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KERATOCONUS: CONTINUUM OF CARE

CHERATOCONO: Aspetti Clinici e
Gestione con Lac

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Organizational Collaboration: Mary Prudden – National Keratoconus Foundation (NKCF)



Mission:

to promote and develop the knowledge base and awareness of the state of the art pertaining to the diagnosis and management of keratoconus and other forms of corneal ectasia. And further to promote the awareness and understanding of the most appropriate and effective treatment strategies for the management of these diseases.

www.keratoconusacademy.com

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TOPICS TO DISCUSS

THE KERATOCONUS EPIDEMIC

NEW TECHNOLOGYS FOR DIAGNOSIS

NEW TREATMENTS

ETIOLOGY AND PREVALENCE

Eziologia e Prevalenza



"Keratoconus is a clinical term to describe a condition in which the cornea assumes a conical shape because of thinning and protrusion"

Impact of Keratoconus on our patient's lives... what we don't hear in the exam rooms:

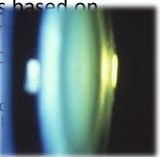


- "I'm really trying to have positive thoughts and attitudes as I deal with keratoconus but some days it's hard. You never really know what you have until it's gone. Every waking moment we use our eyes so every waking moment I am reminded of this struggle. I want to do all I can to help my vision get better..."
- "I wana take my life because of KC I can't see proper my friendz nd fam don't care..."

How common is keratoconus?

- Classically referenced:

1:2,000* based n a registration study in Olmsted County, Minnesota, conducted between 1935-1982; diagnosis was based on the detection of **scissors reflex with retinoscopy and keratometry** outco



*Kennedy RH, Bourne WM, Dyer JA. A 48-year epidemiologic study of keratoconus. Am J Ophthalmol 1986;101(3):267-73.

KERATOCONUS:PREVALENCE

- Likely actual prevalence is likely **< 1: 1,000**
Variable prevalence between 50 – 230/100,000!
Prevalence range 1:50 in Israel to < 1:100,000 in Russia!
- This large discrepancy may in part reflect differences in diagnostic criteria, the age group studied, differences in genetic variation in the populations and possibly environmental differences.

Davidson, Hayes, Harcastle, and Tuft Eye (Lond) 2014 Feb; 28(2): 189-195.
JH, Foster RS, Behr MW. Surv Ophthalmol. 1984;29:299-322.
Rabinowitz YS. Keratoconus. Surv Ophthalmol. 1996; 42:297-319.
Hofstetter HW. A keratoscopic survey of 13,395 eyes. Am J Optom Arch Am Acad Optom. 1959;36:31-1.

AJO, 2017 – “Eye Opening Study”!

Age-specific Incidence and Prevalence of Keratoconus: A Nationwide Registration Study

DANIEL A. GODFREY, G. ARDINE DE WIT, CLAUDIO S. LUTERNAAL, SASKIA M. BHOOF, AND ROBERT P.J. WINE

PURPOSE: To determine the age-specific incidence and prevalence of keratoconus in the modern era of diagnosis.

DESIGN: Epidemiologic study.

SETTING: Total of 4.4 million patients from a nationwide health insurance database.

METHODS: Data were extracted from the largest health insurance provider in the Netherlands. Patients aged 10-80 years were defined as the relevant age groups for newly diagnosed keratoconus and the annual incidence of newly diagnosed keratoconus was determined. The prevalence of keratoconus was estimated based on the annual incidence, mean age at diagnosis, and average life expectancy. Main outcome measures were the annual incidence and prevalence of keratoconus.

RESULTS: The annual incidence of keratoconus was 1.070 in the relevant age category (1.3 cases per 100,000, 95% confidence interval [CI]: 1.6-15.2) and the estimated prevalence of keratoconus in the general population was 1.075 (266 cases per 100,000, 95% CI: 266-276). These values are 5-fold to 10-fold higher than previously reported values in population studies. The mean age at diagnosis was 28.3 years and 65.6% of diagnosed patients were male.

CONCLUSIONS: Both the annual incidence and the prevalence of keratoconus were 5-fold to 10-fold higher than previously reported. (Am J Ophthalmol 2017;171:699-712. © 2016 Elsevier Inc. All rights reserved.)

keras, complex corneal grafting procedures are ultimately indicated in approximately 10%-20% of keratoconus patients.

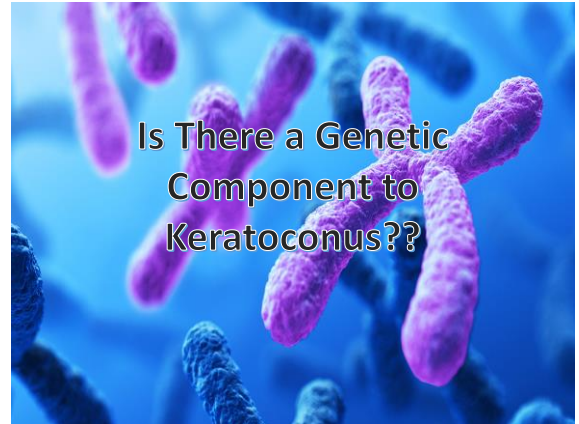
The most frequently cited occurrence of keratoconus is 1:2,000. This value is based on a registration study in the United States that was conducted from 1935 and 1982. This study reported a prevalence of 54.5 cases per 100,000 individuals. Estimates of the annual incidence of keratoconus based on epidemiologic data range from 1,000 to 100,000 per year.¹⁻⁴ This wide range may be attributed to the increased sensitivity of modern diagnostic devices, regional differences with respect to accessibility of health care, and/or differences in study design. Furthermore, ethnic differences with respect to the incidence of keratoconus have also been reported.

Incidence is defined as the number of new cases diagnosed within a specific period of time (usually 1 year), whereas prevalence is the number of existing cases at a given point in time. The onset of keratoconus typically occurs in the second to fourth decade of life (ie, from age 10 through age 40) and the condition slowly progresses for the remainder of their lives.⁵ Therefore, the prevalence of keratoconus is by definition always higher than the annual incidence.

As computer-based technologies and imaging techniques have improved, the ability to diagnose keratoconus has also increased. New treatment options for keratoconus are currently being implemented. Therefore, determining the incidence and prevalence of keratoconus in the modern

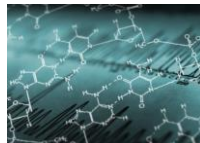
AJO – 2017: Age-specific Incidence and Prevalence of Keratoconus: A Nationwide Registration Study

- Netherlands study: 4.4 million patients from a mandatory health insurance data base
- Prevalence of keratoconus in the general population was **1:375**
- Annual incidence: (new cases) of keratoconus was **1:7,500**
- **Conclusion**: “Both the annual incidence and the prevalence of keratoconus were **five-fold to ten-fold higher than previously reported.**”



Basic Science Research

- Christina Kenney, MD, PhD
- KCN have higher # of mitochondrial DNA deletions that leads to decrease oxidative phosphorylation... increase H₂O₂
- Causes leakage, damages proteins, and results in oxidative stress
- Leads to
 - apoptosis,
 - abnormal healing,
 - inflammation.



Basic Science Research

- Yaron Rabinowitz, MD UCLA
- KCN have suppressed Aquaporin 5 (AQP5)
- AQP5 is the water transport gene that is responsible for cell migration and wound healing.
- Quantitative PCR testing (epithelial cells) could diagnose this
- IOVS April 2006



Genetic Aspects of Keratoconus: A Literature Review

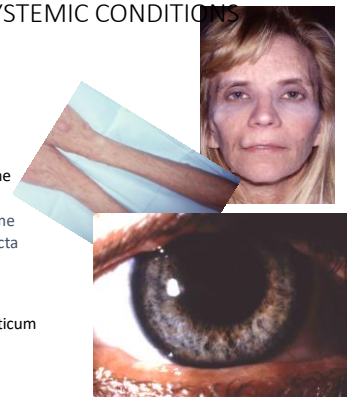


- Twenty-four genes were identified as potential contributors to KC and 49 KC-related comorbidities/syndromes were found.
- More than 85% of the known KC-related genes are involved in glaucoma, Down syndrome, connective tissue disorders, endothelial dystrophy, posterior polymorphous corneal dystrophy, and cataract.

Leal-Martins D, Shalita-Ravitsky S, Lymanowski P, Tostorovich J, Delfino-da-Silva M, Bencze Z, Szilasi M, Kozma A, Kozma S, Zachererova J, Trancik P, Kovacs N, Balazs M, Gattasova Z, Fekete A, Angewandte G. Genetic Aspects of Keratoconus: A Large-Scale Family-Based Genetic Study on Potential Genetic Contributions and Possible Genetic Relationships with Comorbidities. Ophthalmol. 2018 Dec;125(12):2612-2622. doi:10.1016/j.ophtha.2018.05.044. Epub 2018 Sep 6.

ASSOCIATED SYSTEMIC CONDITIONS

- Vernal KC
- Atopic Dermatitis
- Down's Syndrome
- Floppy Eyelid Syndrome
- Mitral Valve Prolapse
- Ehlers-Danlos Syndrome
- Osteogenesis Imperfecta
- Lawrence-Moon-Biedl Syndrome
- Neurofibromatosis
- Psuedoxanthoma Elasticum



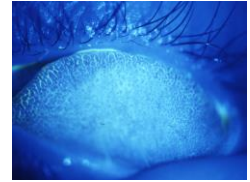
ASSOCIATED SYSTEMIC CONDITIONS

- Vernal KC
- Atopic Dermatitis
- Down's Syndrome
- Floppy Eyelid Syndrome
- PKP >31 lbs. *, 8.7x morbid obese
 - Kristinsson, IDVS 2003
- Mitral Valve Prolapse
- Ehlers-Danlos Syndrome
- Osteogenesis Imperfecta
- Lawrence-Moon-Biedl
- Neurofibromatosis
- PXE



ASSOCIATED SYSTEMIC CONDITIONS

- Vernal KC
- Atopic Dermatitis
- Down's Syndrome
- Floppy Eyelid Syndrome
- Mitral Valve Prolapse
- Ehlers-Danlos Syndrome
- Osteogenesis Imperfecta
- Lawrence-Moon-Biedl Syndrome
- Neurofibromatosis
- Pseudoxanthoma Elasticum



ETIOLOGY OF KCN

- History of trauma that causes weakness
- Recurrent trauma due to rubbing from
 - Blepharitis, CL/lids, 53% have atopic dx
 - Lieber's- rubbing produces scotopsias
 - Pressure on corneal nerves is pleasing (right handed)
- Inflammatory component !!!
 - Rubbing increases temperature and raises IOP 150 mm
 - Decrease proteinase inhibitors
 - Increase collagenase, increase cytokine binding
 - Premature keratocytic apoptosis leads to thinning



Aay, there's the rub

McMonnies CW. Mechanisms of Rubbing-Related Corneal trauma in Keratoconus. *Cornea*. 2009; 28:607-614

Table 1 Correlation matrix between specific genes implicated in keratoconus and clinical symptoms/signs

GENE	GENE NAME / FUNCTION ↓	CLINICAL SIGN/SYNDROME (see legend) →	12	4	11	15	19	5	7	28	9	3	17	14	2	6	16	1	
DOCK1	Indicator Of Cytokinesis 9																		3
FNDC3B	Fibronectin Type III Domain Containing 28																		4
FNDC3B	FNDC3 Domain 5																		4
SFRP2	Multiple TGF-β Domain-Containing Cell Polarity Complex Component																		5
MIR38H	Microrna38b 186																		6
ZNF489	zinc finger protein 489																		6
RAB39AP1	RAB39A GTPase Activating Protein Catalytic Subunit 1																		7
COL4A1	Collagen Type IV Alpha 1 Chain																		8
COL4A1	Collagen Type VII Alpha 2 Chain																		8
FOXO1	Forkhead Box O1																		9
COL4A1	Collagen Type IV Alpha 1 Chain																		9
COL4A1	Collagen Type IV Alpha 1 Chain																		9
COL4A2	Collagen Type VII Alpha 1 Chain																		9
COLX	Cone Rod Homeobox																		9
RYR2A	RyR2A 100																		10
ORL1	Olfactory Receptor Like Receptor 1																		11
COL4A1	Collagen Type V Alpha 1 Chain																		11
SRF	Small Rat Family Transcription Factor																		12
SFAFC	Sarcosyl Sarcosyl Acidic Acid Catalytic Rich																		12
VSX1	Visual System Homeobox 1																		12
LOR	Large Olfactory Receptor																		13
TGFBI	Transforming Growth Factor Beta 1																		13
COL4A1	Collagen Type I Alpha 1 Chain																		14
SOD1	Superoxide Dismutase 1																		14
	NUMBER OF GENE ASSOCIATIONS WITH EACH CLINICAL SYMPTOM / SIGN →	1	1	4	4	6	6	9	11	12	14	15	16	17	18	19	22	24	24
	CLINICAL SYMPTOM / SIGN (ID seen legend below) →	12	4	11	15	19	5	7	28	9	3	17	14	2	6	16	1		

ID	SYMPTOM / SIGN	ID	SYMPTOM / SIGN	ID	SYMPTOM / SIGN
1	Central corneal thinning	7	Corneal (curved) distortion	13	Photophobia
2	Corneal curvature	8	Corneal scarring	14	Irregularity of corneal nerves
3	Corneal protrusion	9	Deep stromal scarring	15	Corneal hydrops
4	Corneal steepening	10	Corneal iron deposits	16	Keratocyte apoptosis

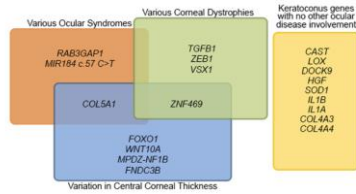
Genetics in Keratoconus: Where Are We?

- The identification of genes responsible for this type of KC has been the main focus of many studies done by many research groups around the world.
- Although environmental factors have been involved in KC pathogenesis, strong underlying genetic susceptibility has been proven.
- Several genes have been implicated across these studies, including genes coding for various collagens and related to extracellular matrix production

Bykhovskaya Y, Margines B, Rabinowitz YS. Genetics in Keratoconus: where are we? Eye Vis (Lond). 2016 Jun 27;3:16. doi: 10.1186/s40662-016-0047-5. eCollection 2016. Review. PubMed PMID: 27350955; PubMed Central PMCID: PMC4922054.

RESEARCH MAY INDICATE NEW THERAPIES

- KCN is unlikely a single gene defect
 - Chromosome 5, 21
- Multiple genes in a common pathway
- Those with the defect may develop KCN naturally or only if exposed to factors that induce oxidative stress: CL over-wear, UV, allergy or refractive surgery
- TX: Anti-inflammatory, Anti-oxidant



SPECIAL ARTICLE

Global Consensus on Keratoconus and Ectatic Diseases

Jose A. P. Gomes, MD, PhD, Donald Tan, MD, PhD,† Christopher J. Rapuano, MD,‡
 Michael W. Belin, MD,§ Renato Ambrosio, Jr, MD, PhD,¶ José L. Guell, MD,||
 François Malecaze, MD, PhD,** Kohji Nishida, MD,†† and Virendra S. Sangwan, MD,‡‡, the Group
 of Panelists for the Global Delphi Panel of Keratoconus and Ectatic Diseases*

Global Consensus on Keratoconus Diagnosis

- Keratoconus (and other ectatic disorders) was recognized as a multifactorial disease with genetic, biochemical, biomechanical, and environmental components.
- Risk factors for keratoconus: Down syndrome, relatives of affected patients especially if they are young, ocular allergy, ethnic factors (Asian and Arabian), mechanical factors, eg, eye rubbing, floppy eyelid syndrome, atopy, connective tissue disorders (Marfan syndrome), Ehlers–Danlos syndrome and Leber congenital amaurosis

Gomes JA, Rapuano CJ, Belin MW, Ambrósio R Jr; Group of Panelists for the Global Delphi Panel of Keratoconus and Ectatic Diseases. Global Consensus on Keratoconus Diagnosis. *Cornea*. 2015 Dec;34(12):e38-9. doi: 10.1097/ICO.0000000000000623. PubMed PMID: 26426335.

Corr (Evid Based). 2016 Nov;41(11):1414-1418. Epub 2016 May 9.

Association between Family History and Keratoconus Severity.

Naderian M¹, Bakhti MT¹, Zamirakhtab P², Naderian M¹, Bakhshi A¹.

© Author Information

Abstract

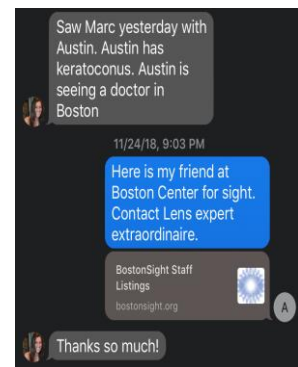
PURPOSE: The high prevalence of positive family history of keratoconus (KC) in KC patients is well-known. However, the results regarding the association between family history of KC and disease severity are controversial. The aim of this study was to evaluate the possible association between family history and severity of KC.

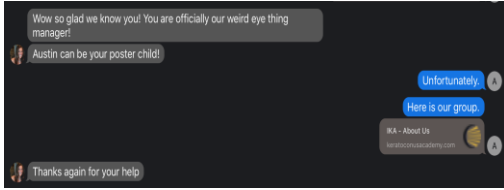
METHOD: Clinical data of 1496 KC patients were evaluated. All participants were asked if they had a family member with KC. Topographic and keratometric measurements of KC patients, including central corneal thickness (CCT), thinnest corneal thickness (TCT), mean, flat, and steep keratometry values (K) by the use of Pentacam, best-spectacle corrected visual acuity (BCVA), spherical equivalent (SE), and astigmatism were recorded and compared according to patients with and without a family history of KC, first- or second-degree family members, and the number of family members with KC. Severity of KC was classified according to the Amstler-Krumeich classification.

RESULTS: Family history of KC was present in 292 (19.5%) patients. Of those 292 patients who had a family history of KC, 159 (54.5%) had one family member with KC and 133 (45.5%) had two or more family members with KC. There was not a significant difference between corneal pachymetry and K values of the patients with and without a family history of KC ($p > 0.05$). However, those with a positive family history of KC had more severe disease, according to the Amstler-Krumeich classification ($p < 0.05$). KC patients who had more family members with KC had significantly lower TCT and significantly higher steep K and astigmatism ($p < 0.05$), and had more severe disease, according to the Amstler-Krumeich classification ($p < 0.05$).

CONCLUSION: We suggest that patients with more family members with KC should be subject to screening to identify early disease.

KEYWORDS: Corneal topography; family history; keratoconus; risk factor; severity



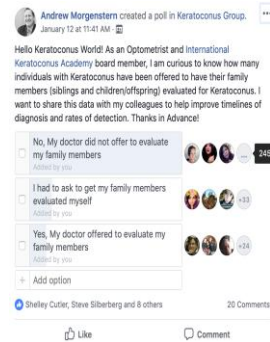


Andrew Morgenstern created a poll.
Yesterday at 11:41 AM

Hello Keratoconus World! As an Optometrist and International Keratoconus Academy board member, I am curious to know how many individuals with Keratoconus have been offered to have their family members (siblings and children/offspring) evaluated for Keratoconus. I want to share this data with my colleagues to help improve timelines of diagnosis and rates of detection. Thanks in Advance!

Response Options

<p>1</p> <p>Yes, My doctor offered to evaluate my family members</p>	<p>2</p> <p>I had to ask to get my family members evaluated myself</p>	<p>3</p> <p>No, My doctor did not offer to evaluate my family members</p>
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CLINICAL FINDINGS

Studi clinici e riconoscimento precoce

“Frustrated in my career because the cornea is so clear”

Jay Krachmer, MD
Professor, University of Minnesota

The Vision Challenge with Irregular Corneas



Continuum of Care for Keratoconus: Contact Lens Choices

Contact Condition	Topography	Pachymetry	Refractive Manifestation	Topography, Astigmatism and Coma Location	Lens Choice
Form Factor	Topography shows eccentric steepening	Normal: 500µm or greater	Mean central K < 48.00D	Wedge and astigmatism less than 5.00D	• Soft toric • Contact with toric • Contact gas permeable • Hybrid
MID	Topography shows inferior steepening	Pachymetry greater than 2 standard deviations from normal (500µm base line)	Mean K ranges from 40.00D to 48.00D	Wedge and astigmatism 5.00 to 6.00D	• Contact gas permeable • Rigid toric design • Hybrid • Thin water soft • Freon toric design
Advanced	Topography shows significant steepening	Central thickness 300-400µm	Mean K ranges from 48.00D to 52.00D	Location of cone is central or paracentral (2.5µm from center)	• Hybrid • Scleral
Severe	Topography shows significant steepening	Central thickness 200-300µm	Mean K greater than 52.00D	Ape is paracentral (beyond central 5µm)	• Scleral • Capsule lined
Proseal	Topography shows significant steepening Significant central scarring	Central thickness < 200µm		Reflection not measurable	

Form Factor

MID

Advanced

Produced by Jeffrey Dennis, D.D., M.D.
© 2014 Syngene Inc. All rights reserved.
Revised October 2014 Edition
Contact: Contact Lens and Contact Lens Center
www.syngene.com



KERATOCONUS STAGEING

MILD/EMERGING

1. Multiple SRX re-make
2. Fleischer Ring, Vogt’s Stria or Scissor reflex
3. Unstable topography
4. No scar
5. Light Sensitivity/glare
6. Steep K < 53 D
7. Pachymetry > 475

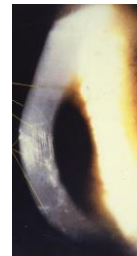
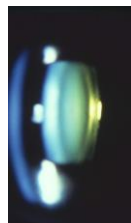
MODERATE/SEVERE

1. Mild to no scarring
2. Refraction not measurable
3. Steep K > 53D
4. Pachymetry <475

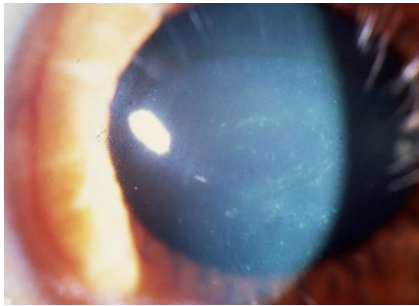
The difference in reimbursement for one carrier is twice for the various levels of medically necessary contact lens fitting

RETINOSCOPY

- Scissors Reflex
- Against motion that breaks apart
- Represents multiple refractive powers within the optic zone



WHORL-KERATOPATHY



FLEISCHER RING

abrupt change
in curvature
50%



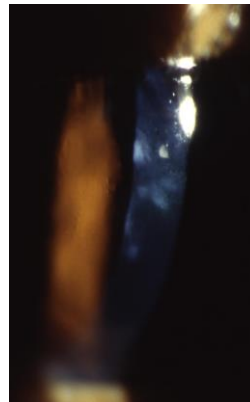
VOGTS'S STRIA (1st Sign)



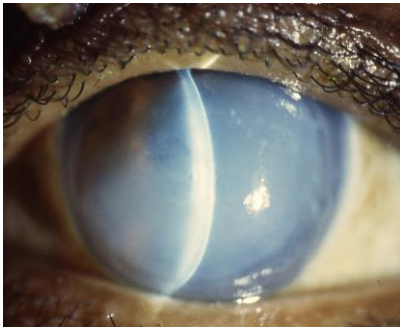
1st Sign
65%

STROMAL SCAR

CLEK showed
Overall 13% had scars
K > 52 38% scarred
43% of flat fits scarred
26% of steep fits scarred
8% ↑ with each hour WT
↑ scar w/ stain, ring,
age, CL (2 fold), ↑FDACL

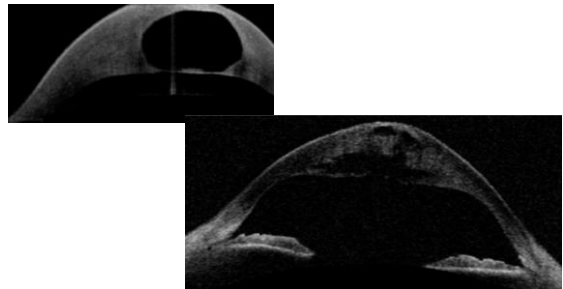


CORNEAL HYDROPS

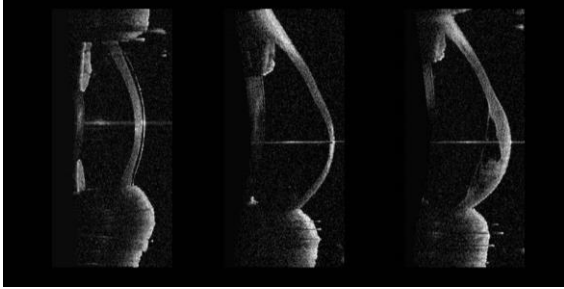


5%

HYDROPS



Evolution of KCN: Ectasia to Hydrops



EXTERNAL FINDINGS

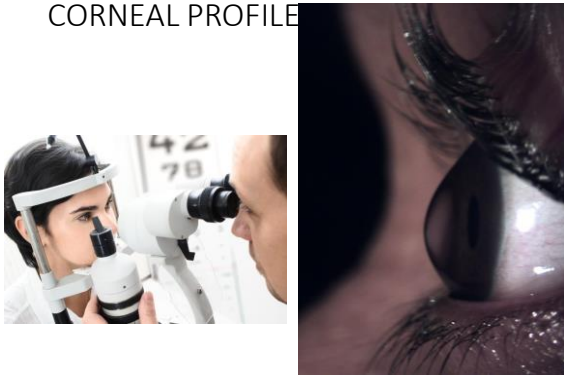


MUNSONS SIGN

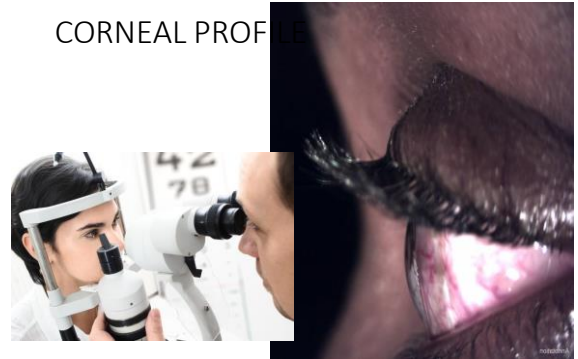


RIZZUTIS SIGN

CORNEAL PROFILE



CORNEAL PROFILE



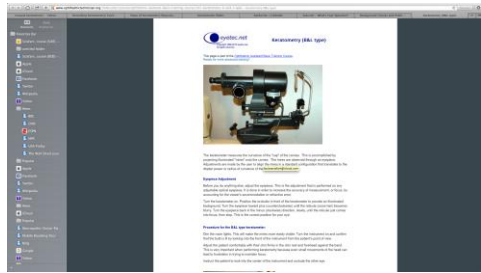
EARLY DIAGNOSTIC TOOLS AND PROGRESSION ANALYSIS

Primary Care Detection of Keratoconus

- Frequent refractive changes, especially with changes in astigmatism greater than typically expected.
- Significant difference in astigmatism between the two eyes
- Increase symptoms related to high order aberrations
- Mild "K" distortion, scissor's Ret. reflex
- Biomicroscopic early findings
- Family history of keratoconus

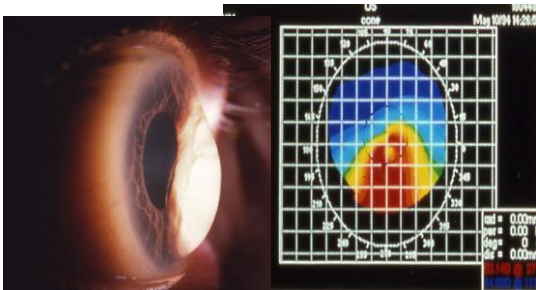
KERATOMETRY (Bausch& Lomb)

Use: K of central 5 mm, regularity, NITBUT



- Initially, mires get small and then there is a lack of parallelism
- Expand perimeters by use of +1.25 SPH and add 7 D to your reading
- Steepening begins infero-temporally and progresses clockwise
- PLACIDO RINGS- get closer

KERATOCONUS



SPECIAL ARTICLE

Global Consensus on Keratoconus and Ectatic Diseases

José A. P. Gomes, MD, PhD,* Donald Tan, MD, PhD,† Christopher J. Rapuano, MD,‡
 Michael W. Rubin, MD,§ Renato Ambrosio, Jr, MD, PhD,¶ José L. Guell, MD,||
 François Malczak, MD, PhD,** Koji Nishida, MD,†† and Virender S. Sangwan, MD,‡‡; the Group
 of Panelists for the Global Delphi Panel of Keratoconus and Ectatic Diseases

Background: Despite extensive knowledge regarding the diagnosis and management of keratoconus and other ectatic diseases, many controversies still exist. For that reason, there is a need for current guidelines for the diagnosis and management of these conditions.

Purpose: This project aimed to reach consensus of ophthalmology experts from around the world regarding keratoconus and ectatic diseases, focusing on their definition, concepts, clinical management, and surgical treatment.

Methods: The Delphi method was followed with 3 questionnaire rounds and was complemented with a focus-like meeting. Thirty-six panelists were recruited and allowed to vote 2 times. Definitions, diagnosis, surgical management or surgical treatment. The level of agreement considered for consensus was two thirds.

Results: Numerous agreements were proposed in definitions, methods of diagnosis and management of keratoconus and other ectatic diseases. Unsurpassed and surgical treatment for these conditions, including the use of corneal cross-linking and corneal transplantation, were presented in a stepwise approach. A Bausch and Lomb keratometry is a rapid management response for keratoconus was found.

Conclusions: This project resulted in definitions, consensus, and recommendations for the diagnosis and management of keratoconus and other ectatic diseases. It also provides an insight into the current worldwide treatment of these conditions.

Key Words: keratoconus, ectatic diseases, corneal cross-linking, corneal transplantation
 (Cornea 2015;33:1-11)

Keratoconus and ectatic corneal diseases have been recognized for more than 150 years.^{1,2} Over the last 2 decades, there has been a revolution in the knowledge related to the diagnosis and management of these conditions. In terms of diagnosis, the advent of corneal topography, and more recently corneal tomography, has increased the ability of ophthalmologists to identify corneal ectasia at a much earlier stage than was previously possible.³ As a result, the previously established prevalence of keratoconus of approximately 1/2000 among the general population⁴ has been challenged with much higher prevalence rates found in many parts of the world.⁵

The surgical treatment for keratoconus reflects this evolution. Alternative procedures, such as the use of intrastromal corneal ring segments (ICRS),⁶ corneal cross-linking (CXL),^{7,8} topographic guided laser treatments including photorefractive keratectomy⁹ and photorefractive

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 Supported by the Area Conyugal System, The Cornea Society, Fundación, and the Panamerican Cornea Society (PACS).

MINIMUM CLINICAL CRITERIA

SPECIAL ARTICLE

Global Consensus on Keratoconus and Ectatic Diseases

José A. P. Gomes, MD, PhD,* Donald Tan, MD, PhD,† Christopher J. Rapuano, MD,‡
 Michael W. Rubin, MD,§ Renato Ambrosio, Jr, MD, PhD,¶ José L. Guell, MD,||
 François Malczak, MD, PhD,** Koji Nishida, MD,†† and Virender S. Sangwan, MD,‡‡; the Group
 of Panelists for the Global Delphi Panel of Keratoconus and Ectatic Diseases

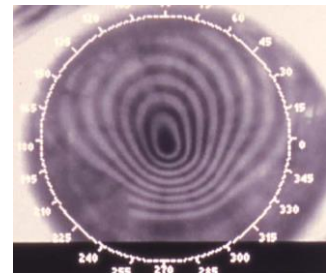
need 2 or more:

- Abnormal posterior ectasia
- Abnormal corneal thickness distribution
- Clinical non-inflammatory corneal thinning*

*Central pachymetry is the least reliable indicator or KCN

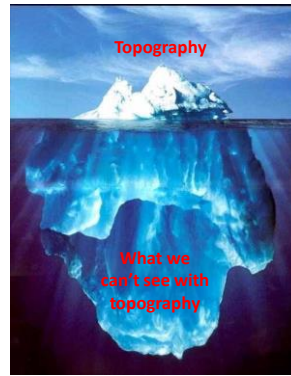
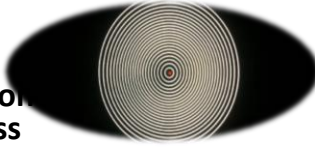
PLACIDO RING IMAGES

- Rings that are closer together represent areas of steeper curvature
- May indicate a tight suture applicable



Placido based topography – What’s missing?

- **No** analysis of posterior corneal surface
- **No** representation of corneal thickness

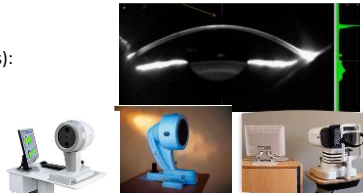


Placido Topography, What are the issues?

Corneal Tomography

a two-dimensional image of a slice or section through a three-dimensional object.

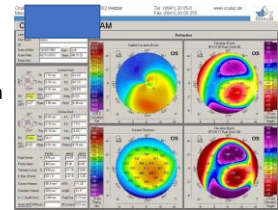
- Pentacam (Oculus):
- Orbscan (B&L)
- Galilei (Zeimer)



Tomography provides:

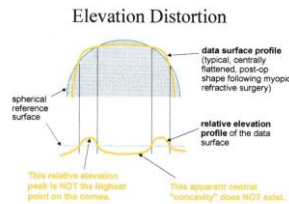


- True Elevation Anterior & Posterior Cornea
- Curvature (Axial and Tangential) based on true elevation data
- Global Pachymetry



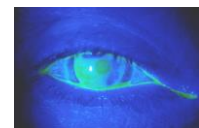
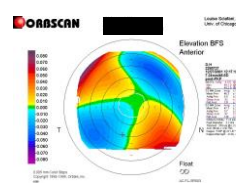
ELEVATION (FLOAT) MAPS

Predicts the relative elevation or depression of the cornea (in mm) using a computer generated BEST FIT SPHERE as a reference and fit at the steepest point



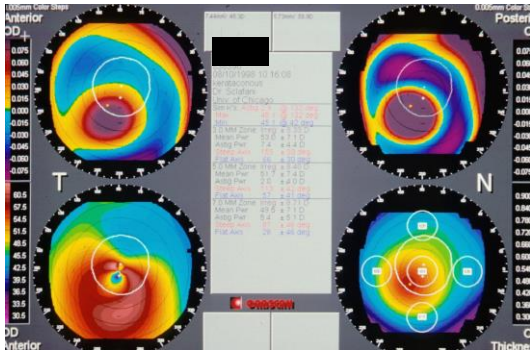
ELEVATION MAPS PREDICT

Na-FL PATTERN



- + VALUES- warm colors points higher than sphere = elevation Areas of bearing or touch
- VALUES- cool colors points lower than sphere = depression Areas of pooling

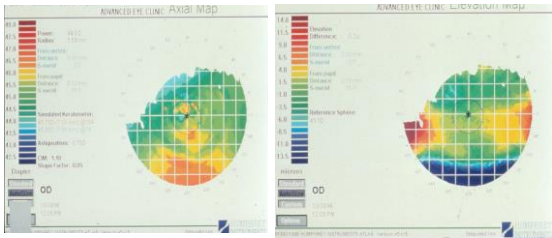
Elevation Map of True Keratoconus



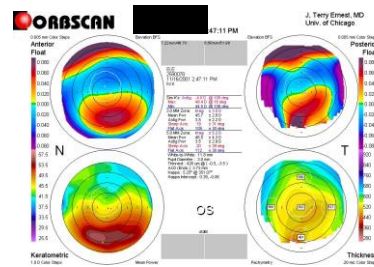
PSEUDOKERATOCONUS

- Corneal warpage topography can mimic KC
- Repeat topography must be performed and a measurable change would indicate pseudo-KC
- Evaluation of elevation maps at steep zone:
- Predicts the elevation or depression of the cornea if the best fit sphere was on cornea

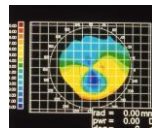
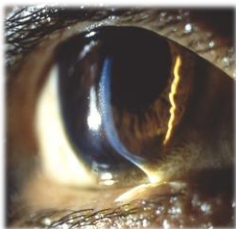
ELEVATION MAP DIFFERENTIATES KERATOCONUS vs. WARPAGE



Pellucid Marginal Degeneration vs. KCN

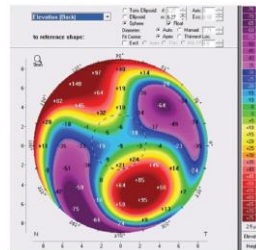


PELLUCID MARGINAL



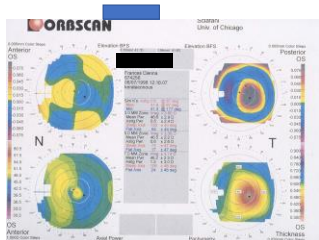
Tear meniscus can creates pseudo-PMD

However, the story or diagnosis is often on the back side!

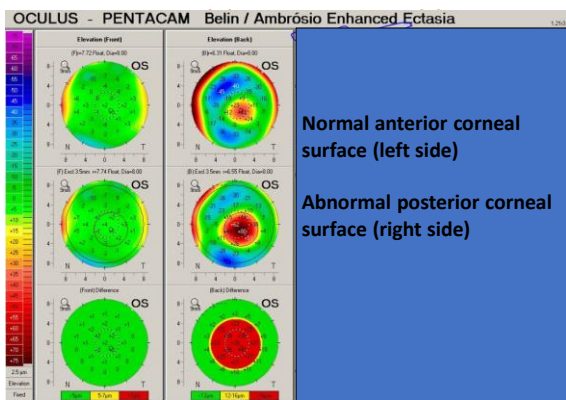
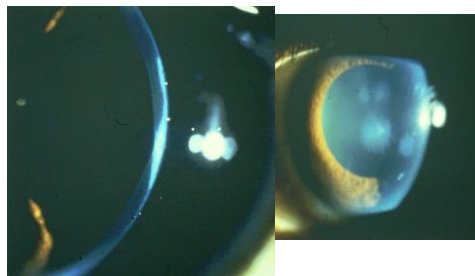


- KC: anterior displacement of both anterior and posterior corneal apex
- **KC: Can have normal anterior corneal curvature & elevation**
- Posterior corneal irregularity has an influence on visual quality albeit less sig vs. anterior corneal irregularity

POSTERIOR KERATOCONUS

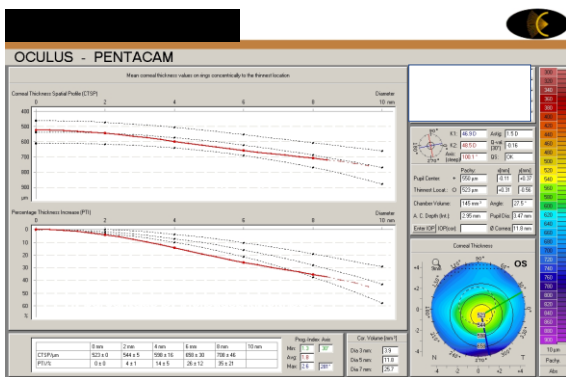
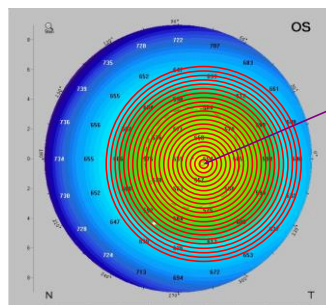


POSTERIOR KERATOCONUS

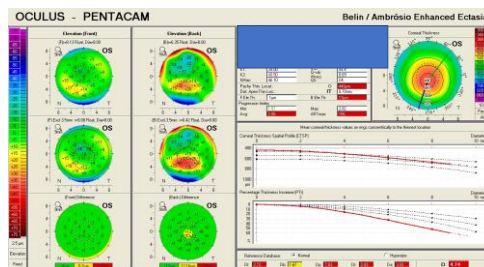


Global Pachymetric Progression

Thickness Progression



“BAD III” – enhanced ectasia detection



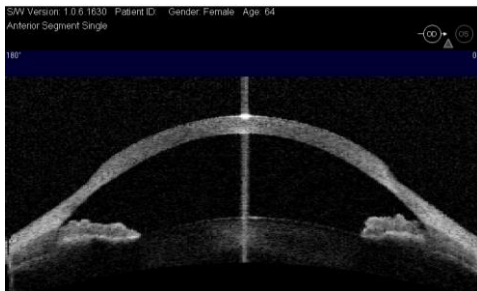
ANTERIOR SEGMENT OCULAR TOMOGRAPHY

AS-OCT

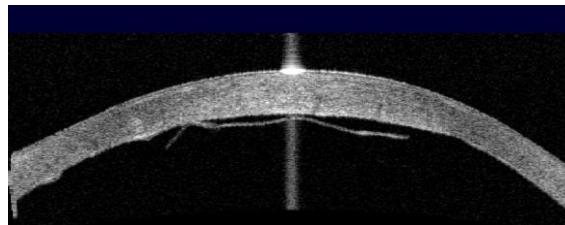
KCN- Thinning



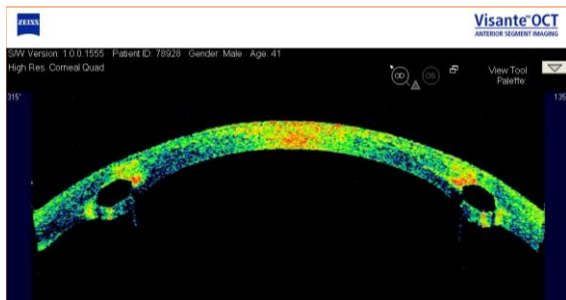
Terrien's Marginal Degeneration



Descemet's Membrane Detachment with Central Corneal Edema



Intrastromal ring segments



Penetrating Keratoplasty

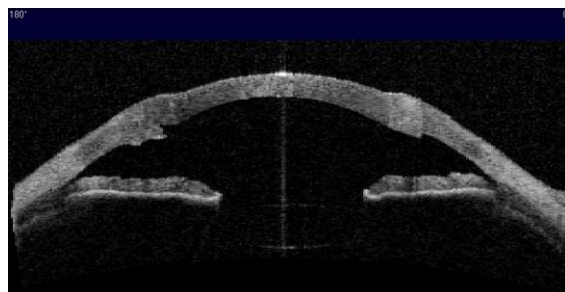
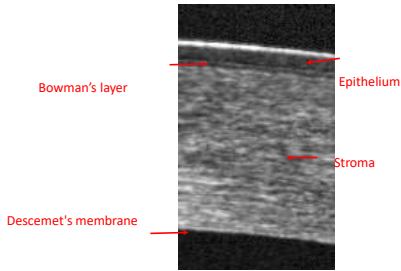


image courtesy of Dr. J. Güell

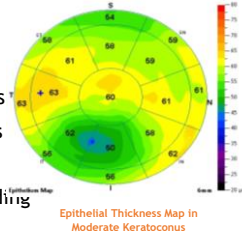
**New Technology in AS-OCT:
Measuring EPITHELIAL Thickness**



Clinical Applications of ETM in Keratoconus

Epithelial Thickness Profile Measurements Keratoconus:

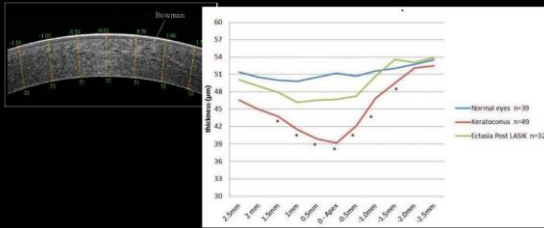
- Mean epithelial thickness only slightly less than in normal eyes
- **Greater variability** in thickness measurements¹ in KC eyes compared to normal eyes (thinning over apex w/surrounding thickening: “donut pattern”)



2277-87

**Epithelial Thickness in KCN
via ASOCT**

J Refract Surg. 2013 Mar;29(3) SD-OCT analysis of regional epithelial thickness profiles in keratoconus, postoperative corneal ectasia, and normal eyes.

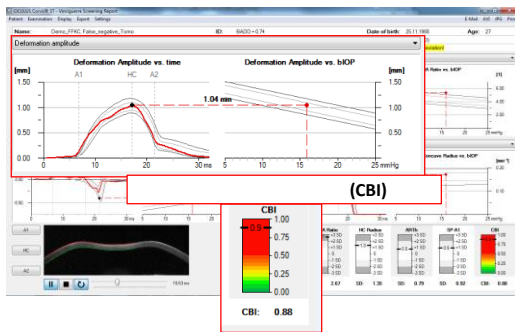
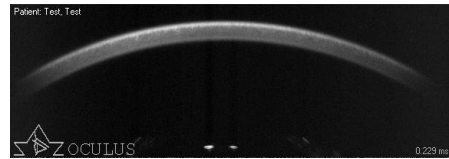


Apical epithelial thickness was significantly thinner in eyes with keratoconus (P < .0001) and ectasia (P = .0007) than in controls.

**Corneal Biomechanical Properties
in Keratoconus / Keratectasia**



Corvis ST By Oculus



**PROGRESSION DETECTION
Riconoscimento della
Progressione**

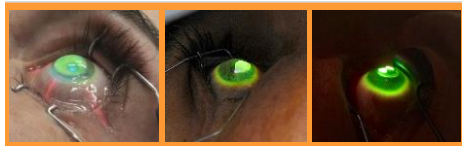
Why do we need to be so concerned about Progression of Keratoconus?

Perche ...

We Now Can Stop Progression of the disease

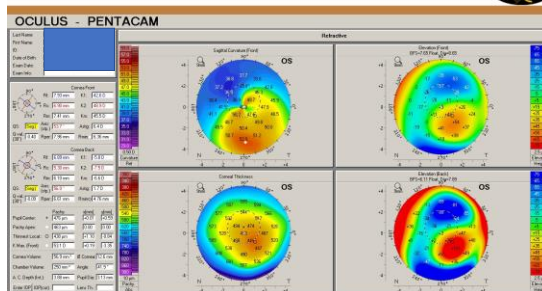
Poi

We Can Preserve Vision.

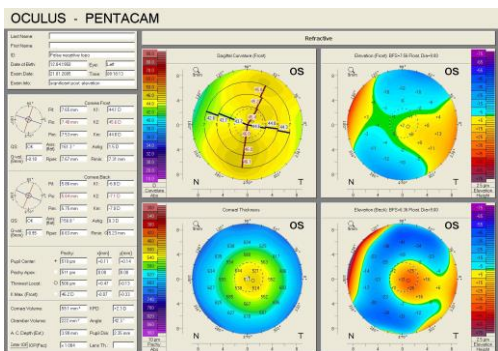


Corneal Steepening & Thinning

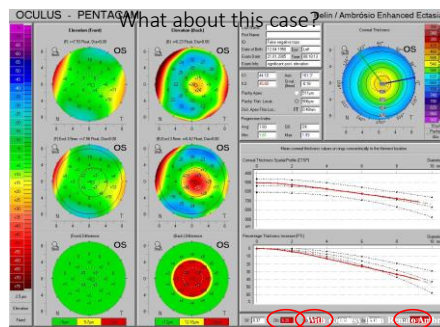
North Suburban Vision Consultants, Ltd.



What about this case?

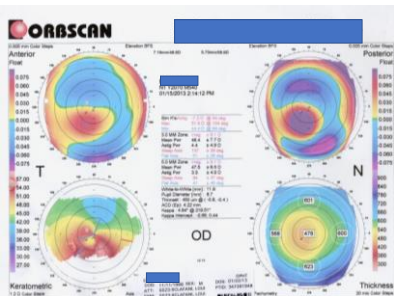


False negative on placido topo, but + Early Ectasia

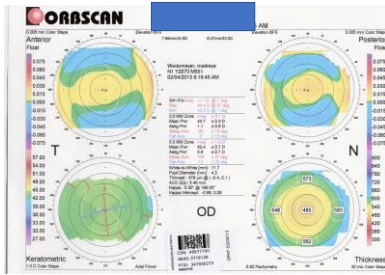


What about this case?

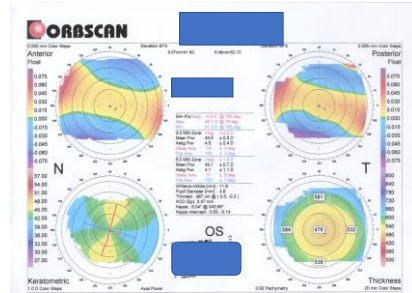
FOR RE



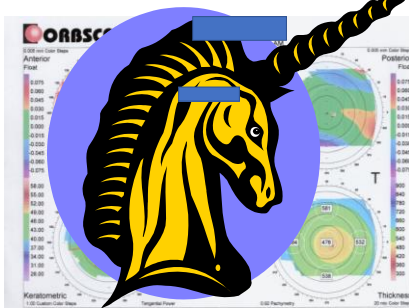
10 YO Asian Female referred by OD for KCN suspect
H/O PED-OMD consult for strabismus but was
determined to be epicanthal folds. No H/O high cyl



10 YO Asian Female referred by OD for KCN suspect
LE +3.50 -5.50 X 160
[41.3 @165/ 45.75 @075](#) central pachs 476



IS IT KERATOCONUS? Normalized Scale
HOW DO YOU COUNSEL? HOW DO YOU TREAT?



Collagen (Corneal) Cross-linking (CXL)



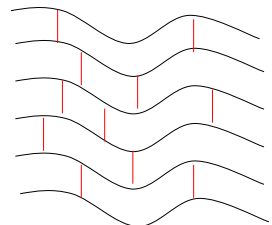
Yaron S. Rabinowitz

“Why don’t we see elderly patients with keratoconus”

- Do they die younger NO
- Do they not visit OD POSSIBLE
- Have they CE/PKP POSSIBLE
- Getting lenses from 1-800
- THEORY BY KRACHMER
 - The eye becomes more rigid as the patient ages and therefore the condition stabilizes

Biomechanics of KCN

- The cross-linking in KCN is abnormal
- Too elastic and the biomechanical resistance is 50%
- Loss of Bowman’s

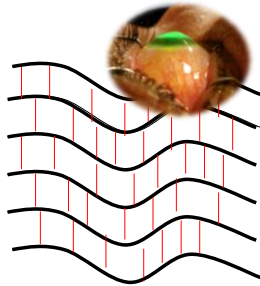


Biomechanical Effect of Combined Riboflavin-UVA

A photochemical reaction Occurs when riboflavin (a photosensitizer) and UV become a triplet and create oxygen radicals that cross-link collagen fibers.

GOAL:

- Increase cross-linking
- Increase diameter
- 12% Anterior 5% Posterior



CORNEAL CROSS-LINKING

INDICATIONS

- The treatment of progressive KCN and ectasia after refractive surgery

Photrex Viscous/Photrex + KXL System (Avedro) is first and only FDA approved 2017

Riboflavin is used as a photosensitizer and protector



avedro



GOAL:

- Stop Progression
- Reduce Steepness
- Improve BCVA; altering index
- Improve CL Tolerance

OFF LABEL INDICATIONS

- < 14 years old > 65 Years old
- Never for pregnant
- Combine with Refractive Sx
- Combine with Intacts
- Recalcitrant MK

CORNEAL CROSS-LINKING

- Epithelial "OFF"

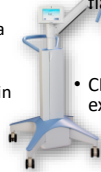
- 9 mm Debridement
- Followed by Loading dose of Photrex Viscous x 30 minutes

- If < 400 um, Photrex q 5-10 seconds until...
- > 400 um, UVA x 30 minutes, PH-V q 2 min
- 365 nm, 3mW/cm²

POST-OP

- Mild Pain, BCL
- Mild haze up to 1 year
- K steepening at month 1 followed by gradual flattening month 3-12

- CL fitting > 1 month with expected changes



POTENTIAL USES OF C3R

- Prevent KCN regression/scars:
 - For young KCN pts. who are getting worse
- Combine w/Topography-linked ablations to smooth KCN or High Myopic or Hyperopic RX to stabilize results (Kannelopoulos)
- Post-Lasik ectasia
- Post CK or Post CRT-to enforce result
- Combine w/ Intacts or ICL for KCN (Wachler)
- Recalcitrant microbial keratitis
- Suture-less corneal SX- cross-link wounds

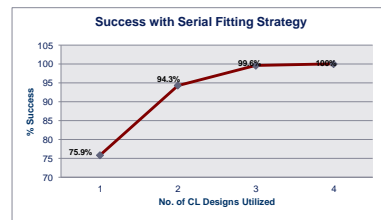
CXL



Christopher Rapuano, MD (Wills Eye)

Post-CXL CLF Study: Single Center Data

Overall Success Rate = 95.1%



Clark Chang, OD; Angie Shin, OD; Peter Hersh, MD (Unpublished)

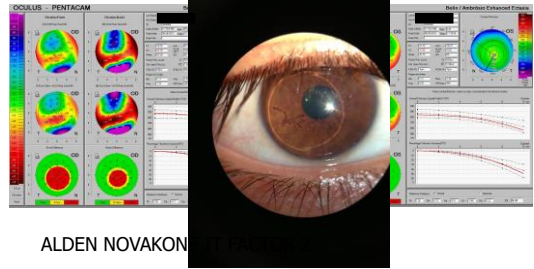
Post-CXL CLF Study: Single Center Data

Retrospective Study (n= 329 Consecutive KC/Ectasia eyes)
 Clark Chang, OD; Angie Shin, OD; Peter Hersh, MD (Unpublished)

	Non-Surgical	Surgical
Success Rate	94.2% (229/243)	97.70% (84/86)
Habitual VA	20/60.52	20/56.14
Final CLVA	20/27.88	20/28.70
Tolerance at Presentation	63.4%*	39.4%*
Tolerance after Fitting	95.8%	98.5%

CXL SUCCESS

Stress importance of treating better eye ...ease in fitting CLS after



ALDEN NOVAKON

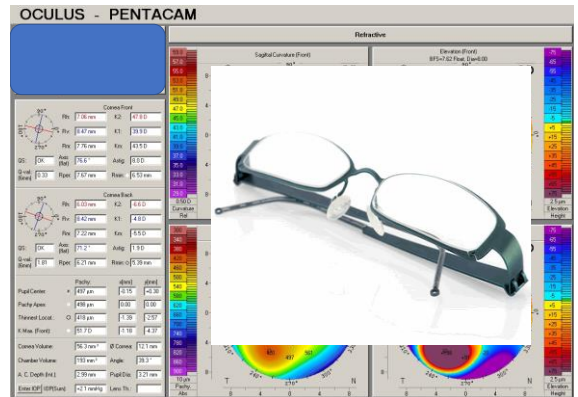
CONTACT LENS
 MANAGEMENT
 Trattamento con lac

Contact Lens Management
 of the Keratoconus Patient



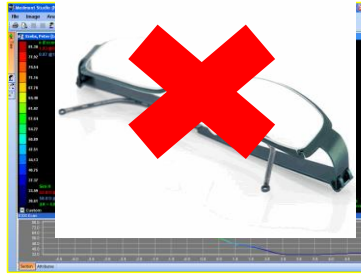
“Frustrated in my career
 because the cornea is so
 clear”

Jay Krachmer, MD
 Professor, University of Minnesota



Keratoconus Challenge

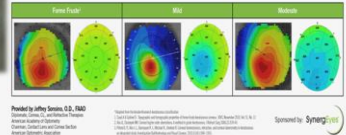
Irregular Corneal Optics: HOAs



Courtesy Dave Kading, OD



Corneal Condition	Topography	Parameters	Refractive Considerations	Specialty Approaches and Considerations	Lens Choices
Form Fringe	Topography shows eccentric steepening	Normal: 53D or greater	Mean central K < 48.00D	Stress and alignment (less than 5.00D)	<ul style="list-style-type: none"> Soft lens Custom soft lens Corneal gas permeable Hybrid
Mild	Topography shows inferior steepening	Pachymetry is greater than 2 standard deviations from normal (520um less than 520um)	Mean K ranges from 48.00D to 49.00D	Stress and alignment (2.00 to 3.00 D)	<ul style="list-style-type: none"> Corneal gas permeable Rigid contact lens Hybrid Hybrid contact lens Refractive surgery
Moderate	Topography shows significant steepening	Corneal thickness 300-400um	Mean K ranges from 49.00D to 52.00D	Location of cone is central or paracentral (25 um from center)	<ul style="list-style-type: none"> Hybrid Soft lens
Severe	Topography shows significant steepening	Corneal thickness 200-300um	Mean K greater than 52.00D	Aqueous is protruded (outside contact lens)	<ul style="list-style-type: none"> Soft lens Custom scleral
Endstage	Topography shows significant steepening. Significant corneal scarring	Corneal thickness < 200um			<ul style="list-style-type: none"> Reflection not measurable



Keratoconus Challenge

Irregular Corneal Optics: Spectacles!

- **Significant Difference Between Eyes**
 - Anisometropia
 - Aniseikonic symptoms
 - Cylinder power/axis adaptation
 - Reversing neuro-compensation



- **Impact of HOAs**
 - Patient characteristics, activity, environment

- **Progression = Frequent Rx Changes !!**

KERATOCONUS STAGEING

MILD/EMERGING

1. Multiple SRX re-make
2. Fleischer Ring, Vogt's Stria or Scissor reflex
3. Unstable topography
4. No scar
5. Light Sensitivity/glare
6. Steep K < 53 D
7. Pachymetry > 475

MODERATE/SEVERE

1. Mild to no scarring
2. Refraction not measurable
3. Steep K > 53D
4. Pachymetry < 475

The difference in reimbursement for one cornea is twice for the various levels of medically necessary contact lens fitting

TREATMENT OPTIONS

- UNI-KONE IN DENIAL
- SPECTACLES (SOLO OR IN TANDEM WITH CLS)
- SOFT TORIC OR SPECIALTY (UNILATERAL, TEMPORARY)
- CORNEAL GAS PERMEABLE
- INTRA-LIMBAL GAS PERMEABLE
- TANDEM SYSTEMS (PIGGY BACK)
- HYBRID LENSES
- SCLERAL LENSES
- ELEVATION SPECIFIC DESIGNS
- CORNEAL CROSS-LINKING
- CORNEAL INLAYS
- CORNEAL TRANSPLANT



General Principles in Contact Lens Fitting for the Keratoconus Patients

Key to Success

- Vision
- Comfort
- Physiological

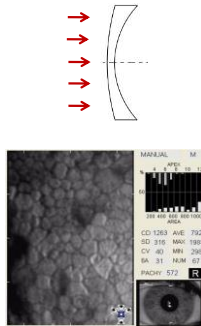


Keys to Fitting

- Avoid mechanical pressure on the apex of the cornea
- Avoid hypoxic corneal stress
- Maximize comfort and vision through design

General Fitting Principles : Hypoxic Stress

- Avoid endothelial cell stress by removing oxygen barrier to endothelium
- Long term wear of any low Dk lens contributes to polymegathism and pleomorphism



Soft Contact Lenses

From the Traditional to the Complex

Soft Lens Use in Keratoconus

Advantages:

- Comfort
- Centration
- Corneal Protection



Limitations:

- Vision (due to draping effect)
- Dehydration
- Hypoxia / microbial contamination

SOFT CONTACT LENSES

Keratoconus does not equal having to fit advanced rigid gas permeable lenses if...

If spectacle vision is largely acceptable...

OR

If the patient is satisfied and is able to perform daily functions...

OR

“hero” surgeon placed a toric IOL or failed Intacs THEN

Soft contact lenses just may work!

CASE: A 59 year old female is referred for a LASIK consult

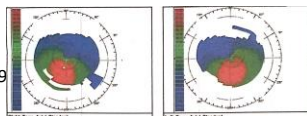
Post-Op Refraction

Post- Toric IOL OD, patient refuses OS sx

- OD: +2.75 -0.25 x 090 20/30-
- OS: -6.00 -1.75 x 090 20/30-

Final Rx

- OD: +2.75 DS
- OS: -5.75 -1.25 x 090



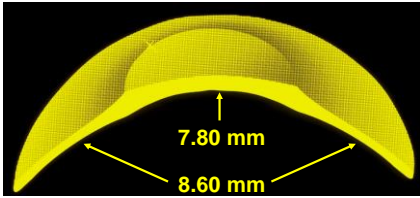
Specialty Soft Contact Lenses

Many soft contact lenses designed specifically to correct the keratoconic cornea:

Two classes

- Increased center thickness to mask irregular astigmatism
- Aspheric designs to limit aberrations

Custom Soft Keratoconus Lens Design



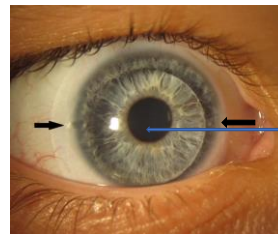
Actual Lens Profile on Eye



Specialty Soft Contact Lenses

- Especially useful for the mild to moderate KCN patient that has hesitation about trying rigid lens designs
- Fitting Pearls
 - Utilize the highest possible dk/t material available
 - Obtain a VERY detailed refraction with special attention to cylinder axis
 - Set proper patient expectations

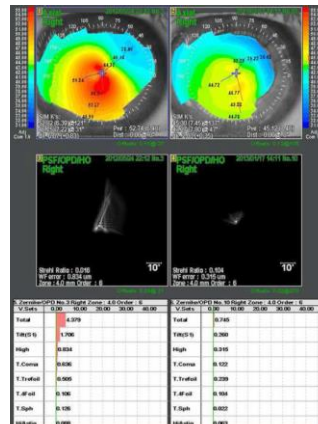
Eg. Custom Soft Astigmatism Contact Lenses for Keratoconus



Central optic zone thickened to "mask" corneal irregularity

Eg. Astigmatism rotation marks
Dots at 3&9

Soft Keratoconic Lens influence on refractive surface regularity



A New Alternative Fitting Approach For Providing An Adequate Comfort And Visual Performance - Soft HydroCore Silicone Hydrogel Keratoconus Lenses

Niray Gupta, MD, FRCOphth
Nisa Kalyani, MD

Is Hypoxia an Issue with these Lenses???

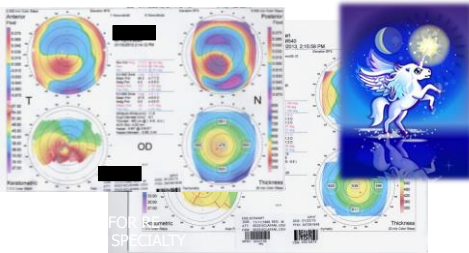
- Thickness limited to the central optic zone
- Thinning via lenticularization peripherally (protects the limbal stem cell area)
- Lenses are fit with significantly greater movement (.5 to .75mm w/blink)
- Designs are now available in higher Dk materials (Contamac's Definitive, Lagado)

Custom Keratoconus Lens Designs:

- **Hydrokone** (Visionary Optics)
- **NovaKone** (Alden)
- **Kerasoft / Kerasoft Thin**
- **Rose K2 Soft**
- **Soft K** (Acculens & Advanced Vision, & SLIC Labs)
- **Continental Kone** (Continental)
- **Keratoconus lens** (Gelflex)
- **Soflex** (Marietta)
- **Ocu-Flex K** (Ocu-Ease, Optech)
- **UCL -55** (United)
- **Flexlens Keratoconus** (X-Cell)
- +++ Others

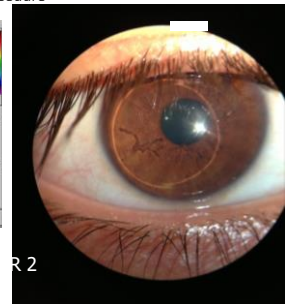
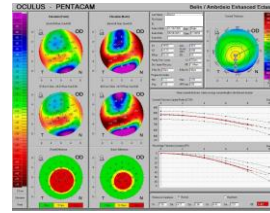


24 yo AA Male, graduate student
 Gradual ↓VA RE = 20/40 LE = 20/20 SC :
 +1.00 -4.00 x 055 51.6/44.4@064 -7.20@064 478um



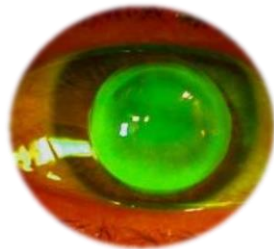
CXL SUCCESS

Stress importance of treating better eye with CXL and ease in fitting CLS after procedure



CORNEAL RGPS

- Those are still used?



CORNEAL RGPS

- The traditional correction for KCN
- Benefits
 - High level of oxygen permeability
 - Healthy corneal physiology maintained: active tear pump
 - Superior optics when compared to SCL/glasses
 - Relatively inexpensive to manufacture
 - Relatively easy for patients to handle
 - Unlimited powers

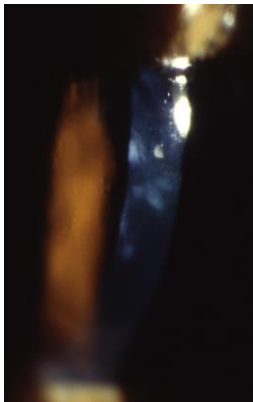
CORNEAL RGPS

- “Negatives”
 - Patient discomfort
 - Increased adaptation time
 - Lack of face to face education on proper fitting with new practitioners
- The Underlying Question
 - CLEK Study: they cause corneal scarring?
 - Flat fitting RGPs appear to cause an increased likelihood of apical scarring

CLEK

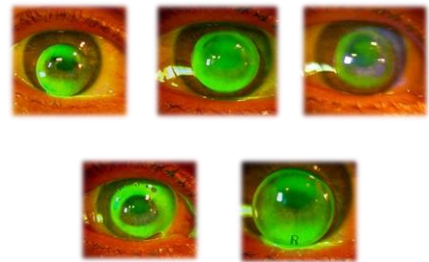
Collaborative Longitudinal Evaluation of Keratoconus

Data courtesy of Drs. Karla Zadnik and Timothy McMahon



STROMAL SCAR

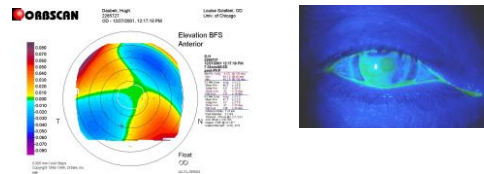
CLEK showed
 Overall 13% had scars
 K > 52 38% scarred
 43% of flat fits scarred (34%)
 26% of steep fits scarred (18%)
 8% ↑ with each hour WT
 Increase scar formation w/
 K- stain, F- ring, Pt. Age
 CLW (2 fold), ↑FDACL



TAKE HOME MESSAGE

- The Axial Map Is...
 - Up to 20X more sensitive than tomography data in regards to front surface refractive changes
- Use the elevation map to:
 - Determine the most appropriate contact lens modality
 - Illuminate early posterior corneal changes
 - Monitor advanced cases of ectasia

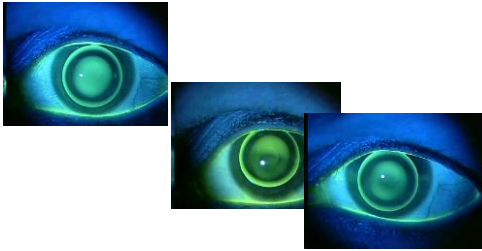
ELEVATION MAPS PREDICT FL PATTERN



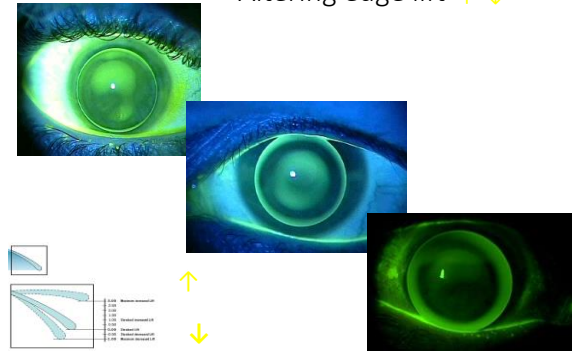
+ VALUES- warm colors
 points higher than sphere = elevation Areas of bearing or touch

- VALUES- cool colors
 points lower than sphere = depression Areas of pooling

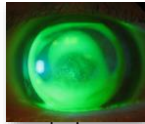
BC Selection
 Start steep then get feather touch*
 Central gaze and wait



Adjust Peripheral System by
 Altering edge lift ↑↓



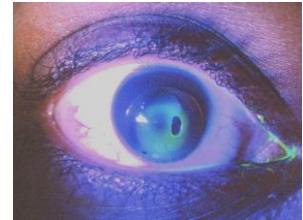
CORNEAL RGPS



- How do you fit a patient that requires the very device that may increase his or her corneal scarring?
- The answer: avoid bearing on corneal apex
- Modern fitting philosophy:
 - Except in severe cases the keratoconic cornea "normalizes" approximately 10mm from the apex
 - Larger corneal RGPs (>10mm) should be utilized with attempts made to clear/lightly touch the corneal apex if at all possible
 - Severe KCN will likely require smaller diameter RGPs

INDICATIONS FOR INTRA-LIMBAL LENSES

- KCN RGP dropouts
- Pellucid Marginal
- Post-PKP
- Astigmatic corneas
- SCL failures: due to neovascularization or poor visual acuity.

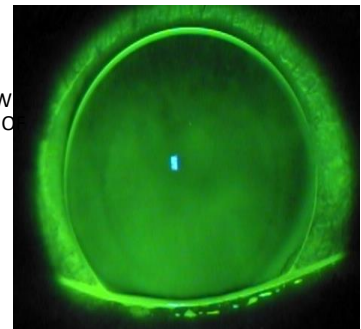


INTRALIMBAL FITTING

- BC is Flatter than expected
 - K @ 4-5mm temporal vs.
 - Average Mid K +.2mm
 - *Ikone, KBA, Dyna, RoseK2IC*
- Goal
 - Light feather touch
 - .2mm < corneal diameter
 - OAD > 9.2 and < 11.5 OAD
 - .1-.2 mm movement
 - .2mm edge clearance
 - High Dk materials



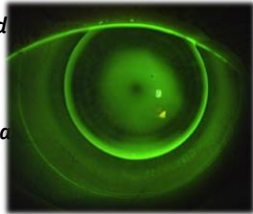
INTRALIMBAL DESIGNS ALLOW FOR VAULTING OF THE CORNEA



TANDEM= PIGGY BACK FITS

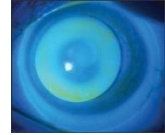
"when the best fitting corneal GP just isn't good enough"

2/2 comfort or erosions
Typically a very High dK materials are used with a Soft Disposable Lens that serves as a base under any RGP design

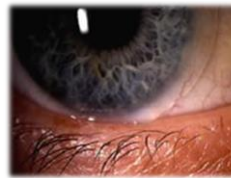
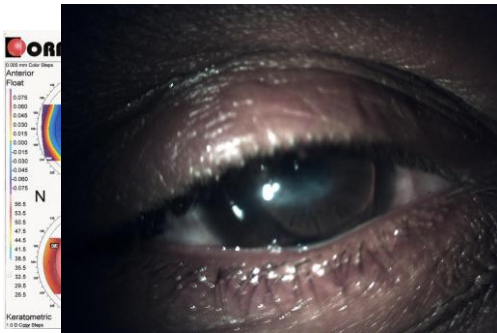


INDICATIONS FOR TANDEM

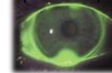
- When the best fit GP isn't 100%
- Improves comfort
- SCL protects cornea from RGP or environment
- Reduces epithelial damage due to touch
- Protects from apical nodules
- Aids in Concurrent EBMD
- Last resort before surgery



"RESCUED" FROM TRANSPLANT 20/25+



Soft Modulus molds to highly toric/steep K and may have less friction



		Dk/t @ -3 =	175
Acuvue Oasys:	0.72		147
Biofinity:	0.75		160
True Eye:	0.71		65
Dailies Total 1:	0.70		151



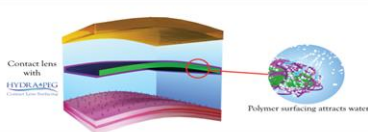
Surface Technology from Tangible Science

Hydra-PHG Contact Lens Surfacing

- Biocompatible Polyethylene Glycol based polymer mixture
- Crosslinked structure hides underlying lens material from ocular surface
- Consistently (permanently) bound to lens surface
- May be applied to hydrogel, silicone hydrogel and gas permeable material
- Scalable process easily integrates into high volume manufacturing

By increasing wettability, surface water retention, tear breakup time, lubricity and deposition resistance, the technology ensures longer wear time and convenience

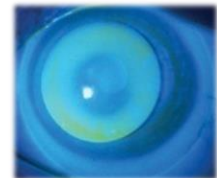
(No alcohol or abrasive solutions)



More information can be found at www.TangibleScience.com

PIGGY BACK AFFECTS FIT

- GOAL is to improve centration
- Most use plano power for the therapeutic effect however using higher powers can effect fit more and contributes to over-all power
- (-) SCL to steepen the RGP fit
- (+) SCL to flatten the fitting relationship of habitual RGP-
 - less sag depth
- Lenses move independently



Power Issues in Tandem Systems

Soft contact lens component will contribute about 20 percent of its power in air to the system.

- Typically low power (+/- 0.50) – has negligible influence on GP fit or net system power
- Use of + power to somewhat mask corneal irregularity and possibly improve GP centration - use of approximately +6.00 D
(+6 = 1.2D net + effect on system)

• Daniel Brazeau, OD

THICK LENS SYSTEM

The soft lens is no longer a thin lens system in "air"

The Tear Layer created between the GP and Hydrogel "negates" some of the SCL power... but not all..

Calculate power between the area behind back surface of the GP and the cornea AKA the TL and SCL.

$$BVP = F1 / (1 - t/n) F1 + F2$$

TABLE 1 Effective Optics of Piggyback Soft Contact Lens (SCL)

SCL true power (D)	Power (D)		Percentage (%)	
	7.80mm	7.00mm	7.80mm	7.00mm
-3.00	-0.63	-0.65	21	22
-1.00	-0.24	-0.25	24	25
-0.50	-0.14	-0.15	28	30
+0.50	+0.06	+0.05	12	10
+1.00	+0.16	+0.14	16	14
+3.00	+0.55	+0.52	18	17

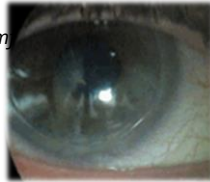
EFFECTIVE POWERS OF SCL UNDER GP IN TANDEM DESIGN IS ABOUT 20% OF ORIGINAL POWER (10-30%)

MINHEE WOO OD AND BARRY WEISMAN OD PHD

Recessed Lens Technology

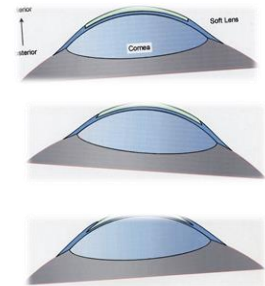
Recessed Pillow Lens (Fusion & EyeVis Technologies)

- Recessed anterior surface for GP
- In development
- Advantages: centering and com
- Indications:
 - Irregular corneas
 - Multifocal GP
 - Regular corneas
 - *Other Recess: Flexlens Piggyback

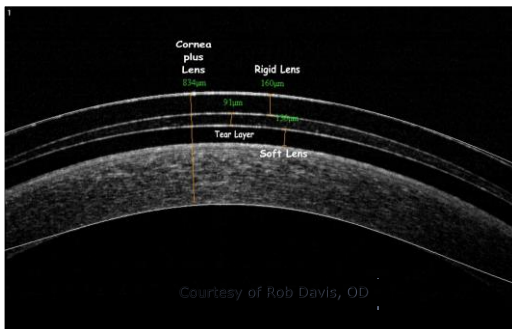


Recessed Hydrogel Platform

- Straight Walled
- Angle Walled
- Overhang



*Courtesy of Rob Davis, OD, S. Barry Eiden, OD EyeVis Vision Technologies



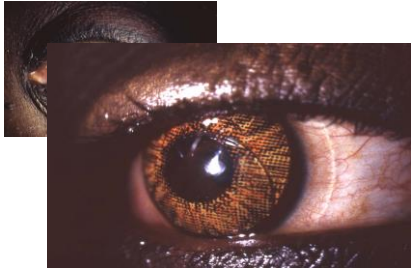
Courtesy of Rob Davis, OD

Care System Issues for Tandem Fits

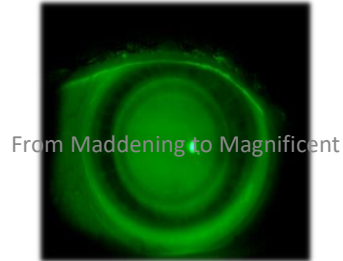
- Option 1:
 - GP solutions for GP
 - SCL solutions for SCL
- Option 2:
 - "One for all & all for one!"
 - (multipurpose SCL solution or peroxide)
 - USE DAILY DISPOSABLE!



Intra-Limbal/PiggyBack for Advanced Keratoconus

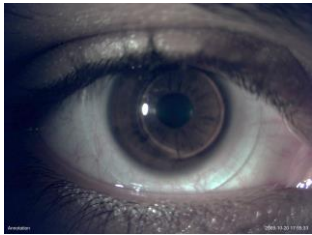


HYBRIDS CONTACT LENSES



From Maddening to Magnificent

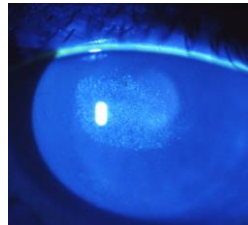
HYBRIDS CONTACT LENSES



HYBRID TECHNOLOGY:

Saturn...SoftPerm...SynergEyes...Duette...UltraHealth

Need to overcome abrasions due to rub, neovascularization from low DK, breakage at the junction, tight lens syndrome, and inflammation, irregular corneas, limited parameters, time consuming fits



SynergEyes 2nd Generation Design

Clear GP vision
Soft lens comfort

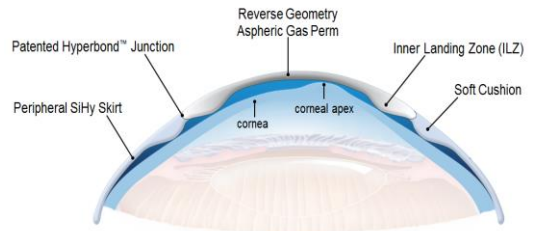
Proprietary GP material
Petrofocon A
OAD 8.5Dk 130
OZ 7.0 mm Duette
OZ 6.0-6.5 UltraHeath

Proprietary silicone hydrogel skirt (Iarafilcon A)
Dk 84
OAD 14.5

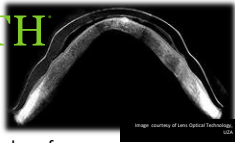
Hyperbond™ junction bonds materials at molecular level

Standardized treatment with Hydra-PEG since 2016

UltraHealth Lens Design: Allows for Vaulting



ULTRAHEALTH



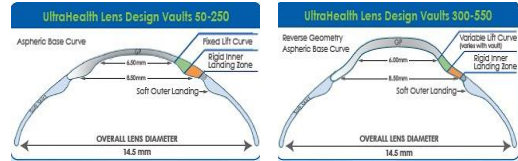
- Hyper Dk GP center: 130
 - Oblate reverse geometry GP back surface
 - Wider and gentler GP landing zone
- High Dk skirt: 84
 - Engineered for tear flow
 - SiHy skirt has a soft cushion design that helps center lens, conforms to the eye shape, provides comfort and tear pump, but does NOT suspend the GP
 - Typically Flat 8.4 SC
- > 80% UVA and 95% UVB

Reverse Geometry Vaulted Design

Variable parameters increase patient candidates

Fixed Lift Curve
250µ and below

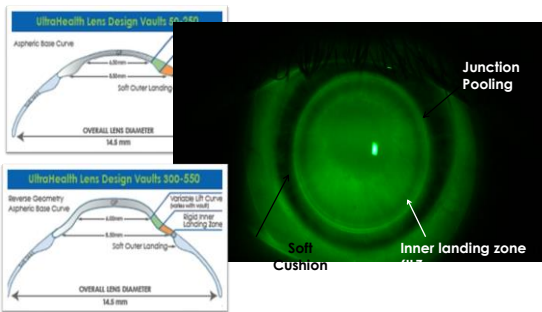
Variable Lift Curve
300µ and above



172

Vaulted Design Pattern

ULTRAHEALTH

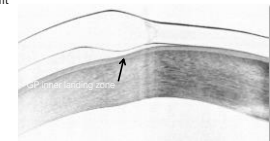


ULTRAHEALTH

Improvements

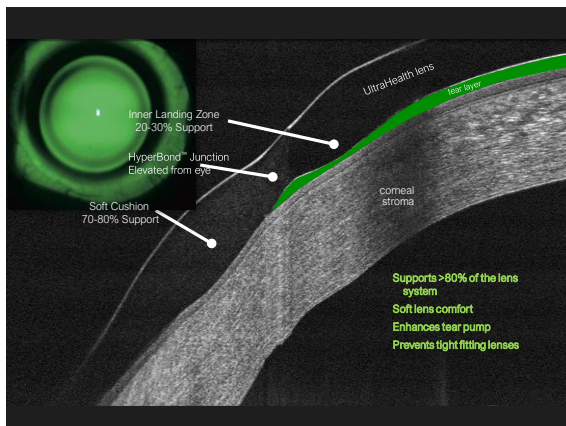
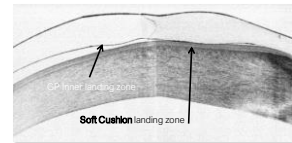
New design, materials & flatter fit

ClearKone 2009
1st Generation

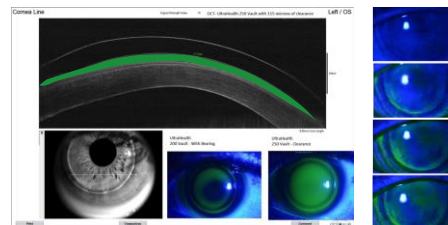


UltraHealth 2013
2nd Generation

Landing zones widened
The outer Soft Landing
bears the bulk of the weight, rather than the GP
2 Zones increase tear circulation... physics



UltraHealth Fitting Basics



Jeff Sorsino demonstrates 2 minute tear exchange...
Multiple LZ provide more opportunity to bump and pump fluid through
No need for high MW Fluorescein in the well.

HYBRID IRREGULAR CORNEA Parameters

ULTRAHEALTH CONTACT LENSES | The Most Advanced Hybrid Lens for Irregular Corneas | **Requires a Diagnostic Set!**

Diameter	14.5mm
Vault Values	50 to 550 in 50µ steps
Skirt Curves	8.7 Flat?, 8.4 Flat, 8.1 Medium, 7.9 Steep 50-250µ 8.4 Flat, 8.1 Medium, 7.9 Steep 300-550µ
Lens Powers	+10.00 to -20.000 +10.00 to +2.500 in 0.500 steps +2.00 to -8.000 in 0.250 steps -8.50 to -20.000 in -0.500 steps
Materials	84 Dk SiHy skirt, 130 Dk GP center
Class II	UVA and UVB
UV blocker	

UltraHealth® Advanced Hybrid Design High Dk (84) SiHy Skirt & Hyper Dk (130) GP utilizing patented HyperBond® technology.

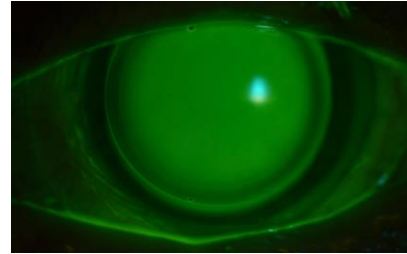
Aspheric Reverse Geometry Vaulted Lens Design

Optimized central lens results in lower powers and reduced aberrations

Reverse geometry, vaulted design clears the vast majority of ectasias

Hyper Dk (130) GP
High Dk (84) SiHy skirt
Optics centered over visual axis

The Hybrid Fitting Process



ULTRAHEALTH®

FITTING COMPONENTS

1. Determine the central vault
2. Assess the ILZ
3. Determine the correct skirt curve
4. Determine the correct power

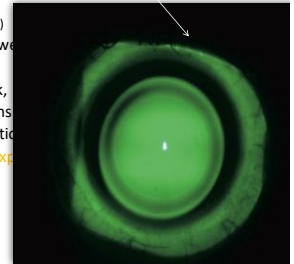


Fitting GOAL ULTRAHEALTH®

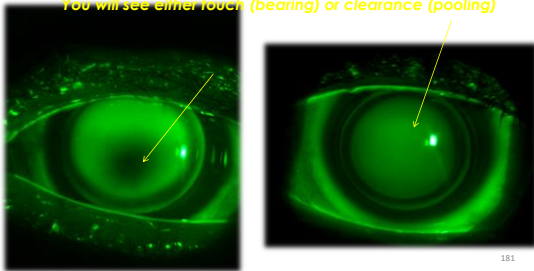
Hybrid Lenses for Ectasias should clear the apex approximately

- 100µm at initial fit (UH)
- 50µm with oblate designs (FC)

- UH Lens settle 40-60µm with w
- FC will settle less
- The lens is about 200µm thick, so clearance should be 1/2 of lens on cross section beam on insertion
- After settling, the final lens is expected to vault the cornea by about 50-75µm
- Feather clearance at the ILZ



Vault Determination for UH
 Ideal fit = 100 to 150µ above the apex of the cornea on insertion
 Start with a 250µ lens and a 8.4 Flat Skirt
 Use NaFl and wait 3-4 minutes
 Note: if immediate touch, no need to wait 3 minutes.
 You will see either touch (bearing) or clearance (pooling)



Central Vault Determination

If central pooling on 250 F, decrease vault 100µ until bearing observed.

If Light Bearing

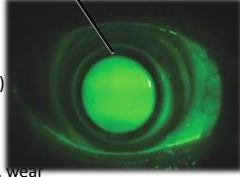
Add 50 µ to lens

If Heavy Bearing

Add 100µ to lens

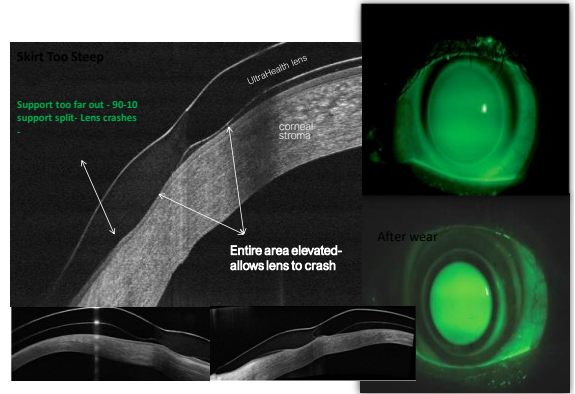
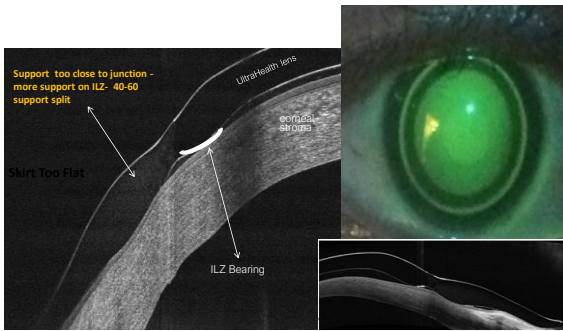
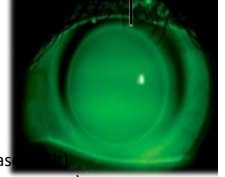
HEAVY ILZ BEARING

- Confirm appropriate vault.
- Over-vault can result in:
 - Poor centration (typically low)
 - Seal-off around GP edge
 - Decreased tear exchange
 - Impression ring on removal
 - Decreased comfort at 3-4 hrs. wear
- Confirm appropriate design
 - Move to Ultra Health FC (variable lift design) if ILZ bearing with correct vault 50-250 μ (fixed lift design) lenses



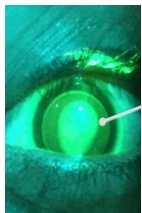
EXCESSIVE ILZ CLEARANCE

- If lens exhibits
 - excessive movement (> 1 mm),
 - decentration,
 - poor initial comfort and/or
 - inconsistent vision:
 - Confirm appropriate vault (decrease)
 - Confirm appropriate design (flatter corneas)
 - Flatten skirt curve to engage ILZ
- If patient is comfortable AND there is no adverse impact on cornea, leave as is.



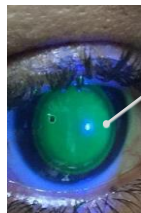
Sufficient Vault vs. Wrong Design

Vault 250 μ in Ultra Health



Central clearance with mid-peripheral-to-ILZ bearing

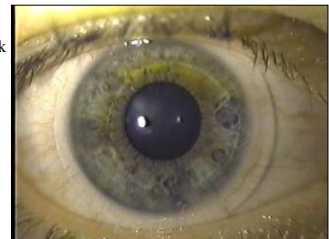
Vault 505 μ in Ultra Health FC



Central and appropriate mid-peripheral-to-ILZ clearance

Lens Movement in Hybrid

- .2mm to .3mm movement with blink
- Slight lag in upward gaze
- Free of scleral impingement
- Free to move on "push up"
- Free of "edge fluting"
- Less movement in UH



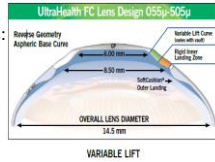
ULTRAHEALTH^{FC}

Vault (µ)	mm	Diopters	Rx Power
55	9.5	35.25	-1.00
105	9.3	34.25	-1.00
155	9.1	37.00	-1.50
205	8.9	38.00	-2.50
255	8.7	38.75	-3.50
305	8.5	39.75	-4.00
355	8.3	40.75	-5.00
405	8.1	41.75	-6.00
455	7.9	42.75	-7.00
505	7.7	43.75	-8.50

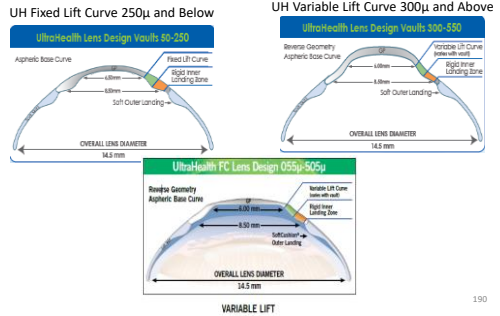
Same design as upper vaults of UltraHealth, with much flatter BCs to achieve great sagittal depth
Severe Oblate Corneas, Flatter Irregularities, Mid Peripheral Steepening

FC = Flat Curve= funny curves

Fit like UltraHealth with 2 differences:
50 µ of vault at dispense vs. 100 Medium skirts for majority of fits
Must fit with diagnostic lenses

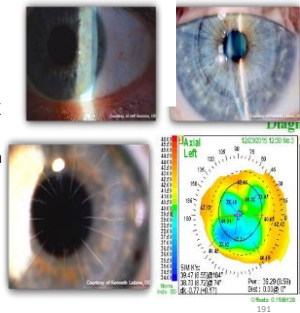


COMPARE ULTRAHEALTH^{FC} FAMILY

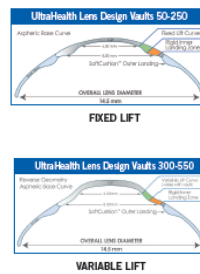


INDICATIONS FOR UH-FC

- Post RK
- Post Refractive Surgery
- Peripheral Ectasias
- PKP corneal grafts or DSEK
- Patients with flat central cornea's unable to be fit in Ultra Health
- Patient with steeper peripheral corneas not appropriate for UH



Base Curve Comparison Chart



UltraHealth KERATOCONUS | UltraHealth^{FC} OBLATE DESIGN

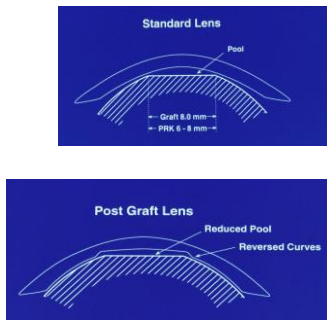
This chart shows the base curves of all UltraHealth^{FC} (UH) and UltraHealth^{FC} (UH-FC) lenses. It is IMPORTANT to not take the base curves at face value for fitting purposes, since much of the sagittal depth over corneal apex is created by the "peripheral lift" design of UltraHealth.

UltraHealth	FIXED LIFT			VARIABLE LIFT		
	Vault	Diameter	Power	Vault	Diameter	Power
UltraHealth FC	55	9.5	35.25	9.5	35.25	-1.00
	105	9.3	34.25	9.3	34.25	-1.00
	155	9.1	37.00	9.1	37.00	-1.50
	205	8.9	38.00	8.9	38.00	-2.50
	255	8.7	38.75	8.7	38.75	-3.50
	305	8.5	39.75	8.5	39.75	-4.00
	355	8.3	40.75	8.3	40.75	-5.00
	405	8.1	41.75	8.1	41.75	-6.00
	455	7.9	42.75	7.9	42.75	-7.00
	505	7.7	43.75	7.7	43.75	-8.50
	190	8.25	7.0	6.50	11	
	190	47.50	7.1	-8.00	12	
	350	49.00	6.9	-9.00	13	
	400	50.50	6.7	-10.50	14	
	500	52.00	6.5	-12.00	15	
	550	53.50	6.3	-14.00	16	
	600	55.00	6.1	-15.50	17	
	650	57.00	5.9	-17.50	18	

The lenses on the left side of the above chart, vaults 50-250, have a fixed lift in the periphery. Sagittal depth increase comes from an increase in the base curve of gas perm.
Note: UH vaults 50-250 are most appropriate for emerging to moderate, more central, possible irregularities, such as keratoconus.

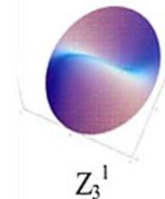
REVERSE GEOMETRY LENS

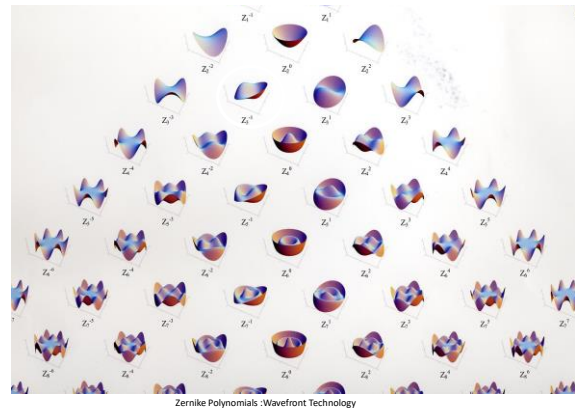
- Sagittal depth > 40 microns affects VA
- Sagittal depth > 80 microns creates bubble
- Utilize the peripheral reverse curve to alter the sag depth without creating excessive tear layer that causes aberrations yet still allows tear exchange
- Bisppheric designs allow for reduced sag



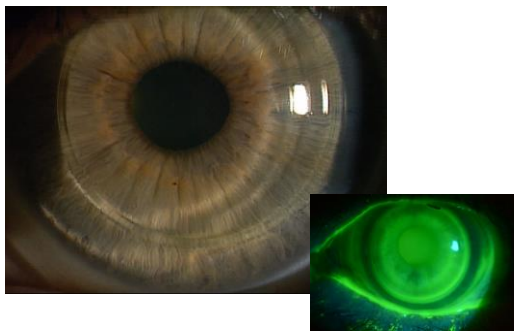
KCN Effects on Vision

- Tim McMahon, OD
- 60% reduction in VA is due to curvature, not just high cylinder
- RGP corrects cylinder however HOA remain
- May consider reverse geometry CLS
- Reduced low contrast VA
- Reads chart slower
- COMA



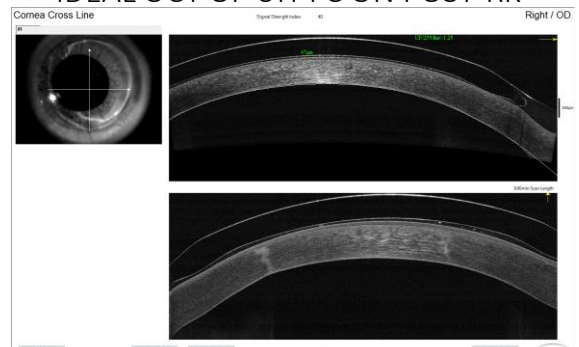


ULTRAHEALTH^{FC}

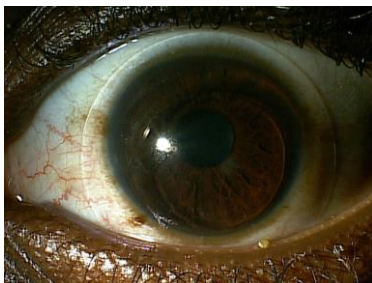


Courtesy of Jeff Sonsino, OD,FAAO

IDEAL OCT OF UH-FC ON POST-RK



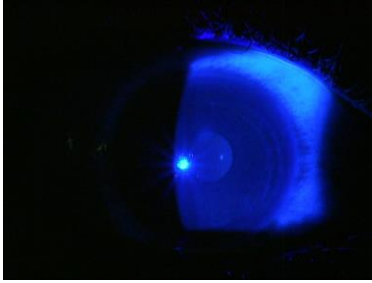
“Successful Hybrid Fit” Post-CXL
 FU= 2 months, VA 20/20 OU, WT = 16 !



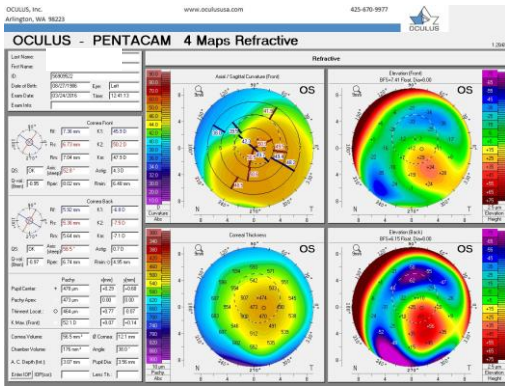
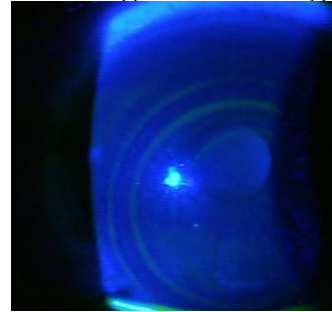
“Successful Hybrid Fit” Post-CXL
 FU= 2 months, VA 20/20 OU, WT = 16



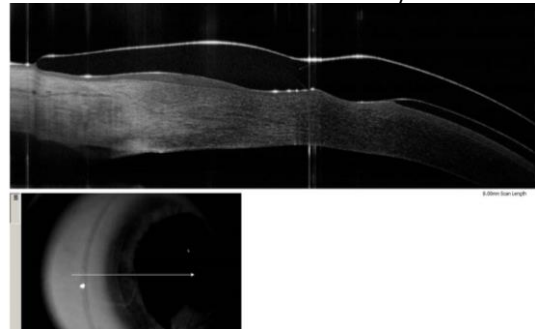
20 minutes post-removal
Impression rings and staining



20 minutes post-removal
Impression rings and staining



BEARING/COMPRESSION FROM
HYBRID LENS AT BOTH ILZ/OLZ



ULTRAHEALTH TO ULTRAHEALTH^{FC}

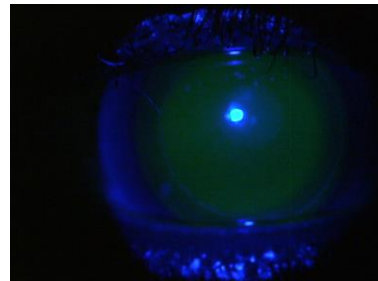
Contact Lens Prescription						
	Brand	Base Curve	Diameter	Sphere	Lens	Addl Specs
Right	Synergeyes	Vault 200	14.5	-5.00	Ultra-Health	skirt = steep
Left	Synergeyes	Vault 200	14.5	-6.50	Ultra-Health	skirt = medium

Manifest Refraction				
	Sphere	Cylinder	Axis	Dist
Right	-1.75	+2.25	138	20/20-1
Left	-6.25	+5.00	025	20/25-3

SPH LE = -1.25 (-500 x 115)

UH Vault 200 = 46.25 Power -6.50 Medium to Flat SC
FK Vault 450 = 42.75 Power -.25 Medium Skirt = 8.1

ULTRAHEALTH TO ULTRAHEALTH^{FC}



Trouble Shooting Tips

- At recheck, if poor lens movement, verify tear exchange by instilling fluorescein
 - Active tear pump should move NaFL under lens even w/o lens movement
- Discomfort at 3-4 hour mark, low-riding lens, and/or difficult removal may indicate over-vault
- If excessive movement with blink and/or bubble uptake *after* insertion, steepen skirt after confirming appropriate vault
- **Dry lens/dry fingers or tissue are key for removal**
- Impression ring may be visible after wear and is acceptable as long as there is no epithelial disruption
 - If there is epithelial disruption recheck the fit for over-vault or ILZ bearing.

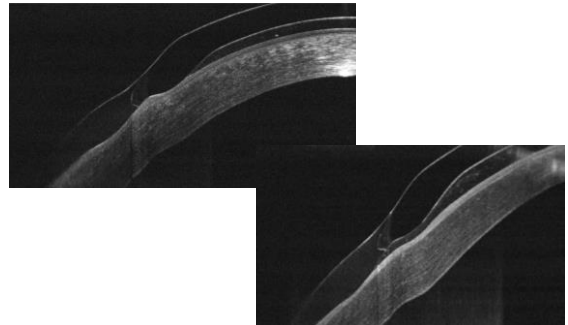
Personal TIPS and Techniques

- During fit, FIND FIRST TOUCH; it is easy to over-vault
- Remember to assess ILZ with each lens
- Set proper patient expectations; reassure there will be initial lens "awareness" that will go away in a few days with gradual build-up of wear time
- Avoid making changes at lens dispense visit
- Have patient review insertion, removal and lens care video **PRIOR TO DISPENSE APPOINTMENT**
- Train staff on I&R; Assure patient that removal is "*Different*" then what they are used to, but not "*Difficult*"
- Have patient remove lenses during office hours first several days

Hybrid Contact Lenses Fitting Tips

- Insert initial lens (250 vault/flat skirt)
- Obtain OCT clearance data
- Steepen the skirt to improve centration
- Flatten the skirt to promote lens movement
- Lens moves in/out
- Patients who will be more of a challenge
 - Chronic dry eye ... however now there is THP
 - Patients with intracorneal ring segments ... FC
 - Patients likely to require toric optics... 1D RA

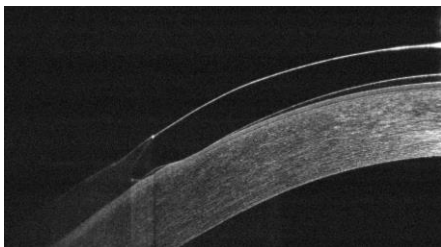
Use gentle Insertion to avoid loss of fluid and resultant Vacuum that can Cause Lens



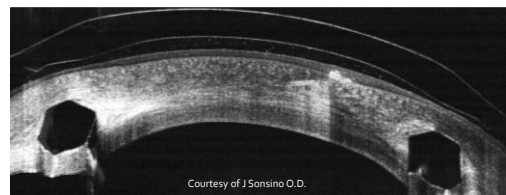
*Use the calliper tool to label the exact vault over the cornea

Vaulting Hybrid Lens Applications

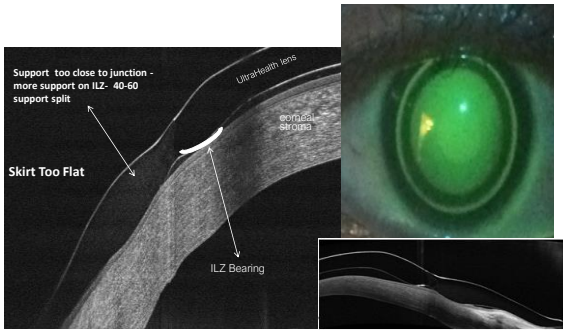
- ASOCT Assessment of Inner Landing Zones (alignment)



Vaulting Hybrid CL Evaluation

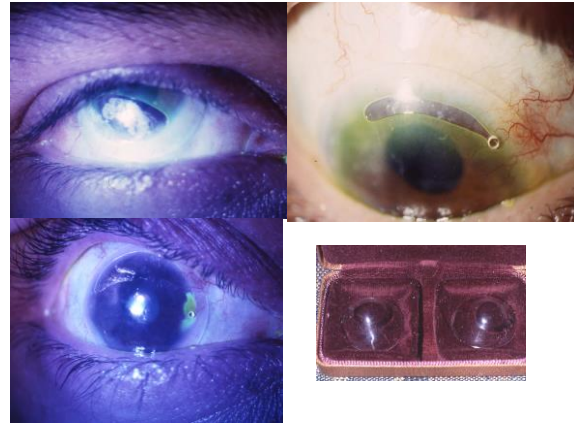


SCLERAL CONTACT LENSES



SCLERAL LENS HISTORY ...

- 1888 Adolph Fick described “blown glass vesicles”
- Eugene Kalt first glass “contact shell” to correct KCN
- 1889 August Mueller “high myopia” ... hypoxia
- 1900’s PMMA more feasible but still fenestrated
- 1970’s Gas Permeable
- TODAY: 16 + labs, SLS



SCLERAL CONTACT LENSES “go to”

BENEFITS

- Improved comfort over corneal GPS
- Stable and superb optics
- Vast parameters

INDICATIONS

- Treatment of corneal disease, trauma, post-surgical
- Treatment of refractive error
- Treatment of “CL dropouts”
- Treatment of dry eye



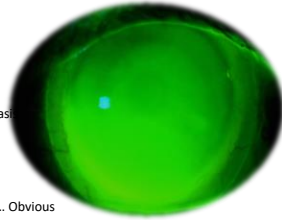
Scleral Lens MARKET

- Jupiter*/Europa series (Visionary, Essilor*)
- OneFit/MSD (Blanchard)
- NormalEyes/ICD (Paragon)
- Macro / SO2Clear (Dakota)
- Ezekiel Scleral Lens (Gelflex)
- Boston Scleral Lens (Boston Foundation)
- Custom Stable (Valley Contax)
- Maxim (Acculens)
- Dyna G (Diversified)
- Sag Sight Technology (AVT)
- EyePrint Prosthetic (AVT)
- Zenlens (Alden)
- ISIGHT Scleral Lens
- SuperFocus MC



SCLERAL DESIGNS basic rules evolving

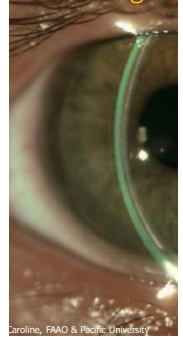
- Don't touch the cornea
- Different Designs utilize different guidelines
- VAULT (μm) vs. BASECURVE
 - (.1 mm BC Δ = 50 μm TL Δ)
- Protect the limbus
 - moderate clearance
 - Pressure "sucks" in ...conjunctival-chelation
- Sicker eyes, need bigger lenses
 - KCN 11.2-16mm
 - DX 17-20mm (EPP = 18)
 - Cell count "800" .. Need to be healthy... Obvious nucleoli = BAD



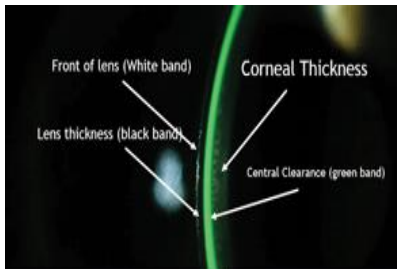
SCLERAL DESIGNS basic rules evolving

- Clearance "150-300 u" (200-250 EP)**
- Scleral CLS take longer to settle
 - Re-insert if bubbles (2/2 steep or technique)
 - Varies across surface...
 - Less clearance for smaller CLS
 - OCT or TL = 2/3 CT_{LENS} or 1/3 Cornea_{THICK}
 - Average Scleral CT = 350 u - 450 u (EPP)
 - Scleral CLS getting thinner.. Caution flexure

- Excess clearance may cause**
- Hypoxia
 - Negative pressure,
 - significant if mid-peripheral
 - Toxic swamp



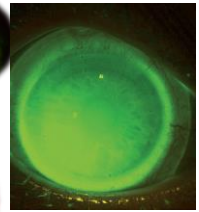
Central Clearance



LIMBAL CLEARANCE

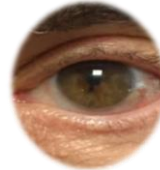
NOT ENOUGH

- Bearing may cause limbal stem cell drop-out

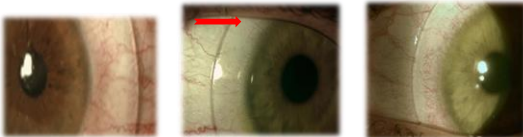


EXCESSIVE

- Potential for conjunctival prolapse



COMPARISON OF VARIOUS SCLERAL LANDING ZONES ON A PATIENT



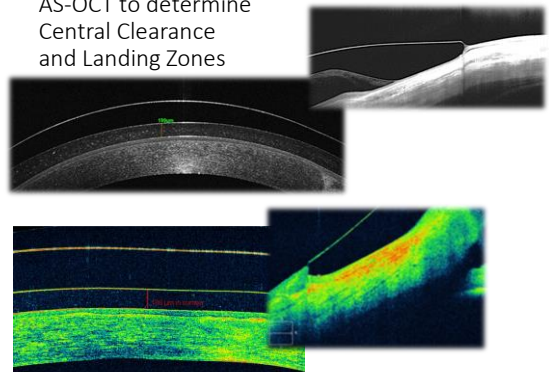
FLAT
Edge lift observed
Classic shadow and discomfort
Mid-Blanching
"Heel Down"

WELL BALANCED

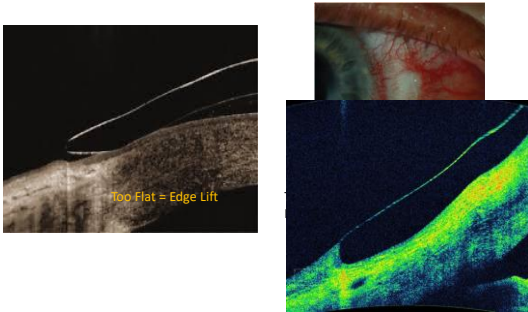
STEEP
Excessive pressure at far edge
Blanching Observed
"Toe Down"

* SLZ = scleral landing zone

AS-OCT to determine Central Clearance and Landing Zones



Conjunctival Landing



SCLERAL LENS CHALLENGES

PHYSIOLOGICAL

- The combination of a thick lens and fluid reservoir can result in decreased oxygen supply to the cornea

RESULTS

- Fit scleral lenses no thicker than 250 microns with no more than 200 microns of central corneal clearance in a material with a dK/t value >150.



SCLERAL LENS CHALLENGES

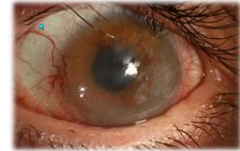
FITTING, HANDLING AND MAINTENANCE

- Requires proper technology for fitting/evaluation
Slit lamp, AS-OCT, Tomography, UNDERSTANDING + TIME
- Size does matter with handling
- Proper cleaning techniques
- Surface treatment: Plasma, Hydro-peg *
 - NO Alcohol or abrasive products
 - In office cleaning at follow-ups: PROGENT
- Create a Preservative-free tear reservoir
 - Inhalation Saline .9% Sodium Chloride
 - Menicon Lacripure, B&L Sclerafill
- At home techniques: Flush and Squeegee!



ETIOLOGY OF FOGGING

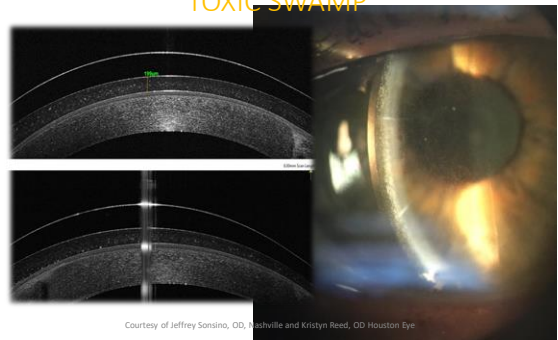
- More contact with goblet cells on the scleral conjunctiva stimulates more mucin production.
- Edge lift can stimulate MG on lids to produce more oils
- Preservatives in reservoir become toxic and set up inflammatory reaction
- Mucin gets trapped post-lens "toxic swamp" due to one way entry in areas of lift due to scleral toricity



FOGGING TREATMENT

- Treat Ocular Surface Disease
 - Dry spots on lens get build-up!
- May need to d/c Restasis due to goblet cell activity
- Give eye time to adapt
- Preservative-free Saline
- Reduce Central or Limbal Clearance
 - Reduce Sagittal Depth
 - Reduce Overall Diameter
 - Use Linear Peri-limbal zones = Tangential
 - Toric Haptics or scleral Landing Zones

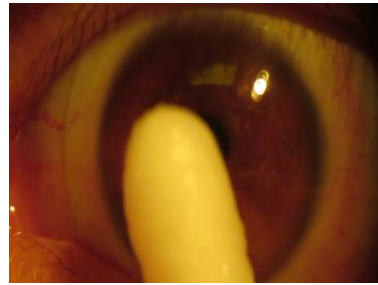
DEBRIS IN Post-Lens Tear Reservoir "TOXIC SWAMP"



Courtesy of Jeffrey Sosino, OD Nashville and Kristyn Reed, OD Houston Eye



SQUEEGEE FRONT SURFACE



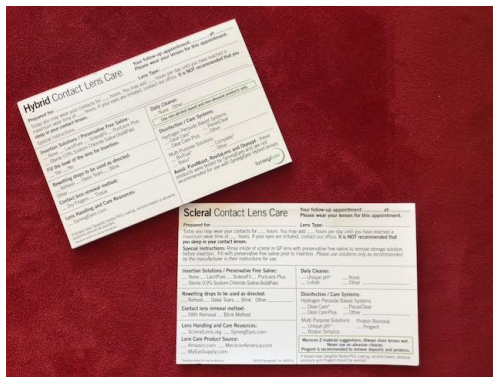
SQUEEGY TIME! Manage the Acne Rosacea



CHALLENGES WITH SCLERAL HANDLING



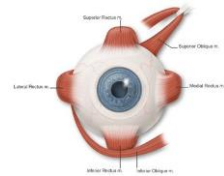
INSERTION/REMOVAL AND MAINTENANCE CHALLENGES WITH SCLERAL DESIGNS



SCLERAL LENS CHALLENGES

ANATOMICAL

- Non-rotationally symmetric
- Scleral toricity increases as you move away fr. Limbus
- Average eye at 16.5mm chord has 150 microns of scleral toricity
- Large scleral lenses tend to decenter infer-temporally
 - Can effect vision
- Smaller scleral lenses risk bearing on limbal stem cells



Research on Sclera Shape

- Toricity in the sclera can be present irrespective of corneal toricity
- Shape of limbus and para-limbal sclera are linear or straight rather than curved
- What is needed is a scleral lens that matched the shape of the sclera. VS LENS



Visser E-S, Van der Linden BJJ, Otten HM, et al. Medical applications and outcomes of bitoric scleral lenses. Optom Vis Sci 2013;90:1076-85

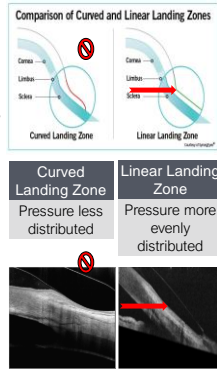
Linear Landing Zone

What's a linear scleral landing zone?

- Research shows that the para-limbal sclera is linear or straight, rather than curved

Why does it matter?

- Aligning a linear or straight sclera with a linear or straight landing zone on a contact lens distributes forces more evenly across the sclera



Study to evaluate IOP during Scleral Lens wear

- Compare common diameters 15.8/18.0
- Due to tightness, mass, and size, potential for:
 - compression of epi-scleral veins can reduce aqueous drainage facility.
 - Mass may displace fluid
 - Risks: thinner sclera, KCN
- Previous studies vary
- Snow-shoe theory



Michaud, L., Intra-ocular pressure variation associated with the wear of scleral lenses of different diameters. Contact Lens and Anterior Eye (2018)

Intra-ocular pressure variation associated with the wear of scleral lenses of different diameters

METHODS

- Prospective randomized
- N= 21 Avg. Age = 25 non-KC
- Spherical haptics, 15.8/18,pl
- IOPS baseline T_g/T_s .. 4 hrs
- Diaton Trans-palpebral T_s

RESULTS

- IOP taken with non-standard trans-palpebral technique rises an average of 5mmHg after 4.3 hours of wear compared to pre-lens wear
 - No difference between different lens diameters
 - Note similar LZ 13.8/14.4
- Limitations but reportable
Close Monitor those at risk



Michaud, L., Intra-ocular pressure variation associated with the wear of scleral lenses of different diameters. Contact Lens and Anterior Eye (2018)

WHAT IS ELEVATION SPECIFIC TECHNOLOGY?

- A prosthetic device is designed using exact contours of the ocular surface that are derived from an IMPRESSION taken of the eye rather than topographical analysis
- Result is a "customized lens" based on ELEVATION rather than curves
- Takes in to account asymmetric scleral toricity AND irregularity



Christine Sindt, OD Keith Parker, NCLECE David Slater NCLECE www.EyePrintPRO.com

The EyePrint Process an impression is made over the Ocular surface



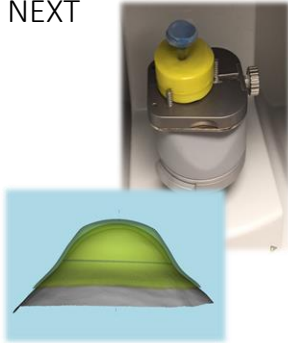
REMOVING THE TRAY



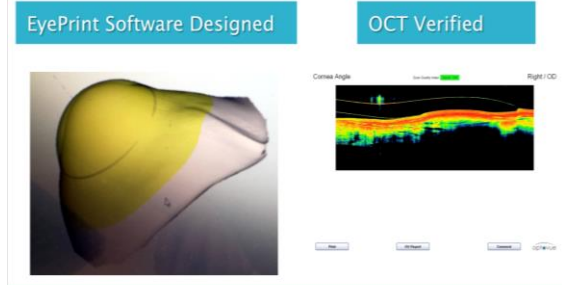
- Allow to set and once the material is no longer tacky... 60 s
- Push lid under upper nasal aspect of the tray to break the suction
- "Roll-off" toward lateral canthus
 - Power is based off an over-refraction performed over a scleral lens of known base curve and sagittal depth

WHAT HAPPENS NEXT

- Once an adequate impression is made, it is sent to lab for analysis and production
- The power is based on known BC and power from habitual/trial
- 3D Scanner analyzes 2 million data points of raw data and creates a "formula" with 250K points.
- The consultant uses this data to design a virtual lens.
- Lens is produced
- Hydrapeg process



Pinguecula



Scleral vs. EyePrint



The Capabilities of EyePrint

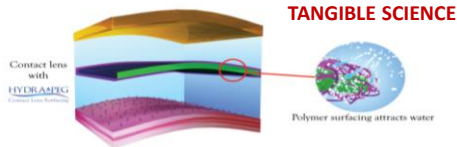
- Beyond providing for an exact fit of the globe the EyePrint can be manufactured with:
 - Front Toric Rx
 - Decentered Visual Axis
 - Prism (up to 4 prism diopters)
 - High Order Aberration correction
 - Multifocal
 - Center-Near or Center-Distance



Latest in Surface Technology:

Hydra-PEG Contact Lens Surfacing

- Biocompatible Polyethylene Glycol based polymer mixture
- Crosslinked structure hides underlying lens material from ocular surface
- Covalently (permanently) bound to lens surface
- May be applied to hydrogel, silicone hydrogel and gas permeable materials
- Scalable process easily integrates into high volume manufacturing



Vic McCray, MD, President and CEO