Comparison of optical aberrations in keratoconus with scleral versus rigid gas permeable lenses

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ECLSO

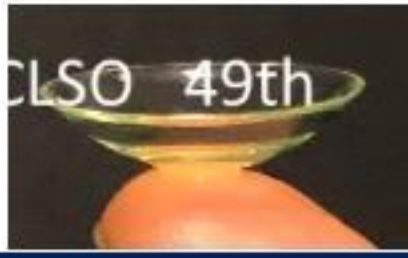
No conflict of interest

- **Optical aberrations**
  - lead to poor quality of vision. (1,2)
  - can be defined as the difference in the shape of the wavefronts entering and leaving the eye
  - two types of aberrations. (3,4)
    - Lower order aberrations (LOA) include refractive errors (hyperopia, myopia, astigmatism).
    - **Higher-order aberrations** (HOAs) defined as **optical aberrations**
      - remain following the optimal correction of defocus and astigmatism with conventional spherocylindrical lenses,
      - can significantly decrease the retinal image quality (3), the accommodation response of the eye (5), and the relative focal plane of different regions of the entrance pupil. (6)
      - result mainly from the deformation of the anterior corneal surface such as in keratoconus. (7)

- **Keratoconus**
  - is a non-inflammatory, usually asymmetric, bilateral corneal dystrophy
  - causes irregular astigmatism and corneal thinning.
  - The central part of the cornea protrudes forward in a conical shape, resulting in highly irregular myopic astigmatism and visual impairment. (8)
  - Improving the visual acuity and delaying the development of the disease are the main clinical intervention purposes.

The use of contact lenses

- an important non-surgical management measure for keratoconus. (9)
- **Customized rigid gas permeable (RGP) lenses** are the first choice for visual rehabilitation in keratoconus, after corrective glasses, and before intracorneal rings or corneal grafts. (10–13)
- **Scleral lenses (SL)** usually appear as a second-line choice after RGP. Covering a larger surface area of the eye with no direct contact with the cornea, they offer greater stability and comfort to the patient but require a more limited wearing time compared to rigid lenses due to the risk of corneal hypoxia. The handling of scleral lenses is also more demanding for the patient. (9,14)



- **Objective**: to compare optical aberrations in the same group of keratoconus patients fitted with rigid gas permeable lenses versus scleral lenses
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- This prospective comparative study included 25 eyes of 14 patients between October 2020 and March 2021.
  - It adhered to the tenets of the Declaration of Helsinki.
  - The cohort was declared to the INDS (Institut National des Donnees de Santé, France), registration number 255645.
  - All patients were selected consecutively during the contact lens consultation at the Quinze-Vingts national ophthalmological hospital (Centre Hospitalier National d'Ophtalmologie des Quinze-Vingts, Paris, France).

- The inclusion criteria
  - **patients with keratoconus, wearing customized rigid gas permeable lenses (Rose K2, Menicon®, Nagoya, Japan) with poor tolerance and requiring fitting with scleral lenses (ICD 16.5 HD, LCS®, Cannes, France).**
- The non-inclusion criteria
  - a history of corneal surgery except for crosslinking (over 24 months ago), a history of cataract surgery or lens opacity, and retinal anomalies.

- Study subjects underwent:
  - **topography** (MS-39®, CSO, Firenze, Italy), with the assessment of the maximum keratometry (maximal apical curvature power)
  - **corneal OCT** (Optovue RTVue-100®; Optovue, Fremont, California, USA), after a period of no lens wear.
  - The **best-corrected visual acuity** (BCVA) **with glasses and with RGP**.
  - The aberrometry tested with **the iTrace® device** (Tracey Technologies, Houston, TX, USA), **without pharmacological dilation**,
    - with the patients wearing **RGP.**
    - with the patients wearing **SL.**

Statistical analysis

- Population characteristics, BCVA with corrective glasses, RGP and SL (LogMar), stage of keratoconus according to the Amsler-Krumeich classification, minimum pachymetry, maximum keratometry (Kmax), and aberrometry findings (total HOAs, Coma, Trefoil) with RGP and SL were analysed
- Statistical analysis was performed with the software program MedCalc Software Ltd ® version 19 (8400 Ostend, Belgium).
  - Anova's test.
  - The relationships between visual acuity and the different variables such as stage, aberrometry findings, pachymetry, Kmax were assessed in RGP and in SL with Spearman's test. Pearson's test, and multiple linear regression.

Population characteristics

- The mean age: 34 years (±8.8) with a sex ratio (male/female) of 9/5.
- 12 left eyes (48.0%) for 13 right eyes.
- The average Kmax: **63.6 D (±11.0).**
- The average minimum pachymetry: **375 µm (±80.0).**

	Mean	Mean difference	Confidence interval at 95%	p-value*
BCVA** RGP† (logMAR)	0.11	-0.02	[-0.06, 0.02]	0.31
BCVA SL‡ (logMAR)	0.09			
BCVA RGP (logMAR)	0.11	0.38	[0.24, 0.52]	<0.0001
BCVA glasses (logMAR)	0.49			
BCVA SL (logMAR)	0.09	0.40	[0.25, 0.55]	<0.0001
BCVA glasses (logMAR)	0.49			

Table: Comparison of best-corrected visual acuity with corrective glasses versus rigid gas permeable lenses and scleral lenses

*Student, α risk < 5%
** Best Corrected Visual Acuity
† Rigid Gas Permeable Lense
‡ Scleral Lense

- The mean BCVA (LogMAR)
  - 0.5 ±4 lines with corrective glasses.
  - 0.2 ±1.6 lines with RGP
  - 0.1 ±1.9 lines with SL.
- no significant differences in the mean BCVA between scleral lenses and rigid lenses.
- the mean BCVAs were significantly better with scleral lenses ($p<0.0001$) and RGP ($p<0.0001$) compared with corrective glasses.

Types of optical aberrations	Mean	Mean difference	Confidence interval at 95%	p-value*
Total HOAs RGP**	0.87	-0.47	[-0.83, 0.11]	0.01
Total HOAs SL†	0.40			
Coma RGP	0.12	-0.08	[-0.13, -0.03]	0.003
Coma SL	0.04			
Trefoil RGP	0.12	-0.09	[-0.14, -0.02]	0.008
Trefoil SL	0.03			

Table: Comparison of total HOAs, coma, and trefoil for rigid gas permeable lenses versus scleral lenses.

*, **, †
* p-val < 5%
** Rigid Gas Permeable Lense
† Scleral Lense

- Total HOAs were significantly lower with scleral lenses than with rigid lenses (p=0.01).
- Specifically, coma (p=0.003) and trefoil (p=0.008) were significantly lower with SL than with RGP.

Correlations

- **BCVA** decreased with:
  - increasing **stage of keratoconus** with **RGP** lenses (r=0.44;p=0.02) and **scleral lenses** (r=0.39;p=0.05).
  - decreasing **minimum pachymetry** with **RGP** (r=-0.59;p=0.002) and **SL** (r=-0.46;p=0.02).
  - the **maximum keratometry** increased with **RGP** (r=0.50;p=0.01) and **SL** (r=0.48;p=0.02).
- An association was found between **BCVA and both total HOAs** (r=0.51;p=0.01) and **coma aberrations (r=0.45;p=0.02) with SL.**
- no significant correlations between the BCVA and the optical aberrations (Total HOAs, coma, and trefoil) in RGP on one hand, and trefoil in SL on the other hand.

BCVA* (LogMAR)

	Rigid gas permeable lens		Scleral lens	
	Correlation coefficient	p-value*	Correlation coefficient	p-value*
Amsler-Krumeich Stage	-0.04	0.31	-0.05	0.18
Minimum pachymetry (µm)	-0.001	<0.001	-0.001	0.01
Maximum keratometry (D)	0.01	0.052	0.01	-0.001
Total HOAs	-0.04	0.33	-0.04	0.78
Coma	0.1	0.71	2.81	0.002
Trefoil	0.05	0.87	-3.42	0.08

Table:Multiple regression linear study between best-corrected visual acuity and Amsler-Krumeich stage, minimum pachymetry, maximum keratometry, total HOAs, coma and trefoil in patients fitted with a rigid gas permeable lens and with a scleral lens.

- In muitiple linear regression, **best visual acuity** (LogMAR) was correlated with:
  - **minimum pachymetry** (p<0.001) and **maximum keratometry** (p=-0.02) with **RGP.**
  - **minimum pachymetry** (p=0.01), **maximum keratometry** (p<0.001) and **coma** (p=0.002) with **SL.**

- **Our study - as opposed to previously reported studies - showed, with the same keratoconus patients, that with scleral lenses, total higher-order, coma, and trefoil optical aberrations were reduced compared to rigid gas permeable lenses**.(15,16)
  - Kumar (15) for instance found that optical aberrations were comparable with RGP and scleral lenses. This difference can be explained by the fact that the patients in our study presented with **steeper Kmax and more severe keratoconus in the Amsler-Krumeich classification**.
  - Yildiz et al. (16) found no differences regarding HOAs between 15 eyes of 15 patients fitted with rigid lenses and 15 eyes of 15 different patients fitted with scleral lenses. However, in our study, **the same group of etter best-corrected visual acuity was fitted with both types of lenses which allowed paired comparison to be performed**.

- **A trend toward better best-corrected visual acuity was observed with SL compared with RGP regardless of disease severity.**
  - However, the difference did not reach significance as in the studies by Kumar (15) and Yildiz (16) found in their respective studies.
  - However, the mean BCVA with scleral lenses and RGP were significantly better than that with corrective glasses.
  - Marsack et al (17) also found a significant improvement in visual acuity with scleral lenses compared to optimal correction with glasses.
- **As with corrective glasses, BCVA for patients fitted with rigid gas permeable lenses and scleral lenses correlated with keratometry and pachymetry**

Limitations of the present study include

- the **low number of patients** and **the reason for SL fitting** (i.e., keratoconus patients wearing customized rigid gas permeable lenses with poor tolerance).
  - however,
    - the primary endpoint (HOAs) was objective and independent of contact lens wear comfort.
    - it was **a prospective matched study.**
- **The aberrometers used in the literature were not the same** (iTrace® versus Hartmann Shack® versus Irx3®) which may reduce the comparability of the results in the different studies (20).

CONCLUSION

- Rigid gas permeable lenses and scleral lenses increased visual acuity in keratoconus patients compared to corrective glasses.
- The use of scleral lenses was an interesting tool to improve the visual quality of patients with severe keratoconus.

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