

Update

June 2024

NKCF

National Keratoconus Foundation



Higher than Expected

Rate of Pediatric Keratoconus in U.S.

A groundbreaking study on the state of pediatric keratoconus in the US was conducted by the Illinois College of Optometry (ICO). The results were recently published in the journal *Eye & Contact Lens*.

In response to several international papers demonstrating the incidence of keratoconus varies by geographic region and among certain ethnic groups, members of the International Keratoconus Academy (IKA) joined forces with ICO to conduct a large-scale pediatric screening in the United States.

Using an existing eye clinic staffed by ICO as the study center, eye care professionals who conduct eye exams also performed tomographic scans on students who volunteered to participate in the study. The clinic serves students from the Chicago Public Schools. Study participants were largely low-income; ethnicity recorded for subjects was Black (60.7%) followed by Hispanic (34.5%), Asian (1.9%), Mixed (1.4%), White (1.2%), and Middle Eastern (0.2%).



2,007 students were enrolled over a 2-year period. Keratoconus (KC) was diagnosed in six, and KC was suspected in another three subjects.

With nine KC or possible-KC subjects, **the prevalence is 1 in 223**, almost 10 times higher than the outdated but often quoted estimate of 1:2000.

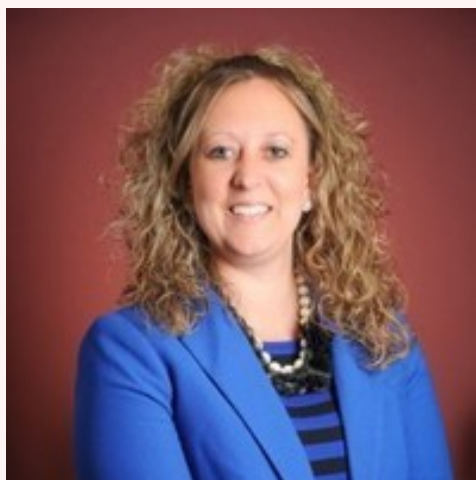
Even if the KC-suspected subjects were excluded, the six students diagnosed with keratoconus computes to 1 in 334 for this urban population. This study demonstrates with certainty that keratoconus is not a rare disease in the U.S.

Investigators were able to include subjects as young as 4 years old; the average participant was 11 years old. Other research has shown that when keratoconus is found in pediatric patients, it can be more aggressive than when corneal changes begin in the late teen or adult years. When children are affected, KC tends to progress faster and is often more advanced when it is finally diagnosed.

Dr. Jennifer Harthan, OD, first author of the paper and Professor at the Illinois College of Optometry, remarked on the importance of the findings, "*These updated prevalence findings can be used to help educate*

patients, caregivers, and pediatric health workers (optometrists, ophthalmologists, pediatricians, and school nurses) to ensure that we aren't missing pediatric keratoconus."

The authors of the Chicago study noted that tomographic scans are typically not included in a comprehensive eye exam, but eye doctors should consider performing scans, particularly in young patients who have risk factors such as high astigmatism or a family history of KC.



Dr. Harthan added, *"It is important for industry to develop affordable instruments for early screening and for practitioners to implement them for timely diagnosis, monitoring, and treatment."*

The authors observed that until the American Medical Association generates a CPT code (Current Procedural Terminology) for pediatric keratoconus screening, insurers will not cover the costs of a tomographic scan. This discourages many doctors from investing in the technology or asking families pay for the test out-of-pocket, which can result in delayed diagnosis for children at risk.

This paper's authors included several key advisors to the National Keratoconus Foundation, including first author, **Dr. Jennifer Harthan OD**; **Dr. John Gelles OD**, **Dr. Steven Greenstein MD** and **Dr. Peter Hersh MD** of the Cornea and Laser Eye Institute in New Jersey and co-founders of the International Keratoconus Academy, **Dr. Andrew Morgenstern OD** and **Dr. Barry Eiden OD**.

Reference: Harthan JS, Gelles JD, *et al*, Prevalence of Keratoconus Based on Scheimpflug Corneal Tomography Metrics in a Pediatric Population from a Chicago-Based School Age Vision Clinic, *Eye Contact Lens*, 50:121-125, 2024.

Second International Keratoconus Academy Symposium a Success!

More than 1000 global participants



**International Keratoconus
Academy**
Of Eye Care Professionals

The International Keratoconus Academy of Eye Care Professionals (IKA), a society of ophthalmologists and optometrists who have a special interest in keratoconus, held their second live conference May 18-19 in Bethesda, Maryland. Over two hundred practitioners attended the event, and more than 1,000 global participants attended the meeting virtually. **Dr. Renato Ambrosio MD, PhD** of Rio de Janeiro, Brazil opened the meeting with a video welcome and discussion of the role of Artificial Intelligence in corneal imaging. A meeting highlight was **Dr. Jennifer Harthan OD** presenting the results of a partnership between IKA and the Illinois College of Optometry on the prevalence of KC in students enrolled in Chicago Public Schools (*see story above*).

In addition to updates on contact lens technology, crosslinking, and a new surgical method of using human tissue as a corneal implant (CTAK), two special patient populations were discussed.

Capt. Joseph Pasternak MD, a cornea surgeon who retired after 30 years in the US Navy and currently at Walter Reed Medical Center, offered encouraging news about keratoconus and the military. Until recently, a diagnosis of keratoconus would deem a candidate unfit for military service. Dr. Pasternak reported that waivers are being considered for individuals who have had successful crosslinking or can document stable disease. Dr. Pasternak reported each branch of the military has adopted slightly different guidelines. Look for more information about this topic in the future.

Dr. Ann Ostrovsky MD of East Carolina University reminded audience members of the high incidence of keratoconus among individuals with Down syndrome and encouraged doctors in the audience to test, closely monitor and, if appropriate, crosslink these patients.

In the final session, keratoconus patient **Rachel Dungan** (*at left*), a Washington, DC-based health policy expert who volunteers with the National Keratoconus Foundation spoke. She shared insights in a session moderated by **Dr. Melissa Barnett OD** (*right*), host of the *Clearly KC* podcast. Rachel emphasized the importance of self-advocacy and finding a support network. She encouraged clinicians not to be afraid to ask their keratoconus patients about anxiety or depression and to share mental health resources with their patients.

Congratulations to the team that assembled two days of informative talks and panel discussions. The success of this annual meeting shows that KC is becoming a top-of-mind diagnosis and that all patients should be evaluated for this condition. The hardworking program chairs for the IKA Symposium were **Dr. Barry Eiden OD** of North Suburban Vision Consultants in Deerfield, IL, **Dr. Andrew Morgenstern OD** of Walter Reed National Military Medical Center in Bethesda, MD, and **Dr. Elizabeth Yeu MD** of Virginia Eye Consultants in Norfolk, VA.



Top Docs for 2024 Named

All eyes are on Texas in 2024. Both of the NKCF Top Docs, the ‘best of the best,’ come from the Lone Star State. They were nominated by patients who experience significant vision disorders in addition to keratoconus. NKCF salutes all the doctors who were recommended by patients for their outstanding care. You can find the list of [2024 nominees here](#).

Dr. Clarke Newman OD of Plaza Vision Center in Dallas was nominated by patient AF, who praised his ability to handle difficult situations, “***Dr. Newman was able to get me great and comfortable vision in my keratoconus-only eye and reasonable vision in my retina-damaged keratoconus eye. Whenever I have problems, he figures it out and gets it repaired.***”

Dr. Newman is well known to NKCF and is one of the country’s leading contact lens experts. A graduate of the Univ. of Houston College of Optometry, he is a Fellow of the American Academy of Optometry, the Scleral Lens Education Society, and the British Contact Lens Association.



He holds a Diplomate from the AAO Section on Cornea, Contact Lens and Refractive Technologies: one of only 150 optometrists to hold this distinction. Dr. Newman was named a 'legend' by the American Optometric Association in 2015. We wholeheartedly agree – he is a legend!



Our top ophthalmologist is **Dr. Tyrone McCall MD**, a graduate of the University of Oklahoma School of Medicine, who completed ophthalmology training at the University of Arkansas and a cornea fellowship in Santa Monica, CA. He is a senior member and partner of Cornea Associates of Texas, a specialty-only practice with four offices in the Dallas/Fort Worth area. Dr. McCall has been an investigator in many clinical trials, including corneal crosslinking for keratoconus beginning in 2010.

Dr. McCall's longtime patient, CD, nominated him, saying, ***"I'm an 80-year-old patient with 40- and 30-year-old corneal transplants. Dr. McCall monitors their health and clearly explains the condition of my eyes and what I should look for in the future."*** The patient added that Dr. McCall also removed his cataracts. Incidentally, Dr. Newman and Dr. McCall co-manage several patients. How lucky the patients in Dallas must be to have two of the country's best on their eye care team!

More than 460 ophthalmologists and optometrists have been nominated by their patients since 2017. Thank you to *Update* readers who took the time to write and tell us what makes their doctor special. Congratulations again to **Dr. Clarke Newman OD** and **Dr. Ty McCall MD** who join our Top Doc All-Stars.

2024

Clarke Newman OD

Tyrone McCall MD

2023

John Gelles OD

Kathryn Hatch MD

2022

Chantelle Mundy OD

Mark Mifflin MD

2021

Tiffany Gates OD

David Hardten MD

2020

Clark Chang OD

Michael Raizman MD

2019

Christine Sindt OD

Erin Stahl MD

2018

Joseph Shovlin OD

Eric Donnenfeld MD

2017

Brian Chou OD

Peter Hersh MD.

Plaza Vision Center, *Dallas, TX*

Cornea Associates of Texas, *Dallas, TX*

Cornea Laser & Eye Institute, *Teaneck, NJ*

Mass Eye & Ear Infirmary, *Waltham, MA*

The Ohio State University, *Columbus, OH*

Moran Eye Center, *Salt Lake City, UT*

Visionary Eye Care, *Broomfield, CO*

Minn Eye Consultants, *Minneapolis, MN*

Wills Eye Hospital, *Philadelphia, PA*

New England Eye Center, *Boston, MA*

Univ. of Iowa, *Iowa City, IA*

Children's Mercy Hospital, *Kansas City, MO*

Northeastern Eye Institute, *Scranton, PA*

Ophthalmic Consultants of Long Island, *NY*

Revision Optometry, *San Diego, CA*

Cornea Laser & Eye Institute, *Teaneck, NJ*



Mark your Calendar: An Expert Just for You!

“**Ask Us Anything**” is the title of the July 9 Evening Webinar with cornea surgeon **Dr. Uri Soiberman MD** of Johns Hopkins University / Wilmer Eye Institute and **Dr. Evan Kaufman OD**, director of optometric services at the University of Virginia School of Medicine.

NKCF will collect questions during June from *Update* readers and we'll use those questions as the focus of a lively discussion. Here is your opportunity to learn from our keratoconus experts.

While your question can be drawn from your own experiences, the doctors are not able to offer a consultation. “**Ask Us Anything**” is an opportunity to have something confusing or unknown about keratoconus explained, not for our doctors to critique your past medical care.



[My Question for the Experts](#)

As with all Evening Webinars, please register in advance. You'll be sent a link and reminder prior to the

Register to attend the July 9 Webinar

Reliability of Subjective Refraction

Anyone who undergoes a comprehensive eye exam has likely answered the question, “Which is better, one or two?” Manifest refraction is the traditional way of measuring refractive error. It relies on the patient's subjective response to which option is clearer after the doctor introduces slight changes in the power and cylinder.

A recent study from Israel compared results of manifest refraction in a group of keratoconus patients with unaffected subjects.



Thirty patients with keratoconus and thirty age-matched healthy controls were first tested using an autorefractor. Patients may be familiar with this device, where an image (often a hot air balloon) comes in and out of focus while the machine automatically determines the *corrected distance visual acuity* (CDVA). For patients with irregular corneas, the measurements may be less reliable, and optometrists will confirm the machine's results using "old school" manifest refraction.

In this study, two experienced optometrists were engaged to perform consecutive subjective refractions after autorefraction. The two tests would take place in the same room, with the same lighting, during the same visit to minimize changes that could be the result of disease progression.



The purpose was to see if subjective refraction results differed significantly. Acceptable deviation has been previously established as 0.10-0.20D (diopters) in healthy subjects. Researchers in this study defined deviations greater than 0.50D to be clinically significant.

In the control group, only 1 subject of 30 had a difference over 0.50D in measurements performed by the two optometrists. In the KC group, 12 of 30 subjects had different CDVAs over 0.50D, and 10 of the subjects recorded a difference greater than 0.75D.

The study found differences up to 1.63D between the two optometrists' results in the KC group.

The ability to read the Snellen eye chart is another method used to collect refraction data. A difference of at least one row of letters between the two optometrist's findings was present in 46.7% of the KC subjects, and 21.7% of the control subjects. The authors concluded there was a tenfold higher likelihood of a measurement difference of at least one line in patients with KC.

New York City-based optometrist, **Dr. Julie Song OD, FAAO**, said this may help to explain why individuals with keratoconus are often disappointed when they visit multiple doctors. *“Inter-practitioner variability can alter results that treatment plans are dependent upon.”* Dr. Song noted, *“the importance of continuity of care with the same practitioners can be inferred from the results of this study. If the same optometrist performs the manifest refraction each time for the same patient, measuring progression through manifest refraction, although outdated, can be more consistent.”*

Treatment decisions, such as corneal crosslinking, are often made based on changes in CDVA. Progression can be based on measurements captured by imaging devices or can be based on more subjective measures like manifest refraction. This study reminds eyecare professionals that reproducibility of results for patients with keratoconus can vary and has the potential to influence clinical decision making.

Reference: Mahler S, Einan-Lifshits A, *et al*, Reproducibility of manifest refraction in patients with keratoconus compared with healthy subjects: A prospective cohort study, *Am J Ophthalmol*, 2024 Apr 25:S0002-9394(24)00168-5. doi: 10.1016/j.ajo.2024.04.023. Online ahead of print.



Dr. Julie Song OD, FAAO is a graduate of the Univ. of Arizona Honors College and the State University of New York (SUNY) College of Optometry. She completed a residency at SUNY, where she specialized in fitting complex contact lenses. Named a 2023 Eye Care Visionary, Dr. Song is recognized as a rising star in the field. Dr. Song is a fellow of the American Academy of Optometry and practices at Fromer Eye Centers in the NYC.

LensBase: An Innovation for Contact Lens Wearers

Since the *Clearly KC* podcast began a year ago, several inspiring guests have shared stories about how keratoconus changed their life. Few have been as directly impacted as Mark Morarie from Denver.

Self-described as high energy, Mark was an accomplished athlete and coach when he began to experience headaches from eye strain and changes to his vision. After three frustrating years of misdiagnosis, and a wide variety of eyeglasses and contact lenses, Mark was starting to lose hope that he would ever see well again. Finally diagnosed with keratoconus in his late 20s, Mark began wearing hybrids, and describes it as one of the most life-changing moments that he's experienced.

Mark was then invited to join an extended scleral lens clinical trial at the University of Houston. Each week, for five years, he visited the College of Optometry where he would try on new scleral lens designs and undergo vision testing.

As Mark described in the podcast, he recalled thinking when he was presented with his first sclerals, *“Wow. These are amazing, but how do you get them in?”* Years into the study, he still had trouble handling the lenses.

Unsatisfied with the tools and methods that existed, Mark channeled his energy into tinkering: sketching ideas for a device that would make every day a little easier for scleral lens users. There were several boxes to tick with his invention: it had to be gentle on the eye, easy to clean, and inexpensive. He also wanted something portable and lightweight that fit into his backpack or back pocket. Finally, he wanted to manage the excess saline that always ended up on his countertop.



After almost ten years and six different 3D-printed prototypes, Mark received the utility patent and LensBase became an FDA registered, class-one medical device. As he shared with Dr. Barnett on the *Clearly KC* podcast, *"It is so cool that something I played with for a decade is something that people want to use. It means the world to me."*

Multiple contact lens companies, and even a saline solution brand, have taken notice of Mark's invention and are working with him to distribute the product to their customers. LensBase is now available in about 750 eye clinics in the US and Canada, and directly from thelensbase.com.

Friends of NKCF can receive a 10% discount when they purchase LensBase by entering the discount code **NKCF** before 12/31/24.

Thank you to Mark for his generosity and inspiration to the keratoconus community!

To hear more about Mark's keratoconus story and his invention of The LensBase, listen to [Episode 26 Clearly KC Podcast with Dr. Melissa Barnett](#).



CLEARLY KC
with Dr. Melissa Barnett

Risky Behavior: Contact Lens Care



Contact lenses are medical devices. Caring for them properly is imperative not only for vision, but overall health. In our February 2024 *Update* issue, we asked readers to share their contact lens bad habits. Thank you to all who participated.

71 people responded, 66.2% were female. Most respondents were 51+ years old (64.8%), followed by 31-50 years old (22.5%), 19-30 years old (11.3%), and 18 years or younger (1.4%). Most wear scleral lenses (59.2%); the second most common lens was gas permeable lenses (23.9%). Here is what we learned:

Do you wash and dry your hands before handling lenses?

Most indicated that they always wash and dry their hands before handling their lenses (64.8%). A minority said they wash their hands once in a while. Washing your hands thoroughly with soap and drying them prevents bacteria and microbes from contaminating your lenses, spreading to your eyes, and potentially causing an infection.

How often do you sleep in your contact lenses?

Sleeping in your contact lenses may seem harmless, especially if it's just for a quick nap, but can be very damaging. With eyelids closed, oxygen is prevented from reaching your cornea and increases the risk of infection. Luckily, most readers report they never sleep in their contacts (74.6%).

How often do you use tap water to clean your lenses and/or case?

Most reported never using tap water on their lenses or lens case (62%), but a good number wrote they frequently (a couple times a week) use tap water (19.7%). A common misconception is that water is a pure, clean substance. Water contains microscopic bacteria that can cause a serious eye infection, *Acanthamoeba keratitis*. One reader asked, "After cleaning my lenses, I rinse them off with water. If not water, what do I use?" Consider using fresh contact lens solution or saline to rinse off your lenses and clean the case.

Do you "top-off" your solution?

Topping off is adding new solution to the existing liquid in a lens case. Most readers report they never top-off (78.9%). However, some admitted they will top-off if they are running low, and others shared that topping-off is part of their contact lens routine. Proper lens hygiene is to dump out the old solution and replace it with fresh

solution every day. Old solution can begin to have bacteria build-up, leading to infection. It's not so different from filling your kitchen sink with water, washing your dishes, and then using the same dishwasher the next week. Yuck!

If the lens case looks okay, do you need to replace it?

Your contact lens case should be cleaned regularly and replaced if it becomes damaged. About half responded they replace their contact lens case every couple of months (3 or 4 times a year). Others reported replacing their case every 6 months, with some people admitting they get a new case 'maybe once a year' or never. Lens cases should be cleaned regularly (using solution, not water!), air-dried with the caps off, and replaced every 3 months. Otherwise, bacteria can grow in the case.



Do you swim or take showers wearing your contact lenses?

Many shared they never swim or take showers in their lenses (42.3%), but a number reported they frequently do. It's understandable since many keratoconus patients can't function without their lenses. However, like cleaning lenses with tap water, swimming or taking showers with lenses on can lead to the lenses becoming contaminated. Ask your doctor about solutions like wearing goggles while swimming or eyeglasses that can help you get ready for activities such as showering.

Most *Update* readers have very good contact lens hygiene, but sometimes we fall into bad habits. Even if you have been wearing lenses for many years, your doctor should regularly review your contact lens routine with you. For a refresher, watch our Webinar recording with **Dr. Susan Gromacki OD** (story below).

**Webinar Rewind - Systems and Solutions for your
Contact Lenses**



At the May 14 Evening Webinar, the audience was treated to a comprehensive overview of contact lens care. **Dr. Susan Gromacki OD, MS, FAAO, FSLs, Dip AAO (Cert)** of First Sight Vision Care in Fulton, Maryland is an acknowledged expert in maintaining lenses. She explained the different components to clean, rinse, disinfect, and store contact lenses and provided name brand examples.



Dr. Gromacki shared the differences in cleaning and caring for soft, hybrid, gas permeable (GP) and scleral lenses. Based on the material used to manufacture the lens, and the ability of oxygen and cleansers to pass through the lens, patients need to select cleaning and disinfecting agents that eliminate deposits but do not harm the lens.

She warned of the importance of reading warnings on labels. For instance, Dr. Gromacki pointed out that opened solution can often be used for a few days as stated on the label, but that beyond the deadline, one should expect the solution's ability to clean adequately or defend against microbes has been compromised and the liquid should be discarded.



She pointed out that hydrogen peroxide is one of her favorite disinfectants and an essential ingredient in many cleansers but warned that “brown bottle” hydrogen peroxide sold as a first aid antiseptic is not a substitute

for the version used for contact lenses. Brown bottle hydrogen peroxide is not sterile and not filtered. It can cause stinging and burning when a contact lens is soaked in it and then inserted into the eye.

Dr. Gromacki spent some time talking about the surface coating Tangible Hydra-peg, which promotes wettability. She pointed out systems can be employed to maintain the coating and finds Hydra-peg is especially beneficial to patients with dry eye.

Finally, she stressed the importance of a knowledgeable doctor and well-trained staff to answer patient questions. Because she finds patients learn in different ways, she provides verbal and written instructions, and also directs patients to instruction videos produced by organizations like the Scleral Lens Education Society (sclerallens.org) or contact lens manufacturers like coopervision.com.

Her take home message is that solutions for contact lenses have specific roles and are not interchangeable. This webinar should be bookmarked and viewed by anyone who wants to fully understand a proper contact lens routine. To watch [Systems and Solutions for your Contact lenses](#), [click here](#).

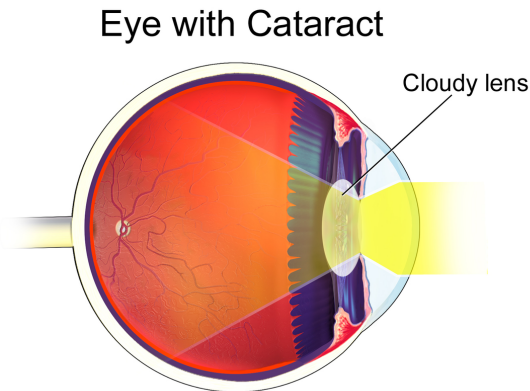
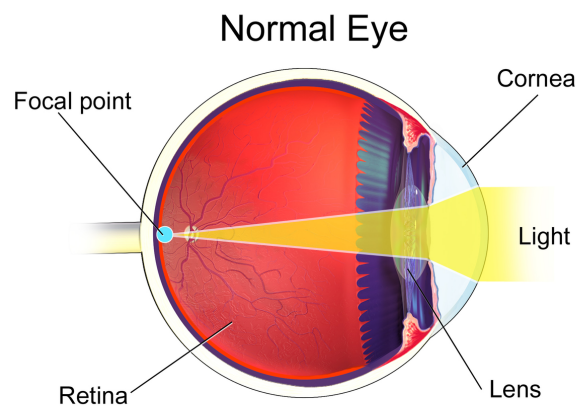
Webinar Rewind - Cataract Surgery and Keratoconus



June is Cataract Awareness Month!

Cataract surgery is the most performed surgery in the US, with millions performed each year. The March 12 Evening Webinar was one of the year's most anticipated talks focusing on cataract surgery for individuals with keratoconus.

Dr. Jay Lustbader MD, professor and chair of ophthalmology at Georgetown University School of Medicine and president of the Washington National Eye Center presented. He was assisted by three Georgetown School of Medicine ophthalmology residents, **Dr. Mazin Elsarrag MD**, **Dr. Anthony Fiacco MD**, and **Dr. Abhishek Naidu MD**.



Cloudy lens, or cataract, causes blurry vision

The seminar offered easy to understand information and reassured audience members that while cataract surgery for individuals with keratoconus takes a bit more planning and focus, outcomes are generally excellent and similar to any patient.

The outpatient procedure takes less than an hour and removes the eye's natural lens which has become cloudy, and replaces it with a clear artificial lens. Replacing the lens allows light to pass through the cornea and lens unobstructed.

In most cases vision improves with a suitable replacement lens. A skilled surgeon will select a lens that compensates the irregular vision caused by keratoconus.

Did You Know? Cataracts develop in individuals with keratoconus at the same rate as the general public. 20.5 million Americans over the age of 40 have cataract in one or both eyes. In the U.S., cataract is the leading cause of vision loss.

Prior to cataract surgery, measurements are taken to determine the appropriate power and type of replacement lens. There are standard formulas for surgeons to use, but the speakers noted that the irregular shaped corneas in keratoconus patients and associated higher order aberrations force surgeons to make adjustments in their lens selection. Surgeons generally choose a lens from among three types:



Monofocal lens. These are the standard replacement lenses that correct for distance and are covered by Medicare. After cataract surgery, patients with monofocal lenses will likely need spectacles for reading.

Multifocal lens. These lenses correct both near and far vision but are generally not recommended for those with keratoconus.

Toric lens. These lenses correct regular astigmatism. Choosing a toric lens for a keratoconus patient requires working with a contact lens fitter to compensate for the toric correction.

The presenters noted cataract surgery requires making a small incision in the cornea. For patients with keratoconus, the surgeon will avoid making the incision in an area affected by scarring or by extreme thinness. Surgical complications after cataract surgery are rare, and vision starts to improve within days.

The speakers also discussed the 'open sky' or 'triple' procedure, where a corneal transplant is done at the same time as cataract surgery. This procedure is only done in cases when cataract surgery alone will not improve vision. Dr. Lustbader noted that this is becoming a rare occurrence. Patients with extreme KC whose vision might improve with a corneal transplant tend to undergo transplants at a younger age, before the onset of cataracts. He reported that patients can be scheduled for cataract surgery even after previous corneal transplant, Intacs, or corneal crosslinking.

For more information about cataract surgery and keratoconus, take time to watch this excellent webinar. You can find the recording [here](#). You can find the NKCF Video Library on the NKCF.org homepage.

Creating a New Tool to Evaluate KC-related Quality of Life

A committee of keratoconus experts in France published their efforts to create a questionnaire that captures many of the quality-of-life (QoL) concerns of individuals with keratoconus.

In 2017, the Keratoconus Outcomes Research Questionnaire (KORQ) was developed in Australia to identify how keratoconus affects QoL for patients with mild, moderate, and severe disease. The KORQ includes two sets of questions: 18 questions about activity limitation (e.g., how much does your vision interfere with using a computer or walking up/down steps, etc.). A second group of 11 questions evaluates the impact of KC-related symptoms (e.g., how much are you troubled by bright sunny days, windy days, smoky environments, etc.). The KORQ has been adapted and used by researchers in several countries.



The French scientists wanted to study aspects of life with keratoconus that are not measured with KORQ. To create a new survey, researchers conducted intensive phone interviews with keratoconus patients to identify areas of concern. Disease severity among the interviewees ranged from mild to severe, and the ages of those interviewed was 22 to 67, with a median age of 35.5 years. The interviews yielded six themes that impact QoL to be incorporated into the final version of the questionnaire:

Social Life impact: The most common complaint was the inability to drive at night or to go out on their own to social gatherings. Study subjects reported that people in their social circle – including family members – had

difficulty understanding their daily struggles.

Psychological impact: Worry and anxiety were reported by subjects, often associated with a fear of becoming blind. Older patients reported being worried that their children may develop the disease.

Professional Life impact: Patients were concerned about the use of sick and vacation time for doctor visits. Some also reported they felt less effective at work due to computer screen fatigue, dusty environments, or difficulty driving. Others reported the need to interrupt their career or change jobs due to KC.

Financial impact: Costs associated with contact lenses, including solutions and replacement lenses, the cost of travelling to doctor visits and purchase of specific tools or software for home use were mentioned along with the time cost managing the disease.

Daily life impact: Study subjects reported struggles with tasks like grocery shopping or orienting themselves in new places. Patients also reported they believed they were less efficient at tasks like cooking, gardening, or cleaning because of KC.

Student life impact: Older patients remembered trouble they had as students and current students reported difficulty seeing what is written on blackboards or keeping up with reading assignments. Some reported changing fields of study because of the challenges encountered.

The authors found that, despite the severity of disease or treatments they had undergone, participants raised common themes and concerns. Creating and validating a KC-specific questionnaire will provide eye doctors with a valuable tool to assess the impact of keratoconus on their patients' quality of life.

Reference: Fournie P, Acquadro M, *et al*, Keratoconus and the Impact of Treatment on Patients' Quality of Life: A Qualitative Study, *Ophthalmol Ther* 12:1939-1956, 2023.

Corneal Transplants in the Age of Crosslinking

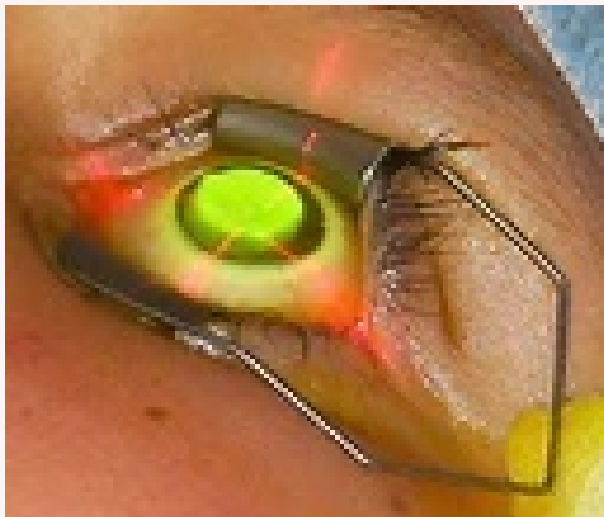


Researchers at University Hospital in Oslo wondered how the introduction of crosslinking (CXL) impacted corneal transplant surgeries. It has been fifteen years since CXL came to in Norway; CXL is fully established and well-known among eye care professionals. Doctors at University Hospital perform corneal transplants in a region of Norway with more than half of the country's population. For those reasons, researchers believed they could gather a fairly accurate picture of the state of corneal transplants among the Norwegian keratoconus community.

Reviewing the national corneal transplant registry, the authors found that while the overall number of corneal

transplants increased, the number of keratoconus-related transplants decreased. In 2005, 55 of the 137 transplants performed at University Hospital were for keratoconus (40.1% of all penetrating keratoplasty surgeries). By 2021, the number of corneal transplants increased to 352, but only 11 were for treatment of keratoconus (3.1%).

Of the 11 patients who underwent corneal transplant, 10 had stage 4 keratoconus (the most extreme disease presentation) and one patient had stage 3 disease. In 2005, more than 1/3 of the patients who underwent a corneal transplant had stage 1, 2 or 3 disease. The authors speculated that before the availability of CXL, surgeons were more likely to recommend a cornea transplant, even if the keratoconus was mild or moderate. Today, transplant is reserved for those with the most severe disease.



In the U.S., the 2022 Eye Bank Statistical Report offers a snapshot of the work done by the 56-member Eye Bank Association of America (EBAA). KC and other ectasias have always been one of the top indications for transplant surgery. In 2017 the number of transplant surgeries for keratoconus among EBAA members was 3,166. Five years later, in 2022, that number had fallen to 2,334. It is very likely the number of corneal transplants for KC will continue to decline as the number of patients who receive crosslinking increases.

In 2020, the Eye Bank Association of America reported for the first time that fewer keratoconus patients underwent initial corneal transplant than patients receiving replacement grafts.

In the U.S., as well as Norway, corneal crosslinking and improved contact lens technology have resulted in fewer individuals with keratoconus needing a transplant. This trend should continue, and there will eventually be two groups of individuals with keratoconus: older patients with corneal grafts that will need to be monitored and who may need occasional surgery to replace failed grafts, and those patients who came of age after CXL where transplants are rarely recommended.

References: Hagem AM, Thorsrud A, Soethre M, *et al*, Dramatic Reduction in Corneal Transplants for Keratoconus 15 years after introduction of corneal crosslinking, *Cornea*, 43:437-442, 2024.

Mathews P, Benbow A, Corcoran K, *et al*, 2022 Eye Banking Statistical Report – Executive Summary, 2023

Have you listened to *Clearly KC with Dr. Melissa Barnett*? The podcast about all things keratoconus can be found on most podcast platforms. You can find it by typing in "clearly kc podcast" in a search engine or visiting nationalkeratocousfoundation.podbean.com.



CLEARLY KC
with Dr. Melissa Barnett

Why Clinical Trials?

Medical device businesses, pharmaceutical companies, the National Eye Institute, university medical centers, and even individual doctors may have a new device, drug, or treatment to evaluate. They want to compare their new product to the existing standard of care. At some point, human volunteers are needed to collect data on safety and effectiveness. This is the clinical trials process.

Investigators design a *study protocol*, a document that contains the recipe for treatment. Issues like drug dosages, length of treatment, schedule of tests, and the types of patients who are eligible to participate are outlined. The protocol is approved by a group of independent experts (called the Institutional Review Board or IRB) who determine if the plan is well constructed with the safety of the human study subjects as the top priority.

The National Institutes of Health do not regulate clinical trials. However, they do maintain an on-line registry of available clinical trials (clinicaltrials.gov). If you have an interest in learning more about a particular clinical trial, you can type in a location or key word (like 'keratoconus') and you'll find a database of active and recently completed studies.

Why Should I Consider a Clinical Trial?



Each person must weigh the pros and cons of enrolling in a clinical trial. In any clinical trial, study subjects can drop out at any time. By participating, you may have access to a new treatment or drug before it is widely available. Enrolling in a study often means you receive comprehensive exams and testing, so you will learn more about your disease.

You may be reimbursed for certain expenses you incur like travel or parking. In some cases, study subjects are paid to participate. Most importantly, what is learned by your participation may be critical to helping other patients and contribute to medical knowledge.

On the negative side, you may experience a reaction or side effect to the treatment or drug. You may be expected to attend multiple follow-up visits over an extended period which may be an inconvenience. If you are participating in a double-blind study, neither you nor your doctor will know if you are receiving the actual investigative treatment or a placebo.

Two very important industry-sponsored clinical trials for keratoconus are underway. **Glaukos**, the company that offers the FDA-approved epithelium-off crosslinking procedure began a clinical trial in March 2022 to test the success of an epithelium-on treatment. 150 subjects between the ages of 18 and 55 were enrolled. Enrollment is closed and all subjects have received treatment. The protocol requires a 1-year follow-up, which is underway now. Data will be analyzed and submitted for FDA review in 2025.

Another large-scale epithelium-on crosslinking clinical trial sponsored by **Epion Therapeutics**. The company began patient enrollment in October 2023 and enrollment is still open to eligible patients. Their goal is to treat 800 individuals between the ages of 8 and 45 years old who have been diagnosed with keratoconus but have not received any previous crosslinking. There are 24 study sites in 17 states. If you have questions about participating in this trial, email info@epiontx.com. Check the company website (epiontx.com) for an upcoming webinar and more information about clinical trial enrollment.

Life Expectancy in the KC Population

Twelve years ago, an Australian optometrist posed an alarming observation. ‘Where,’ he asked, ‘were the older keratoconus patients?’ He observed few older keratoconus patients in his contact lens clinic and wondered if individuals with keratoconus died at a younger age. Other clinicians joined in the discussion and noted that medical conditions associated with keratoconus, like obstructive sleep apnea, obesity, or mitral valve prolapse may indeed shorten the lives of KC patients. The question was never satisfactorily answered.

Recently, researchers in Utah reviewed mortality data and causes of death using the Utah Population Database, which matches hospital health records with death certificates issued in that state. During the period 1996 to 2020, records associated with 7,847 individuals with keratoconus and 38,597 age, sex and race matched controls were selected for the study.

The mortality results between the KC and control groups were similar. At the conclusion of the study, 92% of the subjects with KC were still alive, 7.5% had died by natural causes, and 0.8% by unnatural causes (accident, suicide, or homicide). In the control group, the breakdown was 91% still alive, 7.9% died by natural causes and 0.9% by unnatural causes.



The cause of death in the two groups did not reveal unusual disparities. The authors noted that while KC has been associated with a number of systemic conditions, no red flags for cause of death emerged. For example, a condition linked to KC, obstructive sleep apnea, is associated with increased risk of cardiovascular events and stroke. It might be expected that keratoconus patients would suffer from above average cardiovascular death. Yet no increased mortality was identified.

Only one category showed a minor, but statistically significant difference: 72 individuals with keratoconus

died from diseases of the nervous system or sense organs (0.9%) compared with 241 (0.6%) of the control group. The authors could think of no systemic condition associated with keratoconus to account for this, and concluded additional study would be needed to determine if there was an underlying condition responsible.

When the alarm originally sounded about the absence of older patients in contact lens clinics, the author compared the mean age of non-KC patients with the mean age of keratoconus patients seen in selected doctors' offices and feared a reduced life expectancy. In retrospect, it may be that older KC patients had given up on wearing contact lenses, or perhaps as these patients aged, the idea of traveling to a specialty clinic was too difficult and the patients were getting their eyecare elsewhere. Or perhaps they developed other age-related eye conditions such as a macular degeneration, glaucoma, and cataract, and were being managed by other eye doctors.

The Utah paper reassures us that individuals with keratoconus do not die earlier, or from causes that are any different than their neighbors.

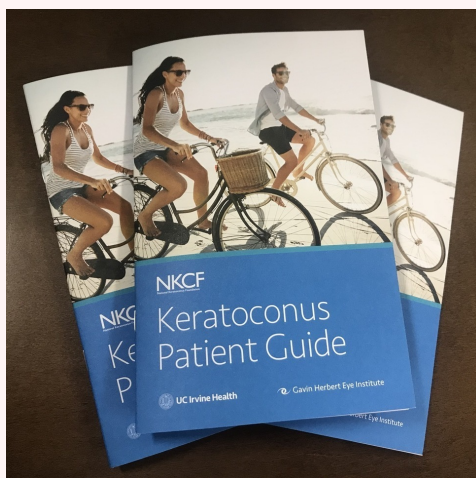
References: McMonnies CW, Quo Vadis Older Keratoconus Patients? Do They Die at Younger Ages? *Cornea*, 32:496-502, 2012.

Meyer JJ, Meets H, *et al*, Mortality and Causes of Death Among Individuals With Keratoconus, *Cornea*, 2024 Apr 26. doi: 10.1097/ICO.0000000000003548. Online ahead of print.

NKCF Resources - *Share the Knowledge*

We hope you'll find answers to your questions about keratoconus on our website, nkcf.org. You can sign up for our Evening Webinars, and view our video library with more than 25 hour-long talks by experts. We have a Referral List with links to doctors expert in managing the disease. You can also find back copies of our newsletter and information about World KC Day online. If you are interested in receiving a copy of our Keratoconus Patient Guide, you can request one [here](#). You may want to share the guide with teachers, employers, or family members to help them understand some of the challenges you face.

NKCF does not have financial resources to assist medical care or the cost of contact lenses.



Your tax-deductible gift of any amount to UCI Foundation helps NKCF improve the quality of life for people with keratoconus through education and advocacy. Make an on-line gift today and join us to raise KC awareness.

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NKCF Update is sent to you compliments of the National Keratoconus Foundation, an outreach program of the Department of Ophthalmology at University of California Irvine.

The mission of NKCF is to increase awareness of keratoconus and to provide information and resources to those living with the disease.

NKCF does not provide medical advice, medical consultation or financial assistance. If you have specific questions about your diagnosis, treatment or outcomes, please contact your eyecare professional.



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