

1




2


Keratoconus (KC)

- **Progressive corneal disease**
 - Focal thinning, steepening, bulging, and irregular shape
 - Loss of biomechanical strength
 - Bilateral, asymmetric, clinically non-inflammatory
- **Caused by a combination of genetic and environmental factors**
 - Allergies and eye rubbing
- **Onset in puberty**
 - Typically progressive to 4th decade of life
 - Previously estimated 1:2000 (1986 US), more recent estimate 1:375 (2017 Netherlands)

Normal



KC



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3

Watch Out for Keratoconus! Potential Signs & Symptoms

Typically onset occurs in teenage years or early twenties

- Frequent Changes in Refraction or Increasing Cylinder
- Reduced Best Corrected Visual Acuity
- Frequent Headaches
- Hales and Glareing

- Family History of Keratoconus
- Excessive Eye Rubbing
- Difficulty Seeing at Night
- Increased Light Sensitivity

If you believe a patient may have keratoconus, please contact us at info@findanexpert.com or find an expert at findanexpert.com to refer them for a KC screening.


LOOK OUT FOR KC!

- Look out for warning signs in medical history
 - History of eye rubbing
 - Family & genetic predispositions
- Look out for visual complaints
 - Blurred vision
 - Distortion of images
- Look out for refractive anomalies
 - Distortion of mires on keratometry
 - Error messages on autorefractors
 - Unsatisfactory attempts at vision correction & progressive loss of UCVA & BCVA
 - Increasing astigmatism

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4

Signs of Keratoconus



Vogt's Striae
Apical thinning and scarring
Fleischer Ring
Munson's sign

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5

Conventional Management of Keratoconus

Increasing complexity of interventions and loss of best corrected visual acuity with disease progression

Disease Severity ↑

- Eyeglasses
- Rigid Contact Lenses
- Specialty and Scleral Lenses
- Intrastromal Ring Segments
- Corneal Transplant


Vision management options may not stop disease progression

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6

Importance of Early Diagnosis in Keratoconus

- As keratoconus progresses, it becomes more challenging to manage
- Progressive keratoconus often results in:
 - Loss of visual acuity
 - Decreased tolerance to contact lens wear, caused by the ongoing changes in the cornea
- The earlier progressive keratoconus is diagnosed, the sooner treatment can be provided that may slow the progression of the disease.¹
- Important to diagnose and educate patients before visual function is lost
- Cross-linking is an early intervention intended to slow or halt the progression of KC



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7


Imaging Tools for Diagnosis of Keratoconus

Topography
- Non-invasive medical imaging technique for mapping the **anterior** surface of the cornea

Tomography
- Analyze both the **anterior** and **posterior** surfaces of the cornea

Epithelial Mapping
- Epithelium thins over the cone, thickens around

Anterior Segment OCT
- Detailed cross-section of cornea
- Identify areas of thinning/ abnormality



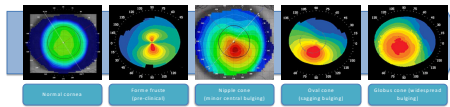
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Topography – A Key to Keratoconus Diagnosis and Monitoring of Progression

KC is often first detected through observation of increasing astigmatism and worsening visual acuity, limiting patients' functional vision

Keratoconus is monitored using corneal topography, an anatomical measure of the curvature of the cornea surface


blue/green = flatter surfaces; yellow/red = keratoconus-related steepening



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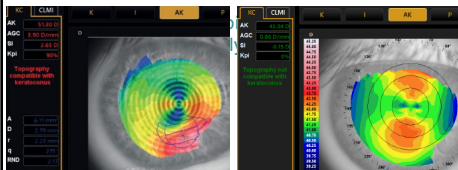
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Topcon CA-800





10

Topcon CA-800 Keratoconus Example with KC Algorithms



11

Topcon CA-800 Serial Analysis/Difference Map



12

History of Corneal Cross-Linking



"I'm now using this blue light to cross-link and harden your filling..."

"EUREKA!"

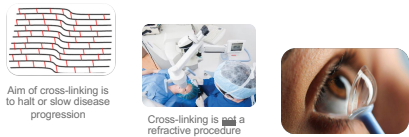
• Hermann KAMR,
since 1980,
Dresden, Germany

• Prof. Theo Seiler
C. 1990 C. 2010

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13

Treatment: Keys to Patient Counseling



Aim of cross-linking is to halt or slow disease progression

Cross-linking is a refractive procedure

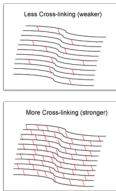
Post-op evaluation for visual correction will be necessary

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14

Mechanism of Action

- Corneal collagen cross-linking combines the use of ultra-violet (UV) light and riboflavin (vitamin B2) drops
- The absorption of UVA by riboflavin generates radical riboflavin and singlet oxygen to form cross-links⁽¹⁾
- Corneal Cross-linking:
 - Creates new corneal collagen cross-links
 - Results in a shortening and thickening of the collagen fibrils
 - Leads to the stiffening of the cornea⁽²⁾



⁽¹⁾Yamada H, Pritchard MD, Shier E, Miller D. Photochemical kinetics of corneal cross-linking with riboflavin. Invest Ophthalmol Vis Sci. 2012;53(2):880-7.

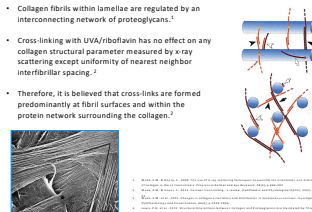
⁽²⁾Wattchow M, O'Donnell C, Rethelshwamy N. Biomechanical properties of corneal tissue after ultraviolet-A-riboflavin crosslinking. J Cataract Refract Surg. 2013;39(5):491-495.

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15

Where do cross-links occur?

- Collagen fibrils within lamellae are regulated by an interconnecting network of proteoglycans.¹
- Cross-linking with UVA/riboflavin has no effect on any collagen structural parameter measured by x-ray scattering except uniformity of nearest neighbor interfibrillar spacing.²
- Therefore, it is believed that cross-links are formed predominantly at fibril surfaces and within the protein network surrounding the collagen.²



¹ Weiss JF, Winkler J. 2006. The nature of the interconnecting network that regulates the structure of collagen fibrils in the cornea. Invest Ophthalmol Vis Sci. 47(12):4000-4008.

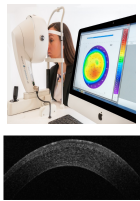
² Weiss JF, Winkler J. 2006. The nature of the interconnecting network that regulates the structure of collagen fibrils in the cornea. Invest Ophthalmol Vis Sci. 47(12):4000-4008.

³ Weiss JF, Winkler J. 2006. The nature of the interconnecting network that regulates the structure of collagen fibrils in the cornea. Invest Ophthalmol Vis Sci. 47(12):4000-4008.

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16

Patient Selection/ Treatment Criteria

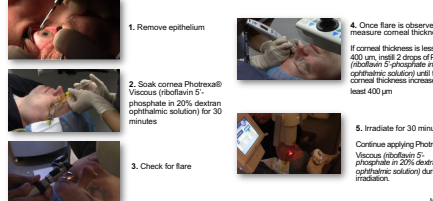


- Screening exams for early diagnosis to identify patients and monitor for progression of keratoconus or development of corneal ectasia following refractive surgery
- Must document progression or loss of BSCVA to qualify for insurance coverage (1 Diopter of Kmax or Cyl)
- Pediatric Use
 - 14 years of age and older
- Geriatric Use
 - No subjects enrolled in the clinical studies were 65 years of age or older

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17

Cross-linking Procedure Summary



1. Remove epithelium
2. Soak cornea Photrexall® Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) for 30 minutes
3. Check for flare
4. Once flare is observed, measure corneal thickness. If corneal thickness is less than 400 µm, instill 2 drops of Photrexall (riboflavin 5'-phosphate in ophthalmic solution) until the corneal thickness increases to at least 400 µm
5. Irradiate for 30 minutes. Continue applying Photrexall Viscous (riboflavin 5'-phosphate in 20% dextran ophthalmic solution) during irradiation.

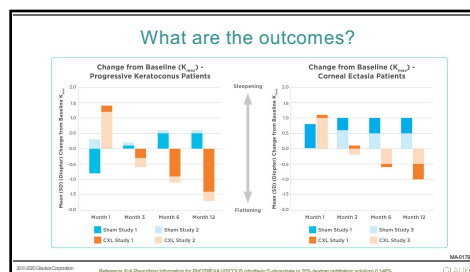
* Refer to prescribing information for entire FDA-approved procedure

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18



19



20

Treatment Emergent Adverse Events (TEAEs)

- The majority of reported adverse events resolved during the first month
- Corneal epithelium defect, corneal striae, punctate keratitis, photophobia, dry eye and eye pain, and decreased visual acuity took up to 6 months to resolve. Corneal opacity or haze took up to 12 months to resolve
- In 1-2% of patients, corneal epithelium defect, corneal edema, corneal opacity and corneal scar continued to be observed at 12 months

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21

Post-Procedure Patient Follow-up Schedule

Visit	Plan
Day 1	<ul style="list-style-type: none"> Topical antibiotic, steroid, Neuronin, BCL Frequent lubricants No eye rubbing!!
Week 1	<ul style="list-style-type: none"> Topical antibiotic, steroid Frequent lubricants No eye rubbing!! Remove BCL once epithelium heals
Month 1	<ul style="list-style-type: none"> Vision & Anterior Segment assessment Assess for resolution of epithelial irregularities Contact lens assessment- return to habitual lens
Month 3, 6, 12	<ul style="list-style-type: none"> Vision & Anterior Segment assessment Tomography or topography Contact lens assessment- evaluate for refitting

Note: Due to zero global period, follow-ups may be billable to insurance when medically indicated.

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22

Payer Coverage Status

More than 7 Plans Cover Cross-Linking in 29 States

Majority of patients in the US now have coverage for FDA-Approved Cross-Linking

6 National and

61 Regional Health Plans

≥95% of Commercial Lives that are Covering Corneal Cross-Linking

For a comprehensive up-to-date list of approved carriers, please visit www.livingwithKC.com

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23

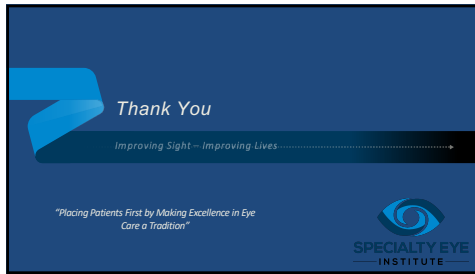
Cross-Linking Insurance Coverage

Online Resources – Links to Coverage Policies on LivingwithKC.com

Links to Coverage Policies

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24



31