STATE BOARD OF OPTOMETRY
2450 DEL PASO ROAD, SUITE 105, SACRAMENTO, CA 95834
P (916) 575-7170 F (916) 575-7292 www.optometry .ca.gov

Continuing Education Course Approval Checklist

Title: Corneal Collagen Cross Linking

Provider Name: NVISION Eye Centers c/o Ms. Leslie Kuhlman

☑Completed Application
Open to all Optometrists? ☑Yes ☐No
Maintain Record Agreement? ☑Yes ☐No

☑Correct Application Fee

☑Detailed Course Summary

☑Detailed Course Outline

☑PowerPoint and/or other Presentation Materials

☑Advertising (optional)

☑CV for EACH Course Instructor

☑License Verification for Each Course Instructor
Disciplinary History? ☐Yes ☑No

STATE BOARD OF OPTOMETRY
2450 DEL PASO ROAD, SUITE 105, SACRAMENTO, CA 95834
P (916) 575-7170 F (916) 575-7292 www.optometry.ca.gov

CONTINUING EDUCATION COURSE APPROVAL APPLICATION

$50 Mandatory Fee

Pursuant to California Code of Regulations (CCR) § 1536, the Board will approve continuing education (CE) courses after receiving the applicable fee, the requested information below and it has been determined that the course meets criteria specified in CCR § 1536(g).

In addition to the information requested below, please attach a copy of the course schedule, a detailed course outline and presentation materials (e.g., PowerPoint presentation). Applications must be submitted 45 days prior to the course presentation date.

Please type or print clearly.

Course Title	**Course Presentation Date**
Corneal Collagen Cross Linking	03/05/2017

Course Provider Contact Information

Provider Name

Leslie (First) Kuhlman (Last) Ann (Middle)

Provider Mailing Address

Street 75 Enterprise **City** Aliso Viejo **State** CA **Zip** 92673

Provider Email Address Leslie.Kuhlman@nvisioncenters.com

Will the proposed course be open to all California licensed optometrists?	☑ YES ☐ NO
Do you agree to maintain and furnish to the Board and/or attending licensee such records of course content and attendance as the Board requires, for a period of at least three years from the date of course presentation?	☑ YES ☐ NO

Course Instructor Information

Please provide the information below and attach the curriculum vitae for each instructor or lecturer involved in the course. If there are more instructors in the course, please provide the requested information on a separate sheet of paper.

Instructor Name

Franklin (First) Lusby (Last) _____ (Middle)

License Number _____	**License Type** MD
Phone Number (310) 784-2020	**Email Address** Franklin.Lusby@nvisioncenters.com

I declare under penalty of perjury under the laws of the State of California that all the information submitted on this form and on any accompanying attachments submitted is true and correct.

Signature of Course Provider *Date* 3/1/17

OPTOMETRY

STATE BOARD OF OPTOMETRY
2450 DEL PASO ROAD, SUTIE 105, SACRAMENTO, CA 95834
P (916) 575-7170 F (916) 575-7292 www.optometry .ca.gov

For Office Use Only

Receipt No. _____

ATS No. _____

Date Rec'd _

Request for Approval of Continuing Education Course(s)

Leslie Kuhlman
NVISION Eye Centers
75 Enterprise, Suite 200
Aliso Viejo, CA 92656

Requests for approval of continuing optometric education (CE) courses should be submitted on this form. The California State Board of Optometry requires the following information in order to process a course approval request:

- **$50** processing fee
- Name of provider
- Course title(s)
- Date(s) the course is scheduled to be offered
- Topical outline of the course subject matter
- Any announcements, notices or advertisements of the course
- Curriculum vitae (CV) of all instructors and lecturers involved (NOTE: CVs should include every term of employment, academic credential, publication, contribution or significant achievement)

Requests for approval and the supplemental information should be submitted to the Board office at least 45 days prior to the first date that the course will be offered. Requests will be reviewed by staff and forwarded to the CE Committee for final review. If necessary, Board staff will contact the requestor for additional information. Course approvals are valid for 12 months or until the course is modified.

The CE Committee's decision(s) will be noted and a copy of this form will be returned to the provider to serve as official notification of approval and/or disapproval of the course(s). Please remember to include the contact person's name and mailing address in the space provided above.

_____

CE Committee Member

YOU'RE INVITED

ORANGE COUNTY REGIONAL 5-HOUR CE EVENT

Sunday, March 5, 2017 / 7:00 am - 1:30 pm
Improv Comedy, Irvine, CA

Join NVISION for an exciting continuing education event including networking, breakfast, lunch and raffles.

FEATURED EVENTS

Exciting Presentations, Fantastic Raffle Prizes,
Vendor Booths, Delicious Food & Drinks,
and Breakfast & Lunch

SPEAKERS

Tom Tooma, MD • Franklin Lusby, MD
Sheri Rowen, MD • John Nolan, MD
Jonathan Pirnazar, MD

TOPICS

LRS, Ocular Nutrition, Crosslinking, Corneal Inlay

Limited availability. Registration ends 3/3/17.
For more information and to RSVP, visit:
https://ocregional5hrce.eventbrite.com

CA State Board of Optometry - Pending Approval

NVISION EYE CENTERS

NVISION
EYE CENTERS

STATE BOARD OF OPTOMETRY
2450 Del Paso Road, Suite 105
Sacramento, CA 95834

On behalf of NVISION Eye Centers, we are writing to request approval of Continuing Education to California doctors of optometry. The education will be delivered by Board Certified Ophthalmologists, clinical investigators and experts in technology and patient consultation.

We are writing in response to your letter for information pursuant to CCR 1536 (g), to address why our application was submitted earlier than 45 days for course accreditation. As well as additional content requested.

The reason why our application was submitted earlier than 45 days for the course named "Coneal Collagen Cross Linking" given March 5, 2017 access to the final presentation not available. Once information required, we moved quickly to process accreditation requests. Please accept our apologies and deepest regrets. Going forward, we will make every effort to process these applications in a timely manner.

Course Description: This course will present an historical overview of Corneal Crosslinking, helping attendees to understand the key learnings from the past, current, and what to expect in the future. Course coverage will include mechanism of action, biomicroscopic changes, modes of treatment, case examples, clinical outcomes, accelerated CXL protocols, future advancements, and refractive CXL.

Course Objective: To allow attendees to develop a comprehensive understanding of Corneal Crosslinking and the treatment and management of Keratoconic and Corneal Ectasia patients.

Conditions of Availability: This course will be open to all licensed ODs. They will be notified through flyers, Eventbrite, and fax by request.

Records: NVISION Eye Centers to maintain and furnish to the Board and/or attending licensee such records of course content and attendance as required for a minimum of three years.

Professional Advancement: NVISION Eye Centers seeks to offer professional education to local and regional optometrist. As a leading practice in the ophthalmology field, NVISION doctors are engaged in research and latest developments on procedures, technology, and clinical therapies. The field of optometry is constantly evolving at a rapid pace and optometrists need to keep up. All Things Refractive in an interactive presentation. This CE activity will help attending ODs learn a full understanding of refractive surgery technology, clinical treatments and procedures, candidates, post-op & pre-op care, cost, co-management, how it is performed, and benefits.

The contact person for this program is myself, and I can be reached at 949.234.8129 or Leslie.Kuhlman@nvisioncenters.com.

Sincerely,

Leslie Kuhlman
NVISION Laser Eye Centers
Continuing Education and Special Projects Coordinator

NVISION
EYE CENTERS

Presenter – Franklin W. Lusby, M.D.

Course Title – CORNEAL COLLAGEN CROSS LINKING

Course Outline –

- Keratoconus
- Keratoconus comes from the latin words:
    - Meaning "cone-shaped cornea"
- Keratoconus is a progressive disease of the cornea which affects about 1:2000 people (about 2-4x the incidence of post-LASIK ectasia)
- It typically begins in the teen years, and progresses through the 20's and 30's. It usually stabilizes in the 40's or 50's.
- It always affects BOTH eyes but usually asymmetrically
- Keratoconus
- The disease is characterized by a progressive thinning and bulging of the cornea
- The change in corneal shape produces increasing myopia and astigmatism, and corneal irregularity and scarring resulting in a loss of vision quantity, quality, and sharpness
- Vision not correctable with glasses, only rigid gas permeable or specialty lenses
- Keratoconus
- In the past, once contact lenses did not provide adequate vision, corneal transplantation was required
- Keratoconus has been related to Down's Syndrome and Atopic Dermatitis, both which are associated with severe eye rubbing
- Eye rubbing in absence of these to conditions now a risk factor for KC
- Corneal Ectasia
- Corneal Ectasia occurs when a patient with a genetic weakness of the cornea, that is a predisposition to keratoconus, has LASIK (or PRK) and develops the same progressive bulging of the cornea.
- Pre-operative corneal mapping is designed to detect patients who may have sub-clinical (*forme fruste*) keratoconus.
    - Presumably, these patients can be "de-stabilized" by LASIK and become ectatic (without LASIK, they remain *forme fruste*).
- Eliminate the need for eventual penetrating keratoplasty
- Keep patient in "simple" contacts for as long as possible
- Maintain good spectacle and/or uncorrected VA if present initially
- CXL with Riboflavin and UV-A

Goal:

- Improve the tensile strength of the cornea
- Arrest the progression of keratoconus/ectasia
- Improve vision (possibly)
- Recently achieved FDA approval (Avedro)

UV-A light 370 nm and Riboflavin

- Increases free radicals (amino groups on collagen)

- Promotes covalent bonds (cross linking)
- Increases tensile rigidity in human cornea by ~300%
- Effect on anterior 300 microns
    - Optimal pre-UV thickness
- Role of Riboflavin
- Vitamin B2 – yellow
- Large molecule
- Promotes free radicals
- Absorbs UV light
- Does not penetrate epithelial tight junctions
    - Solution -
        - disrupt tight junctions (chemically)
        - disrupt epithelium (mechanically)
        - remove epithelium
- Cross-linked vs.
  Non-cross-linked Cornea
- Background of Corneal Cross-Linking
- Interlamellar Cohesion after CXL using Riboflavin and UVA Light
- CCXL increases the tensile strength of corneal collagen by about 300%
- Interlamellar and interfibrillar slippage proposed to be pathogenic mechanisms
- Crosslinking seems to stabilise only inter-fibrillar cohesion but not interlamellar cohesion.
- BJO 2011 Jun;95(6):876-80 Wollensak G, et al. Halle, Germany.
- Intra-/interhelical and inter fibrillar XL
- Indications
- Demonstrable progression of Keratoconus
- Ectasia following refractive surgery
- Safety
- Toxicity
- - High UV-A energy can damage:
- - Endothelium – if cornea < 350 microns
- - Keratocytes (reduced after CXL – recover)
- - Retina – macula
- - Current dose: 18 mW/cm^2 = safe (Avedro: $3mW/cm^2$)
- - Riboflavin must fully impregnate cornea - seen in AC
- For Corneas < 400 Microns
- Use hypotonic Riboflavin solution
- Measure cornea till central thickness becomes > 400 microns
- CL assisted
- Optimal pre-UV thickness: 400 Microns
- Currently 2 different riboflavin solutions
    - One "thins" cornea
    - One "thickens cornea
- Monitor pachymetry during riboflavin application
- CL assisted if < 350 (off-label)

- Validation of CXL
- One-year Follow-up of Confocal Microscopy after CXL for Post Lasik Ectasia and KC
- 5 eyes with ectasia and 5 with KC.
- Subepithelial nerve plexus was absent immediately post op. Regenerated within 3 months.
- Keratocytes were absent in anterior 300µ of stroma in first 3 months.
- Full thickness keratocyte repopulation occurred at 6 months.
- No changes in corneal endothelium.
- AJO 2009 May. Kymionis GD, et al Crete, Greece
- Permanent Haze after Riboflavin-UVA-induced CXL in KC
- 163 eyes with KC
  - ➢ 8.6% developed clinically significant stromal haze
- Mean K pre-op was 62D in the clear group and 71D in the haze group
- Mean thickness was 478µ in the clear group and 420µ in the haze group
  - ➢ Pre-op K and Pach could be predictive factors in the development of haze post-op
- JRS 2009 Sep. Raiskup F, et al Dresden, Germany
- Safety of CXL in Progressive KC
- 14 eyes
- Endothelium was assessed with specular microscopy
- Central retina was assessed with biomicroscopy and OCT
- Preop, 1wk,1,3,6,9, and 12 mos.
  - ➢ Stable endothelial cell density and stable foveal thickness was observed
- Cornea 2010 Apr Godich Y, et al Israel
- CXL for KC and Corneal Ectasia: One-year Results
- UDVA improved from 20/137 to 20/117. CDVA from 20/45 to 20/34.
- Max K decreased by 1.7D +/-3.9D
- KC eyes had more improvement in topo measurements than patients with ectasia
- JCRS 2011 Jan;37(1):149-60 Hersh PS, et al. New Jersey
- Detection of biomechanical changes after CCXL using ORA software
- 50 eyes with KC
- Measurements before and 1 year after CCXL
- Matched with 96 eyes of normal corneas
- 37 parameters were measured
- Area under Peak 2 appears to be a more sensitive parameter to detect biomechanical changes after CCXL than CH or CRF
- JRS 2011 Jun;27(6):452-7 Spoerl E, et al. Dresden Germany.
- Corneal Topography Indices after CXL for KC and Corneal Ectasia: One Year Results
- The cornea becomes more regular and more symmetrical
- 71 EYES: 49KC and 22 post lasik ectasia
  - ➢ Significant improvement in the index of surface variance, index of vertical asymmetry, and keratoconus index.
  - ➢ No difference between groups.
- JCRS 2011 Jul:37(7): 1283-90.
- Corneal Thickness Changes after CXL for KC and Corneal Ectasia
- 82 eyes – 54KC and 28 ectasia after Lasik

- Pre 440µ +/-53µ
- 1 month thinned -24 microns
- 3 months thinned -7 microns
- 6 months thickened +21 microns
  - 1 year – returned to pre-CXL thickness -7 microns
  - Return of thickness more rapid in ectasia group
- JCRS 2011 Apr;37(4):691-700 Greenstein SA, et al.
- Long Term Results of CXL for KC in Italy: The Siena Eye Cross Study
- 44 KC eyes
- 2004 to 2008 – 363 eyes with progressive KC
- 44 eyes with mean follow up 52 mo (48-60 months)
  - Completely stable compared with other eye progression of 1.5D in > 65% after 24 months
  - Mean K decreased by 2D and coma reduced with corneal symmetry improvement in >85% of patients
  - BSCVA improved 1.9 lines and UCVA improved 2.7 lines
- AJO 2010 Apr. Caporossi A et al Siena, Italy
- Wollensak Study
- CXL was first used in 1998
- 23 eyes with moderate to advanced KC
- Mean pre op Kmax was 50.93D
- Mean pre op progression of Kmax was 1.42D over past 6 months
  - After CXL Kmax decreased an avg of 2.01D with up to 47 months of follow up
  - Contralateral control eyes – Kmax increased 1.48D
  - BSCVA improved 1.26 lines, MRSE improved 1.4 D
- Corneal and lens transparency, IOP, endothelial cell density were unchanged.
- German Study - Dresden
- 150 eyes
- Follow up of 60 months
- Progression was stopped in all eyes
  - 81.7% of eyes had a decrease of Kmax of 2.87D
- No adverse events
- Conclusions – CXL
- Role in Keratoconus/Ectasia
  - - Safe – endothelial cell count/keratocytes
  - - Appears to stop progression
  - - Improves
    - - average K
    - - cylinder
  - - Useful in the management of post-refractive surgery ectasia.
- FDA clinical Trial
- 48 eyes with progressive KC
- 35 eyes with post lasik ectasia
- 12 months of follow up
- At 6 months Kmax decreased 1.39D
- At 6 months Pachymetry decreased 14µ

- No adverse events
- Topcon Study
- Evaluate long term safety and effectiveness of the VEGA UV-A Illumination system for CXL
- VEGA UV-A Illumination system = UVA 370nm wavelength light source and the photosensitizer Roboflavin 0.1% /Dextran 20% solution.
- Pretreat cornea with riboflavin 0.1% solution for 20 to 30 min before UVA exposure to saturate the corneal tissue with photosensitizer
- Low-dose UVA irradiation of 3mW/cm2 for 30 min
- Release of reactive oxygen species (ROS) stimulates covalent bond formation between collagen fibers.
- Induces cross-linking of collagen fibrils – increases tensile strength and diameter of fibrils
- Procedures that can be Combined with CXL for KC to Improve Uncorrected VA
- Toric phakic IOL's (ICL's)
- Refractive lens exchange
- PRK
- Intacs
- Corneal Inlays
- Combined CXL and PC Toric ICL for KC
- 29 y/o with KC
- ICL 12 months after CXL
- 3 month post op – UCVA improved from CF to 20/40
- BCVA improved from 20/100 to 20/30
- ➢ Seems to be safe procedure for KC + high myopia
- Ophthalmic Surg Lasers Imaging 2011 Feb 17 Kymionis GD, et al Crete, Greece
- Artiflex Phakic IOL after CXL in Keratoconic Eyes
- ➢ 11 eyes with ACIOL 6 months after CXL
- Progressive KC, no opacities, CCT >450µ, endo cell count> 2500, AC depth >3.2mm
- ➢ All achieved UCDVA of 20/60 or better. No loss of BCVA
- JRS 2011 Jul:27(7):482-7 Izquierdo L Lima, Peru
- Sequential Versus Concurrent Kerarings (Intacs) Insertion and CXL for KC
- 16 eyes – 2 groups. One simultaneous and the other 6 to 14 months later, with Kerarings first
- ➢ No difference between groups in UCDVA and CDVA
- ➢ Simultaneous had more improvement in K's and better topos, but more stromal haze
- BJO 2011 Jan;95(1):37-41 El-Raggal TM. Cairo, Egypt
- Refractive and Topographic Results of Transepithelial CXL Treatment in Eyes with Intacs
- 25 eyes underwent Intacs implantation with subsequent CXL 4 months later
- ➢ CXL after Intacs resulted in additional improvement in UCVA (1.2 lines), BCVA (0.36), sphere, cyl and K.
- Cornea 2009 Aug Ertan A, et al Ankara, Turkey
- CXL to Stop Corneal Ectasia Exacerbated by RK
- UCVA and BCVA improved from 0.2 to 0.6 (20/100 to ~20/35) and from 0.3 to 0.8 (~20/65 to 20/25) in a 12-month follow-up
- Corneal topography and corneal symmetry index improved as well
- Seems to be a promising procedure
- Cornea 2011 Feb;30(2):225-8 Mazzotta C, et al Siena, Italy
- Comparison of Sequential vs. Same-day CXL and Topo-guided PRK for Treatment of KC

- 325 eyes. 127 sequential 6 months apart and 198 had simultaneous treatment. Mean f/u of 36 months (24 to 68 months)
  - ➢ Simultaneous group did better in improvement of UCVA and BSCVA.
- JRS 2009 Sep. Kanellopoulos AJ Athens, Greece
- Stability of Simultaneous Topo-guided PRK and CXL for Progressive KC
- 2 eyes. 70% treatment of myopia and cyl with topo-guided T-CAT module of Allegretto Wave Eye-Q laser.
- PRK first then CXL same session
- Epith healed in 5 days
- Cyl and aberrations reduced in first eye allowing CTL wear in 3 months. 36 months f/u showed improved myopia and K's
- 2nd eye emmetropic outcome 20/20 UCDVA remained stable for 30 months post op
- JRS 2010 Oct;26(10):827-32 Krueger RR Et al Cleveland, Ohio
- Simultaneous Topo-guided PRK and CXL for the Treatment of KC and PMD
- 12 patients
- Topo-guided ablations followed by CXL
- Mean UCVA increased from 20/1000 to 20/125 at 12 months
- BSCVA increased from 20/57 to 20/35
- Cyl decreased from 5.4 to 2.7
- Keratometric asymmetry decreased from 6.38 to 2.76
- Results were stable
- JRS 2010 Feb Stojanovic A, et al Norway
- Infectious Keratitis Treated with CXL
- 7 eyes with severe infectious keratitis treated with CXL.
- 3 patients CTL users
- All had corneal melting
- Symptoms improved in all within 24 hours
- Corneal melting arrested and complete epithelialization.
- Hypopyon resolved in 2 days
- Cornea 2010 Dec;29(12):1353-8 Makdoumi D Sweden
- IOP Measurements after CXL in Eyes with KC
- 55 eyes. IOP by Goldman tonometry
- IOP increased at 6 and 12 months
  - ➢ Pre 9.95mmHg. At 6 months 11.40mmHg and at 12 months 11.35mmHg
- Change in IOP did not correlate with age, pre-op pach, or pre-op K readings
- Change in IOP related to increased corneal rigidity
- JCRS 2010 Oct;36(10):1724-7 Kymionis GD et al Crete, Greece
- Indications
- Progressive keratoconus
- Iatrogenic keratoconus
- Pelucid marginal degeneration
- Bullous keratopathy
- Prevention of keratectasia
- Infectious keratitis
- CCL Vario

- CXL
- Study Design
- Open-label
- Prospective
- Non-randomized
- Multicenter study
- Epithelium off – riboflavin pre-treatment
- UVA light for 5 minutes 18 mW/cm^2
- Follow up at 1 day, 1 week, 1 month, 3, 6, 12 months,and 24 months
- Pentacam, corneal topo, MR, uncorrected and BSCVA and IOP measured at baseline, 1, 3 , 6, 12, and 24months
- Treatment Guidelines
- Topography typical for KC or post-LASIK ectasia
- Minimum age: 14 years
- Kmax >= 47
- Minimum pach >=400
- Epithelium off – riboflavin induction 30 minutes
- UVA light for 30 minutes 3 $mW/cm^{2;}$; 9mm treatment diameter
- Recovery similar to PRK
- Avedro CXL
- Inclusion Criteria
- 12 years of age or older
- KC or post-refractive corneal ectasia
- Central or inferior steepening on Pentacam
- Topography consistent with KC or ectasia
- Kmax = or > 47.00D or I-S ratio 1.9 on Pentacam map or topographic map
- BSCVA 20/20 or worse
- Remove CTL – soft 3D, soft extended 1wk, soft toric 2wk, RGP 2 wk, hybrid lenses (synergEyes; rose K' Clear Kone) 2wk.
- Sign informed consent
- Exclusion Criteria
- Pachymetry <350µ measured by Pentacam
- Previous ocular condition such as HSV, HZO, Recurrent erosions, corneal melt or dystrophy
- Corneal scarring in area of treatment
- History of chemical injury or delayed healing
- Pregnancy or lactation during course of RX
- Nystagmus
- Ocular surface disease that would delay epithelial healing
- Post-op Care
- Zymar, Zymaxid or Vigamox QID until epithelialized
- PF 1% QID for 2 weeks
- Ketorolac QID for up to 4 days
- Preservative free tears as needed
- Follow up visits at 1D, 1wk, 1,3,6,12 and 24 months

- K's, UCVA distance, BSCVA distance, MR, pentacam topography, pach, keratometry, Scheimpflug Photography
- IOP, endothelial cell count at 6mos, dilated fundus exam at 6mos, subjective complaint and VFQ-25 questionnaire.
- Results
- MO

		BCVA	UCVA
• Pre:	+0.50 – 1.00 x 040	20/40	20/60
• 3 - mo:	+0.25 -2.75 x 017	20/25	20/25-2

- Results
- MM

		BCVA	UCVA
• Pre:	-1.50 – 4.25 x 072	20/25	
• 3 - mo:	-1.50 – 4.75 x 078	20/25-2	

- Results
- ER

		BCVA	UCVA
• Pre:	+0.50 – 3.50 x 017	20/25	
• 3 - mo:	+0.75 – 4.50 x 016	20/30	

- Results
- BC

		BCVA	UCVA
• Pre:	-1.50 -1.25 x 105	20/80	20/150
• 3-mo:	+1.50 -5.50 x 111	20/40+	20/150

- Results
- WH

		BCVA	UCVA
• Pre:	pl – 1.50 x 122		20/30
• 3-mo:	+0.25 – 1.25 x 128	20/30	
• 6-mo:	pl – 0.75 x 016	20/20-1	

- Results
- AP

		BCVA	UCVA
• Pre:	-11.25 – 2.00 x 040	20/30	
• 4-mo:	-11.75 – 2.50 x 016	20/25	
• 7-mo.:	-12.00 – 1.75 x 031	20/20-1	

- Results
- AA

		BCVA	UCVA
• Pre:	-11.25 – 2.00 x 040	20/30	
• 4-mo:	-11.75 – 2.50 x 016	20/25	
• 7-mo.:	-12.00 – 1.75 x 031	20/20-1	

- CXL Outcomes: Review
- CXL effective in halting progression of KC
- Reduce max K >2D
- Post-op SEQ reduced by average of 1D.
- No loss of BCVA
- Reduces corneal and total aberrations
- No decrease in endo cell density.
- Postpone need for LKP and PKP
- CXL Outcomes: Review

- 17 year worldwide experience
- RARELY improves VA
- RGP wear will NOT SLOW or PREVENT progression of disease, only mask it
- Early treatment is key.
- Simultaneous LASIK and CXL
- Contralateral eye study; CXL in non-dominant eye
- Post ablation, 1 min Riboflavin soak then rinse and restore flap then 75 second UVA exposure 30mW/cm2
- VA, K, endo cell count, confocal microscopy
- LASIK and LASIK Extra (LASIK + CXL) were equally safe with equal results
- Topo-guided CXL as treatment for refractive error
- Based on premise the CXL changes shape of cornea
- More stable?
- First choice for irregular corneas without KC (or ff)
- Requires combined mapping delivery device
- Progressive disease
    - Topography every 3-6 months
    - Eye rubbing accelerates disease
    - Disease slows after age 40
- Very young patients URGENT treatment
- Steep Ks > 54D URGENT treatment and HIGHER RISK

Patient Counseling

1. RGP wear or specialty KC CLs provide good vision but DO NOT STOP the PROGRESSION of the disease
2. Refer these patients for CXL stabilization, then refit with CLs
3. If YOUNG, then URGENT referral, even if mild as progression can occur rapidly and there is NO ability to regain the loss.
4. Important to emphasize to patients that KC is a progressive disease, CXL is for stabilization and to prevent progression NOT vision improvement.
5. CXL may be combined with other procedures to improve vision – PRK & ICRS
6. CXL may need to be repeated infrequently (<5%)

- Referral for CXL

CRITICAL UNDERSTANDING

4. Important to emphasize to patients that KC is a progressive disease, CXL is for stabilization and to prevent progression NOT vision improvement.
5. CXL may be combined with other procedures to improve vision – PRK & ICRS
6. CXL may need to be repeated infrequently.

- SUMMARY

1. 17 YEAR history worldwide
2. CXL is GOLD STANDARD Treatment for Keratoconus > Stops Progression in 95%
3. SURGEONS would treat their OWN FAMILY
4. CXL does NOT IMPROVE VISION
5. CXL will NOT recover lost vision, so early treatment is BEST
6. RGP wear will NOT SLOW or PREVENT progression of disease

- SUMMARY

1. 17 YEAR history worldwide

2. CXL is GOLD STANDARD Treatment for Keratoconus > Stops Progression in 95%
3. SURGEONS would treat their OWN FAMILY
4. CXL does NOT IMPROVE VISION
5. CXL will NOT recover lost vision, so early treatment is BEST
6. RGP wear will NOT SLOW or PREVENT progression of disease

- FDA Status
- Recently recommended for approval
- Pricing?
- Insurance re-imbursement
- Off-label (study) procedures will likely continue

CORNEAL COLLAGEN CROSS LINKING

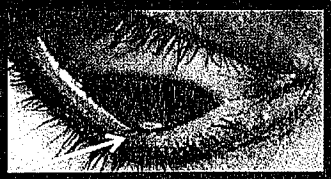
Franklin W. Lusby, M.D

NVISION

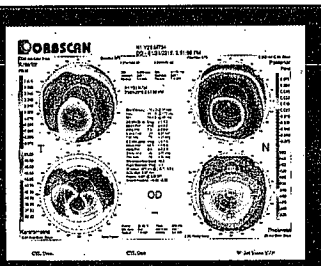
KERATOCONUS

- The disease is characterized by a progressive thinning and bulging of the cornea
- The change in corneal shape produces increasing myopia and astigmatism, and corneal irregularity and scarring resulting in a loss of vision quantity, quality, and sharpness
- Vision not correctable with glasses, only rigid gas permeable or specialty lenses

NVISION

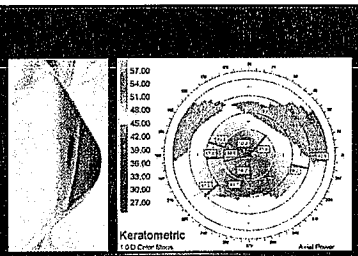


NVISION



NVISION

NVISION



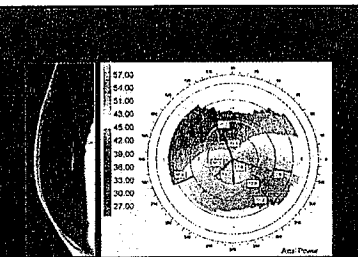
NVISION

KERATOCONUS

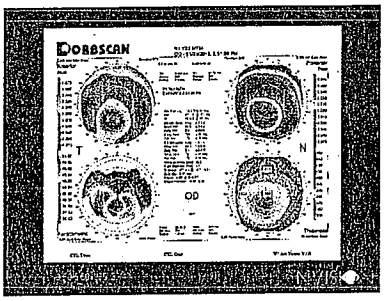
- Keratoconus comes from the latin words:
  - Meaning "cone-shaped cornea"
- Keratoconus is a progressive disease of the cornea which affects about 1:2000 people (about 2-4x the incidence of post-LASIK ectasia)
- It typically begins in the teen years, and progresses through the 20's and 30's. It usually stabilizes in the 40's or 50's
- It always affects BOTH eyes but usually asymmetrically

NVISION

NVISION



NVISION



New Paradigm for the Management of Keratoconus and Ectasia

- Eliminate the need for eventual penetrating keratoplasty
- Keep patient in "simple" contacts for as long as possible
- Maintain good spectacle and/or uncorrected VA if present initially

History

In the 70's polymerization compounds came into use in dentistry

Compounds were fixed by cross-linking of polymer side chains

KERATOCONUS

- In the past, once contact lenses did not provide adequate vision, corneal transplantation was required
- Keratoconus has been related to Down's Syndrome and Atopic Dermatitis, both which are associated with severe eye rubbing
- Eye rubbing in absence of these to conditions now a risk factor for KC

CXL with Riboflavin and UV-A

Goal:

- Improve the tensile strength of the cornea
- Arrest the progression of keratoconus/ectasia
- Improve vision (possibly)

- Recently achieved FDA approval (Avedro)

UV-A light 370 nm and Riboflavin

- Increases free radicals (amino groups on collagen)
- Promotes covalent bonds (cross linking)
- Increases tensile rigidity in human cornea by ~300%
- Effect on anterior 300 microns
  - Optimal pre-UV thickness

CORNEAL ECTASIA

- Corneal Ectasia occurs when a patient with a genetic weakness of the cornea, that is a predisposition to keratoconus, has LASIK (or PRK) and develops the same progressive bulging of the cornea.
- Pre-operative corneal mapping is designed to detect patients who may have sub-clinical (*forme fruste*) keratoconus.
- Presumably, these patients can be "de-stabilized" by LASIK and become ectatic (without LASIK, they remain *forme fruste*).

Natural crosslinking

- Cross linking of human collagen is a physiological process
- stiffening of connective tissue is well known in diabetes and aging
- Diabetes is a protection factor against keratoconus (smoking too!)
- During cross-linking new chemical bonds are induced

Chemistry

1. Combined application of UVA and riboflavin

riboflavin (vit. B2) · Ultraviolet radiation

2. Creation of oxygen radicals

O_2

3. Induction of collagen cross-links

collagen fiber · collagen fiber

Role of Riboflavin

- Vitamin B2 – yellow
- Large molecule
- Promotes free radicals
- Absorbs UV light
- Does not penetrate epithelial tight junctions
  - Solution -
    - disrupt tight junctions (chemically)
    - disrupt epithelium (mechanically)
    - remove epithelium

NVISION

Background of Corneal Cross-linking

NVISION

NVISION

Fluorescence Microscopy

3000ms Exposure time; 10x

courtesy D Stulting, MD

Riboflavin for 30 min.
No UVA, with Epithelium

Riboflavin for 30 min.
No UVA, no Epithelium

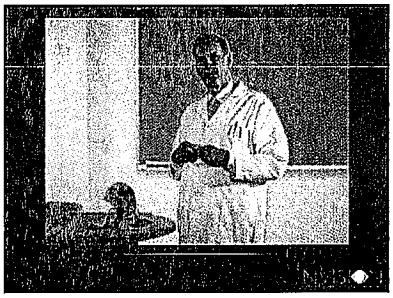
Kanellopoulos, MD www.brilliantvision.com

Interlamellar Cohesion after CXL using Riboflavin and UVA Light

- CCXL increases the tensile strength of corneal collagen by about 300%.
- Interlamellar and interfibrillar slippage proposed to be pathogenic mechanisms
- Crosslinking seems to stabilise only inter-fibrillar cohesion but not interlamellar cohesion.

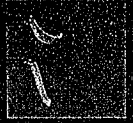
BJO 2011 Jun;95(6):876-80. Wollensak G et al. Interlamellar

NVISION



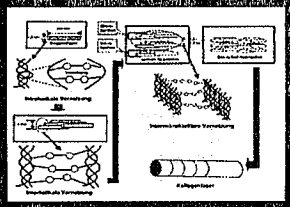
NVISION

Cross-linked vs. Non-cross-linked Cornea

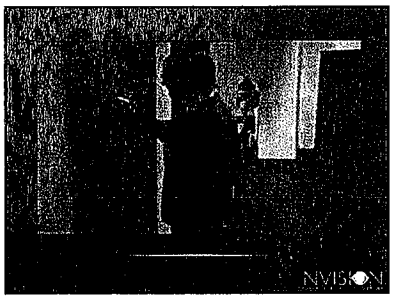


NVISION

Intra-lamellar and inter-fibrillar XL



NVISION



NVISION

Indications

- Demonstrable progression of Keratoconus
- Ectasia following refractive surgery

For Corneas < 400 Microns

- Use hypotonic Riboflavin solution
- Measure cornea till central thickness becomes > 400 microns
- CL assisted

One-year Follow-up of Confocal Microscopy after CXL for Post Lasik Ectasia and KC

- 5 eyes with ectasia and 5 with KC
- Subepithelial nerve plexus was absent immediately post op. Regenerated within 3 months.
- Keratocytes were absent in anterior 300µ of stroma in first 3 months
- Full thickness keratocyte repopulation occurred at 6 months
- No changes in corneal endothelium.

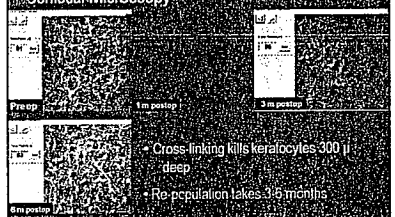
Safety

- Toxicity
  - High UV-A energy can damage
    - Endothelium – if cornea < 350 microns
    - Keratocytes (reduced after CXL – recover)
    - Retina – macula
  - Current dose: 18 mW/cm² = safe (Avedro: 3mW/cm²)
  - Riboflavin must fully impregnate cornea - seen in AC

Optimal pre-UV thickness: 400 Microns

- Currently 2 different riboflavin solutions
  - One "thins" cornea
  - One "thickens cornea
- Monitor pachymetry during riboflavin application
- CL assisted if < 350 (off-label)

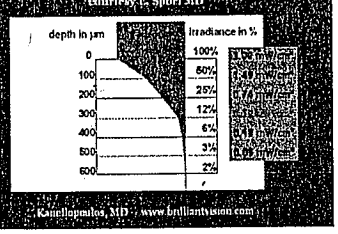
Confocal Microscopy



- Cross-linking kills keratocytes 300 µ deep
- Re-population takes 3-6 months

Decrease of UV-intensity

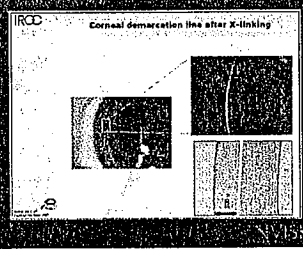
courtesy L. Spoerl MD



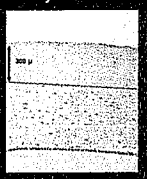
Kanellopoulos, MD :: www.brilliantvision.com

Validation of CXL

Corneal demarcation line after X-linking



Keratocytes



Safety of CXL in Progressive KC

- 14 eyes
- Endothelium was assessed with specular microscopy
- Central retina was assessed with biomicroscopy and OCT
- Preop, 1wk,1,3,6,9, and 12 mos.
- Stable endothelial cell density and stable foveal thickness was observed

Cornea 2010 Apr Caruso Y et al Italy

DETECTION OF BIOMECHANICAL CHANGES AFTER CCXL USING ORA SOFTWARE

- 50 eyes with KC
- Measurements before and 1 year after CCXL
- Matched with 85 eyes of normal corneas
- 37 parameters were measured
- Area under Peak 2 appears to be a more sensitive parameter to detect biomechanical changes after CCXL than CH or CRF

JRS 2011 Jun;27(6):452-7 Spoerl E et al Dresden Germany

Clinical signs of CCL

Kanellopoulos, MD www.brilliantvision.com

Keratoconus

- A disease where the cornea bulges forward giving a distorted retinal image and failing vision
- Keraloconus is something that develops in young age and has a tendency to progress
- It is treated by glasses, contact lenses or surgery

Corneal Topography Indices after CXL for KC and Corneal Ectasia: One Year Results

- The cornea becomes more regular and more symmetrical
- 71 EYES: 49KC and 22 post lasik ectasia
- Significant improvement in the index of surface variance, index of vertical asymmetry, and keratoconus index
- No difference between groups

JCRS 2011 Jul;37(7), 1253-60

Permanent Haze after Riboflavin-UVA-induced CXL in KC

- 163 eyes with KC
- 8.6% developed clinically significant stromal haze
- Mean K pre-op was 62D in the clear group and 71D in the haze group
- Mean thickness was 478µ in the clear group and 420µ in the haze group
- Pre-op K and Pach could be predictive factors in the development of haze post-op

JRS 2009 Sep Rudnisky et al Dresden Germany

CXL for KC and Corneal Ectasia: One-year Results

- UDVA improved from 20/137 to 20/117, CDVA from 20/45 to 20/34.
- Max K decreased by 1.7D +/-3.9D
- KC eyes had more improvement in topo measurements than patients with ectasia

JCRS 2011 Jan;37(1):149-60 Hersh PS et al New Jersey

Corneal Thickness Changes after CXL for KC and Corneal Ectasia

- 82 eyes – 54KC and 28 ectasia after Lasik
- Pre 440µ +/-53µ
- 1 month thinned -24 microns
- 3 months thinned -7 microns
- 6 months thickened +21 microns
- 1 year – returned to pre-CXL thickness -7 microns
- Return of thickness more rapid in ectasia group

JCRS 2011 Apr;37(4):697-710 Greenstein SA et al

Long Term Results of CXL for KC in Italy: The Siena Eye Cross Study

- 44 KC eyes
- 2004 to 2008 – 363 eyes with progressive KC
- 44 eyes with mean follow up 52 mo (48-60 months)
- Completely stable compared with other eye progression of 1.5D in > 65% after 24 months
- Mean K decreased by 2D and coma reduced with corneal symmetry improvement in > 85% of patients
- BSCVA improved 1.9 lines and UCVA improved 2.7 lines

Conclusions – CXL

- Role in Keratoconus/Ectasia
  - Safe – endothelial cell count/keratocytes
  - Appears to stop progression
  - Improves
    - average k
    - cylinder
  - Useful in the management of post-refractive surgery ectasia

Results for Keratoconus

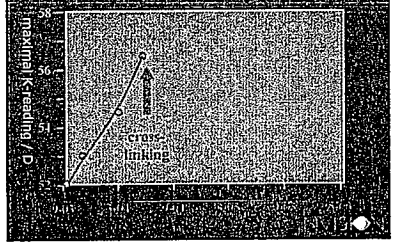
Wollensak Study

- CXL was first used in 1998
- 23 eyes with moderate to advanced KC
- Mean pre op Kmax was 50.93D
- Mean pre op progression of Kmax was 1.42D over past 6 months
- After CXL Kmax decreased an avg of 2.01D with up to 47 months of follow up
- Contralateral control eyes – Kmax increased 1.48D
- BSCVA improved 1.26 lines, MRSE improved 1.4 D
- Corneal and lens transparency, IOP, endothelial cell density were unchanged

FDA Clinical Trial

- 48 eyes with progressive KC
- 35 eyes with post lasik ectasia
- 12 months of follow up
- At 6 months Kmax decreased 1.39D
- At 6 months Pachymetry decreased 14µ
- No adverse events

Results in Keratoconic Eyes



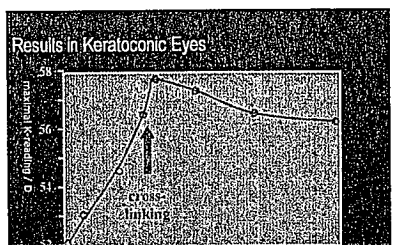
German Study - Dresden

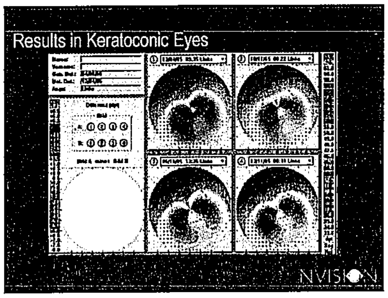
- 150 eyes
- Follow up of 60 months
- Progression was stopped in all eyes
- 81.7% of eyes had a decrease of Kmax of 2.87D
- No adverse events

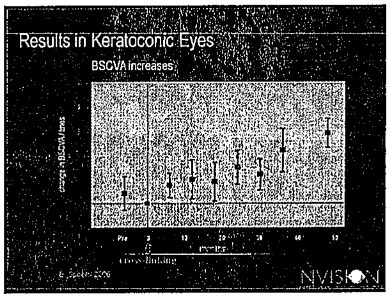
Topcon Study

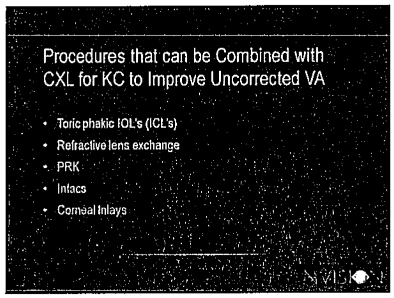
- Evaluate long term safety and effectiveness of the VEGA UV-A illumination system for CXL
- VEGA UV-A illumination system = UVA 370nm wavelength light source and the photosensitizer Riboflavin 0.1% /Dextran 20% solution
- Pretreat cornea with riboflavin 0.1% solution for 20 to 30 min before UVA exposure to saturate the corneal tissue with photosensitizer
- Low dose UVA irradiation of 3mW/cm2 for 30 min
- Release of reactive oxygen species (ROS) stimulates covalent bond formation between collagen fibers
- Induces cross-linking of collagen fibrils – increases tensile strength and diameter of fibrils

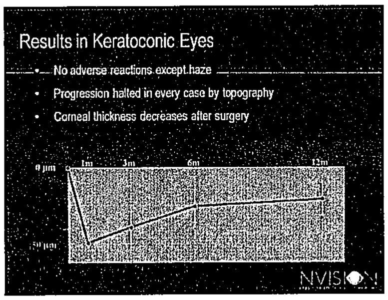
Results in Keratoconic Eyes

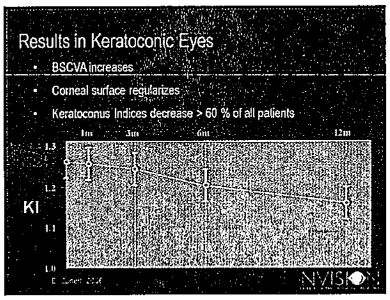


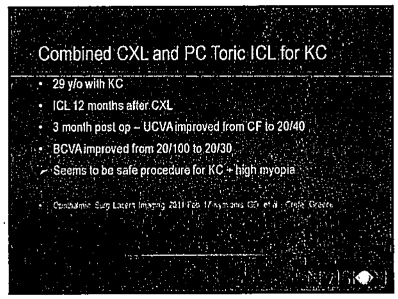

Results in Keratoconic Eyes
NVISION

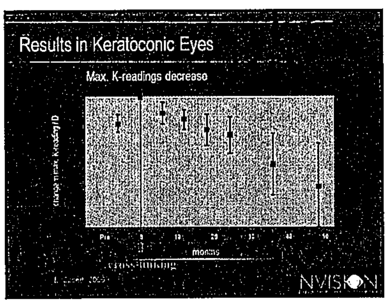

Results in Keratoconic Eyes
BSCVA increases
NVISION

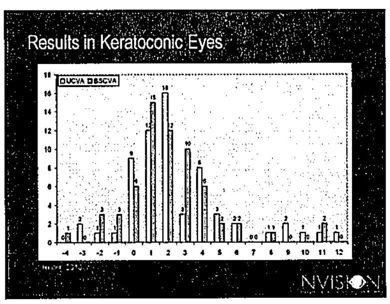

Procedures that can be Combined with CXL for KC to Improve Uncorrected VA
• Toric phakic IOL's (ICL's)
• Refractive lens exchange
• PRK
• Intacs
• Corneal Inlays
NVISION

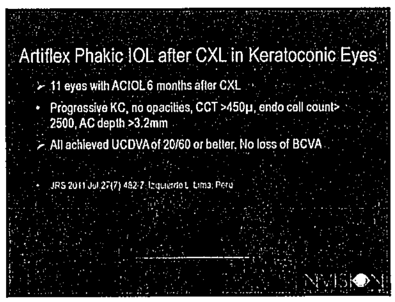

Results in Keratoconic Eyes
• No adverse reactions except haze
• Progression halted in every case by topography
• Corneal thickness decreases after surgery
1m
3m
6m
12m
NVISION


Results in Keratoconic Eyes
• BSCVA increases
• Corneal surface regularizes
• Keratoconus Indices decrease > 60 % of all patients
1m
3m
6m
12m
KI
NVISION


Combined CXL and PC Toric ICL for KC
• 29 y/o with KC
• ICL 12 months after CXL
• 3 month post op – UCVA improved from CF to 20/40
• BCVA improved from 20/100 to 20/30
➢ Seems to be safe procedure for KC + high myopia
NVISION


Results in Keratoconic Eyes
Max. K-readings decrease
months
NVISION


Results in Keratoconic Eyes
UCVA
BSCVA
NVISION


Artiflex Phakic IOL after CXL in Keratoconic Eyes
➢ 11 eyes with ACIOL 6 months after CXL
• Progressive KC, no opacities, CCT >450μ, endo cell count> 2500, AC depth >3.2mm
➢ All achieved UCDVA of 20/60 or better. No loss of BCVA
• JRS 2011 Jul 27(7) 482-7 Izquierdo L. Lima, Peru
NVISION

Sequential Versus Concurrent Kerarings (Intacs) Insertion and CXL for KC

- 16 eyes – 2 groups. One simultaneous and the other 6 to 14 months later, with Kerarings first
  - No difference between groups in UCDVA and CDVA
  - Simultaneous had more improvement in K's and better topos, but more stromal haze
- BJO 2011 Jan 95(1):37-41. El-Raggal TM. Cairo, Egypt

Comparison of Sequential vs. Same-day CXL and Topo-guided PRK for Treatment of KC

- 325 eyes. 127 sequential 6 months apart and 198 had simultaneous treatment. Mean f/u of 36 months (24 to 68 months)
  - Simultaneous group did better in improvement of UCVA and BSCVA.
- JRS 2009 Sep. Kanellopoulos AJ. Athens, Greece

Infectious Keratitis Treated with CXL

- 7 eyes with severe infectious keratitis treated with CXL
- 3 patients CTL users
- All had corneal melting
- Symptoms improved in all within 24 hours
- Corneal melting arrested and complete epithelialization
- Hypopyon resolved in 2 days
- Cornea 2010 Dec 29(12):1353-8 ... Sweden

Refractive and Topographic Results of Transepithelial CXL Treatment in Eyes with Intacs

- 25 eyes underwent Intacs implantation with subsequent CXL 4 months later
  - CXL after Intacs resulted in additional improvement in UCVA (1.2 lines), BCVA (0.36), sphere, cyl and K
- Cornea 2009 Aug. Ertan A et al. Ankara, Turkey

Stability of Simultaneous Topo-guided PRK and CXL for Progressive KC

- 2 eyes, 70% treatment of myopia and cyl with topo-guided T-CAT module of Allegretto Wave Eye-Q laser
- PRK first then CXL same session
- Epith healed in 5 days
- Cyl and aberrations reduced in first eye allowing CTL wear in 3 months. 36 months f/u showed improved myopia and K's
- 2nd eye emmetropic outcome 20/20 UCDVA remained stable for 30 months post op
- JRS 2010 ... 227-32 ... RR et al. Cleveland, Ohio

IOP Measurements after CXL in Eyes with KC

- 55 eyes. IOP by Goldman tonometry
- IOP increased at 6 and 12 months
  - Pre 9.95mmHg. At 6 months 11.40mmHg and at 12 months 11.35mmHg
- Change in IOP did not correlate with age, pre-op pach, or pre-op K readings
- Change in IOP related to increased corneal rigidity
- JCRS 2010 Oct 36(10):1724-7. ... et al. Crete, Greece

CXL to Stop Corneal Ectasia Exacerbated by RK

- UCVA and BCVA improved from 0.2 to 0.6 (20/100 to ~20/35) and from 0.3 to 0.8 (~20/65 to 20/25) in a 12-month follow-up
- Corneal topography and corneal symmetry index improved as well
- Seems to be a promising procedure
- Cornea 2011 Feb 30(2):225-6. Mazzotta C et al. Siena, Italy

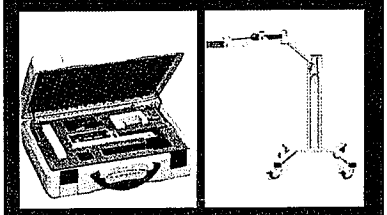
Simultaneous Topo-guided PRK and CXL for the Treatment of KC and PMD

- 12 patients
- Topo-guided ablations followed by CXL
- Mean UCVA increased from 20/1000 to 20/125 at 12 months
- BSCVA increased from 20/57 to 20/35
- Cyl decreased from 5.4 to 2.7
- Keratometric asymmetry decreased from 6.38 to 2.76
- Results were stable
- JRS 2010 Feb ... A et al. ...

Indications

- Progressive keratoconus
- Iatrogenic keratoconus
- Pelucid marginal degeneration
- Bullous keratopathy
- Prevention of kerateclasia
- Infecticus keratitis

CCL VARIO



Treatment Guidelines

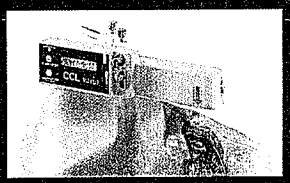
- Topography typical for KC or post-LASIK ectasia
- Minimum age: 14 years
- Kmax >= 47
- Minimum pach >=400
- Epithelium off – riboflavin induction 30 minutes
- UVA light for 30 minutes 3 mW/cm ; 9mm treatment diameter
- Recovery similar to PRK

NVISION

Application of UV

NVISION

CXL



NVISION

NVISION

Inclusion Criteria

- 12 years of age or older
- KC or post-refractive corneal ectasia
- Central or inferior steepening on Pentacam
- Topography consistent with KC or ectasia
- Kmax = or > 47.00D or I-S ratio 1.9 on Pentacam map or topographic map
- BSCVA 20/20 or worse
- Remove CTL – soft 3D, soft extended 1wk, soft toric 2wk, RGP 2 wk, hybrid lenses (synergEyes, rose K, Clear Kone) 2wk
- Sign informed consent

NVISION

Study Design

- Open-label
- Prospective
- Non-randomized
- Multicenter study
- Epithelium off – riboflavin pre-treatment
- UVA light for 5 minutes 18 mW/cm
- Follow up at 1 day, 1 week, 1 month, 3, 6, 12 months, and 24 months
- Pentacam, corneal topo, MR, uncorrected and BSCVA and IOP measured at baseline, 1, 3 ,6, 12, and 24months

NVISION

AVEDRO CXL

NVISION

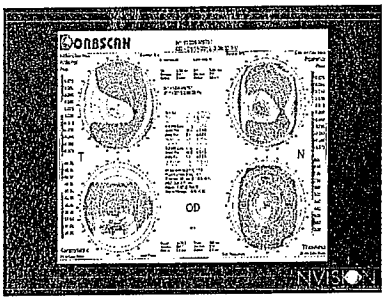
Exclusion Criteria

- Pachymetry <350µ measured by Pentacam
- Previous ocular condition such as HSV, HZO, Recurrent erosions, corneal melt or dystrophy
- Corneal scarring in area of treatment
- History of chemical injury or delayed healing
- Pregnancy or lactation during course of RX
- Nystagmus
- Ocular surface disease that would delay epithelial healing

NVISION

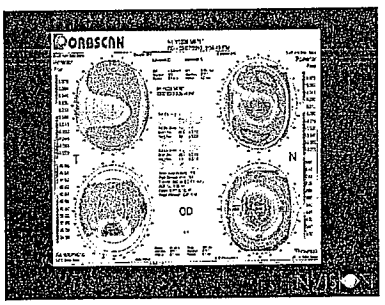
Post-op Care

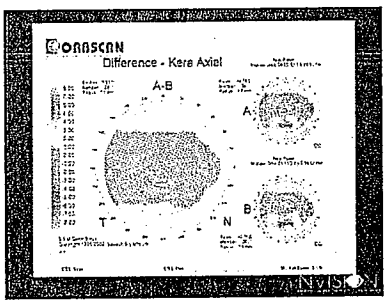
- Zymar, Zymaxid or Vigamox QID until epithelialized
- PF 1% QID for 2 weeks
- Ketorolac QID for up to 4 days
- Preservative free tears as needed
- Follow up visits at 1D, 1wk, 1,3,6,12 and 24 months
- K's, UCVA distance, BSCVA distance, MR, pentacam topography, pach, keratometry, Scheimpflug Photography
- IOP, endothelial cell count at 6mos, dilated fundus exam at 6mos, subjective complaint and VFQ-25 questionnaire

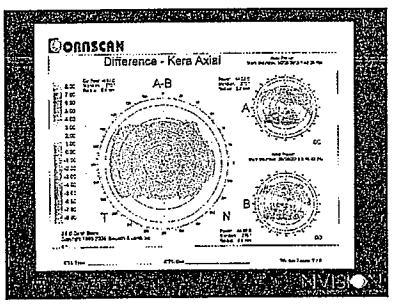


Results

MM		BCVA	UCVA
Pre	-1.50 – 4.25 x 072	20/25	
3 - mo	-1.50 – 4.75 x 078	20/25-2	

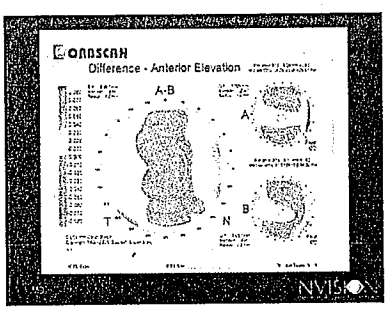


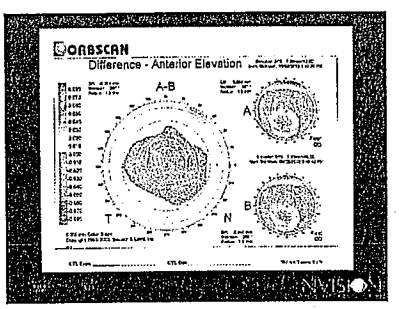




Results

MO		BCVA	UCVA
Pre	+0.50 – 1.00 x 040	20/40	20/60
3 - mo	+0.25-2.75 x 017	20/25	20/25-2





Results

- ER — BCVA UCVA
  - Pre: +0.50 – 3.50 x 017 — 20/25
  - 3 - mo: +0.75 – 4.50 x 016 — 20/30

NVISION

Results

- BC — BCVA UCVA
  - Pre: -1.50 -1.25 x 105 — 20/80 20/150
  - 3-mo: +1.50 -5.50 x 111 — 20/40+ 20/150

NVISION

Results

- WH — BCVA UCVA
  - Pre: pl – 1.50 x 122 — 20/30
  - 3-mo: +0.25 – 1.25 x 128 — 20/30
  - 6-mo: pl – 0.75 x 016 — 20/20-1

NVISION

ORBSCAN

Difference - Kera Axial

A-B

A

B

T

N

NVISION

ORBSCAN

Difference - Kera Axial

A-B

A

B

N

T

NVISION

ORBSCAN

Difference - Kera Axial

A-B

A

B

N

T

NVISION

ORBSCAN

Difference - Anterior Elevation

A-B

A

B

T

N

NVISION

ORBSCAN

Difference - Anterior Elevation

A-B

A

B

N

T

NVISION

ORBSCAN

Difference - Anterior Elevation

A-B

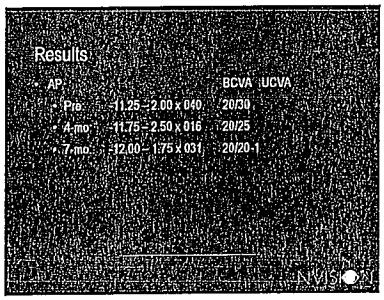
A

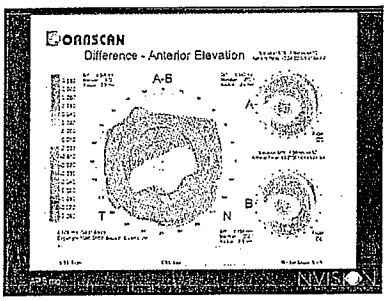
B

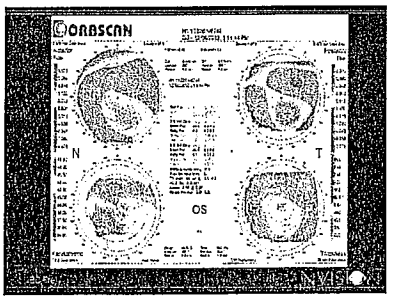
N

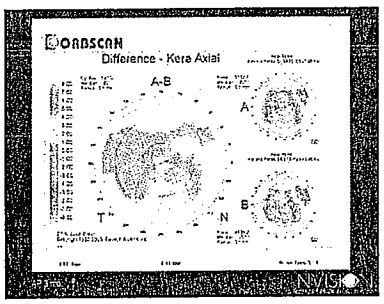
T

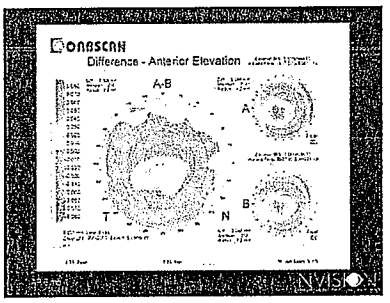
NVISION

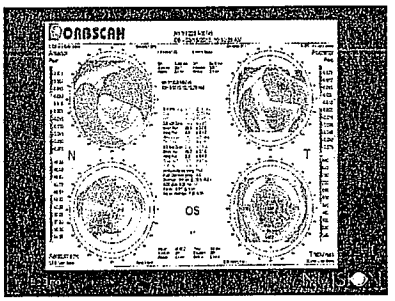

Results
AP
BCVA UCVA
Pre -11.25 -2.00 x 040 20/30
4-mo -11.75 -2.50 x 016 20/25
7-mo -12.00 -1.75 x 031 20/20-1

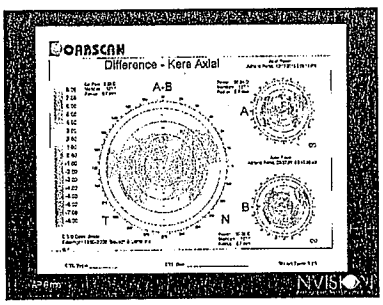

ORBSCAN
Difference - Anterior Elevation
A-B
A
B
T
N

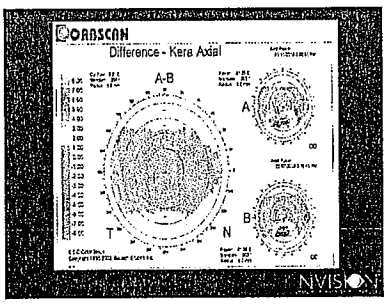

ORBSCAN
N
T
OS

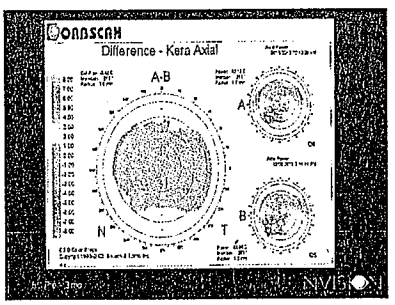

ORBSCAN
Difference - Kera Axial
A-B
A
B
T
N


ORBSCAN
Difference - Anterior Elevation
A-B
A
B
T
N


ORBSCAN
N
T
OS

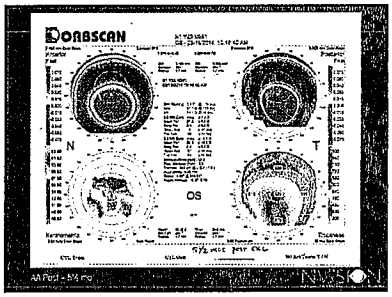

ORBSCAN
Difference - Kera Axial
A-B
A
B
T
N


ORBSCAN
Difference - Kera Axial
A-B
A
B
T
N


ORBSCAN
Difference - Kera Axial
A-B
A
B
T
N

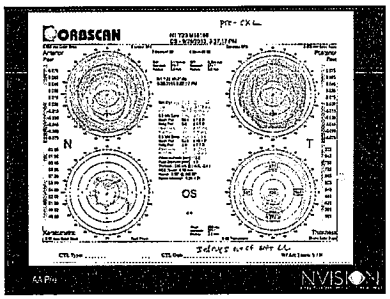
Results

- AA
  - Pre: -11.25 – 2.00 x 040 BCVA UCVA 20/30
  - 4-mo: -11.75 – 2.50 x 016 20/25
  - 7-mo.: -12.00 – 1.75 x 031 20/20-1



Simultaneous LASIK and CXL

- Contralateral eye study: CXL in non-dominant eye
- Post ablation, -1 min Riboflavin soak then rinse and restore flap then 75 second UVA exposure 30mW/cm2
- VA, K, endo cell count, confocal microscopy
- LASIK and LASIK Extra (LASIK + CXL) were equally safe with equal results

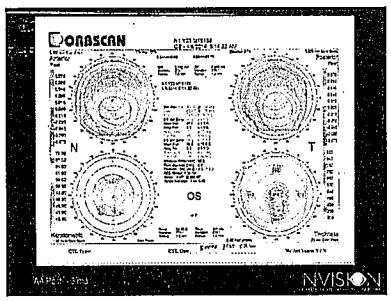


CXL Outcomes: Review

- CXL effective in halting progression of KC
- Reduce max K >2D
- Post-op SEQ reduced by average of 1D
- No loss of BCVA
- Reduces corneal and total aberrations
- No decrease in endo cell density
- Postpone need for LKP and PKP

Topo-guided CXL as treatment for refractive error

- Based on premise the CXL changes shape of cornea
- More stable?
- First choice for irregular corneas without KC (or if)
- Requires combined mapping delivery device



CXL Outcomes: Review

- 17 year worldwide experience
- RARELY improves VA
- RGP wear will NOT SLOW or PREVENT progression of disease, only mask it
- Early treatment is key.

Patient Management

- Progressive disease
  - Topography every 3-6 months
  - Eye rubbing accelerates disease
  - Disease slows after age 40
- Very young patients URGENT treatment
- Steep Ks > 54D URGENT treatment and HIGHER RISK

Patient Counseling

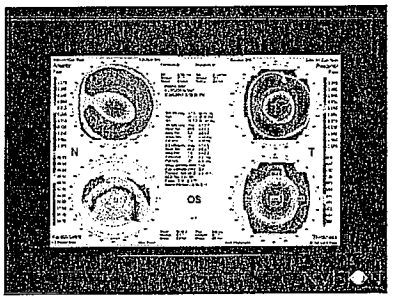
1. RGP wear or specialty KC CLs provide good vision but DO NOT STOP the PROGRESSION of the disease
2. Refer these patients for CXL stabilization; then refit with CLs
3. If YOUNG, then URGENT referral, even if mild as progression can occur rapidly and there is NO ability to regain the loss.
4. Important to emphasize to patients that KC is a progressive disease; CXL is for stabilization and to prevent progression NOT vision improvement
5. CXL may be combined with other procedures to improve vision – PRK & ICRS
6. CXL may need to be repeated infrequently (<5%)

NVISION

SUMMARY

1. 1 YEAR history worldwide
2. CXL is GOLD STANDARD Treatment for Keratoconus > Stops Progression in 95%
3. SURGEONS would treat their OWN FAMILY
4. CXL does NOT IMPROVE VISION
5. CXL will NOT recover lost vision; so early treatment is BEST
6. RGP wear will NOT SLOW or PREVENT progression of disease

NVISION



REFERRAL FOR CXL

CRITICAL UNDERSTANDING

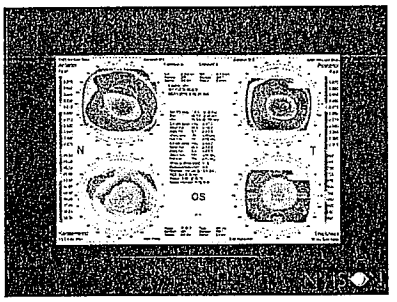
- Important to emphasize to patients that KC is a progressive disease; CXL is for stabilization and to prevent progression NOT vision improvement
- CXL may be combined with other procedures to improve vision – PRK & ICRS
- CXL may need to be repeated infrequently

NVISION

FDA Status

- Recently recommended for approval
- Pricing?
- Insurance re-imbursement
- Off-label (study) procedures will likely continue

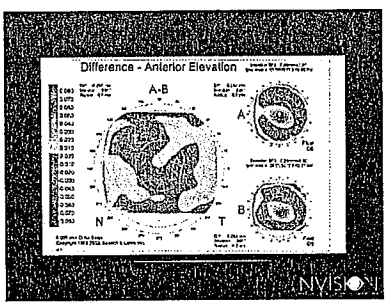
NVISION



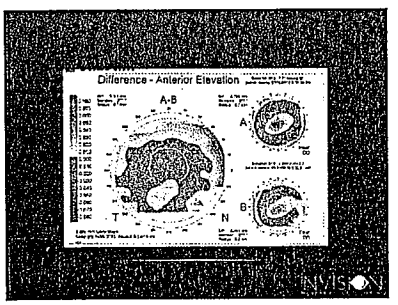
SUMMARY

1. 1 YEAR history worldwide
2. CXL is GOLD STANDARD Treatment for Keratoconus > Stops Progression in 95%
3. SURGEONS would treat their OWN FAMILY
4. CXL does NOT IMPROVE VISION
5. CXL will NOT recover lost vision; so early treatment is BEST
6. RGP wear will NOT SLOW or PREVENT progression of disease

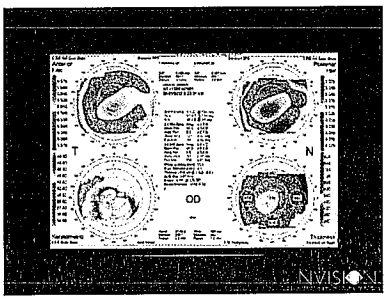
NVISION

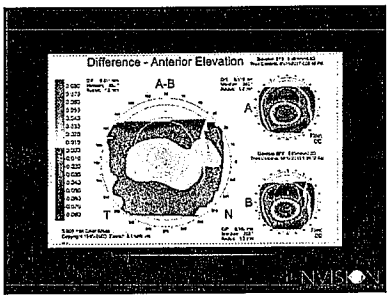


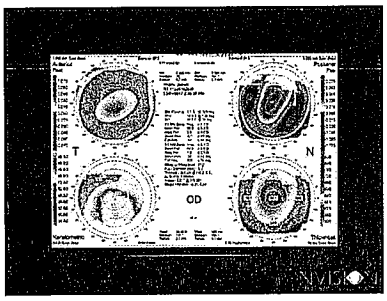
NVISION

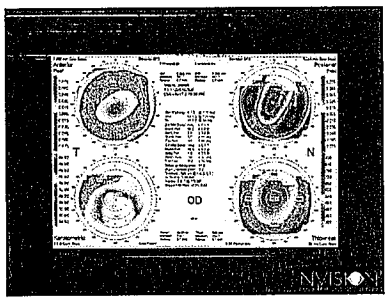


NVISION


T
N
OD
NVISION


Difference - Anterior Elevation
A-B
A
B
T
N
NVISION


T
N
OD
NVISION


T
N
OD
NVISION

NVISION
LASER EYE CENTERS | THE EYE DOCTORS' #1 CHOICE

Franklin W. Lusby,M.D.

Medical Director, NVISION Laser Eye Centers

Dr. Franklin Lusby is a board certified ophthalmologist and began specializing in ophthalmology in 1980. By 1989, the focus of his practice had become refractive surgery. For years now, Dr. Lusby has been considered an expert in LASIK, performing more than 250 procedures a month. Although Custom LASIK with Intralase comprises the bulk of his practice, he also performs other vision correction procedures such as PRK. Dr. Lusby achieved board certification in 1985. As of 2010 he has performed over 45,000 refractive procedures.

In 1995, he was certified by Chiron to perform ALK, a complex precursor of LASIK. This led to a LASIK fellowship with Stephen Slade, M.D., in January, 1996. The fellowship took place in Shanghai, China, since many of the latest techniques in LASIK were not available in the United States at that time.

Born and raised in Maryland, Dr. Lusby graduated Magna Cum Laude from Columbia Union College in Takoma Park, Maryland. He then attended the prestigious Loma Linda University School of Medicine in Loma Linda, California. He served his internship at Malden Hospital, which is affiliated with Boston University School of Medicine in Massachusetts.

Dr. Lusby completed the Basic Science Course for Ophthalmology at the Massachusetts Eye and Ear Infirmary at Harvard Medical School in Boston before returning to the west coast for his residency at White Memorial Medical Center in Los Angeles. Following this, he completed a sixteen month fellowship in Anterior Segment Surgery with James McCaffery, M.D., at Glendale Eye Medical Group.

Dr. Lusby served as Chief of the Ophthalmology Section at Glendale Adventist Medical Center from 1992 until 1996. Distinguished among his peers, he has written numerous articles which have appeared in medical publications such as the Journal of Cataract and Refractive Surgery, as well as Current Opinion in Ophthalmology. Dr. Lusby is frequently invited as a guest lecturer. He often supervises new surgeons as they develop their refractive surgery techniques. "Being in charge of a portion of the education of young doctors is personally rewarding and really keeps you on your toes."

"Almost every time I see a new patient, I discover that I have cared for their spouse, sibling or friend. As a physician, this confidence of referral is the greatest compliment I can receive; I feel fortunate to be in such a gratifying profession. It never gets old hearing a patient remark on the clarity of their vision and how it has improved their quality of life." Franklin W. Lusby, M.D.

1-877-91-NVISION | NVISIONCenters.com

Biography

Education

1974 B.A. in Chemistry, Magna Cum Laude, Columbia Union College
1978 M.D., Loma Linda University School of Medicine, Loma Linda, CA

Professional Training

1979 Internship, Malden Hospital, Boston University School of Medicine
1979 Fellowship, Massachusetts Eye and Ear, Harvard Medical School
1983 Residency in Ophthalmology, White Memorial Medical Center, Los Angeles, CA

Fellowships

1984 Extracapsular Cataract Extraction and Intraocular Lens Implantation
James M. McCaffery, M.D. Glendale Eye Medical Group

Board Certification

1985 American Board of Ophthalmology

Professional Affiliations

Fellow - American Academy of Ophthalmology
Member - American Society of Cataract and Refractive Society
Charter Member – American College of Eye Surgery
Member – David Paton Society
Member – Research to Prevent Blindness Ophthalmological Society
Member – Orange County Medical Society

Special Interests & Recognition

- America's Top Ophthalmologist Award
- Adjunct Clinical Professor at SCCO (Southern California College of Optometry)
- Mentor: UCSD Health Professions Preparation Program
- Missions: Refractive surgeon/instructor with Bishop-Ballesteros Mission Project.
Flying doctor with Liga International.