



## INCIDENCE AND PREVALENCE OF KERATOCONUS

**1:2000<sup>1</sup>**

- Based on a registration study in Olmsted County, Minnesota, conducted between 1935-1982; diagnosis was based on the detection of scissors reflex with retinoscopy and keratometry outcomes

Reference	Prevalence	Geography
Kennedy et al. 1986	0.05% or 1:2000	US
Jonas et al. 2009	2.3%	India
Milodot et al. 2011	2.3%	Israel
Xu et al. 2012	0.9%	China
Hashemi et al. 2014	2.5%	Iran
Godefrooij et al. 2017	0.26% or 1:375	Netherlands
Torres Netto et al. 2018	4.79%	Saudi Arabia
Chan et al. 2020	1.2% or 1:84	Australia
Hashemi et al. 2020*	0.14% or 1:700	Global Meta-Analysis

**1:375<sup>2</sup>**

- 4.4 million patients in the Netherlands from a mandatory health insurance data base; topography utilized

Hapshemi H, et al. Cornea. 2020 Feb 13;39(2):263-70.

1. Kennedy MK, Bourne WM, Dyer JA, Am J Ophthalmol 1986;101(1):207-71.  
2. Godefrooij JA, et al. American journal of ophthalmology. 2017 Mar 1;173:149-72.

## CORNEAL TOPOGRAPHY IN KC

Normal cornea

Forme fruste (pre-clinical)

Nipple cone (minor central bulging)

Oval cone (sagging bulging)

Globus cone (widespread bulging)

## ECONOMIC IMPACT OF KC

- Modeled a hypothetical cohort of people with clinically significant KC
- Defined by the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study
- Included costs of
  - Clinic visits
  - Fitting fees
  - Contact lenses
  - Surgical procedures
  - Complications
- Survival curves of corneal transplants and complications
- Modeled using data from the 2007 Australian Graft Registry

**The Lifetime Economic Burden of Keratoconus: A Decision Analysis Using a Markov Model**

RONALD L. KEBINTSCH, STEVEN M. KYMES, JEFFREY J. WALLINE, AND MAE O. GORDON

Kebintsch RL, Kymes SM, Walline JJ, Gordon MO. The lifetime economic burden of keratoconus: a decision analysis using a markov model. Am J Ophthalmol. 2011; Mar;151(3):788-773. doi: 10.1016/j.ajo.2010.10.034. Epub 2011 Feb 18. PMID: 21310384. PMCID: PMC4714341

## ECONOMIC IMPACT OF KC

- Expected value of the lifetime cost of the treatment of KC over myopia **\$25,168**
- Factors that most influenced the lifetime cost
  - Probability of initial corneal transplant
  - Subsequent regrant
- Combining corneal transplant with the significantly impaired vision-related QoL and relatively young onset of disease
- Expected lifetime cost of treatment of KC
  - Significant cost to patients and payors
- Economic burden of the treatment of KC represents a significant public health concern

**The Lifetime Economic Burden of Keratoconus: A Decision Analysis Using a Markov Model**

RONALD L. KEBINTSCH, STEVEN M. KYMES, JEFFREY J. WALLINE, AND MAE O. GORDON

	Mean	Median	Number Occurrence
Total cost	\$24,168	\$19,247	\$17,198
Cost of non-surgical treatment	\$15,024	\$9847	\$9702
Age of death (years)	77	77	0.97
Time with disease (years)	37	37	0.4
Number of penetrating keratoplasties in non-working eye	1.14	0.48	1.15
Number of penetrating keratoplasties in both-working eye	0.43	0	0.9

Parameter	Base Case Value of Parameter	Parameter Value in Sensitivity Analysis	Percentage Change in Lifetime Cost
Cost of 1 contact lens	\$111	\$50	(17)%
		\$300	(30)%
Cost of penetrating keratoplasty	\$7000	\$6000	(14)%
		\$10000	(18)%
Discount rate	3%	5%	(20)%
		1%	(2%)
Probability of complication after penetrating keratoplasty	48%	20%	(17)%
		70%	(14)%
Probability of regrant	20%	20%	(0)%
		0%	(23)%
Yearly probability of requiring a penetrating keratoplasty	Function	10%	(13)%
		100%	(23)%

Kebintsch RL, Kymes SM, Walline JJ, Gordon MO. The lifetime economic burden of keratoconus: a decision analysis using a markov model. Am J Ophthalmol. 2011; Mar;151(3):788-773. doi: 10.1016/j.ajo.2010.10.034. Epub 2011 Feb 18. PMID: 21310384. PMCID: PMC4714341

## ECONOMIC BURDEN OF KC

Patients pay more than **\$25,000** for cost of care over their lifetime post-diagnosis

46% of patients pay more than **\$1,000** annually for treatment costs

Kebintsch RL, Kymes SM, Walline JJ, Gordon MO. The lifetime economic burden of keratoconus: a decision analysis using a markov model. Am J Ophthalmol. 2011; Mar;151(3):788-773. doi: 10.1016/j.ajo.2010.10.034. Epub 2011 Feb 18. PMID: 21310384. PMCID: PMC4714341

## CHANGES IN THE QUALITY-OF-LIFE OF PEOPLE WITH KERATOCONUS

Changes in the Quality-of-Life of People with Keratoconus

STEVEN M. KYMES, JEFFREY J. WALLINE, MAE O. GORDON, JEFFREY HERRICK, AND MAE O. GORDON, ON BEHALF OF THE COLLABORATIVE LONGITUDINAL EVALUATION OF KERATOCONUS STUDY PARTICIPANTS

- Evaluated changes that occurred in V-QoL over 7 years of follow-up.
- Prospective study
- 1,166 participants for seven years

**TABLE 3. Overall Clinical Outcomes and Vision-Related Quality of Life (V-QoL) of Follow-up for 95% Collaboration Longitudinal Evaluation of Keratoconus Study Participants**

Variable	N	Baseline Mean (SD or 95% CI)	7y Mean (SD or 95% CI)	% Change
Visual acuity (logMAR) (log corrected)	955	0.2 (0.05)	0.19	(-11.1%)
Distance acuity	955	62 (24.6)	61	(-1.6%)
Near acuity (near vision) (log uncorrected)	955	3.8 (0.3)	3.7	(-2.6%)
Visual function (VF) (log uncorrected)	955	103 (40.0)	101	(-14.4%)
Distance VF (log uncorrected)	955	30 (14.1)	29	(-7.2%)
Near VF (log uncorrected)	955	73 (25.2)	72	(-13.2%)
Distance quality of vision (QoV)	955	38 (16.4)	37	(-2.6%)
Near QoV	955	64 (21.4)	63	(-15.1%)
Overall QoV	955	51 (18.1)	50	(-15.1%)
Distance VF (log uncorrected)	955	30 (14.1)	29	(-7.2%)
Near VF (log uncorrected)	955	73 (25.2)	72	(-13.2%)
Distance QoV	955	38 (16.4)	37	(-2.6%)
Near QoV	955	64 (21.4)	63	(-15.1%)
Overall QoV	955	51 (18.1)	50	(-15.1%)
Distance VF (log uncorrected)	955	30 (14.1)	29	(-7.2%)
Near VF (log uncorrected)	955	73 (25.2)	72	(-13.2%)
Distance QoV	955	38 (16.4)	37	(-2.6%)
Near QoV	955	64 (21.4)	63	(-15.1%)
Overall QoV	955	51 (18.1)	50	(-15.1%)

Kymes SM, Walline JJ, Quirk K, et al. CLEK study group. Changes in the quality-of-life of people with keratoconus. Allerg Immunol 2008 Apr;54(4):611-617. doi: 10.1030/ajm.2007.11.017. Epub 2008 Jan 28.

### CHANGES IN THE QUALITY-OF-LIFE OF PEOPLE WITH KERATOCONUS

- All scales showed modest decline except ocular pain and mental health.
- Baseline factors were not associated with longitudinal change in NEI-VFQ scores.
- Significantly larger declines in V-QoL associated with
  - 10 letter decline in high-contrast binocular VA
  - 3.00D increase in corneal curvature
- In multivariate analysis, factors associated with a 10-point decline in NEI-VFQ scale scores.
- ★ KCN is associated with significantly impaired V-QoL that continues to decline over time.

Changes in the Quality-of-Life of People with Keratoconus

SEVDIA AYDIN KURMA,<sup>1</sup> AHMET ALTUN,<sup>2</sup> TUĞHA GENÇGAZ,<sup>3</sup> SEREN AKKAYA,<sup>4</sup> AND TOMRIS SENGEL<sup>5</sup>

AND WHO IS LONDON, ON BEHALF OF THE COLLABORATING COLLEAGUES AT INSTITUTIONS OF RELATIVES VISITORY GROUP

TABLE 4. Odds Ratios for a 10-Point Decline in NEI-VFQ Scale Scores over Seven Years after Adjustment for Age, Education, Baseline NEI-VFQ Scale Score, Baseline Reading Speed, Baseline Binocular VA, and Change in Binocular VA

Factor	No. with Event	Relative Risk (95% CI)	95% CI	Relative Risk (95% CI)	95% CI	Relative Risk (95% CI)	95% CI
Gender (male)	100 (22)	1.01 (0.49-2.08)	0.49-2.08	1.01 (0.49-2.08)	0.49-2.08	1.01 (0.49-2.08)	0.49-2.08
Age (years)	100 (22)	0.98 (0.94-1.02)	0.94-1.02	0.98 (0.94-1.02)	0.94-1.02	0.98 (0.94-1.02)	0.94-1.02
Year education	100 (22)	1.02 (0.97-1.07)	0.97-1.07	1.02 (0.97-1.07)	0.97-1.07	1.02 (0.97-1.07)	0.97-1.07
Baseline reading speed (words per minute)	100 (22)	1.01 (0.99-1.03)	0.99-1.03	1.01 (0.99-1.03)	0.99-1.03	1.01 (0.99-1.03)	0.99-1.03
Baseline binocular VA (logMAR)	100 (22)	1.02 (0.97-1.07)	0.97-1.07	1.02 (0.97-1.07)	0.97-1.07	1.02 (0.97-1.07)	0.97-1.07
Change in binocular VA (logMAR)	100 (22)	1.02 (0.97-1.07)	0.97-1.07	1.02 (0.97-1.07)	0.97-1.07	1.02 (0.97-1.07)	0.97-1.07
Change in corneal curvature (D)	100 (22)	1.02 (0.97-1.07)	0.97-1.07	1.02 (0.97-1.07)	0.97-1.07	1.02 (0.97-1.07)	0.97-1.07
Constant	100 (22)	0.98 (0.94-1.02)	0.94-1.02	0.98 (0.94-1.02)	0.94-1.02	0.98 (0.94-1.02)	0.94-1.02
Model	100 (22)	0.98 (0.94-1.02)	0.94-1.02	0.98 (0.94-1.02)	0.94-1.02	0.98 (0.94-1.02)	0.94-1.02
Adjusted R <sup>2</sup>	100 (22)	0.08		0.08		0.08	

### QUALITY OF LIFE IN PATIENTS WITH KC

- National Eye Institute Visual Function Questionnaire-25 (NEI-VFQ-25)
  - 30 patients with KCN
  - 20 RGP wearers
  - 10 non-contact lens wearers
- 30 healthy patients (control group)

Research Article

#### Vision Related Quality of Life in Patients with Keratoconus

Sevda Aydin Kurma,<sup>1</sup> Ahmet Altun,<sup>2</sup> Tuğha Gençgaz,<sup>3</sup> Seren Akkaya,<sup>4</sup> and Tomris Sengel<sup>5</sup>

<sup>1</sup>Fatih Sultan Mehmet Education and Training Hospital, Ophthalmology Clinics, Ornezi Park 2. Stage No. 2, Kadiköy, Istanbul, Turkey; <sup>2</sup>Yildirim Beyazıt Hospital, Ophthalmology Clinics, 34797 Istanbul, Turkey; <sup>3</sup>Atilla University Florence Nightingale Hospital, Ophthalmology Clinics, 34797 Istanbul, Turkey

Table 1. Demographic characteristics of the patients (age, gender, education, and contact lens use) and high contrast (HCD) and low contrast (LCL) acuity (letters) according to the groups (\*P < 0.05, \*\*P < 0.001)

	Keratoconus group	Control group	P
Age	28.36 ± 5.64	30.11 ± 6.92	0.375
Gender	50 (50%)	50 (50%)	0.986
Education level	50 (50%)	50 (50%)	0.986
Primary school	2 (2%)	6 (6%)	0.206
High school	20 (20%)	11 (11%)	0.362
University	27 (27%)	32 (32%)	0.542
Contact lens wear			
None	10 (33%)	0	0.001**
Soft	10 (33%)	0	0.001**
Rigid	10 (33%)	0	0.001**
Visual acuity	6/7.5 (0.31) ± 0.21 (logMAR)	6/6 (0.00) ± 0.02 (logMAR)	0.001**
High contrast	6/4.5 (0.25) ± 0.15 (logMAR)	6/6 (0.00) ± 0.02 (logMAR)	0.001**
Low contrast	20/20 (0.30) ± 0.12 (logMAR)	20/20 (0.00) ± 0.02 (logMAR)	0.001**

### QOL KC

- CL wearers had better BCVA compared with non-CL wearers (P = 0.028)
- ★ Vision related quality of life worse in patients with KC
  - Success with CLs and maintaining better visual acuity may improve vision related quality of life.

Research Article

#### Vision Related Quality of Life in Patients with Keratoconus

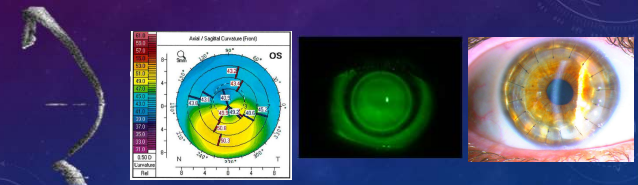
Sevda Aydin Kurma,<sup>1</sup> Ahmet Altun,<sup>2</sup> Tuğha Gençgaz,<sup>3</sup> Seren Akkaya,<sup>4</sup> and Tomris Sengel<sup>5</sup>

<sup>1</sup>Fatih Sultan Mehmet Education and Training Hospital, Ophthalmology Clinics, Ornezi Park 2. Stage No. 2, Kadiköy, Istanbul, Turkey; <sup>2</sup>Yildirim Beyazıt Hospital, Ophthalmology Clinics, 34797 Istanbul, Turkey; <sup>3</sup>Atilla University Florence Nightingale Hospital, Ophthalmology Clinics, 34797 Istanbul, Turkey

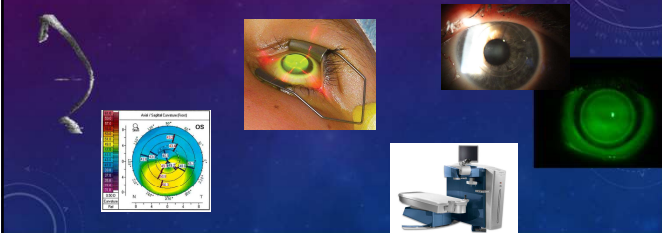
Table 2. NEI-VFQ-25 subscale scores according to the groups (\*P < 0.05, \*\*P < 0.001)

NEI-VFQ-25 subscale	Keratoconus group	Control group	P
General health	65.0 ± 20.8	79.7 ± 17.8	0.001**
General vision	60.2 ± 24.4	80.7 ± 19.3	0.001**
Visual pain	54.8 ± 23.8	73.8 ± 17.8	0.001**
Near vision	76.0 ± 23.0	83.5 ± 13.6	0.004**
Distance vision	54.8 ± 19.0	78.7 ± 8.7	0.001**
Social functioning	63.0 ± 24.0	80.8 ± 8.8	0.001**
Adapted health	67.0 ± 27.0	80.8 ± 8.8	0.001**
Role difficulties	77.2 ± 26.4	96.8 ± 7.8	0.004**
Dependence	64.7 ± 26.4	80.8 ± 8.8	0.076
Color vision	81.0 ± 17.0	87.6 ± 6.6	0.024
Peripheral vision	80.7 ± 17.4	94.1 ± 9.3	0.020**
Overall composite score	75.2 ± 17.2	93.2 ± 5.6	0.001**

### KCN: Old Mantra



### KCN: New Mantra



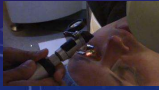

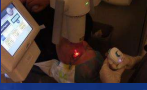


### THE PROCEDURE



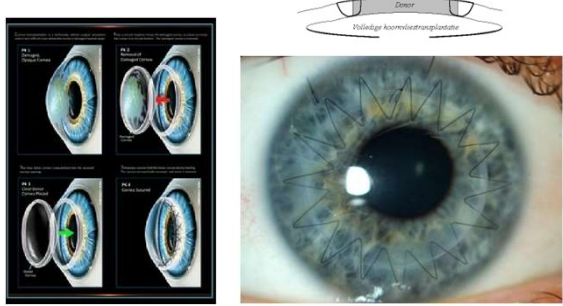


### FDA-APPROVED I-LINK CROSS-LINKING PROCEDURE SUMMARY

1. Remove epithelium. 
2. Soak cornea with Photexa® Viscous (riboflavin 5-phosphate in 20% dextran ophthalmic solution). 
  - ✓ 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 Photexa (riboflavin 5-phosphate in ophthalmic solution) until the corneal thickness increases to at least 400 µm.
5. Irradiate for 30 minutes. 
  - ✓ Continue applying Photexa Viscous (riboflavin 5-phosphate in 20% dextran ophthalmic solution) during irradiation.

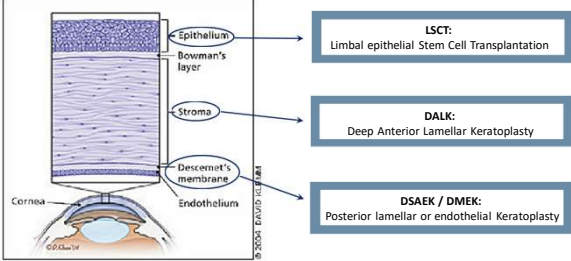
## CORNEAL TRANSPLANTATION

### Full thickness or penetrating keratoplasty (PK)



The image shows diagrams of donor and recipient corneas, and clinical photographs of the eye during the procedure. Labels include 'Donor', 'Tissue', and 'Dilatige hornelstransplante'.

### Modern day lamellar transplant surgery: Anatomically targeted replacement of corneal tissue

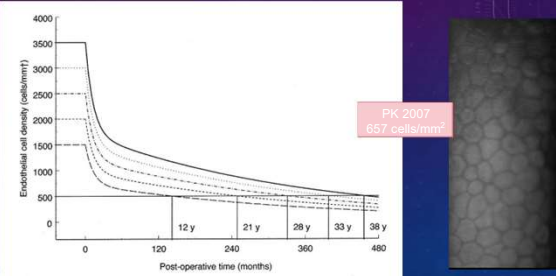


The diagram illustrates the layers of the cornea: Epithelium, Bowman's layer, Stroma, Descemet's membrane, and Endothelium. Targeted replacement techniques are shown:

- LSCT:** Limbal epithelial Stem Cell Transplantation (targeting Epithelium)
- DALK:** Deep Anterior Lamellar Keratoplasty (targeting Epithelium, Bowman's layer, and Stroma)
- DSAEK / DMEK:** Posterior lamellar or endothelial Keratoplasty (targeting Descemet's membrane and Endothelium)

### Graft survival – how long the graft stays clear

Lower endothelial cell counts and hypoxia




The graph shows Endothelial cell density (cells/mm²) on the y-axis (0 to 4000) and Post-operative time (months) on the x-axis (0 to 480). The density starts at approximately 3500 cells/mm² at 0 months and decreases over time. A pink box highlights a specific data point: PK 2007, 657 cells/mm².

Side credit: Carola Kosonen MD PhD  
 Article 3: Predicting endothelial cell loss and long-term graft survival. Invest Ophthalmol Vis Sci. 2003;44(18):326-333.

### RISK OF GRAFT REJECTION

- Higher risk
  - Vascularized corneas
  - Previous rejection
  - Herpetic and ocular surface disease
- Lower risk
  - Non-vascularized corneas
- Endothelial rejection most common
  - Use corticosteroid drops for at least one year
  - Life long risk of rejection



Labels for the images: Superior neovascularisation and edema, and Khodadoust line.

Side credit: Carola Kosonen MD PhD

### RISK OF GRAFT REJECTION

- Require routine monitoring, at least twice a year
- Recognize rejection and refer as emergency
- Any sign of inflammation (often atypical such as ciliary redness, cells in the anterior chamber, precipitates, edema)
- Reevaluate CL fit and material
  - Ensure that the corneal physiology and the ocular surface are not disturbed by the lens (avoid hypoxia, inflammation, neovascularization)
- Inform patient of urgent symptoms = **redness, photophobia, pain, decreased visual acuity**
- Symptoms can occur anytime during lifetime

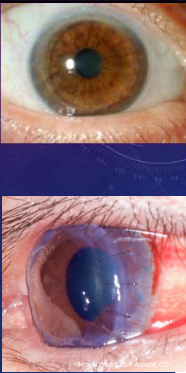


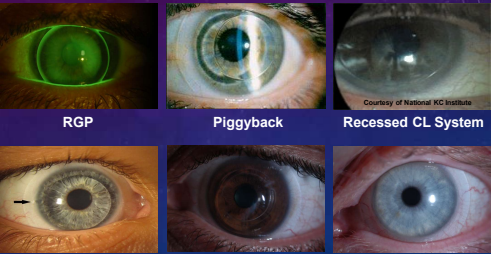
Image credit: Cadena Kononov MD PhD

### IRREGULAR CORNEAS: WHERE DO I START?



Slide credit: Clark Chang, OD

### IRREGULAR CORNEAS: WHERE DO I START?




RGP      Piggyback      Recessed CL System  
Courtesy of National KC Institute

Soft/Soft KC      Hybrid      Scleral

Slide credit: Clark Chang, OD

### WHY CHOOSE A CORNEAL GP?

- Rigid optics → Good vision!
- Wide range of parameters
- Easily obtained

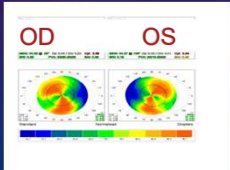


### Carrie

---

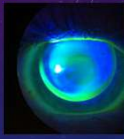
- 31 year old female
- Resident physician
- Eyes dry with current contact lenses
- History of GP contact lens wear for 15 years
- History of atypical keratoconus

OD	VA (CLs)	OS
20/30		20/250
46.49 / 44.30 / 030 Irregular Astigmatism	Topo Sim Ks	46.63 / 44.38 / 146 Irregular Astigmatism
-9.00+6.00x061 20/40-1	Refraction	-8.25+6.00x112 20/50
476	Pachymetry	471




OD		OS
Normal	L/L	Normal
1+ chemosis	Conjunctiva	1+ chemosis
Mild thinning Faint Fleisher Ring	K	Mild thinning Faint Fleisher Ring
Deep and Quiet	A/C	Deep and Quiet
Clear	Lens	Clear
0.35	C/D	0.30
Normal	Macula	Normal
Normal	Peripheral Retina	Normal

OD	CL FITTING	OS
45.62 / -3.25 / 9.5 Green	Gas Permeable Kone Design	46.00 / -3.25 / 9.2 Blue
	Vision Good	
	Comfort Good able to wear lenses all day	
Lid attachment, centered, alignment, good peripheral fit Good movement	Fit	Lid attachment, centered, alignment, good peripheral fit Good movement
20/25+2	VA	20/20
Plano	SOR	Plano




### WHY CHOOSE A CORNEAL GP?

- Corneal lenses are less costly and often less complex than other CL options



### MATERIAL CONSIDERATIONS

- High oxygen, but stable, materials
  - Usually high minus powers
  - Movement may be compromised
  - Stability important for good vision
    - Flexure
    - Warpage

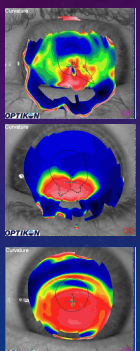


### DESIGN CONSIDERATIONS

- Reverse Geometry Design
  - Oblate (periphery steep) cornea
    - Eg. post-RK
- Prolate Design
  - Prolate (centrally steep) cornea
    - Ex. keratoconus

### CONE TYPES

- Nipple (or central)
- Oval (usually inferior-temporal)
- Globus (or generalized)
- PMD (near lower limbus)
- Undefinable?



## ASSESSING THE CONE

- Where?
- How large?
- How steep?



## ASSESSING THE CONE

- Where?
  - Central: 28.7%
  - Off-center:
    - Below horizontal: 87.8%
- How large?
  - Nipple (3 mm): 28.7%
  - Oval (3-5.5 mm): 44.3%
  - Globus (5.0 mm or above): 6.7%
- How steep?

## BASIC FITTING CONCEPTS

- Small, central cone (eg. Nipple cone)
  - small diameter (<9.9 mm)
- Larger, more decentered cone (eg. Oval cone)
  - larger diameter (10.0-12.0 mm)
- REALLY BIG or extremely decentered cone (eg. Globus or PMD)
  - really big!
    - Scleral / Mini-scleral design

## BASIC FITTING CONCEPTS

- The steeper the cone:
  - Steeper the base curve
  - Smaller the back optic zone



## DIAGNOSTIC FITTING

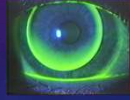
- Start with central (apical) fit
  - Look for light (feather) touch





## DIAGNOSTIC FITTING

- Start with central fit
- Second: peripheral fit
  - Only after central fit achieved
  - Flatten or steepen accordingly

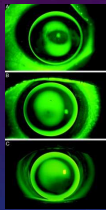


## CORNEAL GP COMFORT & KERATOCONUS

- No association with disease severity
- No association with apical (central) fitting relationship
- Minimal peripheral clearance may decrease comfort

Variables Affecting Rigid Contact Lens Comfort in the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study *Optom & Vis Sci*, March, 2004 81(3):182-188.

## PERIPHERAL CLEARANCE



Minimal acceptable

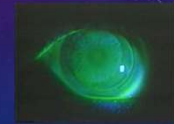
Average

High acceptable

Variables Affecting Rigid Contact Lens Comfort in the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study *Optom & Vis Sci*, March, 2004 81(3):182-188.

## DIAGNOSTIC FITTING

- Key performance characteristics
  - Centration
    - Pupil within back optic zone
  - Movement
    - "adequate" lens movement



## PIGGYBACK (PB) LENS SYSTEM

- Definition
  - A corneal GP lens is placed over a soft lens
    - GP provides good vision
  - Soft:
    - Protects cornea
    - Improves comfort



## PIGGYBACK FITTING PRINCIPLES

- Improved GP and soft lens materials provide better oxygen permeability and prevent corneal edema and hypoxia
- Use high DK RGP lens and daily replacement soft lenses
  - Plus powered soft lens - flatten the RGP fit
  - Minus powered soft lens - steepen the RGP fit



## ADVANTAGES

- Better comfort than standard RGP CL
- No corneal compromise or complications
- No hypoxia
- Improved comfort compared with RGP lens alone
- Same or increased wearing time vs. the RGP lens worn alone
- Same or better visual acuity

## DISADVANTAGES

- More difficulty and inconvenience with piggyback lens system
- Loss of GP lens
- Damage to soft lens
- Multiple lens care systems

## PIGGYBACK (PB) LENS SYSTEM

- Indications
  - Poor comfort with a corneal GP
  - Minor corneal abrasion with GP wear
    - Temporary use of soft lens

## PIGGYBACK (PB) LENS SYSTEM

- Challenges
  - Extra cost
  - Extra hassle
    - Daily disposable soft minimizes added care

## PIGGYBACK (PB) LENS SYSTEM

- Fitting Tips- Approach #1
  - Fit corneal GP first
    - Then fit "near plano" soft lens underneath
    - Good for temporary use (ie. abrasion)



## PIGGYBACK (PB) LENS SYSTEM

- Fitting Tips- Approach #2
  - Fit soft lens first
    - If steep cornea, fit minus lens
      - Provides flatter fitting surface
    - If flat cornea, fit plus lens
      - Provides steeper fitting surface
  - Then fit GP lens to front surface of SCL



**CUSTOM SOFT LENSES**

- Indications
  - Corneal GP intolerance
  - Mild to moderate corneal irregularities
  - Simple to transition from a soft toric contact lens
- Challenges
  - Vision may not be as good as that provided by rigid optics
  - Added thickness may lead to corneal hypoxia

Manufacturer	Contact Lens Name
ABB Optical Group	Concise K
	KeraSoft IC & KeraSoft Thin
Acculens	Soft K
Advanced Vision Technologies	Soft K & Soft K Definitive
	NaturaSOFT IC & ICR
	NovaKone & NovaKone Toric
Alden Optical	KeraSoft Thin
Art Optical	Continental Kone
Continental	YamaKone IC
GP Specialists	Keratoconus Lens
Gelflex USA	Soflex
Marietta	Revitaleyes & Revitaleyes Definitive
Metro Optics	KeraSoft Thin
	Ocu-Flex K
Ocu-Ease, Optech	KeraSoft IC & KeraSoft Thin
TruForm Optics	UCL K-Lens
United Contact Lens	HydroKone & HydroKone Toric
Visionary Optics	Flexlens ARC & Flexlens Tri-Curve
X-Cel Contacts	

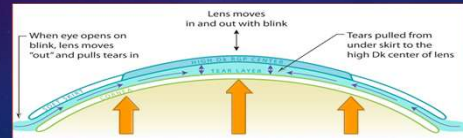
SPECIALTY SOFT CONTACT LENSES FOR KERATOCONUS  
 TABLE ADAPTED FROM CLINICAL MANUAL OF CONTACT LENSES FIFTH EDITION AND THOMPSON TT

**HYBRID LENSES**

- Definition
  - Rigid center
  - Soft skirt
- Indications
  - Those who can't tolerate a corneal GP
- Challenges
  - Proper lens movement
- Empirical fitting

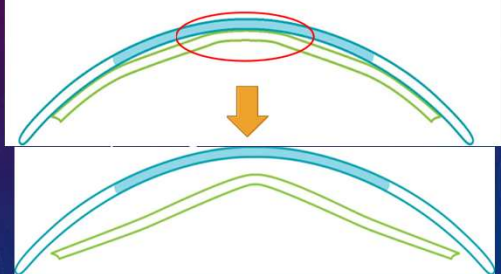
**A Trip Beyond Limbus**

- Irregular Corneas: Evolution of Hybrid CL**  
 Redefining Hybrid platform for irregular corneas
- ▢ Fitting Parameters: Central and junctional SAG depth
  - ▢ Metabolic requirement: Higher gas diffusion constant (DK)
  - ▢ Comfort/Cost/Compliance: Junctional adherence
  - ▢ Comfort: Surface wetting chemistry



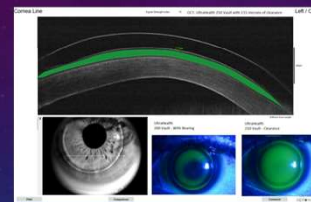
**A Trip Beyond Limbus**

*Irregular Corneas: Evolution of Hybrid CL*

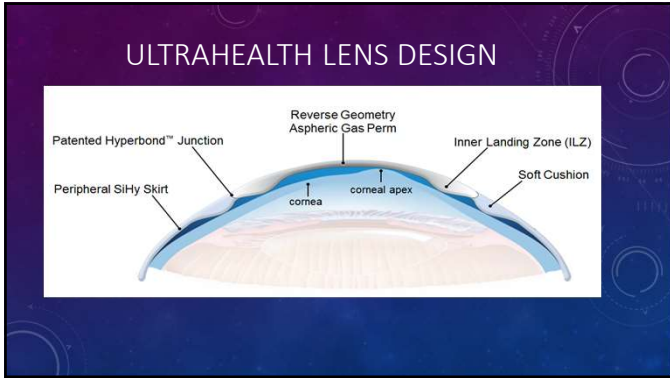


**A Trip Beyond Limbus**

*Irregular Corneas: Evolution of Hybrid CL*



Proper Vault Maintains 2 minute tear exchange  
 Semi-Sealed Environment



### EMPIRICAL FITTING

- Provide a topography (PDF or raw data) with the following information
- Keratometry readings
- Eccentricity data, often listed as E, E squared, CEI, Shape factor, or Q value
- Manifest Rx
- Prior RGP/Scleral base curve and power with over Rx
- HVID

### EMPIRICAL FITTING

- A first lens will be designed and ordered from the measurements
- Alternatively, a first lens from the diagnostic set will be recommended as a starting point for an in-office fitting
- Ideal fit
- 100 microns clearance over apex
- After settling, 40-50 microns centrally and feather clearance at the inner landing zone (ILZ)

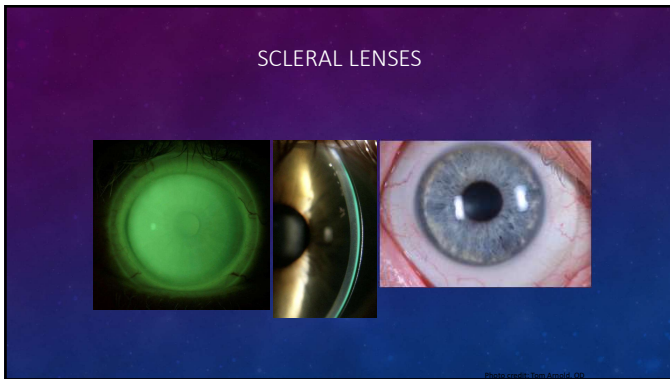
Pachymetry setting on OCT used to verify the fit. Note the thin bearing ring on the inner landing zone.

### CLINICAL APPLICATIONS FOR HYBRID LENSES

- Corneal Ectasia
  - Off-center and central nipple cones
  - PRK/LASIK Ectasia
  - PMD
  - Keratoglobus
- Post-surgical Corneas
  - PKP
  - Intacs
  - Collagen Crosslinking (CXL)
- Post-refractive surgery
  - s/p corneal perforation
  - s/p RK/AK
  - s/p HSV stromal scar

Post-SK (nodule removed) and INTACS  
Image: Clark, OD

Post-INTACS  
Image: Jeff Sorsino, OD



### MAIN SCLERAL LENS INDICATIONS

- Visual rehabilitation in irregular corneas
- Therapeutic treatment of ocular surface disease
- Correction of refractive error in normal or healthy eyes

The illustration shows a scleral lens being positioned over the cornea of an eye, highlighting its application for visual rehabilitation and therapeutic treatment.

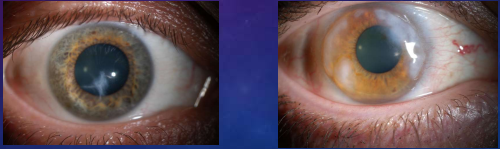
### SCLERAL LENS: INDICATIONS

- Corneal ectasias
  - Primary corneal ectasias
    - Advanced (notably decentered) keratoconus
    - Keratoglobus
    - Pellucid marginal degeneration
  - Secondary corneal ectasias
    - Post-LASIK
    - Post-PRK
    - Post-RK



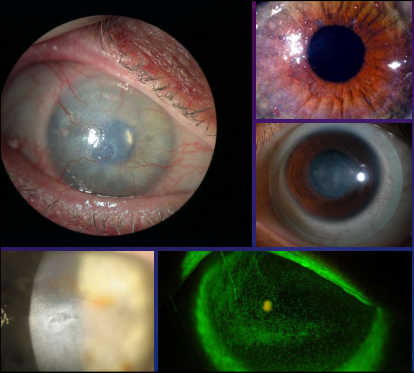
### SCLERAL LENS: INDICATIONS

- Corneal transplants
- Trauma
- Corneal scars
- Corneal degenerations or dystrophies
  - Salzmann's nodular degeneration
  - Terrien's marginal degeneration



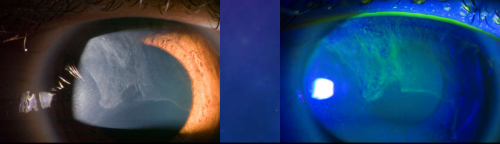
### THERAPEUTIC SCLERAL LENS INDICATIONS

- Neurotrophic Keratitis
- Exposure Keratitis
- Dry Eye Syndrome
- Graft vs Host Disease
- Steven Johnson Syndrome
- Ocular Cicatricial Pemphigoid
- Chemical Burns
- Limbal Stem Cell Failure
- Sjogren's Disease
- Persistent Epithelial Defects



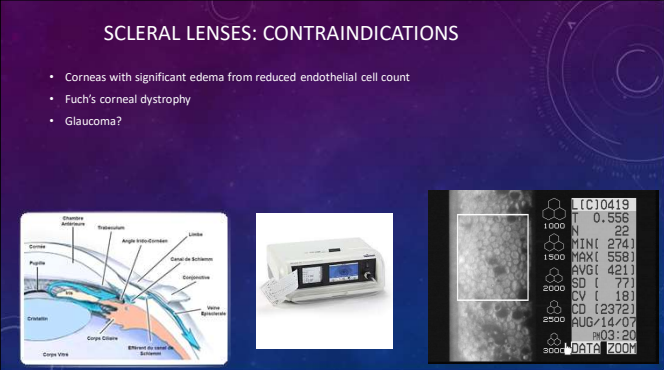
### SCLERAL LENS INDICATIONS

- Inflammatory conditions
  - Limbal stem cell deficiency
  - Ocular cicatricial pemphigoid
- Neovascularization with hybrid lens designs
- Poor comfort with traditional gas permeable designs
- High refractive error



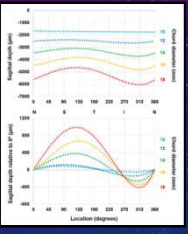
### SCLERAL LENSES: CONTRAINDICATIONS

- Corneas with significant edema from reduced endothelial cell count
- Fuch's corneal dystrophy
- Glaucoma?



### SCLERAL TORICITY

- Scleral toricity, the greatest difference in scleral sagittal height between two perpendicular meridians (over a specified chord),<sup>1</sup> increases further from the limbus
- On average ~100–200 μm at 15 mm chord and up to 400 μm at 20 mm<sup>2-4</sup>
- Significant variation between individuals



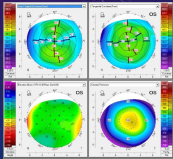
Sagittal depth (elevation) profile for the right eye of a healthy individual over a range of chord diameters derived from Eye Surface Profiler (top). The variation in sagittal depth increases with increasing chord diameter. Visualized when the elevation profile is normalized to the sagittal depth at a single location (0° in this example) (bottom). N-nasal, S-superior, T-temporal, I-inferior.<sup>5</sup>

1. Gilmann, C. Ocular Toricity. JAMA Ophthalmol. 2014;32(10):1080-1081.  
 2. Kohnen, H. Corneal Toricity. JAMA Ophthalmol. 2014;32(10):1080-1081.  
 3. Kohnen, H. Corneal Toricity. JAMA Ophthalmol. 2014;32(10):1080-1081.  
 4. Kohnen, H. Corneal Toricity. JAMA Ophthalmol. 2014;32(10):1080-1081.  
 5. Kohnen, H. Corneal Toricity. JAMA Ophthalmol. 2014;32(10):1080-1081.



## CORNEAL AND SCLERAL TORICITY

- Corneal and scleral toricity are not typically correlated
- In healthy eyes with minimal astigmatism<sup>1,2</sup>
- In high astigmatism<sup>3</sup>
- The sclera shows greater irregularity in irregular corneas<sup>4,5</sup>



1. Hossain, M. M., et al. (2018) 'An analysis of anterior corneal shape and fit rate in the design and fitting of scleral contact lenses'. *Contact Lenses* 2017, 11(14), 410-415. doi: 10.1093/cls/2017.11.010.  
 2. Hossain, M. M., et al. (2017) 'The influence of corneal thickness on scleral lens fitting'. *Contact Lenses* 2016, 11(12), 410-415. doi: 10.1093/cls/2016.11.010.  
 3. Corio, A., et al. (2018) 'Scleral Shape and Its Correlations with Corneal Astigmatism'. *Contact Lenses* 2017, 11(12), 410-415. doi: 10.1093/cls/2017.11.010.  
 4. Hossain, M. M., et al. (2018) 'Correlation of Corneal and Scleral Topography in High Astigmatism and Irregular Corneas'. *Contact Lenses* 2018, 11(12), 410-415. doi: 10.1093/cls/2018.11.010.  
 5. Hossain, M. M., et al. (2018) 'The relationship between corneal and scleral topography in high astigmatism and irregular corneas'. *Journal of Contact Lens Research & Science* 2018, 11(12), 410-415. doi: 10.1093/cls/2018.11.010.

## THE SCLERA, THE GREAT UNKNOWN

The scleral shape is most likely asymmetric, irregular or toric but rarely spheric.

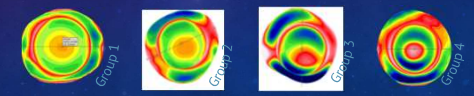
n = 152 (12 excluded due to incomplete data)

- Spherical = 5,7%      GROUP 1
- Regular toric = 28,6%      GROUP 2
- Quad specific = 40,7%      GROUP 3  
(asymmetric depressions/elevations with approx. 180° periodicity)
- Irregular = 26%      GROUP 4  
(toric pattern w. elevations/depressions irregularly spaced)

### Qualitative Assessment of Scleral Shape Patterns Using a New Wide Field Ocular Surface Elevation Topographer

The SSSG Study

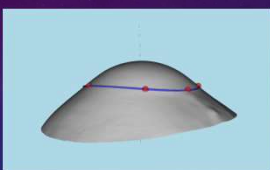
Gregor Delleker Senior Eye Surgeon Donald Sanders Director, Center for Clinical Research Paul van der Worp Public University College of Optometry	Jasen Jellicks Indiana University School of Optometry Lange Michael University of Montreal School of Optometry Boris Morison University of Houston School of Optometry
--	---



© eaglet-eye

Journal of CONTACT LENS RESEARCH & SCIENCE

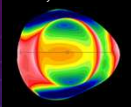
- 4 primary categories of scleral shape
- Measurement of the sclera allows for more efficient and accurate determination of lens design
- Results suggest that majority of eyes may benefit from custom back surface haptics beyond a toric design



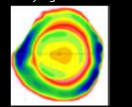
Hossain, M. M., et al. (2018) 'Qualitative Assessment of Scleral Shape Patterns Using a New Wide Field Ocular Surface Elevation Topographer'. *ICRS* 2018, 11(12), 410-415. doi: 10.1093/cls/2018.11.010.

### Scleral Profilometry

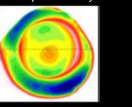
*Toricity with the rule*



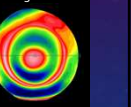
*Toricity against the rule*



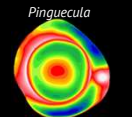
*Oblique toricity*



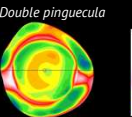
*Irregular*



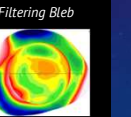
*Pinguecula*



*Double pinguecula*



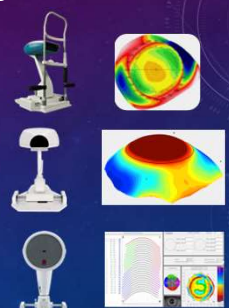
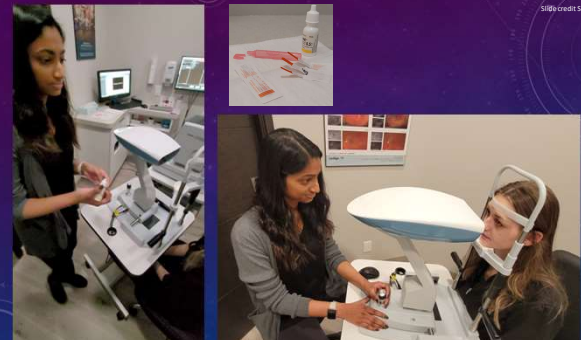
*Filtering Bleb*



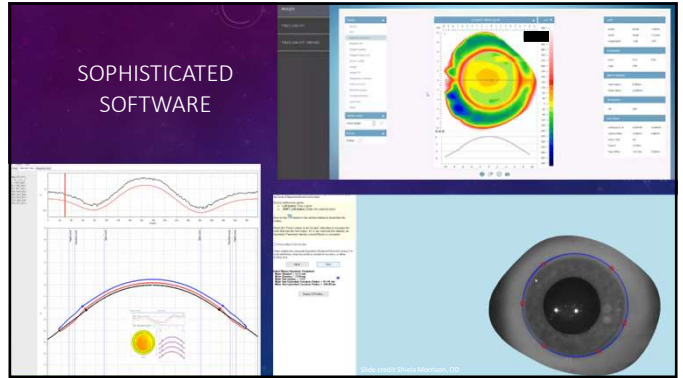
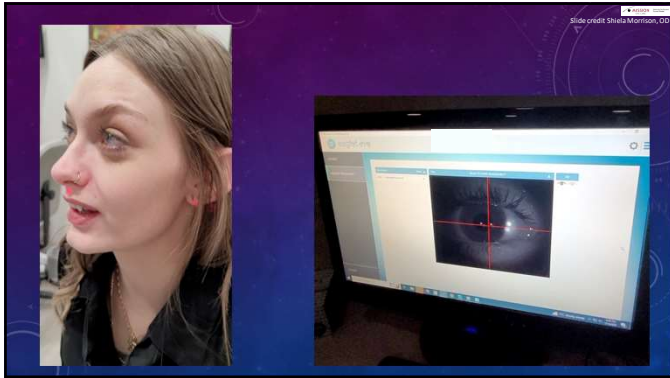
© eaglet-eye

## PROFILOMETRY DEVICES

- Eaglet Eye Surface Profiler (ESP)
- Visionary Optics sMap3D
- Oculus Pentacam Cornea Scleral Profile (CSP)

© Vision Science  
Slide credit: Sheila Morrison, OD



### VISIONARY OPTICS SMAP3D

- Ocular surface imaging
  - 3 images
  - Images are stitched together
  - Rasterstereography device
  - Reflection
  - NaFL
- More than 22mm range
- 360° scleral coverage
- Over 1 million measurement points
- 10 micron precision

Three eye images showing different gaze directions: 'Up Gaze', 'Straight Gaze', and 'Down Gaze'. Below them is a 3D model of an eye with a grid overlay. The text 'Image credits: G. Dehner, MD' is visible at the bottom right.

### KERATOCONUS

- 53 YO ♂ Keratoconus OD
- Previously failed corneal GP
- Previously failed scleral lens
  - Midday fogging
- Wearing hybrid lens

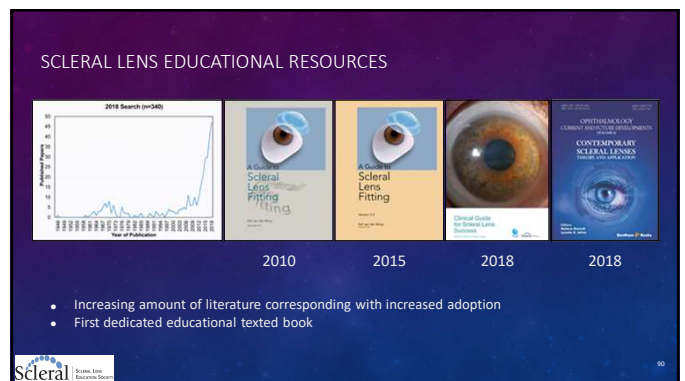
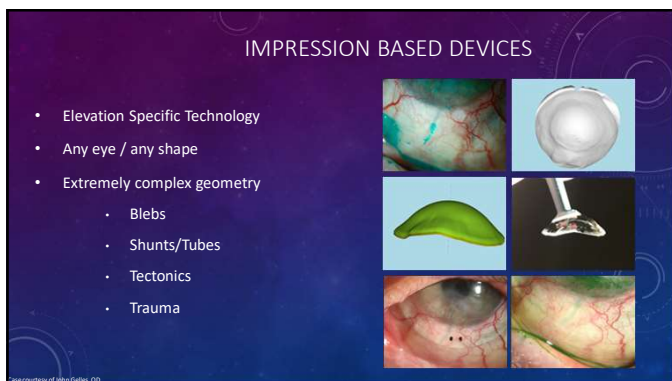
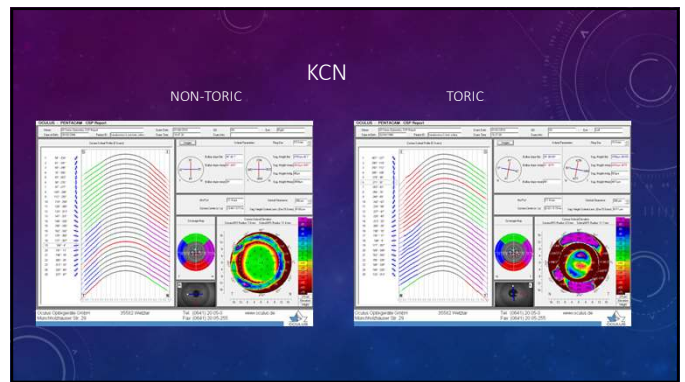
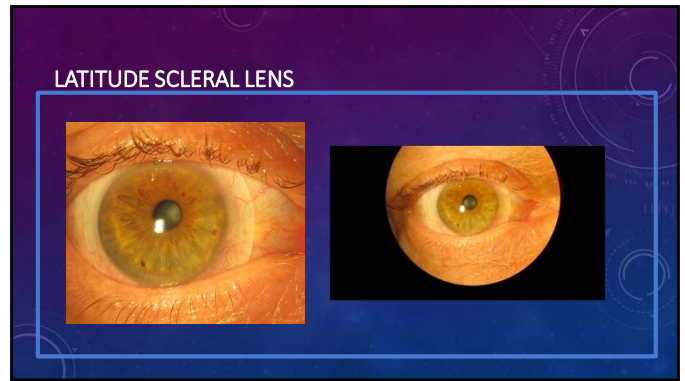
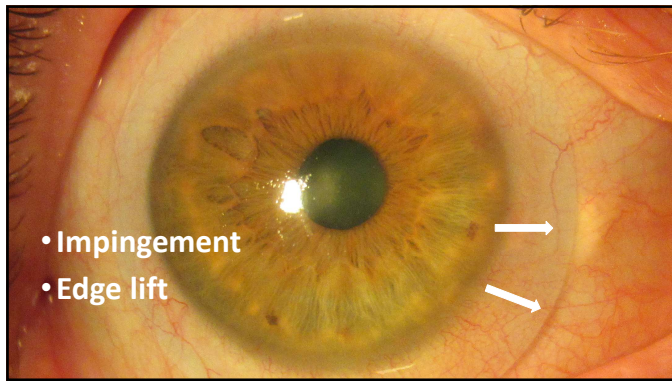
A topographic map of a cornea showing keratoconus. The map is color-coded, with red and yellow indicating areas of high curvature (steepening) and blue indicating areas of low curvature (flattening). The steepening is most prominent in the inferior and nasal quadrants.

### KERATOCONUS

Compression of the hybrid lens  
-resulting in lens failure

A 3D model of an eye showing a green hybrid lens. The lens is shown in a compressed state, with a bright green line indicating the point of failure or compression. The text 'KERATOCONUS' and 'Compression of the hybrid lens -resulting in lens failure' is displayed on the left.

A topographic map of a cornea showing a significant difference in curvature between 305° and 360°. The map is color-coded, with red and yellow indicating areas of high curvature and blue indicating areas of low curvature. The text '600µ DIFFERENCE BETWEEN 305° -360°' is displayed at the bottom. To the right is a 3D model of an eye showing a green hybrid lens.





### NEWEST SCLERAL LENS EDUCATIONAL RESOURCES

2021 PubMed Results      2020      2021      2021

- Continued increase in publications
- Second dedicated educational textbook and new educational supplements

## SL HANDLING

- Difficulty with lens handling is greater in scleral (63%) compared to rigid corneal lens wearers (40%)<sup>1</sup>
- Handling is the primary reason for scleral lens drop out<sup>2,3</sup>

1. K. Yoneda, M. Minoura, I. Hattori, A. Naka, J. Goto, et al. Professional contact lens wearers with scleral lenses. Optometry, 91(12), pp. 70-76. 2. J.D. Sheehy, J. Dethlefs, J. Geyer. Scleral lens handling in scleral lens wearers. Optometry, 87(1), pp. 44-48. 3. J.D. Sheehy, J. Dethlefs, J. Geyer. Scleral lens handling in scleral lens wearers. Optometry, 87(1), pp. 44-48.

### APPLICATION AND REMOVAL

- Difficulty with lens handling greater in scleral (63%) compared to rigid corneal lens wearers (40%)
- Scleral lens handling primary reason for scleral lens drop out
- Patient education materials are helpful

### Healthy Scleral Contact Lens Habits

Congratulations on your new Scleral contact lens!

To ensure continued success with your Scleral lenses, review these healthy lens habits:

- Wash your hands thoroughly...
- Do not use eye makeup...
- Use contact lens solution...
- To maintain comfortable lens wear...
- Use tear break solutions...
- Always use your solution bottles after each use.
- If you have a question...
- Before using any type of eye drops...
- Completely empty the solution reservoir...
- Change the lens with your wearing solution...
- To maximize the life of your lens...
- Healthy lens wear should not cause redness, discomfort, or visual disturbances.

Available in several different languages (<https://aoacle.org/index.php/healthy-scleral-lens-habits/>)

### SCLERAL LENS CARE INSTRUCTIONS

**LENS APPLICATION**

- Wash your hands...
- Use contact lens solution...
- To maintain comfortable lens wear...
- Use tear break solutions...
- Always use your solution bottles after each use.

**LENS REMOVAL**

**BEST PERFORMANCE BY THE SCLERAL LENS IN THE SCLERAL LENS CARE INSTRUCTIONS**

For more help with application, removal, and care of scleral lenses, please visit our website to view our comprehensive video and written care instructions and Q&A section: [www.scleral-lens.org](http://www.scleral-lens.org)

### RINSE AND APPLICATION SALINE

NaCl 0.9% Inhalation Solution	LacriPure (Menicon)	Sclerafil (B+L)	Nutrifill (Contamac)	VibrantVue Scleral Saline (ABB)	Puriflens (The LifeStyle Company)
No buffers, no preservatives	No buffers, no preservatives	Contains borate buffer, no preservatives	Phosphate buffer, no preservatives, contains electrolytes	No buffers, no preservatives	Contains borate buffer, no preservatives
Off-label	FDA approved	FDA approved	FDA approved	FDA approved	FDA approved
3 ml or 5 ml vials	5 ml vials	10 ml vials	10 ml vials	5 ml vials	4oz bottle
Available in box of 100 vials	Available in box of 98 vials	Available in box of 30 vials	Available in box of 35 vials	Available in box of 100 vials	Bottle replaced every 15 days



### DISINFECTION AND STORAGE SOLUTIONS



Reminder: avoid abrasive cleaners so as not to prematurely remove plasma or other surface treatments.



- General Guideline Created by
- AOA/AO/GPII /CLMA
- Joint publication in OVS

**TECHNICAL REPORT**

**Technical Report: Guidelines for Handling of Multipatient Contact Lenses in the Clinical Setting**

Christina Smith, OD, F.A.C.O.,<sup>1,2</sup> Ed Bennett, OD, MEd, F.A.C.O. (AOO CLS),<sup>1,2</sup> Lorinda Kucinski-Pryor, OD, FPD, F.A.C.O. (AOO CLS),<sup>1,2</sup> Louise Siskione, OD, F.A.C.O. (AOO CLS),<sup>1,2</sup> and Melissa Barnett, OD, F.A.C.O.,<sup>1,2</sup> for The American Academy of Optometry (AAO) Section on Contact Lenses & Reflective Technologies, and The American Optometric Association (AOA) Contact Lens and Contact Section

**AMERICAN OPTOMETRIC ASSOCIATION**

**In-Office Disinfection of Multi-Patient Use Diagnostic Contact Lenses**

Gas permeable	Hybrid and Soft
1 Place 3% hydrogen peroxide with GP lens in a non-neutralizing case for 3+ hours.	1 Place 3% hydrogen peroxide with soft or hybrid lens in non-neutralizing case for 3+ hours.
2 Disinfect lens for 3+ hours.	2 Transfer soft or hybrid lens to neutralizing case. Fill with fresh 3% hydrogen peroxide. Add neutralizing disc or tablet as recommended by manufacturer.
3 Rinse GP lens with Multipurpose Solution (MPS). Do not dry alone.	3 Neutralize lens for 6+ hours, or as directed by manufacturer.
	4 Rinse soft or hybrid lens with MPS. Store in a distributed case with MPS.

© 2020 American Academy of Optometry. All rights reserved. This document is intended for informational purposes only and is not intended to constitute an offer of insurance, investment, or any other financial product or service. It is not intended to be relied upon in making any decision. The American Academy of Optometry and the American Optometric Association assume no liability for any loss or damage resulting from the use of this document. For more information, please contact the American Academy of Optometry at 1-800-545-2333 or the American Optometric Association at 1-800-545-2333.

THANK YOU FOR YOUR TIME AND ATTENTION!