

ROSE K Menicon

**PROS AND CONS OF
CORNEAL -SCLERALS
VS
SCLERAL LENSES**

ADVANTAGES AND DISADVANTAGES!

Dr. Paul Rose
B Sc. Dip Opt
FCCLNZ, CNZM

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**SO WHY THE DRAMATIC INCREASE
IN THE USE OF SCLERAL LENSES
OVER THE LAST 5 YEARS?**

WHAT FACTORS HAVE DRIVEN THIS CHANGE?

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SCLERAL LENSES

ADVANTAGES

BUT IS THERE ANY POSSIBLE DOWNSIDE?

- COMFORT(*INITIAL?*)
- STABILITY
- EASY TO FIT ?
- IDEAL FOR "DUSTY" ENVIRONMENTS
- IDEAL FOR DRY EYE
- FINANCIAL : BETTER RETURNS FOR LABS AND FITTERS

Terminology

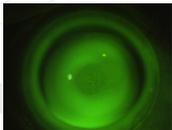
Lens	Alternate Name	Diameter	Bearing	Tear Reservoir
Corneal	-	8.0 to 12.5 mm	All on cornea	No tear reservoir
Corneo-scleral	Corneal-Limbal Semi-scleral Limbal	12.5 to 15.0 mm	Shared bearing on cornea and sclera	Limited tear reservoir capacity
Scleral	Haptic	Mini-scleral 15.0 to 18.0 mm Large-Scleral 18.0 to 25.0 mm	All on Sclera	Somewhat limited tear reservoir capacity Almost unlimited tear reservoir capacity

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**WE HAVE SUCCESSFULLY RESTED GP LENSES
ON THE
CORNEA FOR MANY YEARS !**

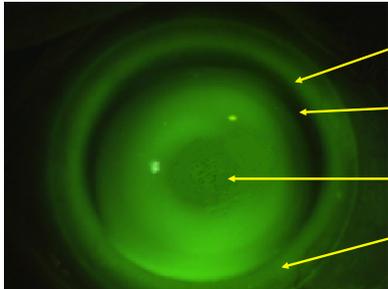
**WHY SUDDENLY THE
NEED IN SEMI-SCLERAL DESIGNS
TO COMPLETELY VAULT
THE CORNEA?**



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MY PHILOSOPHY



20-30 micron Clearance over the limbus

Landing zone Inside the limbus

"Feather touch" = Clearance

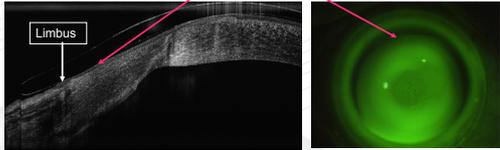
Parallel to the sclera Tear exchange

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MY PHILOSOPHY

Landing zone

Limbus



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SO ARE THERE ANY SCLERAL LENS COMPLICATIONS?

GSLs 2017

Poster by **Yeung and Sorbara** conducted a survey of scleral lens prescribing trends and complications in North America. Of the respondents' patient population, **26.8% experienced midday fogging**. **Limbal hyperemia was present in 23.7%** of the patients, and corneal staining was observed by respondents in 13.3% of the patient population.

CONJUNCTIVAL PROLAPSE- Pat Caroline 25 to 30% of scleral lens wearers

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NKCF/Mayo Clinic

What are the Corneal complications of Scleral Lens wear?

- **989 EYECARE PROFESSIONALS PARTICIPATED**
- **85,000 PATIENTS FITTED**
- **CORNEAL OEDEMA REPORTED IN 385 PATIENTS**
- **NEW BLOOD VESSEL GROWTH IN 238 PATIENTS**
- **INFECTIONS IN 70 PATIENTS**
- **GRAFT REJECTION IN 2 PATIENTS**

Although scleral lenses are a dome of clear tissue that may lead to a different treatment of keratoconus. Scleral lenses may interact with the eye's cornea differently than smaller contact lenses. The SCOPe (Scleral lenses in Current Ophthalmic Practice: an Evaluation) study group surveyed eye care providers from all over the world about complications they had encountered with their patients wearing scleral lenses. 989 eye care professionals participated in the survey, treating nearly 85,000 patients who had been fitted with scleral lenses. The most common scleral lens complication reported was corneal edema. 385 patients reported corneal edema. 238 patients reported new blood vessel growth. 70 patients reported infections. 2 patients reported graft rejection. 0 patients reported keratoconus.

SUMMARY:

COMPLICATIONS ARE RARE HOWEVER KERATOCONUS PATIENTS SHOULD BE ESPECIALLY VIGILANT

These findings are encouraging. Scleral lenses may be a safe and effective treatment for keratoconus. However, patients who wear scleral lenses should follow their eye care professional's recommendations for lens care products and their advice for applying and removing their lenses. KC patients should be especially vigilant, and should see their eye doctor promptly if they develop eye pain, redness, reduced vision, or if something just "doesn't feel right".

Thank you to the SCOPe study participants for sharing their observations and patient outcomes. To learn more about the researchers who led this study, visit:

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SO WHAT FACTORS SHOULD WE CONSIDER WHEN COMPARING CORNEO-SCLERAL LENSES TO SCLERAL LENSES?

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2. Lens settling(fitting) time
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6. Corneal changes – eg Epithelial bogging?
7. Conjunctival changes- eg. prolapse
8. Comfort
9. Handling and removal

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1. OXYGEN AVAILABILITY TO THE CORNEA (and LIMBUS)

CONTACT LENSES TODAY Sunday, January 4, 2015

RESEARCH REVIEW S. Barry Eiden, OD, FAAO

Hold on now...Don't forget about oxygen transmission with Hybrid and Scleral contact lenses

This study looked at tear layer oxygen tension levels beneath scleral contact lenses. The authors found that **only in the best case scenario for current scleral gas permeable lenses considering lens thickness, material Dk and tear layer thickness values beneath the lenses, would they allow for sufficient tear layer oxygen tension (approximately 100mmHg) to preclude corneal hypoxia.** They suggested that clinicians would be prudent to prescribe scleral GP lenses manufactured in the highest Dk materials available and to fit **without excessive corneal clearance** to minimize anterior segment hypoxia.

OXYGEN AVAILABILITY



Corneal Graft

Angiogenesis is the physiological process through which new blood vessels form from pre-existing vessels

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FACTORS INFLUENCING OXYGEN AVAILABILITY TO THE CORNEA?

- Lens center thickness
- Average lens thickness over the cornea
- Material Dk
- Tear layer thickness
- ~~Lens movement = tear exchange~~

TYPICALLY SCLERAL LENSES DO NOT MOVE SO HAVE NO TEAR EXCHANGE. CORNEO-SCLERAL LENSES HAVE SOME MOVEMENT

HYPOTHETICAL MODEL FOR OXYGEN AVAILABLE TO THE CORNEA UNDER A SCLERAL LENS

Study: Predicting estimates of oxygen transmissibility for scleral lenses
Langis Michaud*, Eef van der Worp, Daniel Brazeau, Richard Warde, Claude J. Giasson

RESULTS for DK = 100

If material Dk is 100 then Dk available to the cornea is **56.3 x10-9**

Lens Thickness (µm)	Centre Tear layer thickness
250	13.3
300	12.5
350	11.7
400	11.1
450	10.6
500	10.0

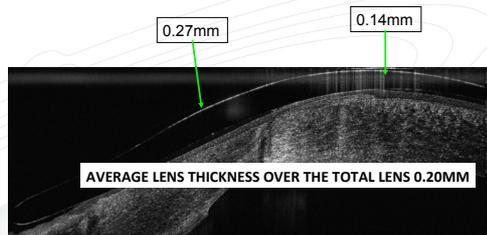
Corneo-scleral ROSE K2XL CT 140 microns
Tear layer 35 microns
Menicon Z Dk163

Dk available to the cornea is 81.8 x10-9

Holden/Mertz criteria for daily wear 24.1 x10-9
Harvitt and Bonanno criteria is 35 x 10-9

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IS CENTRE LENS THICKNESS APPROPRIATE WHEN CALCULATING OXYGEN AVAILABILITY ?



0.27mm
0.14mm

AVERAGE LENS THICKNESS OVER THE TOTAL LENS 0.20MM

Rose K2 XL lens thickness Profile

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However, most clinical studies report amounts of corneal oedema that are within the range of physiological oedema that occurs during sleep (4%), and, in most cases, this amount is less than 2% after 8 hrs wear, despite post-lens tear layer thicknesses being greater than 250µm??

SO WHAT COULD EXPLAIN THE DIFFERENCE BETWEEN THE HYPOTHETICAL MODEL AND WHAT WE ARE SEEING IN PRACTICE?

SCLERAL LENSES

SOME FACTORS TO CONSIDER

- Most studies are done on normal healthy corneas
- Studies are only up to 8 hrs wear. Patients wear lenses longer than this.
- With the 3 to 4% normal corneal swelling overnight, if lenses are then placed on the cornea on first awakening, does the cornea get a chance to recover to baseline?
- After daily wear does the cornea have sufficient time to recover to baseline before retiring?
- If the cornea does not recover to baseline, is the oedema accumulative over time?
- Do fitters take into account the endothelial count? Significantly less for keratoconic corneas and grafts. Full thickness grafts avg cell count only 800 per sq mm. Also decreases with age.

CORNEAL GRAFTS
ENDOTHELIAL COUNT

SO IS IT SAFE TO REDUCE OXYGEN LEVELS FURTHER TO THESE ALREADY COMPROMISED CORNEAS WITH LOWER ENDOTHELIAL COUNTS ?

Trans Am Ophthalmol Soc. 2004 Dec; 102: 57-66.
CORNEAL ENDOTHELIUM AND POSTOPERATIVE OUTCOMES 15 YEARS AFTER PENETRATING KERATOPLASTY
 Sanjay V Patel, BMBS,* David O Hodge, MS, and William M Bourne, MD[§]

After the importance of the corneal endothelium in penetrating keratoplasty was established in the 1970s,¹ we reported 5- and 10-year data on a cohort of patients who had undergone this procedure.^{2,3} The annual rate of endothelial cell loss from 3 to 5 years after penetrating keratoplasty was 7.8% per year,² and from 5 to 10 years, was 4.2% per year.³ The 10-year cumulative risk of developing glaucoma, graft rejection, and graft failure was 21%

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Landing zone nearly completely on the cornea inside the limbus

“Feather touch” = Clearance

Parallel to the sclera Tear exchange

Decreased Clearance between a 15mm Scleral Contact Lens and the Cornea after 2 Hours of Lens Wear

CONCLUSIONS

- 15-mm scleral lenses settle by approximately 50% of the initial clearance after two hours of continuous wear.
- Adequate time must be allowed to let the lens settle on the eye before making an accurate assessment of the fit.
- Excessive settling of the lens could greatly reduce the fluid reservoir volume and increase contact with the cornea. This would limit the value of using these lenses in patients with severe ocular surface disease.
- The optimum time required for adequate lens settling has yet to be determined.**

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SETTLING TIME AFTER INSERTION

- **ROSEK2 XL – USUALLY WITHIN 20 MINS OF INSERTION (CORNEAL EPITHELIUM ONLY COMPRESSES SLIGHTLY AROUND 20 TO 30 MICRONS MAXIMUM)**
- **SCLERAL LENSES TAKE SEVERAL HOURS AND THE DEGREE OF COMPRESSION IS VERY UNPREDICTABLE (THE CONJUNCTIVA CAN COMPRESS OVER 150 MICRONS)**

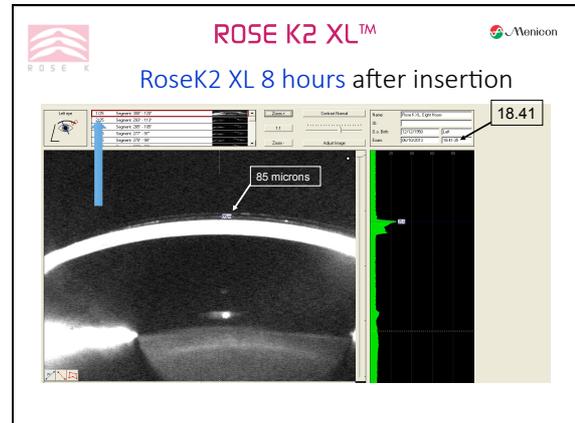
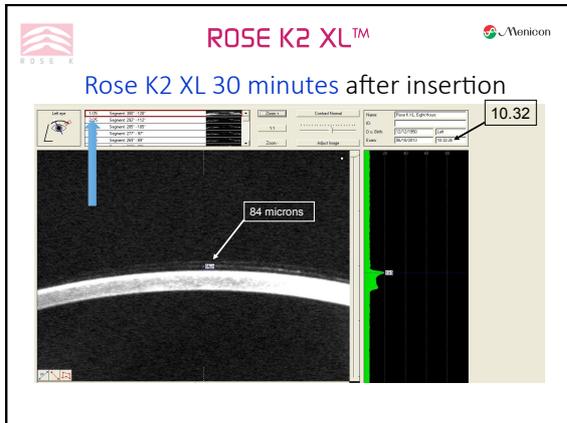
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SETTLING TIME –Rose K2 XL just after insertion

85 microns

10.03

POST GRAFT OBLATE CORNEA



- ROSE K2 XL™
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Lens Movement - Ideal

- Judge movement at 6 o'clock – patient look up and blink.
- First insertion: lens should move 0.5 to 1mm on blinking
- After lens settles: Just discernable movement
- Excessive movement: uncomfortable.

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Lens Movement

CORNEO-SCLERAL LENS

EXCESSIVE

SCLERAL LENS

NO MOVEMENT

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HOWEVER IS TEAR EXCHANGE? THAT IMPORTANT?

[Contact Lens and Anterior Eye, February 2019, Volume 42](#)
Tear dynamics under Scleral lenses

Purpose
 To evaluate post-lens tear dynamics at 20 min and 5 hrs of scleral lens wear in **20 neophytes**.

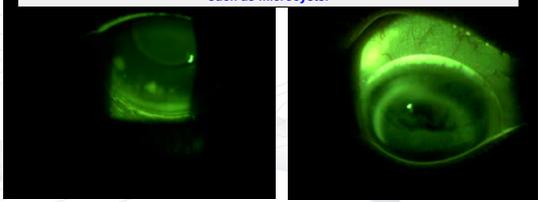
Methods
 All subjects wore bilaterally scleral lenses for 5 hr on 3 separate visits. Post-lens tear exchange was measured using Out-in method, whereby 5 µL of 2% FITC-Dextran was instilled on the bulbar conjunctiva during lens wear. Time taken to observe the first sign of fluorescence in the post-lens tear reservoir was recorded with a stopwatch.

Conclusion
 Some tear flow into the tear reservoir under a scleral lens on subjects with healthy cornea occurred at 20 min and 5 hrs after lens insertion. After 5 hrs of lens wear, **roughly one third of the subjects had no tear flow** into post-lens reservoir. The observed decline in post-lens tear fluorescence was predominately due to lens settling

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TEAR EXCHANGE VIA THE PUSH-UP OR PUSH-DOWN TEST WITH A ROSE K2XL CORNEO-SCLERAL LENS

Without tear exchange, reduced oxygen levels, trapped metabolites and discarded epithelial cells, PH and Osmolarity changes under the lens must occur. This poses a higher risk of long-term metabolic and physiological complications such as microcysts.



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Comparison of the influence of corneo-scleral and scleral lenses on ocular surface and tear film metrics in a presbyopic population.

[Cont Lens Anterior Eye, 2018 Feb;41\(1\):122-127. doi: 10.1016/j.clae.2017.09.014. Epub 2017 Sep 28](#)
[Lafosse E, Romin DM, Esteve-Taboada J, Wolffsohn JS, Talens-Estareles C, García-Lázaro S.](#)

PURPOSE:
To assess and compare the effect of the corneo-scleral lenses (C-Scl) and scleral lenses (Scl) on tear film parameters and central corneal thickness (CCT) in healthy presbyopic subjects.

METHODS:
Thirty subjects wore two contact lenses, C-Scl and Scl randomly assigned, of neutral power, with a material (HS100) and centre thickness (0.29mm). The **tear meniscus area (TMA)** and CCT was measured (with optical coherence tomography) as well as tear osmolarity at baseline, 20min after insertion and at 8h.

RESULTS:
TMA revealed statistical differences for both lenses at 20min ($p < 0.001$), and also at 8h ($p = 0.003$), with C-Scl leading to a lesser reduction in the TMA and a lower induced hypoxic stress than the Scl. CCT showed statistical differences for both lenses at 20min ($p = 0.002$), and also at 8h ($p = 0.001$), being lower for the C-Scl. Osmolarity was statistically different at 8h ($p = 0.03$), being lower for the C-Scl.

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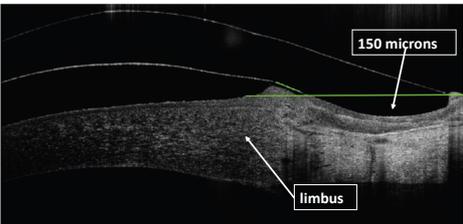
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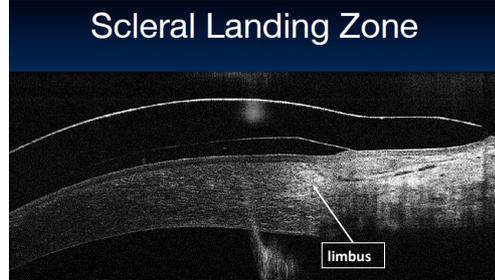
If you land the lens totally on the conjunctiva, the landing zone, and therefore the overall diameter of the lens needs to be bigger

Why?

Scleral lens indenting



Scleral Landing Zone



Scleral lens indenting

The wider the bearing area the less the indentation

SO LENSES THAT LAND ENTIRELY ON THE CONJUNCTIVA NEED TO BE LARGER TO PREVENT THE LENS SINKING INTO THE CONJUNCTIVA AND CONSEQUENTLY BINDING OFTEN BIGGER THAN 16MM

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WHY GO BIGGER THAN YOU NEED TOO?

- Smaller diameters have better alignment with sclera. (Up to 15mm the eye is more rotationally symmetrical) - Less toricity .
- Need for toric periphery or asymmetric options is reduced
- Easier to handle- insertion and removal. The bigger the more difficult.
- Less fear provoking than sclerals- similar diameter to a soft lens (RoseK2XL std diameter is 14.6mm)

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MIDDAY FOGGING

Post-Lens Clouding/midday fogging
 Patrick Caroline reported that approximately 30% scleral contact lens wearers experience a significant decrease in vision after **two to four hours** due to solution

VERY INFREQUENT WITH CORNEO-SCLERAL LENSES-WHY?

University , found that although protein content was unchanged in the tear layer of these patients, **the lipid content increased** . It appears that this problem is greater with excessive lens clearance (i.e., >300 microns), which is not uncommon with scleral lenses.

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MIDDAY FOGGING

IDEAL BASE CURVE

Keratoconus

Post Graft (PK)

MINIMUM TEAR LAYER THICKNESS

CONJUNCTIVA WITH THE GOBLET CELLS IS NOT TRAPPED UNDER THE LENS

BASE CURVE SELECTION

IDEAL

THE SHALLOWER THE TEAR LAYER THE LESS LIKELYHOOD OF MIDDAY FOGGING

Min 30 to 40 microns

Keratoconus

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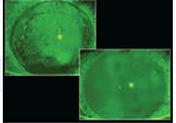
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EPITHELIAL BOGGING!

BY PATRICK J. CAROLINE, FAAO, & MARK P. ANDRÉ, FAAO
 The environment beneath scleral lenses is incredibly unique and something we are just beginning to understand. Posters presented by Morrison et al and by [unclear]

NO CASES OF EPITHELIAL BOGGING REPORTED WITH ROSE K2XL!

This means that the preservative free (PF) saline or PF artificial tears placed into the bowl of the lens upon application will remain in contact with the ocular surface throughout the wearing schedule



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CONJUNCTIVAL PROLAPSE

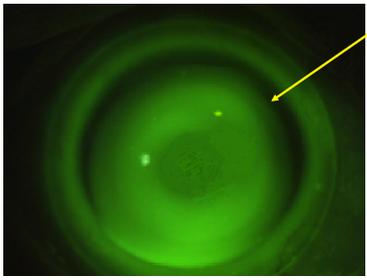
In some scleral contact lens wearers, the conjunctiva is sucked up into the bowl of the scleral contact lens resulting in wavy white folds at the peripheral cornea.

CANNOT OCCUR WITH A CORNEO-SCLERAL DESIGN –WHY?



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Landing zone nearly completely on the cornea inside the limbus



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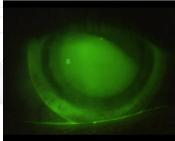
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COMFORT

BECAUSE OF MOVEMENT AND A HIGHER EDGE LIFT
INITIAL COMFORT ON INSERTION WITH A CORNEO-SCLERAL LENS
IS NOT QUITE AS GOOD AS A SCLERAL LENS.
HOWEVER THIS QUICKLY SETTLES IF THE EDGE LIFT IS CORRECT

THE TIGHTER THE EDGE LIFT THE BETTER THE INITIAL COMFORT



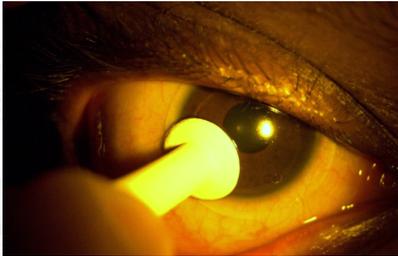
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REMOVAL



If the BC or Peripheral fit is too steep the lens will be more difficult to remove

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BECAUSE OF SUCTION SCLERAL LENSES ARE
MORE DIFFICULT TO REMOVE
REQUIRING A FORCE OF BETWEEN 100 TO 200
GRAMS FOR REMOVAL

LENS REMOVAL

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Cont Lens Astheto Ekt. 2019 Feb;42(1):104-110. doi: 10.1016/j.cole.2018.07.004. Epub 2018 Jul 24.

Intra-ocular pressure variation associated with the wear of scleral lenses of different diameters.
Michaud L¹, Samaha O², Glasnon C³.

Author information

Abstract
PURPOSE: To evaluate the variation of intra-ocular pressure during scleral lens wear, and the influence of the lens diameter on the results.
METHODS: This is a prospective, randomized study performed on Caucasian subjects (18 F, 5 M), aged 24.7 ± 4.1 y.o. A diurnal variation

Wearing a 15.8mm lens, IOP rose from 10.1 ± 1.9 mm HG to 14.4 ± 5.5 mm HG after 4.5 ± 0.3 hrs
Wearing a 18mm lens IOP rose from 9.2 ± 2.1 mm HG to 14.4 ± 4.8 mm Hg
19% of patients showed an increase of >10mm HG
One patient the IOP increased by 15mm HG
The average for all subjects was a 5mm > in IOP

CONCLUSION: These results suggest that, as evaluated with a non-standard transpalpebral methodology, IOP during scleral lens wear may be increased in average by 5 mm Hg, regardless of the lens diameter. More work is needed to confirm if practitioners should be warned when using SL on populations at risk for glaucoma.

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KEYWORDS: Glaucoma, Intra-ocular pressure, Scleral lenses, Transpalpebral tonometry

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CORNEO-SCLERAL LENSES VS SCLERAL LENSES

DISADVANTAGES OF CORNEO-SCLERALS

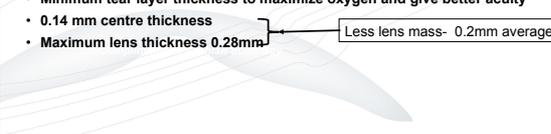
- COMFORT (INITIAL?)
- REQUIRE A MORE PRECISE FIT ?
- NOT AS SUITABLE FOR DRY EYE?
- NOT AS SUITABLE FOR PRK
- NOT AS SUITABLE FOR CORNEAS WITH EXTREMELY HIGH SAGS
EG KERATOGLIUS

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So what are the advantages of a Corneo-scleral lens design over a scleral design?

- Much less binding than scleral lenses-Conjunctival compression less than sclerals
- Much less risk of increasing the IOP
- Significantly more tear exchange (without fenestrations) than sclerals
- Some movement to refresh the tear layer under the lens
- Minimum tear layer thickness to maximize oxygen and give better acuity
- 0.14 mm centre thickness
- Maximum lens thickness 0.28mm

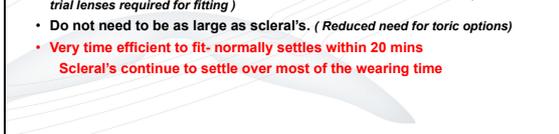
Less lens mass- 0.2mm average



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So what are the advantages of a Corneo-scleral lens design over a scleral design?

- More oxygen available to the cornea than scleral designs- **Less risk particularly to grafts.**
- Fitting not based on judging tear layer thickness or sagittal height.
 - Fluorescein pattern much faster and easier to assess
- Guide for the first trial lens is more accurate than for sclerals- (*reduced no. of trial lenses required for fitting*)
- Do not need to be as large as scleral's. (*Reduced need for toric options*)
- Very time efficient to fit- normally settles within 20 mins
- Scleral's continue to settle over most of the wearing time



ROSE K2 XL™ 

So what are the advantages of a Corneo-scleral lens design over a scleral design?

- Easier to check the fit on follow up examinations- Does not require the lens to be removed for fluorescein insertion to check the central fit /cornea etc
- No conjunctival "bunching/prolapse"
- Lens clouding/fogging under the lens-(*midday fogging*) is very uncommon
- Much less frequently required to be removed and refilled during lens wear
- Easier to remove – suction forces much less



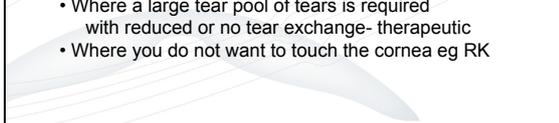
THIS OR → THIS

Corneo-scleral Scleral

ROSE K2 XL™ 

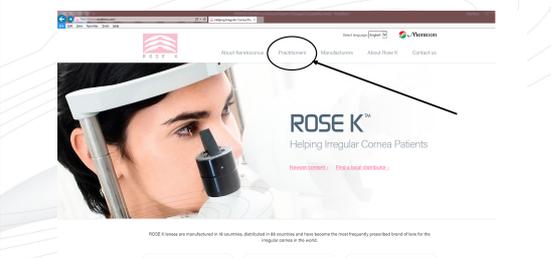
When is a scleral lens indicated?

- Severe dry eye including Steven Johnson Syndrome
- Extreme steepening over a large corneal area eg. Keratoglobus
- Where a large tear pool of tears is required with reduced or no tear exchange- therapeutic
- Where you do not want to touch the cornea eg RK



ROSE K2 XL™ 

For online fitting guide for ROSE K2 go to www.roselens.com



ROSE K lenses are manufactured in 16 countries, distributed in 60 countries and have become the most frequently prescribed brand of lenses for the irregular cornea in the world.

ROSE K2 XL™ 

About the Lenses

The ROSE K lens was invented by Paul Rose, an optometrist from Hinton, New Zealand. Paul Rose was frustrated about what he could do for patients with keratoconus, a progressive condition in which the surface of the cornea becomes cone shaped.

"The problem with traditional contact lenses is that they do not fit unusual corneal shapes." Realizing that existing lenses did not mirror the shape of the eye very well, Paul Rose set out to develop a contact lens that would be much more comfortable for patients, be easier to fit, and give better vision.

Paul Rose began development on the ROSE K keratoconus lens in 1985. After going through testing 700 lenses and 22 different designs, he came up with a set of 28 lenses from which all patients could be fitted.

A further two years were spent in a development stage to perfect the lens design.

The ROSE K lens was first launched in the New Zealand market and now 80 percent of New Zealand's keratoconus patients are fitted with them.

The ROSE K lens is now manufactured and distributed in many countries and has become the most frequently prescribed lens for keratoconus.

In 1995 the American Food and Drug Administration gave approval for the ROSE K lens to be marketed in the United States.

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- Lens Types
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- Articles & Presentations
- Academic Papers
- Testimonials
- Frequently Asked Questions about ROSE K2 XL
- ROSE K Fitting Tips
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