

Medical Applications of Contact Lenses

Susan A. Resnick, OD, FAAO, FSLC
 New York, NY
 Sresnick525@gmail.com

1

Disclosures

- Alcon
- Allergan
- Bausch + Lomb
- JNJ
- Santen
- Sight Sciences
- Visioneering Technologies



2

Defining Medical Contact Lenses

- Any type of contact lens that is worn for the primary purpose of treating an underlying disease state or complicated refractive status
- May or may not correct refractive error
- Prescribed for reasons other than the cosmetic purpose of eliminating the need for spectacles
- Some lenses are specifically labelled for use as bandage lenses or for therapeutic purposes
- Therapeutic applications often involve the use of adjunctive strategies

3

History of Material Advances

- 1886-1888 Fick fabricated first successful afocal glass scleral lens/Kalt/Muller brothers
- 1930s: plastic lenses were invented (PMMA)/William Feinbloom hybrid glass and plastic
- 1950s and 1960s: first corneal PMMA lenses
- 1970s Wichterle and Lim: Hydrophilic soft contact lenses
 - Bausch and Lomb Soflens: first FDA approved soft lens 1971
- 1978: FDA approve first GP material CAB
- 2000: launch of first silicone hydrogels
- 2002: Overnight OK approved by FDA

4

Classification of Medical Use

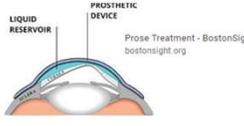
- Therapeutic or Bandage
- Rehabilitative

Current FDA approved soft therapeutic lenses

Brand	Manufacturer	Most +	Most -	BC	Diam	Dk	CT	H ₂ O
Acuvue Oasys with Hydraclear Plus	Johnson & Johnson Vision	+8.00	-12.00	8.4, 8.8	14.0	103.0	0.070	38.0
Air Optix Night & Day Aqua	Alcon	+6.00	-10.00	8.4, 8.6	13.8	140.0	0.080	24.0
PureVision	Bausch + Lomb	+6.00	-12.00	8.3, 8.6	14.0	99.0	0.090	36.0
UCL 55%	United Contact Lens	+20.00	-20.00	8.3, 8.6, 8.9, 9.4, 9.7, 10.0, 10.3	14.0, 14.5, 15.0, 16.0 to 24.0 in 2.0 steps	18.8	0.130	55.0

5

FDA Approval of Scleral Lenses for Medical Use



B+L Receives FDA Approval for Therapeutic Use of Gas Permeable Materials

Tuesday, August 15, 2017

The Boston XO and Boston XO2 materials are reportedly used in a variety of custom specialty lenses, such as the Zenlens™ scleral lens from Alden Optical, a part of the Bausch + Lomb Specialty Vision Products business, and are also indicated for daily wear for the correction of refractive ametropia and the management of irregular corneal conditions.

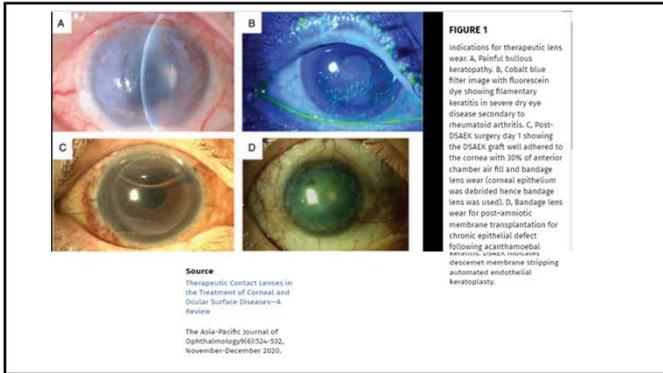
Ampleye Scleral Now FDA Approved for Ocular Surface & Dry Eye Disease Management

By Staff
 Monday, September 25, 2017 12:30 AM

GRAND RAPIDS, Mich.—Ald Optical Contact Lens, a leading independent custom lens manufacturer, has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) on their Ampleye scleral lens for the therapeutic management of ocular surface disease from the eye care optical based firm, introduced earlier 18 months ago.

According to Michael A. Johnson, FCLSA, director of consultation services at Ald Optical, in addition to using scleral lenses for the management of irregular corneal conditions, specialty contact lens filters have routinely prescribed them for patients with dry eye.

6



7

Bandage Lenses

Overview

- Ocular Discomfort
- Corneal Support
- Environmental Protection
- Mechanical Irritation
- Drug Delivery

8

Bandage CL vs. Amniotic Membrane

Bandage CL	Amniotic Membrane
Acute and Chronic	Acute
Comfort: Greater	Comfort: Lesser
Cost: Low	Cost: High
Drug Depot	Drug Depot
Ease of Insertion	Great Difficulty
OK for post-trab	Avoid Post-trab
Efficacy: Excellent	Efficacy: Excellent; faster in some conditions



9

BSCL Fit Considerations

- SiHy vs. HEMA?
 - Oxygen : Minimum requirement for overnight wear Dk/L=125
- Fit with minimal movement
- Ensure full corneal coverage
- Drawbacks to the use of BSCLs in the acute setting are the same as for other CL uses, specifically the potential for infection
- Adjunctive topicals
 - Non-steroidal
 - Steroid
 - Antibiotic
 - Lubricant

10

Cautions and Complications

<p>Cautions</p> <ul style="list-style-type: none"> Corneal anesthesia Significant exposure keratopathy 	<p>Complications</p> <ul style="list-style-type: none"> Infective keratitis Corneal Hypoxia Tight Lens Syndrome Lens Loss
---	--



Tight Lens Syndrome

11

Post-op Benefits of BSCL

- Reduce pain
- Reduce need for topical and/or systemic analgesia
- Protection from shear stress induced by blinking
- Promote re-epithelialization
- Strong evidence supporting use Post-PRK and CXL
- Minimal support for use post-LASIK

12



13

Clinical Indications for BSCL

- Post keratorefractive procedures
- Abrasions
- Perforations
- Burns
- Recurrent Erosions
- Bleb Leaks

Acute Conditions

14

The left photo shows a corneal abrasion; the right photo shows a bandage soft contact lens over a corneal abrasion. In this case, the contact lens acts a barrier to further epithelial disruption and corneal nerve stimulation by the shearing force of the upper lid during the blink. Additionally, there is evidence that a lens can prolong contact time of topical ocular medications.

<https://www.healio.com/news/optometry/20120225/bandage-contact-lenses-help-manage-corneal-disorders>

15

Over Adhesive for Lacerations and Perforations

- Fibrin and cyanoacrylate tissue adhesive are used in patients with corneal perforation
 - cyanoacrylate adhesive more effective than fibrin for larger perforations
- The surface of the adhesive is rough and may be dislodged by squeezing or blink
- There is little study guidance as far as the optimal lens materials or fitting parameters

<https://www.nature.com/articles/6700560tfigure/6>

A hydrogel lens used in conjunction with cyanoacrylate glue in the management of corneal perforation associated with rheumatoid arthritis.

16

Bleb Leaks

- Early or Late Stage
- Tamponade
- Facilitates re-epithelialization over wound margin

17

Efficacy and Safety of Contact Lenses Used in Trabeculectomy

- 1990: large diameter lens fitted on 10 patients 5 with shallow anterior chambers and 10 with leaking blebs (1)
- 2015: Between October 2011 and April 2013, 11 patients with early bleb leak following fornix-based trabeculectomy were instructed to wear a soft bandage contact lens 14 mm in diameter continuously for 1-2 weeks (2)
- 2019: 200 patients randomized to either no lens or lens after surgery; 14.0mm PureVision lenses were used (3)

(1) M. Birk, J. Kok, C. Van M, E. Greve, A. Kijstra Use of the megasoft bandage lens for treatment of complications after trabeculectomy *Am J Ophthalmol*, 110 (1990), pp. 264-268. doi:10.1016/0002-9394(93)90362-2

(2) Wu Z, Huang C, Huang Y, Zhang W, Ma D. Soft Bandage Contact Lenses in Management of Early Bleb Leak Following Trabeculectomy. *Eye Science*. 2015 Mar;26(1):13-17. PMID: 26390792.

(3) *Journal of Ophthalmology* Volume 2019, Article ID 1838712, 6 pages <https://doi.org/10.1155/2019/1838712>

18

Bleb Leaks: Fitting Considerations

- Cover superior conjunctiva with a minimum of 2 to 3 mm above the limbus
- Check fit after 30 minutes
 - No air bubble
 - Adequate coverage
 - Proper movement

19

Therapeutic Contact Lenses

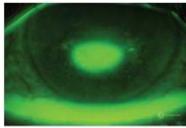
- Silicone Hydrogel
- Corneal GP
- Hybrid
- Scleral

Chronic Conditions

20

Persistent Epithelial Defects

Surgical complications
Neurotrophic keratopathy
Ocular surface disease
Infection
Trauma

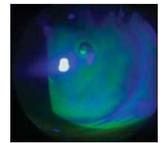


- Epithelial defects non-responsive to treatment after 2 weeks
- Epithelial debridement
- BSCLs a standard therapy
- Lubrication
- Autologous serum
- Punctal occlusion (with caution)
- Scleral lens

21

Recurrent Corneal Erosion

Abrasions
Dystrophies
Prior Ocular Surgery



Highest rates of RCE occur in patients who also have dry eye syndrome, diabetes mellitus, blepharitis, and ocular rosacea

Treatment includes contact lens, medical, and surgical options

22

RCE: Contact Lens Management

- Bandage contact lenses used to protect the epithelium from the shearing force of the lids
- Avoid tight lens syndrome.
 - This condition involves acute tightening of the contact lens, which leads to decreased lens movement, inflammatory debris beneath the lens, increased inflammation and pain.
- Non-preserved artificial tears help to flush inflammatory debris and improve comfort.
- Topical prophylactic antibiotics should be used to decrease the risk of microbial keratitis, which may be caused by extended use of bandage soft lenses.
- Patients may wear bandage contact lenses continuously for six to 12 weeks to allow for restoration of tight epithelial basement membrane adhesions.
- Replace lens as appropriate.

23

RCE: Medical Management

- Once the epithelium is healed, hypertonic saline solution can be administered during the day, followed by ointment at bedtime for 6-12 months to promote adequate epithelial attachment
- Doxycycline 50 mg BID and topical corticosteroids
- Biologic or Autologous Serum drops

24

RCE: Surgical Management

- Epithelial Debridement - treats active erosion but may not prevent recurrence
- Diamond Burr Polishing - good for long term but risk of haze
- Alcohol Delamination - low incidence of corneal haze
- PTK- good short term results; works well for trauma and EBMD

25

Corneal Dystrophy



Acute/Chronic

- Pain
- Foreign Body Sensation
- Recurrent Corneal Erosions
- Lacrimation
- Reduced Vision

- Bilateral
- Noninflammatory
- Nonvascularized
- Slowly progressive

26

Corneal Dystrophy: Therapeutic Goals

- Pain reduction
- Ocular surface protection
- Visual Rehabilitation
- Supportive therapy
- Amniotic membrane
- Contact Lenses
- Surgical Management

Corneal Dystrophies That May Present With Epithelial Defects	
Condition	Epithelial defects
Epithelial & Subepithelial Dystrophies	
Epithelial basement membrane dystrophy	Corneal erosions
Epithelial recurrent erosion dystrophy	Recurrent corneal erosions
Marginal dystrophy	Subepithelial vesicles
Marginal's (Stocker-Roth) dystrophy	Punctate epithelial erosions
Guttate-dimple corneal dystrophy	Flap-like shaped lesions
Brown's Layer Dystrophy	
Rain-Bowden's corneal dystrophy	Recurrent corneal erosions
Total lamellar corneal dystrophy	Recurrent corneal erosions
Stromal Dystrophies	
Lattice dystrophy (Type 1, 2, 4, 6)	Recurrent corneal erosions
Granular dystrophy	Recurrent corneal erosions
Axial dystrophy (Scrambled dystrophy type 2)	Mild recurrent corneal erosions
Macular dystrophy	Severe recurrent corneal erosions
Endothelial & Subendothelial Dystrophies	
Fuchs' endothelial dystrophy	Epithelial edema, epithelial bullae, & erosions

27

Contact Lens Management of Corneal Dystrophy

- BSCL for acute epithelial defects/pain
- Corneal GPs not a problem for EBMD with intact epithelium/asymptomatic patients
- Piggy-backing when needed for acute or chronic epithelial compromise
- Hybrids
- Sclerals

28

Fuch's Corneal Dystrophy



- Most frequent endothelial dystrophy in the U.S.
- Corneal guttata = excrescences on a thickened Descemet's membrane
- More common and more severe in women (sex ratio 3-4:1)
- Autosomal dominant with incomplete penetrance
- Onset 5 or 6th decade
- Generalized corneal edema
- Decreased visual acuity
- Painful erosions

29

Contact Lens Management in Fuch's

- Low modulus soft bandage lenses for acute epithelial erosions or bullae
- RGPs for irregular corneal surface; aim for apical clearance and good edge lift using highest Dk materials
- AVOID SCLERALS
- Hypertonic drops during the day/ointment at night (work best when epithelium is not severely compromised)

30



Figure 1: Therapeutic Hyper-CL™ lens design. The lens design consists of a dual base curve, fenestrations, and a reservoir for accumulation of therapeutic solutions.

Diameter 15.5 BC 8.5 Hioxifilcon D

Therapeutic Hyper-CL™ Soft Contact Lens for Short-time Wear (up to 7 consecutive days) is a CE-marked hydrogel contact lens, containing 59% water, by weight, with a Dk/t of 26. The lens is designed, with dynamic base curves, fenestrations, and reservoir (shown in Figure 1).

31

Research Article
Therapeutic HL-Contact Lens versus Standard Bandage Contact Lens for Corneal Edema: A Prospective, Multicenter, Randomized, Crossover Study

Ofer Daphna,¹ Michael Mimouni,¹ Yariv Kesbet,² Meydan Ben Ishai,³ Irina S. Barquet,⁴ Boris Kayazer,⁵ Iwa Mrukwa Kominck,⁶ Tomasz Zarnowski,⁷ Malca Chen-Zion,⁸ and Aric Marcovitch⁹

49 patients enrolled
 Control lens was PureVision

https://www.researchgate.net/publication/345333068_Therapeutic_HL-Contact_Lens_versus_Standard_Bandage_Contact_Lens_for_Corneal_Edema_A_Prospective_Multicenter_Randomized_Crossover_Study

BCVA improvement	Hyper-CL (%)	Control (%)	P-value
>1 line	67.8	34.8	0.01
>2 lines	43.5	20.3	0.03
>3 lines	26.1	17.1	0.08

Adverse event	Hyper-CL (%)	Control (%)	P-value
Pain or discomfort	8.9	11.1	0.31
Conjunctival irritation	2.2	4.4	0.31
Bubble-related corneal erosion	6.7	2.2	0.19
Lens intolerance	2.2	0.0	0.25

32

American Journal of Ophthalmology Case Reports
 Volume 25, March 2022, 101242

Case report
Therapeutic contact lens for Fuchs endothelial corneal dystrophy: Monitoring with Scheimpflug tomography

Nir Erdinest¹, Naomi London^{2,3,4,5}, Nadav Levinger^{6,7,8,9}, Itay Iavry⁸

The patient was fit with Therapeutic Hyper-CL™ soft contact lenses for eight days extended wear and instilled 5% sodium chloride six times a day. Visual acuity improved in the right and left eye from 0.5(-2) and 0.5(+1) to 0.4(+2) and 0.3(-1), respectively. Corneal thickness at the thinnest point decreased from 650µm to 632µm-632µm and 604µm in the right and left eye respectively

33

Filamentary Keratitis

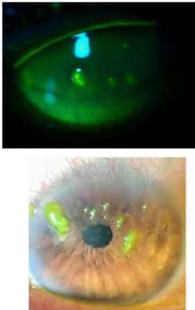
Underlying Causes:

- Dry eye
- Superior limbic keratoconjunctivitis
- Prolonged patching following ocular surgery
- Epitheliopathy due to aerosol or radiation keratitis
- Herpetic keratitis
- Recurrent corneal erosion
- Neurotrophic keratitis
- Bullous keratopathy

34

Filamentary Keratitis: Epidemiology

- Prevalence unknown but more common
 - As age increases
 - Females
 - Immune deficient
 - Connective tissue disorders



35

Filamentary Keratitis: Signs and Symptoms

- Hyperemia, especially limbal
- Pseudoptosis in some patients
- Corneo-mucous filaments are the hallmark finding
- Symptoms range from mild discomfort to pronounced pain

36

Filamentary Keratitis: Management

- Remove filaments
- Topical anti-inflammatory agents
- Ocular lubricants
- 10% acetylcysteine eye drops used four times daily
- Bandage soft contact lenses/corneal lenses/scleral lenses
- Amniotic membrane therapy
- Botox (onabotulinumtoxinA, Allergan) injection to the pretarsal orbicularis muscle

37

Ocular Surface Disease

Chronic

- Chronic graft versus host disease
- Sjogren syndrome (limited evidence)
- Stevens-Johnson syndrome (SJS)
- Mucous membrane pemphigoid
- Limbal Stem Cell Deficiency (LSCD) (caution)
- Exposure Keratopathy
- Neurotrophic Keratopathy

38

Scleral Lenses for OSD: Fitting Considerations



- Scleral lenses should be considered after ocular lubricants and prescription eyedrops and before long-term topical corticosteroids and surgical treatments for DED.
- Patients with healthy corneas who may benefit from scleral lenses include those who have astigmatism who experience fluctuating vision with soft toric lenses, presbyopic patients with DED who wish to continue contact lens wear, and contact lens wearers who experience ocular dryness with their existing lenses.
- Scleral lenses can be used for corneas that have a regular, normal, prolate shape and no disease, ectasia, or irregularities
- Patients who have OSD and other conditions such as ocular rosacea and meibomian gland dysfunction are susceptible to fogging of the anterior surface of the scleral lens.
 - H2O2
 - Progent
 - Tangle Hydra-Peg
 - Conventional management options for anterior scleral lens fogging are increased lubrication with preservative-free artificial tears throughout the day and removal, manual cleaning, rinsing, and reapplication of the lenses. A squeegee technique with on-eye surface cleaning may also be used

39

Ocular GVHD

Chronic

Can affect many ocular structures:

- Lacrimal and meibomian glands
- Conjunctiva
- Cornea Crystalline Lens
- Posterior Segment
- May be acute or chronic

- The first reports on the use of contact lenses in the management of ocular cGVHD were published in the 1970s
- Reports on the long-term benefit and effectiveness of scleral lenses in management of ocular cGVHD found a 90 % continuation rate of scleral lens wear at 32 months and a 75 % continuation rate at 5 years (M.M. Schomack, J. Pyke. S.V. Pate/Scleral lenses in the management of ocular surface disease Ophthalmology, 121 (2014), pp. 1399-1405)

40

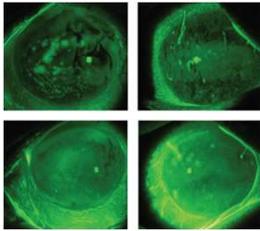
Management of Ocular GVHD

*The National Institutes of Health formulated consensus guidelines with 4 major supportive care goals:

1. Lubrication
2. Control of Tear Evaporation
3. Control of Tear Drainage
4. Decrease of Ocular Surface Inflammation



41



Advantages of Scleral Lenses:

1. Tear Reservoir
2. Cannot dislodge
3. Excellent Vision
4. Protect greater ocular surface area

Disadvantages of Scleral Lenses:

1. Handling/Insertion with small fornix/conjunctival irregularities
2. Cost

These images depict a GVHD patient's eyes before (top) and after scleral lens wear, showing an improved ocular surface, including a reduction in filaments, after just a few hours of wearing time.

<https://www.reviewofoptometry.com/article/ro1117-graftvshost-disease-how-why-and-what-next>

42

Neurotrophic Keratopathy

Chronic

- Degenerative condition caused by impairment of trigeminal nerve function
 - reduced corneal sensation
 - persistent corneal epithelial defects
 - ulcers and perforation

43

CL Considerations In NK

- Prevent progression of corneal damage
- Promote epithelial healing
- Fit with caution; both sclerals and sily have been used
- Use antibiotic prophylaxis/discontinue when epithelial healing occurs
- Daily wear
- Avoid steroids
- Can use contact lens carrier over (dehydrated) amniotic membrane



44

Lid Abnormalities

Ptosis
Blepharospasm



<https://www.clypeitron.com/news/2020/november-2020/the-scleral-lens-visit>

Scleral Contact Lenses

- Ptosis
 - Increased Palpebral Aperture
 - Increased Marginal Reflex Distance
- BEB
 - Reduced blink rate
 - Reduced photophobia
 - Reduced dryness

45

Case Study

- 67 yo WF
- Bilateral blepharospasm (BEB: benign essential blepharospasm)
- Meds: Botulinum Toxin, Lorazepam
- Previously tried Punctal Occlusion and RESTASIS® : "No Help"
- CC: chronic dry eyes/ eye pain (scores 9 on SPEED questionnaire)

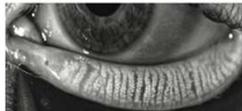


46

Benign Essential Blepharospasm/Dry Eye

Ocular Surface Evaluation

- Osmolarity OD 299 OS 304
- Tear Prism .25mm OU
- Inflammadry "Mildly Positive" OU
- TBUT 5 seconds OU
- Meibomian Gland Imaging: mild dilation OU
- Diagnostic Expression: minimal yield with force
- No significant corneal or conjunctival staining



47

BEB/Dry Eye

Impression and Plan

- Poor lipid quality/evaporative dry eye
- Erratic blink pattern due to blepharospasm
- Treat blocked glands
- Scleral lens fitting

Outcome: patient continues to experience significant relief from spasms and dry eye symptoms two years post fitting.

48

Therapeutic Tinted Lenses

Clinical Indications

- Aniridia
- Irregular pupil
- Occlusion
- Albinism

49

Therapeutic Tinted Lens Design Options

- Manufacturing
 - Standard Translucent
 - Standard opaque
 - underprint/black backing
 - "Semi-Custom" (e.g. decentered pupil)
 - Hand Painted
- Design
 - Black Pupil, Clear Iris
 - Clear pupil, Tinted iris
 - Pupillary "frill"/starburst
 - Limbal ring

50



Figure 2. Clockwise from top: (A) an iris occlusion lens with an open pupil; (B) a pupil occlusion lens with a translucent, tinted iris; (C) both an iris and pupil occlusion tinted lens; (D) a pupil occlusion lens with a translucent, tinted iris; and (E) a pupil occlusion lens with a clear iris.

Contact Lens Spectrum 3/1/15

51

Patient Education: Managing Expectations

- There's no such thing as perfect – small differences between the two eyes have to be accepted
- More time involved to fit than conventional sight correction
- Pupil size is fixed to one size
- Casual observers are about 3 feet away
- Light color iris more difficult to match than dark
- The artificial iris is in the corneal plane, not behind so dimensionally different
- Wearing time may be limited

52

Diagnostic Work-up

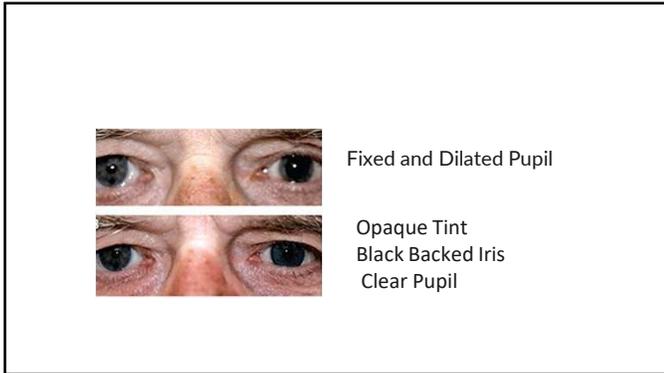
- HVID
- Pupil Size
- Refraction of both eyes when indicated
- Visual acuity of each eye
- Iris Color
- Hyperemia
- Careful inspection of tears, lids, conjunctiva
- Position and nature of any scar tissue

53

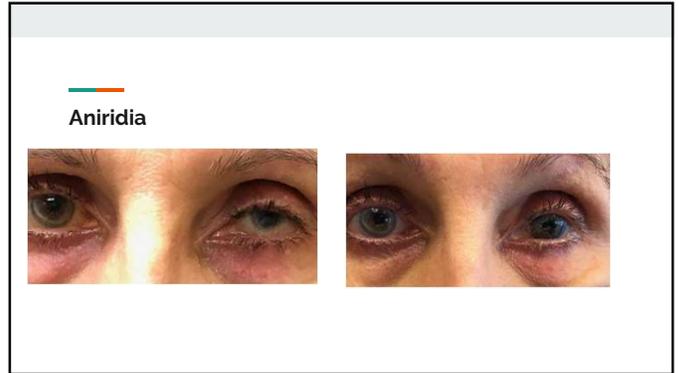
Lens Design and Fitting

- Base Curve
- Back Vertex Power
- Total Diameter
- Iris Diameter
- Pupil Diameter
- Need Good Centration: Fit larger and steeper as needed
- Minimum movement (.25 to .5mm with blink)
- Aim for a pupil size to match fellow eye in average photopic conditions/err smaller
- For unusual parameters or when only able to fit one eye with difficult iris match use hand painted lens

54



55



56

Visual Rehabilitation

- Disease
- Surgery
- High Refractive Error
- Aphakia
- Trauma
- Infection

57

Refractive Management Irregular Cornea

Ectasia

Fitting Considerations

- Location of Corneal Apex
- Presence of Intrastromal Rings
- Wearing Comfort
- Cost

58

Design Selection Scheme

Corneal Condition	Custom Soft	Corneal GP	Intralimbal	Hybrid	Piggyback	Scleral
Low/Mod Irreg Centered Apex	Green	Green	White	Green	Green	Yellow
Decentered Apex	Yellow	White	Green	Yellow	White	Green
Scleral Irreg	Yellow	Green	Green	Yellow	Green	Yellow
Tolerance	Green	White	Yellow	Green	Green	Green

59

Diameter	Base Curve	Sphere Power Range	Cylinder Power Range	Axis
12.5mm to 16.0mm	6.9mm to 9.5mm	±25.00D (0.10D steps)	-0.25 to -8.00 (0.1D steps)	0° to 360° (1° steps)

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

Lens	Indication
SynergEyes KC	central prolate corneas, KC
SynergEyes PS	Oblate post-surgical corneas
SynergEyes ClearKone	Central and decentered ectasia and KC
SynergEyes UltraHealth	prolate corneas, KC

60

> Cont Lens Anterior Eye. 2020 Dec;43(6):568-576. doi: 10.1016/j.clae.2020.03.009. Epub 2020 Mar 29.

Do visual performance and optical quality vary across different contact lens correction modalities in keratoconus?

Preetam Kumar ¹, Praveen K Bandela ², Shrikant R Bharadwaj ³

- Hypothesis: different contact lens designs would have varying impact on visual performance and optical quality in advanced KCN but not early to moderate disease
- Methods: 28 mild to advanced KCN pts new to lenses, 10 age matched controls
 - All data were collected on keratoconic subjects with their spectacles and with conventional RGP, Kerasoft®, Rose K2® and Scleral RGP® CL's in randomized order, at least a week apart from each other.
- Results: All outcome variables deteriorated with keratoconus severity and improved with CL wear, relative to spectacles ($p < 0.05$). This improvement was smaller for Kerasoft CL ($p < 0.05$) and higher but comparable for the other three CL designs ($p = 0.3$), across all disease severity. Visual functions and optical quality outcomes never reached control levels for any correction modality ($p < 0.05$).

61

KCN Fitting Goals for Corneal GPs

- Minimal vault over corneal apex
- Mid-peripheral alignment and moderate peripheral clearance
- Smaller diameter for paracentral "ripple cones"
- Medium or larger diameter for oval or decentered cones
- Consider asymmetric peripheral curves for better edge alignment
- Consider Piggy-backing for epithelial protection/ better centration/ better tolerance

Rose K2, ComfortKone, TruKone, Dyna Z Cone, V Cone, C Cone and E Cone

Intra-limbal designs include Dyna Intra-Limbal, Rose K2 IC.

62

Scleral Lenses for KCN

- Many designs
- Start with two that offer varied diameters
- Expect that most will need toric haptic
- Centration is key
- Fit first, then assess need for toric optics
- Consider profilometry to enable empirical fitting
- Several designs offer aberration control
- Wavefront guided technologies are emerging

63

Comparison of Wavefront-Guided and Best Conventional Scleral Lenses after Habituation in Eyes with Corneal Ectasia

Gareth D. Hastings, MPhil, BOptom, Raymond A. Apolegate, OD, PhD, FAAO, Lan Chi Nguyen, MBA, Matthew J. Kauffman, OD, Roxana T. Hammati, OD, and Jason D. Marsack, PhD, FAAO

Optom Vis Sci. 2019;96(4):238-247.
doi:10.1097/OPX.0000000000001365

- Ten subjects (20 eyes) participated in a randomized cross-over study where best conventional scleral lenses and WFG scleral lenses (customized through the 5th radial order) were worn for eight weeks each.
- Outcomes measured: residual higher-order aberrations (HORMS), visual acuity (VA), letter contrast sensitivity (CS), and visual image quality (logVSX).
- Mean HORMS reduced 43% from conventional to WFG.
- Mean logMAR VA improved from habitual (+0.12) to conventional (-0.03) and further with WFG (-0.09)
- Six eyes gained >1 line with WFG over conventional.
- Eyes achieving normal levels: HORMS: conventional 40%, WFG 85%;
- Reduction in aberrations with WFG lenses best correlated with posterior cornea radius of curvature.

64

Refractive Management Irregular Cornea

Post-Surgery

- In patients with keratoconus that proceed to PK, between 31 % and 56 % return to contact lens wear after surgery
- Topography
- Endothelial Cell Count

65

Post PK Fitting Considerations

- Typically 6 to 12 months after surgery
- Subsequent suture removal may necessitate fit adjustments
- Careful pre-fitting documentation
 - properly identify clinical signs of graft failure or rejection.
 - endothelial rejection is easily the most common presentation

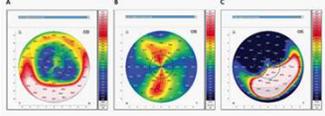


Endothelial rejection post-corneal graft with presentations of stromal edema, stromal folds, and endothelial keratic precipitates

<https://www.cdspectrum.com/issues/2018/june-2018/contact-lenses-after-corneal-transplantation>

66

Post PK CL Selection



Axial topography of post-PK corneas. (A) Oblate corneal curvature. (B) Prolate astigmatic corneal curvature. (C) Steep-to-flat corneal curvature.

- Soft contact lenses can be used when higher-order aberrations (HOAs) are not significant
 - Custom designs for extended range; oxygen considerations
- Corneal GP lenses when HOAs are high
 - standard spherical-back-surface GP design if the corneal toricity is centrally localized, 5,000 or less in magnitude, assumes a prolate profile, and/or when peripheral eccentricity approximates that of a normal cornea (i.e., 0.5 to 0.7)
 - standard back-toric GP designs for orthogonal astigmatism

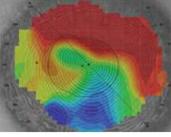
67

Post PK CL Selection

- Custom keratoconus GP and intralimbal designs for moderate to severe central steepening
 - Consider the advantage of large OZ to minimize mechanical interaction at graft host junction
 - When the steeper half of the graft is 180° away from the flatter half
 - Initial trial lenses can be selected based on topography utilizing the dioptric value 3mm from the center or the average keratometry value
- Piggy-back for unacceptable comfort or fit
 - aids in GP centration and can decrease GP bearing that may compromise corneal integrity
 - monitor for hypoxia
- Hybrids for low cylinder, prolate, low to moderate eccentricity

68

Scleral Lenses Post PK



- For more extreme topographical irregularity
 - ECC should minimally be greater than 800 to 1,000 cells/mm²
- Document vessels in graft prior to fitting and monitor
- Use ultra high Dk materials
 - Central clearance of 200 microns and limbal vault of 50 microns
- Topography based digital designs
- Impression based designs

69

Post RK

- Performed 30-40 years ago
 - Patients are presbyopic and suffer from over-correction, hyperopic drift, and diurnal variations
- Low modulus soft lenses
- Custom soft reverse geometry
- Standard or reverse geometry RGPs
- Sclerals are now the most commonly used modality

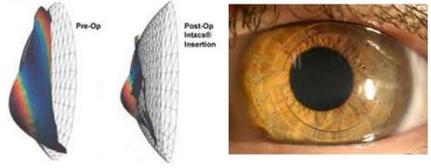
70

Intra-Corneal Ring Segments

- US FDA first approved INTACS® (Addition Technology Inc.) intracorneal rings in 1999
 - an alternative to contact lenses
 - use of ICRS to treat keratoconus and contact lens intolerance first reported in 2000
- Contact lenses are frequently required to achieve BCVA after the insertion of ICRS, especially with advanced keratoconus
 - improve visual function after implantation of ICRS by reducing higher order corneal aberrations
 - PRK can also be performed after INTACS to reduce the residual refractive error or reduce the astigmatism enough to improve tolerance
- Can use virtually all modalities

71

Post-Intacs



- Commence fitting/refit after three months
- Evaluate insertion site
- Corneal apex is generally well-centered
- Standard KC designs work well
- Aim for minimal apical clearance to feather touch and avoid seal-off over segments

72

Case: KCN/Post-CCXL/INTACS

- Follow-up visit:
 - Pt. reports excellent comfort with 10 to 12 hours of wear
 - Very happy with vision, but would like "better if possible"
 - VA and OR were consistent with that on original dispensing
 - Resultant was calculated

79

Case: KCN/Post-CCXL/INTACS

- Second Dispensing:
 - OD: 8.6 (15.0) -4.75-1.75 x 75 8.6 IT 1
 - OS: 8.6 (15.0) - 4.50-0.75 x 66 8.6 IT1
- Final Disposition:
 - VA: OD 20/20
 - OS 20/20
- No rotation/good centration and movement
- Patient doing well one year later

80

Myopia Management

- Medically necessary?
- Contact lens/treatment optics
- Product options

81

Myopia: Prevalence and Epidemiology

In 2050, the number of patients with myopia will double

Recent population-based studies of young urban adults

82

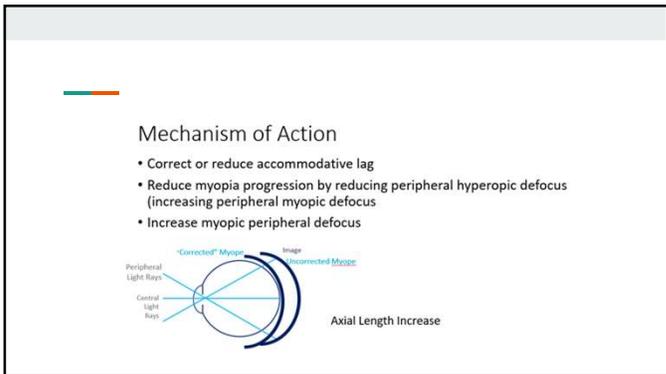
Myopia: Risk of Ocular Pathology

	DEGREE OF MYOPIA		
	-0.50 to -3.00 D	-3.00 to -6.00 D	-6.00 D or more myopic
MMD	13.6	73	846
RETINAL DETACHMENT	3.2	8.8	12.6
VISUAL IMPAIRMENT†	0.9	1.7	5.5*

*Applies only to myopia of -6.00 to -10.00 D. Odds ratios are 7.8 for myopia of -10.00 to -15.00 D and 88 for myopia more than -15.00 D.
†Decimal visual acuity of 0.30 to 0.05 (approx 20/60 to 20/400).

Haarman AE et al. The Complications of Myopia: A Review and Meta-Analysis. Invest Ophthalmol & Vis Science 2020 Apr; 61:49

83



84

Contact Lens Options

- Daily Disposable Hydrogel
 - Alternating rings
 - EDOF
- Monthly planned replacement hydrogel or silicone hydrogel
 - Center Distance: use minimum of +2D add
- Hybrid (Center Distance Progressive: customizable zone)
- Overnight Orthokeratology
 - Works best with higher myopes

85

Dispensing and Follow Up

- Insertion and Removal Training
- Wearing schedule
- Up to date spectacle correction
- One week, one month three months
- Every three to six months, thereafter
- Annual comprehensive exams including cycloplegic refraction and axial length measurement if available

86

Potential Complications and Troubleshooting

- Incidence of corneal infiltrative events in children wearing soft contact lenses is no higher than in adults and if anything may be markedly lower. (Mark A. Bullimore; Optom Vis Sci. 2017 Jun; 94(6): 638–646.
 - May be lower in 8-11-year olds due to daily disposables, daily wear and parental supervision
- Allergy
- Visual Quality
 - Contrast
 - Acuity
 - Aberrations

87

New and Future Applications

Smart Contact Lenses:
Biosensing and Drug Delivery

- Allergies
- Diabetes
- Glaucoma
- Retina
- Wound Healing

88

Benefits of Drug Delivery via Contact Lenses

- Increased bioavailability
- Compliance
- Dosage regimens may be improve
- Less systemic toxicity may be expected because of the total amount of drug administered compared to multidrop

Figure 2. Schematic representation of drug release time for contact lenses and conventional type of formulation.

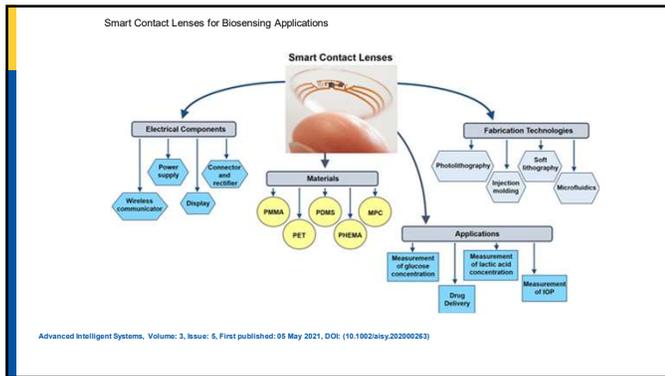
89

Allergy

- Etafilcon A
- Approved in Canada and Japan
- Contains Ketotifen, an H1 histamine receptor antagonist
- Medication is slow released up to 5 hours for 12 hours of relief
- Preservative free

<https://www.jj.com/innovation/latest-eye-innovations-1d-contact-lens-technology>

90



91

Biosensing

SENSIMED Triggerfish®

- Daily disposable silicone hydrogel
- Worn for up to 24 hours
- 14.1 diameter
- 585 µm ct
- 8.4, 8.7, and 9.0 mm base curves
- Embedded within the contact lens are two strain gauges, a microprocessor, and an antenna
- The strain gauges detect changes in corneal shape, and a high correlation between CLS output and imposed IOP has been demonstrated

The product received the CE mark in 2010 and was approved by the FDA in 2016.

92

Wound Healing

RESEARCHERS AT THE UNIVERSITY OF NEW HAMPSHIRE HAVE CREATED A HYDROGEL THAT COULD ONE DAY BE MADE INTO A CONTACT LENS TO TREAT CORNEAL MELTING. THE HYDROGEL WORKS LOCALLY BY DEACTIVATING THE HARMFUL HMP ENZYMES ONLY IN THE CORNEA.

CREDIT: UNH/UCD

<https://www.unh.edu/unhfiledy/news/feature/2019/05/12/unh-researchers-create-hydrogel-contact-lens-treat-rare-eye-disease>

93

SCIENCE ADVANCES | RESEARCH ARTICLE

APPLIED SCIENCES AND ENGINEERING

Wireless smart contact lens for diabetic diagnosis and therapy

Keum et al., *Sci. Adv.* 2020; 6: eaba3252 24 April 2020

94

Summary

- Contact lenses play an important role in managing a wide range of pathology, both chronic and acute
- Virtually all modalities may be selected, depending upon the clinical presentation
- Concomitant therapy is important
- Proper follow-up and management of adverse events is critical
- Innovation in materials and electronics is driving future applications

95

Thank You!

www.eyewise.com

96