. Benjamin hopes that improved inserts will help expand contact lens practice into the larger area of ophthalmic devices and ocular prosthetics.

Another Tiny CLEKkie
Announcing the arrival of Coner Gray Benetz, 11:08 pm April 18, 2001!!! Coner weighed in at 7lbs, 5oz and 20” long. He has brown wavy hair and, of course blue eyes. Mom (Beth Ann Benetz at University Hospitals of Cleveland) and baby are doing great. They are scheduled to go home today. They can be reached at: 17610 Schenely Ave., Cleveland, OH 44109, bab15@po.cwru.edu.
Bravo!
Check out the April 15, 2001 issue of Review of Optometry for Joe Shovlin’s article, “Is the Sun Setting on Contact Lenses?” He’s put together a terrific issue on the issues facing optometric contact lens care today.


On March 6-7, the dedicated CLEK Study coordinators met in Worthington, Ohio. They brainstormed about ways to enhance retention in the CLEK Study for visits 7 and 8 and shared stories and strategies for dealing with study patients. Attendees included Maria Voce from the University of Alabama at Birmingham School of Optometry, Kim Schach and sister Stephanie Shaffer from Case Western Reserve/University Hospitals, Donna Carter from Indiana University, Lillian Andaya from UCLA, Pat Sanders from University of Missouri-St. Louis, Patricia Mc Masters from Northeastern Eye Institute, Lindsay Florkey from Ohio State, Theresa Sanogo from the Pennsylvania College of Optometry, Lourdes Asiain from SCCO, and Kim Wegner from the University of Utah. The Coordinating Center sent webmaster Joel Achtenberg and staff extraordinaire, Teresa Roediger and Pat Nugent. The CPRC was ably represented by Gloria Scott-Tibbs and Beth Oglevee. All meeting planning, organization, and execution was done by Jodi Malone and Nora McFadden of the Chairman’s Office. Thanks to everyone for all the time and effort in this important conference to enhance the scientific import of the CLEK Study!

Champagne All Around
The CLEK Clinics at Nova Southeastern University, Indiana University, Ohio State University, the Pennsylvania College of Optometry, and the University of Utah were awarded mini-champagnes at the Full Investigators Group meeting in Philadelphia for a job well done!

Author, Author


Star of Stage and Screen
On Thursday, February 28, 2002, Case Western Reserve-based CLEKkie (and Department of Ophthalmology chairman there), Jonathan Lass, and new associate clinical professor, Loretta Szczotka, were interviewed by their local news station. The story told was about a CLEK patient who underwent successful corneal transplant surgery.

For Your Reading Pleasure

BRAVO!
At the Fall Assembly at SCCO on the opening day of fall quarter, our own Tim Edrington received the first-ever Dr. Richard Hemenger Faculty Research Award (and we knew him when ...). Congratulations, Bernie!
CLEK ON DECK
The Official Newsletter of the
Collaborative Longitudinal Evaluation of Keratoconus Study

Volume 9, Issue 2 August 19, 2002

CLEK Randomized Clinical Trials Bent on Bethesda
On July 1, 2002, six copies each of 19 grant proposals jumped into boxes together at Ohio State, bound for the Center for Scientific Review at the National Institutes of Health in Bethesda, Maryland. Proposals went in from Karla Zadnik at Ohio State (Chairman’s grant), Mae Gordon at Washington University (Coordinating Center); Joe Barr at Ohio State (CPRC grant); Tim McMahon at University of Illinois at Chicago (CTRC); and Carol Rosenstiel at the University of Alabama at Birmingham; Denny Burger at Permanente Medical Center in Oakland, California; Loretta Szczotka at University Hospitals of Cleveland; Heidi Wagner at NOVA Southeastern University; Colleen Riley at Indiana University; Charlotte Joslin at University of Illinois at Chicago, Barry Weissman at Jules Stein Eye Institute; Larry Davis at UMSL; Barbara Fink at Ohio State; Julie Yu at SCCO; Harald Olafsson at University of Utah; Dave Libassi at SUNY; Peter Bergenske at Pacific University; Marjie Rah at NEWENCO; and John Mark Jackson at Southern College of Optometry (clinics). Whew! Kudos to Jodi Malone, Nora McFadden, and Dione Allen at Ohio State for collating, xeroxing, shepherding, and blessing the proposals before they were submitted. Karla Zadnik submitted the CLEK Randomized Clinical Trial as supplemental information at the beginning of August. The proposals should be reviewed in late 2002. Good luck to us!

Author, Author


New Kid in Town
If you call the Chairman’s Office, introduce yourself to its new secretary, Lanna Blue. She’s a veteran Buckeye at Ohio State and enjoys genealogy, cooking, reading, and gardening.

Summer Camp Revisited
The eighth Summer Research Institute, co-sponsored by the American Optometric Association and the American Academy of Optometry, was held at SCCO August 7-11, 2002. You old-timers may recall that CLEK was born at the 1988 summer camp. Current CLEKkies in attendance were campers Loretta Szczotka, Charlotte Joslin, Pete Kollbaum, Jason Nichols and Peter Bergenske and camp counselors Tim Edrington, Tim McMahon, and Karla Zadnik.

Transitions
Loretta Szczotka got married in July and is now Loretta Szczotka Flynn. And just when we’d learned to spell and pronounce Szczotka! ☺

Larry Davis is the new dean at the School of Optometry, University of Missouri-St. Louis. Congratulations (or condolences?) to Larry!

A Limerick
By Burgess Baria on keratoconus-link:
On me lies the unenviable onus,
Of telling my friends about keratoconus.
Though I try not to squint in the light,
And don dark glasses to cover my plight,
Living with KC, you’d agree, is no bonus!
Reee-ten-tion!

This just in from the Coordinating Center … The number of CLEK patients seen for their year 05 and year 06 follow-up visits was 958 and 957 respectively. We may be stemming the tide of patients who are not being seen. The Clinics should be congratulated on their tenacity and commitment to the CLEK Study.

Longitudinality

“Scott Takes Five,” a column in the August 18, 2002 issue of the Milwaukee Journal-Sentinel writes about decreasing numbers of males entering college, desegregation of the Milwaukee Public Schools 40 years ago, and the importance of a college education. Mr. Scott is the former executive director of the Milwaukee Urban League and, at age 86, an urban affairs consultant for the Metropolitan Milwaukee Association of Commerce. He was honored recently for his commitment to education (he’s raised $200,000 himself to send 12 students to college) by the United Negro College Fund.

Wesley Scott, Wesley Scott … why should you know that name? He’s our own Gloria Scott-Tibbs’s dad. (Gloria points out she won’t be working at 86, no matter how long CLEK goes on!).

You’ll Be Missed

Kimberly Schach from the University Hospitals of Cleveland CLEK Clinic writes, “I wanted to let you all know that Friday Sept 27th will be my last day working at University Hospitals & working with the CLEK study. I have taken a position elsewhere & wanted you all to know that I will miss working with you & seeing you all. You are the best group of people & have made my years with CLEK wonderful!!! I wish you all the best & if you wish to stay in contact, I can be reached at klsjrs@yahoo.com.

Be on the Lookout …

… for materials to send to your Institutional Review Boards to get approval for some questions assessing the economic impact of keratoconus. Steven Kymes, PhD, a new member of the Coordinating Center has lent his expertise to trying to address how our patients’ lives are affected by keratoconus. The Chairman’s Office will send a complete packet of information to each CLEK Observational Study Principal Investigator for implementation for the year 08 visits, beginning spring 2003.

Bravo, Bravo

Carol Rosenstiel at the University of Alabama at Birmingham, Department of Ophthalmology, has been promoted to the rank of Associate Professor. Congratulations, Carol!