The Effect of Different Reservoir Solutions on the Clinical Performance of the Mini-Scleral Lens: A Pilot Study

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Disclosure Statement of Financial Interest

The authors have no financial interest in the subject matter of this presentation.

INTRODUCTION

- The lens reservoir should be filled with a solution to provide a post-lens tear reservoir between the scleral contact lens (ScCL) and the ocular surface before fitting
- A sterile, single dose, preservative-free saline solution is recommended to fill the ScCL reservoir
- It is available as buffered or unbuffered formulations in the specific pH range

Fadel, D.; Toabe, M. Sclera Lens Issues and Complications Related to Handling, Care and Complications. JCLRS 2018, 2, e1-e13.

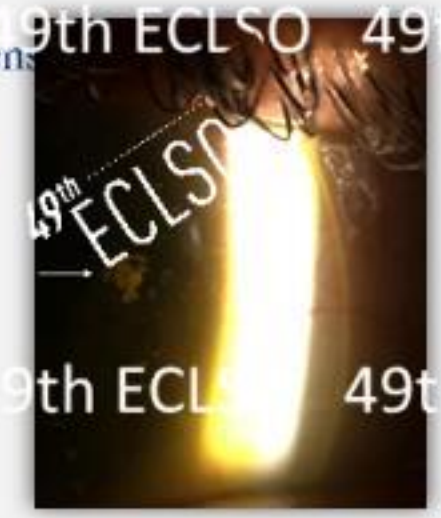
INTRODUCTION

Midday Fogging of Scleral Contact Lenses: Current Perspectives

Jennifer Swingle Fogt

Clinical Optometry 2021:13 209–219

- After long-term use of ScCL, the accumulation of particles in the post-lens tear reservoir with increased density and the development of symptoms such as blurred vision/discomfort: *Midday Fogging*
- *%26-46*
- *Need to remove, clean and refitting the lens during the day !*

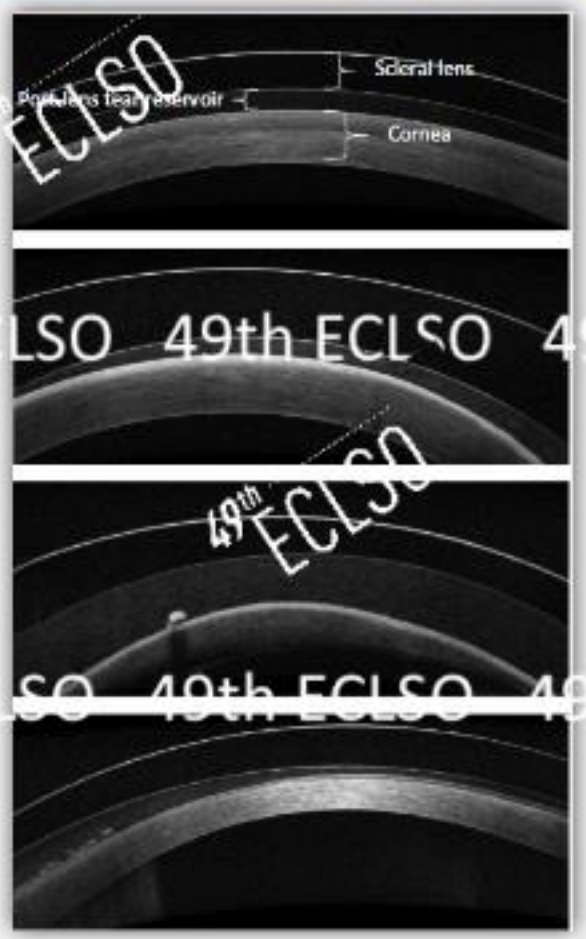


Fot JS. Midday Fogging of Scleral Contact Lenses: Current Perspectives. Clin Optom (Auckl). 2021;13:209-219

INTRODUCTION

Particulate accumulation in the fluid behind the lens can be visualized in several ways:

- Biomicroscopy
- Anterior Segment Optical Coherence Tomography (AS-OCT)
- Scheimpflug Tomography



Fogt JS. Midday Fogging of Scleral Contact Lenses: Current Perspectives. Clin Optom (Auckl). 2021;13:209-219.

INTRODUCTION

	Symptoms and Clinical Signs	Etiology	Management
Midday Fogging	Discomfort Reduced visual acuity Patients dissatisfaction Presence of debris in the reservoir Diffused corneal punctuate staining	Atopic disease Excessive vault Tight lens Spherical ScCL fit on a significantly toric or asymmetric sclera. Release of cells from the cornea with preservative sensitivity	Manage atopic diseases primarily Reduce the lens sagittal height Reduce the ScCL diameter Switch to a scleral lens with a toric back periphery or quadrant- specific design Use preservative-free solutions for filling, cleaning, and storing ScCL Wash eyes with an eyebath in the morning before lens application ***Use a more viscous solution for lens filling***

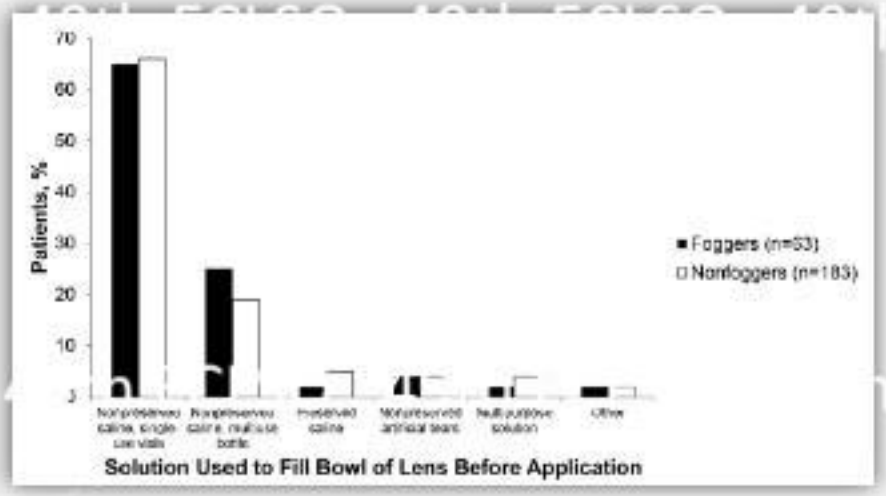
Fadel D. Scleral Lens Issues and Complications Related to a Non-Optimal Fitting Relationship between the Lens and Ocular Surface. Eye & Contact Lens-Science and Clinical Practice. 2019;45:152–163.

INTRODUCTION

Factors associated with patient-reported midday fogging in established scleral lens wearers*

Muriel M. Schornack[a,*], Jennifer Fogt[b], Jennifer Harthan[c], Cherie B. Nau[a], Amy Nau[d], Dingcai Cao[e], Ellen Shorter[e]

- Demographic features
- ScCL usage indication
- ScCL diameter and design
- **Cleaning/storage/filling solutions***
- ***No particular lens design or care product was associated with patient-reported midday fogging.***



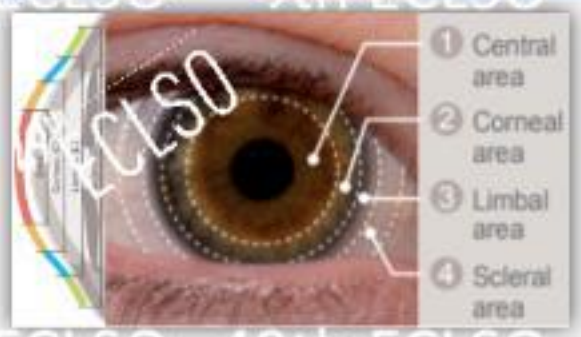
Schornack MM, Fogt J, Harthan J, et al. Factors Associated with Patient-Reported Midday Fogging in Established Scleral Lens Wearers. Cont Lens Anterior Eye. 2020;43(6):602–608.

PURPOSE

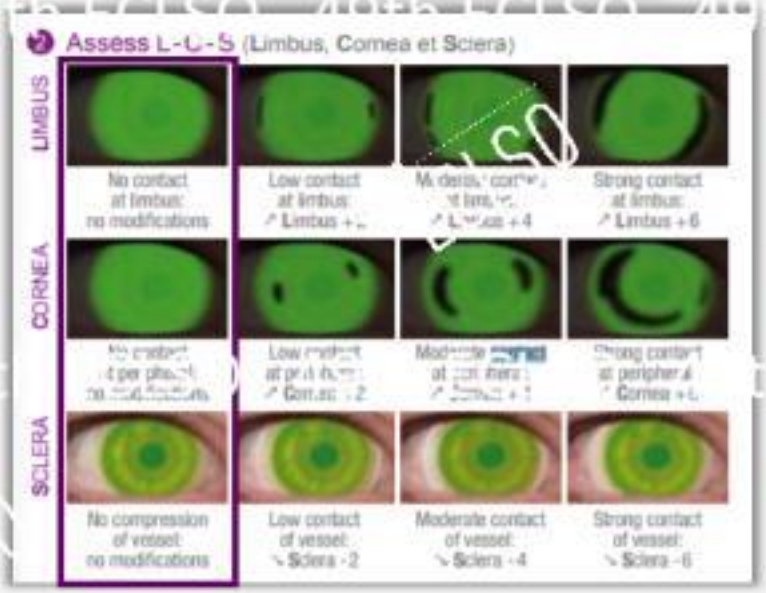
To evaluate and compare the effects of the solutions used in the lens reservoir on the clinical performance of the mini-scleral lens.

METHODS

- Twenty-three eyes of 14 patients with keratoconus were fitted with 15mm mini-scleral lenses (AirKone Scleral lenses; Laboratoire LCS, Normandy, France).



AirKone Mini-Scleral Lens	
Material	Dk 200
Thickness	0.20 mm
Diameter	14.50 – 17.50 mm



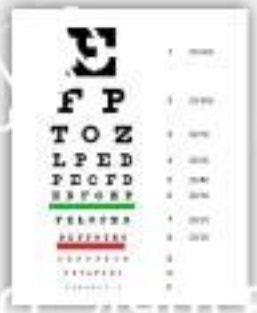
METHODS

- The lens was inserted in the right eye of the patients with preservative-free sodium hyaluronate solution (Luroan 0.15% single-dose, Deva, Turkey)
- The left eye with saline
- Targeting an average corneal clearance of 300-350 µm

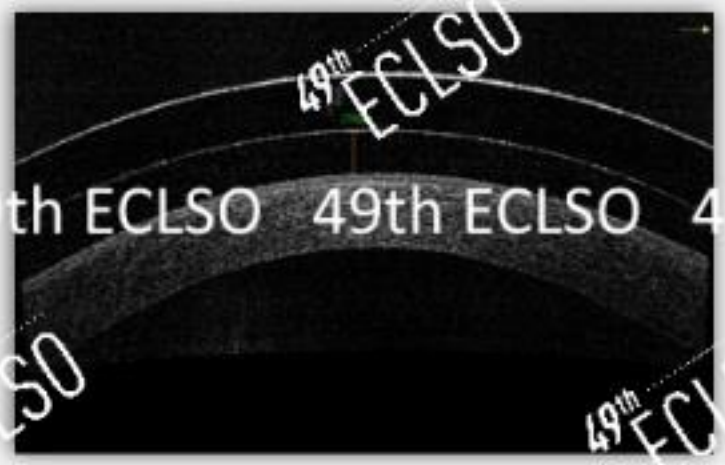
METHODS

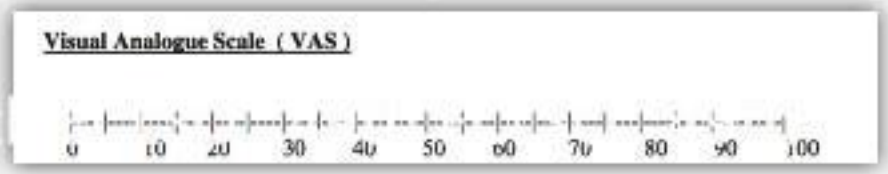
At every visit;

- High-contrast visual acuity with Snellen chart,
- Low-contrast visual acuity with Pelli-Robson chart,
- Overall satisfaction was assessed with the 100-mm VAS.



- Corneal clearance was measured with AS-OCT (Cirrus HD-OCT; Carl Zeiss Meditec, Jena, Germany)

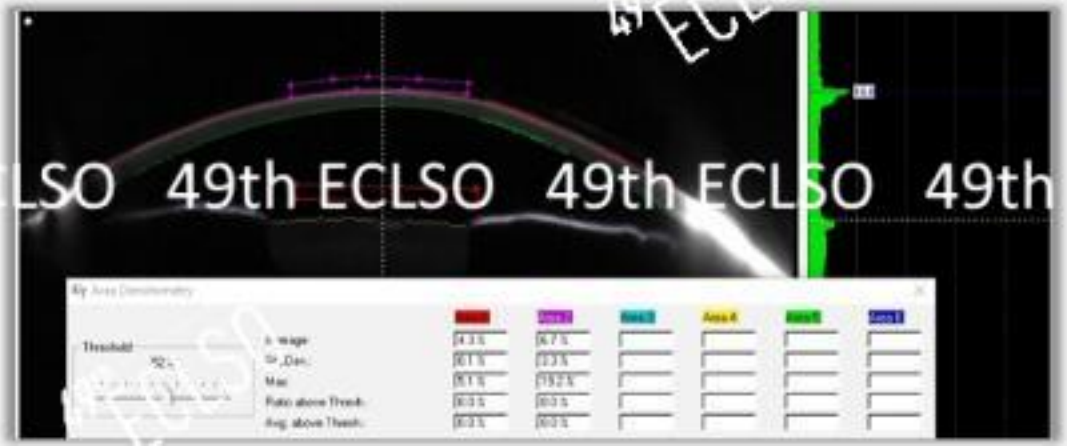




METHODS

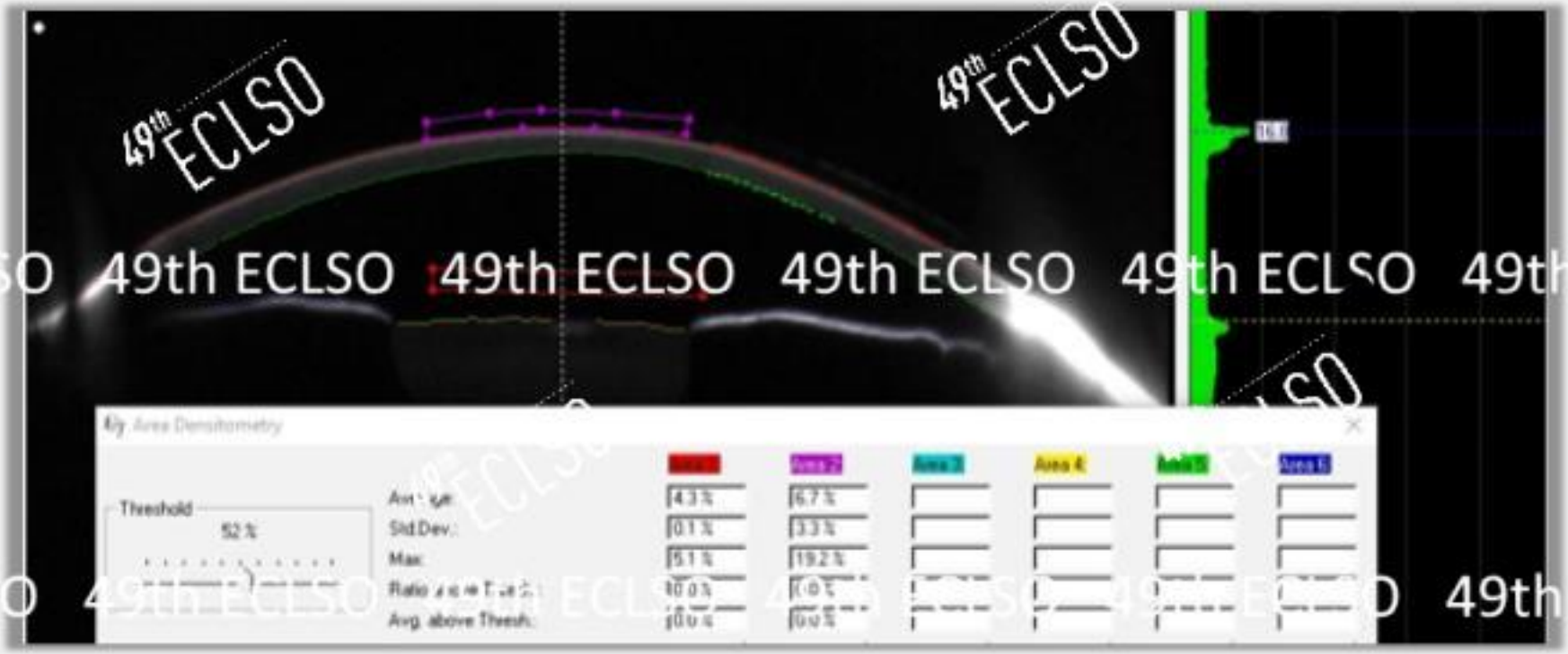
At every visit

- Optical density of the posterior lens fluid was measured by Scheimpflug tomography.
- Greenstein et al.* developed a method for measuring corneal density changes after corneal collagen crosslinking.
  - The 4.0 mm central segment of the area between the back of the lens and the cornea was drawn manually using the perimetry software included in the device.
  - The device automatically calculated the average density of the displayed area.



*Greenstein SA, et al. Natural history of corneal haze after collagen crosslinking for keratoconus and corneal ectasia: Scheimpflug and biomicroscopic analysis. Journal of Cataract Refract Surg. 2010

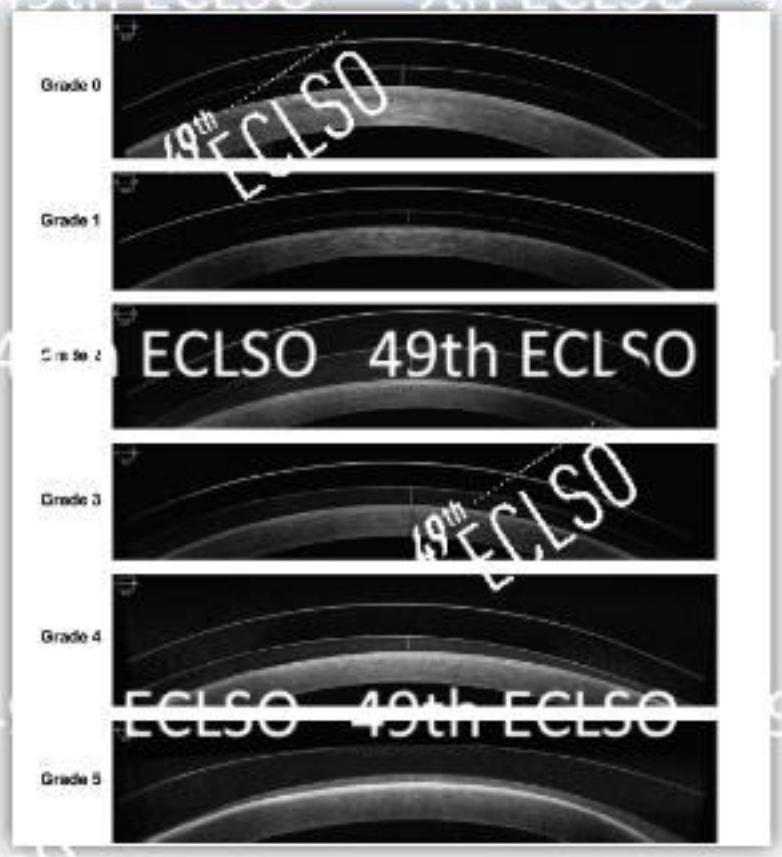
METHODS



*Greenstein SA, et al. Natural history of corneal haze after collagen crosslinking for keratoconus and corneal ectasia: Scheimpflug and biomicroscopic analysis. Journal of Cataract Refract Surg. 2010

METHODS

- Fogging was graded on the AS-OCT, as blinded and not on the same day as the visits.
- Grading was based on Fogt et al.* examples:
  - 0- clear
  - 1-trace
  - 2- easily visible
  - 3- medium
  - 4- heavy
  - 5- dense



*Fogt JS, Karres M, Barr JT. Changes in Symptoms of Midday Fogging with a Novel Scleral Contact Lens Filling Solution. Optometry and Vision Science: September 2020 (97) 690-696.

RESULTS

5 females, 9 males

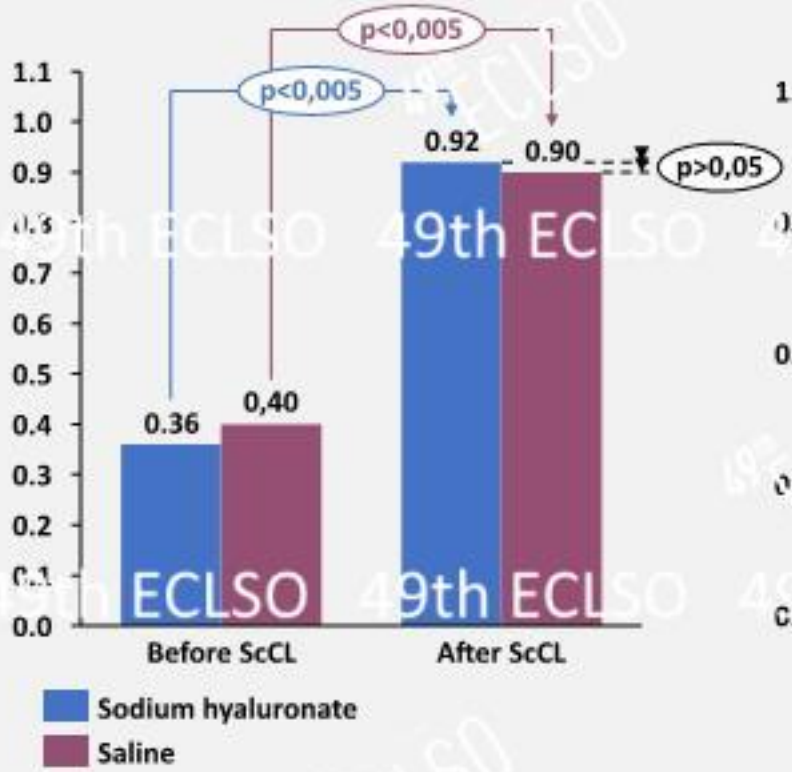
Age 27.7±7.3 (range:16-38)

Mean Kmean: 46.36 (range:42.50-53.80)

Mean Kmax: 54.94 (range:47.40-64.90)

RESULTS

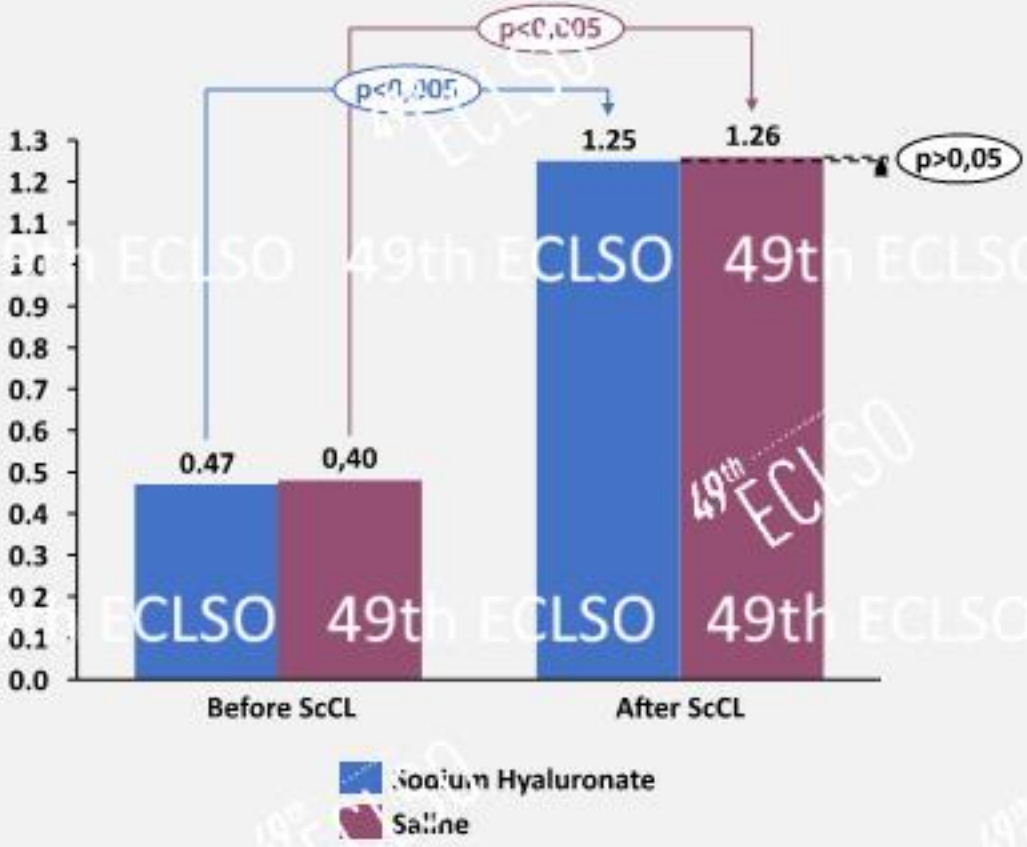
High-Contrast Visual Acuity and Change



- High-contrast visual acuity increased significantly with ScCL application in the right and left eyes regardless of solution.
- It remained stable in both groups during the 8-hour follow-up.

RESULTS

Low-Contrast Visual Acuity and Change



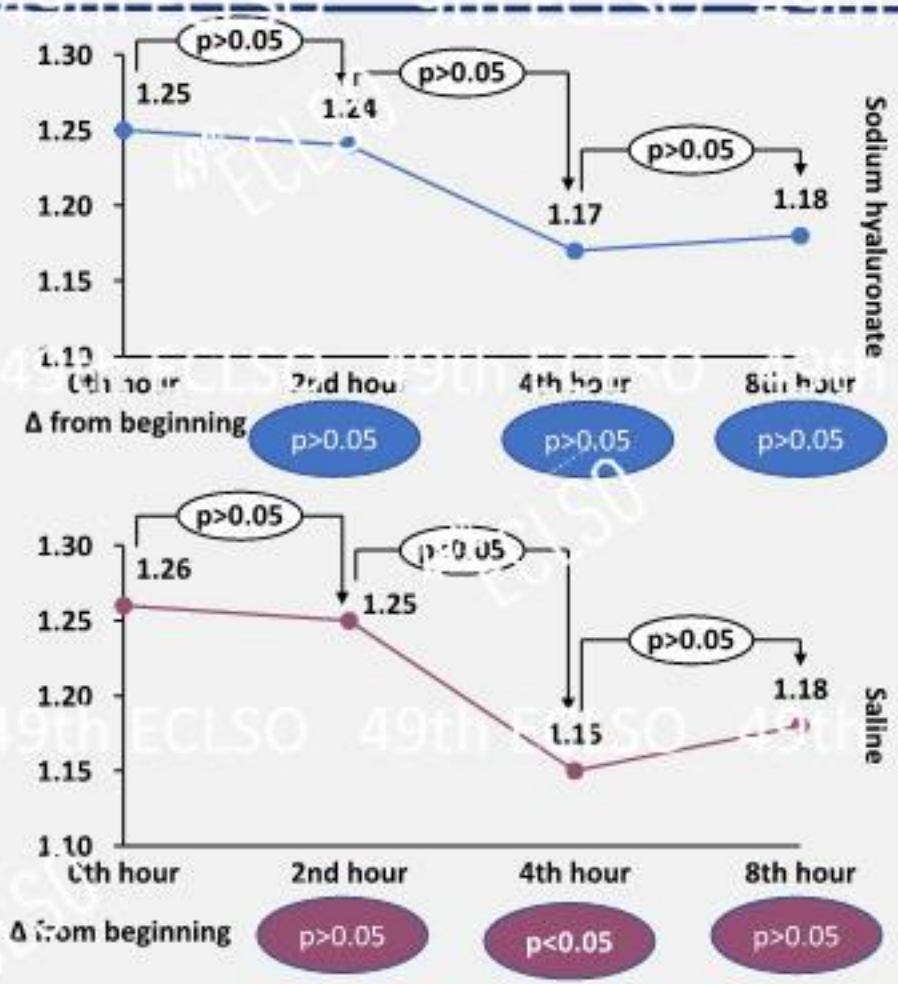
Low-contrast visual acuity increased significantly in both groups.

There was no difference between the two eyes.

RESULTS

Low-Contrast Visual Acuity and Change

While low-contrast visual acuity remained stable up to 8 hours in the sodium hyaluronate group, a significant decrease was observed between the 2nd and 4th hours in the saline group.



RESULTS

Optical Density (%) Change

Δ from beginning	2nd hour	4th hour	8th hour
Saline	p<0.005	p<0.005	p<0.005
Sodium Hyauronate	p<0.05	p<0.05	p<0.005

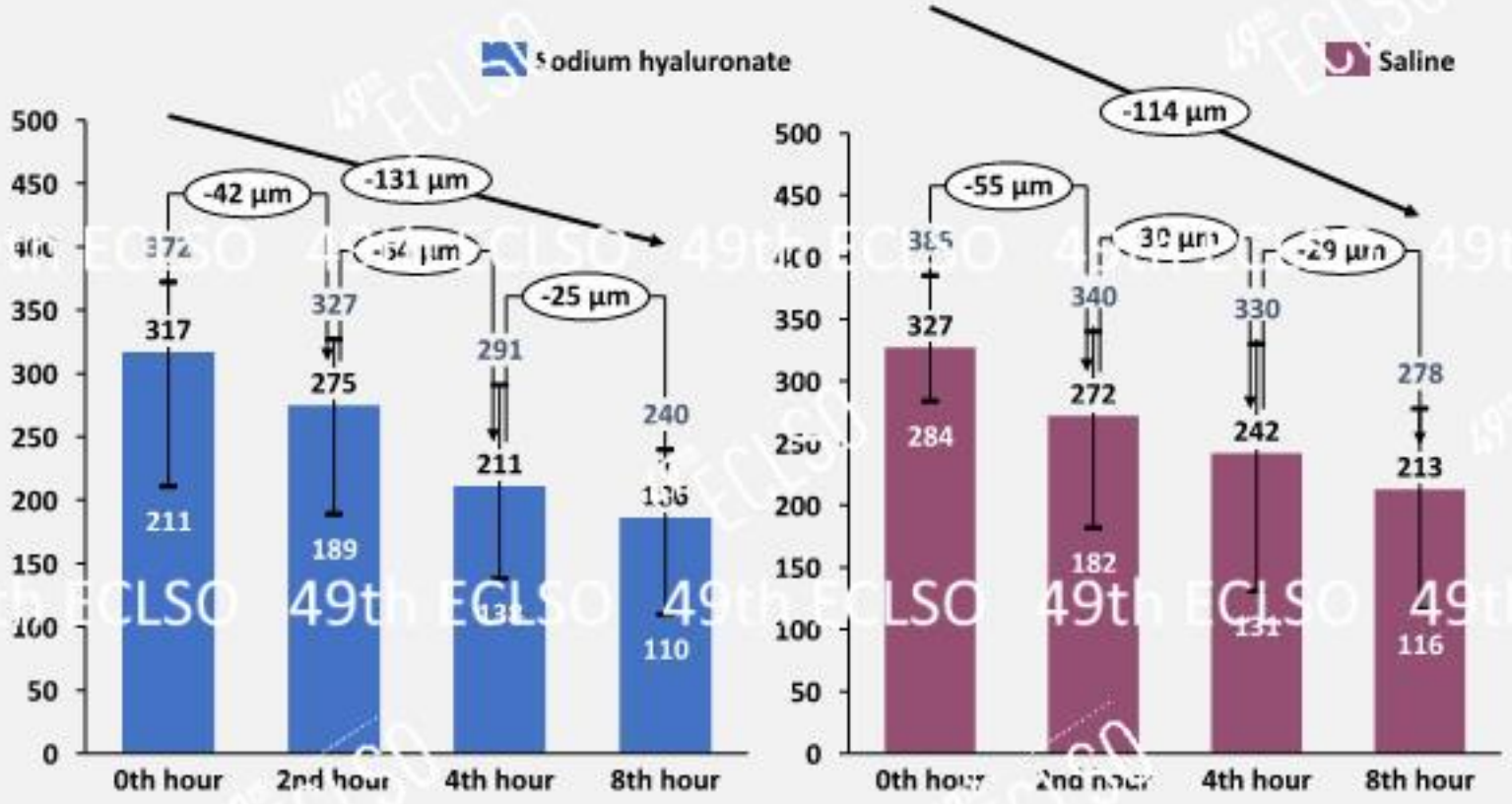
A significant increase was observed in the optical density and degree of midday fogging in both groups.
There was no significant difference between the two groups at any visit.

Midday Fogging AS-OCT Grading

Δ from beginning	2nd hour	4th hour	8th hour
Saline	p<0.05	p<0.05	p<0.005
Sodium Hyauronate	p<0.05	p<0.05	p<0.005

RESULTS

Central Corneal Clearance and Settling Amount (µm)



At the end of 8 hours, the total settling rate and amount were similar in both groups.

Most of the lens settling (*80% in sodium hyaluronate group and 74% in saline group*) took place in the first 4 hours.

RESULTS

Time	Overall Satisfaction (100-mm VAS)	
	Sodium Hyaluronate	Saline
0th hour	95.45	93.75
2th hour	95.27	92.41
4th hour	94.54	91.75
8th hour	92.45	91.08

P>0.05

DISCUSSION

Midday Fogging of Scleral Contact Lenses: Current Perspectives

Jennifer Swingle Fogt

Clinical Optometry 2021:13 209–219

Some clinicians have reported success in reducing midday fogging by adding preservant-free artificial tears to saline to which they add to the lens reservoir.*

Hypothesis regarding the mechanism by which the addition of viscous solution reduces midday fogging:

- Presence of nutrient ions
- Osmolality difference
- Viscosity difference

However, there is no comparative study on this subject!

In our study, the effect on midday fogging was investigated by using high-viscosity and anti-inflammatory sodium hyaluronate solution as a lens reservoir solution, compared to saline.

Inflammation can lead to an increase in the putative all midday fogging particle types.

In the study of the SCOPE group, the only significant difference between those with and without midday fogging was redness and irritation.**

Lens Reservoir Solution

Inflammation

*Fadel D. Scleral Lens Issues and Complications Related to a Non-Optimal Fitting Relationship between the Lens and Ocular Surface. Eye & Contact Lens-Science and Clinical Practice. 2019;45:152–163.

**Schornack MM, Fogt J, Harthan J, et al. Factors associated with patient-reported midday fogging in established scleral lens wearers. Cont Lens Anterior Eye. 2020;43(6):602–608.

DISCUSSION

Clin Exp Optom 2017

Post-lens tear turbidity and visual quality after scleral lens wear

Gonzalo Carracedo , PhD, Maria Serramito-blanco , MSc, Alba Martin-gil , MSc, Zicheng Wang , MD, Candela Rodriguez pomar , MSc & Jesús Pinero , PhD

- 26 keratoconus patients
- 16.5-mm scleral lens
- Particle analysis with AS-OCT after 8 hours of wear
- 8X increase in turbidity!
- Significant decrease in visual acuity and contrast sensitivity !

In our study, OCT fogging degrees at the end of the 8th hour

6.3X increase in the sodium hyaluronate group

6.8X increase in the saline group

DISCUSSION

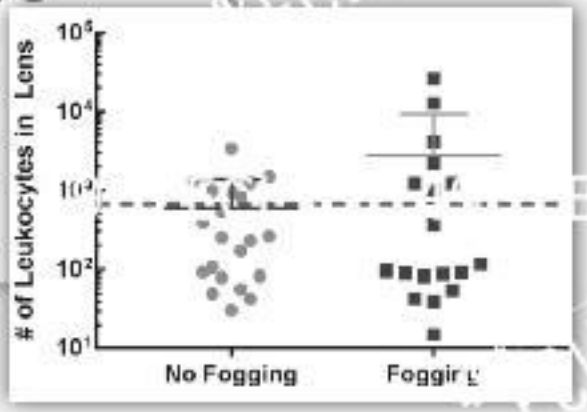
Invest Ophthalmol Vis Sci. 2019 Jan; 60(1): 226–233.

Identification of Leukocytes Associated With Midday Fogging in the Post-Lens Tear Film of Scleral Contact Lens Wearers

Cameron K. Postnikoff, Andrew D. Pucker, [...] and Jason J. Nichols

Table 1. Breakdown of Observed Post-Lens Tear Film Fogging by ScCL Indication With 39 Total Eyes

Keratoconus	●●◑◑◑○○○
Soft contact lens failure	●●●○
Dry eye	◑○
Corneal ectasia/scar	◕○
Post-radial keratotomy	○○
Corneal/conjunctival pterygium	◔
Vision correction	◑



- 39 eyes of 19 patients with full-time ScCL users
- Patient reported midday fogging 46%
- Leukocyte analysis by washing the ScCL and eye surfaces with PBS after at least 4 hours of wear
- Higher leukocyte count in patients with fogging; but not at a significant level!

In the study, at the 4th hour, Optical density (7.54% vs. 8.06%) and OCT grading (1.09 vs. 1.33) were slightly lower in the sodium hyaluronate group

DISCUSSION

Changes in Symptoms of Midday Fogging with a Novel Scleral Contact Lens Filling Solution

Jennifer Swingle Fogt, OD, MS, FAAO, Matthew Karres, OD, and Joseph T. Barr, OD, MS, FAAO

Optom Vis Sci. 2020 Sep; 97(9): 690–696.

- 22 scleral lens wearers describing midday fogging
- Evaluation after 7-9 days of ScCL use with test solution
- Significant relief in symptoms however objective assessment of midday fogging with biomicroscopy and OCT images → No difference

TABLE 1. Unit dose vials sterile fill (% wt/volume)

Sodium chloride	0.73
Calcium chloride	0.0068
Potassium chloride	0.051
Sodium phosphate dibasic	0.3530
Magnesium chloride	0.0023
Purified water	
pH	7.2-7.6

Osmolarity by freezing point or vapor pressure 300 to 325 mOsmol/L.

In our study, while low-contrast visual acuity was stable in the sodium hyaluronate group, it decreased between 2-4 hours in the saline group.

Similarly, no difference between optical density and OCT grades

TABLE 2. Median (interquartile range) of subjective assessments of symptoms associated mid-day fogging with scleral lens wear

	OSDI	CSS: burning/stinging	CSS: grittiness/foreign body sensation	CSS: dryness	CSS: blur/fluctuating vision	CSS: overall pain/discomfort
Median score (IQR) with habitual saline	27.1 (21.7)	1.5 (8.8)	3.5 (16.5)	15.3 (40.4)	15.8 (45.9)	3.0 (20.3)
Median score (IQR) with test solution	[illegible]	(.8 (3.4)	1.0 (6.0)	1.5 (3.6)	1.3 (10.4)	1.0 (2.0)
Median change in score	7.3 ($P = .006$*)	1.3 ($P = .04$*)	2.3 ($P = .005$*)	16.0 ($P = .001$*)	15.5 ($P = .001$*)	4.4 ($P = .004$*)

*Statistically significant change in symptom when using test scleral lens filling solution compared with habitual filling solution as assessed by Wilcoxon signed rank test. CSS = Current Symptoms Survey; IQR = interquartile range; OSDI = Ocular Surface Disease Index.

DISCUSSION

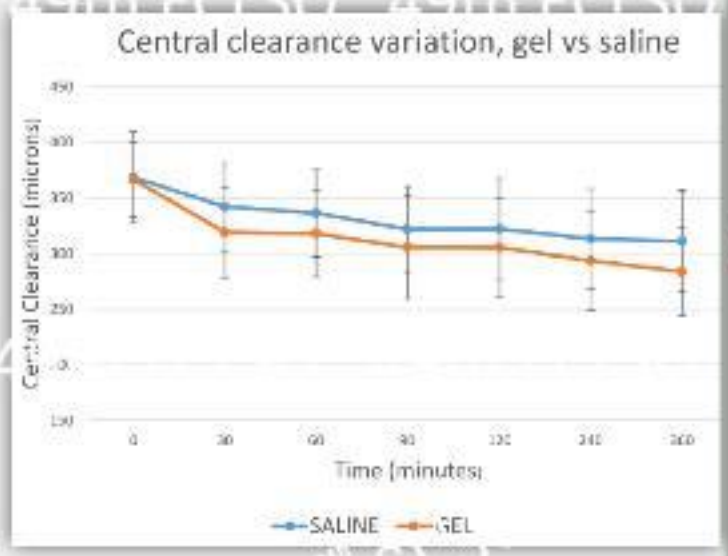
Contents lists available at ScienceDirect

Contact Lens and Anterior Eye

journal homepage: www.elsevier.com/locate/clae

Variation of clearance considering viscosity of the solution used in the reservoir and following scleral lens wear over time☆

Claudine Courey[a], Langis Michaud[b,*]



- Prospective, non-randomized control study
- 18mm ScCL, 400 µm central corneal clearance target
- ScCL fitting one eye with a preservative-free carboxymethylcellulose gel solution (1%-Refresh Cellulose, Allergan, Irvine) and saline in the other eye
- Every 30 minutes for up to 2 hours and every 2 hours [illegible] central clearance measurement with OCT
- The average amount of settling after 6 hours is 70.0 ± 9.8 µm, half of it in the first 30 minutes
- **No difference between saline and gel solution**

In our study, the average amount of settling after 8 hours

- **131µm** in the sodium hyaluronate group
- **114 µm** in the saline group

No difference between solutions

CONCLUSION

- While AS-OCT-based midday fogging grading and optical density increased in both groups over time, no significant difference was found between the two groups at visits.
- The amount of settling and overall satisfaction were similar in both solutions.
- Low-contrast VA remained stable until the 8th hour in the sodium hyaluronate group, whereas it decreased after 2 hours in the saline group.
- *The use of sodium hyaluronate as a reservoir solution may be advantageous over saline in terms of preserving low-contrast visual acuity.*
- *Despite its more viscous content, sodium hyaluronate may be a good candidate for a scleral lens reservoir solution because it does not increase midday fogging and has advantages over the ocular surface.*

THANK YOU