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Short Commentary

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# To Fit or Not to Fit: That is the Clinical Question A Review of Oxygen Transmissibility through Scleral Contact Lens Fits

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## Introduction

The clinical decision to fit a patient in scleral lenses is often a balance between potential risks and benefits [1,2]. Scleral lenses have been increasingly used to improve vision due to refractive challenges resulting from corneal irregularities and various ocular surface diseases, to delay or prevent surgery, and to reduce post-surgical complications [1,3,4]. While scleral lenses can be helpful in all these situations, their use is not without risk [1-6]. Little is known about the long-term impact of scleral lenses on ocular health nor are there evidence-based guidelines regarding optimal fit characteristics [1,3]. As clinicians, are we utilizing all available tools and incorporating the most updated information when formulating a treatment plan?

## Consider the Following Case

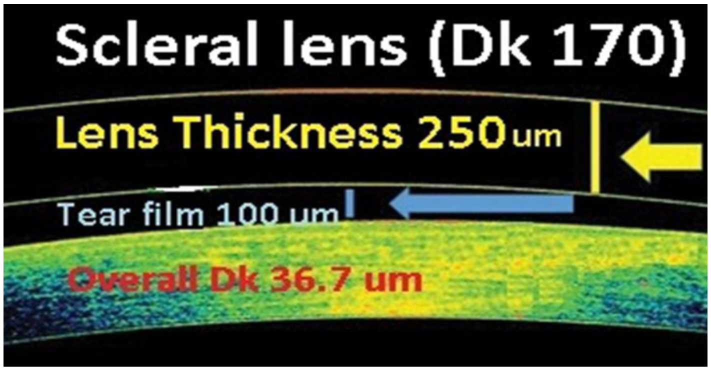
A 23-year-old African-American male presented with a complaint of blurry vision at distance and near. He had a history of moderate to severe keratoconus in both eyes. The patient had no other significant ocular or medical issues, but reported he was unable to tolerate Rigid Gas Permeable (RGP) contact lenses. His corrected distance visual acuity was 20/100 OD and 20/50 OS with his current hybrid lenses. Monocular best-corrected visual acuity by manifest refraction was 20/400 OD and 20/100 OS, with high myopia, five diopters of an isometropia and corneal astigmatism of 3 diopters OD and 7 diopters OS. A slit lamp examination revealed limbal opacification at 10 o'clock, corneal neovascularization, and a small area of mild to moderate corneal scaring near the visual axis of both eyes. The patient reported good comfort when fitted with scleral lenses that vaulted each cone by at least 100µm. The lenses showed adequate movement without impingement and improved his vision to 20/40 OU. Achieving 20/40 vision in both eyes for a fairly advanced Keratoconus leaves the patient with good functionality. We concluded that scleral lenses were his best option given this marked visual improvement despite our concern that scleral contact lenses could further damage his endothelia. It is our intent to examine the potential damage that scleral contact lenses could have on corneal endothelial cells.

## Is Patient History, Vision and Comfort Enough?

When fitting a patient for contact lenses it is the goal of a practitioner not only to balance optimal vision and comfort, but to consider the relationship of the lens to the eye. Contact lenses act as a barrier between the environment and the ocular surface. While this barrier function may provide certain benefits to the patient, it also affects oxygen transmissibility.

A scleral lens is generally considered to be a lens that rests entirely on the sclera-a term that describes the fitting relationship of the lens to the eye, as opposed to a lens of fixed diameter [4]. Like other lens designs, oxygen transmissibility through a scleral lens affects the health and fitting relationship to the eye. While scleral lenses can now be manufactured with high oxygen permeable materials, the overall lens design is such that it creates a thick tear layer between the lens and the ocular surface which can be highly variable[1,3,4,6].This tear layer acts as an additional barrier to the flow of oxygen and depending on its thickness, can then lead to an overestimation of the overall oxygen transmissibility of the tear-lens system[1].T he thicker the tear layer created by the lens, the greater the resistance to oxygen transmission through the lens system, and the greater the risk for ocular complication [1].

Michaud, et al.[1]suggested lens parameters for healthy fitting relationships to a non-diseased eye based on mathematical models that consider minimal oxygen transmissibility standards, lens material, lens thickness, and the thickness of the tear lake created by the system [1]. By their recommendation using a lens material with a calculated oxygen permeability (Dk) of 150 and having a thickness of 250µm (to avoid flexure), a tear layer should not exceed 200µm in order to maintain minimal oxygen transmissibility. According to this model, even when considering higher Dk materials, very few combinations of lens parameters satisfy the theoretical minimum safe oxygen transmissibility standards. Consequently, finding an optimal lens design for a patient presenting with an irregular corneal surface such as keratoconus becomes difficult.




## What About Long-Term Corneal Health?

The corneal surface is living tissue that is replaced frequently and requires a minimum amount of oxygen to function normally [1-4,6,7].Without adequate oxygen, the corneal surface becomes hypoxic [6,7]. Hypoxia stimulates glycolysis. This leads to an increase in lactic acid[7]which acts as an osmolyte, drawing water into the corneal stroma across both the epithelial and endothelial surfaces, adversely affecting vision and comfort [7]. Endothelial cells on the posterior surface of the cornea preserve the cornea's integrity, ordered structure, and minimize light scatter by actively maintaining fluid and electrolyte balance [8].

Studies evaluating corneal swelling in non-diseased patients who were fit optimally with scleral lenses using the model of oxygen transmissibility proposed by Michaud, et al. showed 1.6% corneal swelling with shallow tear reservoirs and 3.9% swelling for deep tear reservoirs after three hours of wear [2]. This amount of swelling is within the physiological normal range for lens-free closed-eye conditions such as sleep [2]. It is possible that subclinical corneal edema may yet exist even in patients fit with high Dk materials, but it is not known whether this "physiological" level of edema will have long- term consequences on the viability and structure of the corneal endothelium [2,6].

## What Objective Method (s) Exist for Monitoring Long-term Corneal Health?

The corneal endothelium is a monolayer of highly specialized cells of roughly hexagonal morphology that do not have the ability to replicate [9,10]. In Caucasians, endothelial cell counts can be as high as 4000 cells per mm2 at birth and into early childhood. Typically, this number declines until late adolescenteand stabilizes at about 2900 cells per mm2. It remains here until approximately age 50, and then decreases slowly to around 2400-2600 per mm2 after age 60 [9,11,12].

Endothelial cell counts are influenced by genetics, age and race. The counts may be reduced by disease, trauma, surgery, UV exposure, infection, chemical toxicity, and mechanical stress. Pertinent to this discussion, cell counts may also be reduced by contact lens-induced hypoxia[10,11].As cells degenerate, the surviving cells enlarge and spread to maintain a contiguous monolayer [12]. During this morphology process, cedensity- leave "cell density" as is changes to compensate for cellular loss [12].

Given the non-replicating nature of this monolayer and this tissue's integral relationship to the health of the overall cornea, tracking the cellular density of the corneal endothelium provides a way to monitor damage done to it by scleral contact lenses. Corneal endothelial specular microscopy is a non-invasive, objective tool used to evaluate the structure and function of the corneal endothelium described by Mc Carey, et al. in a 2008 report [12]. Specular microscopy works by capturing and projecting a highly-magnifiedimage that reflects the optical interface between the aqueous humor and corneal endothelium[9,12]. A computer provides measures of the Number of Cells (NUM), the Cell Density (CD), the percentage of normally shaped cells (HEX), and the variation of sampled areas, the Coefficient of Variation (CV) [9,12].

## Specular Microscopy Considerations

Currently the clinician faces several challenges in the use of specular microscopy to follow the potential deleterious effects of scleral lens. To our knowledge, normative values for HEX and CV have not been published [10]. Cell density appears to diminish as the distance from the center of the cornea increases in healthy eyes. Pathologic conditions such as keratoconus presumably have variable and possibly geographically heterogenous cell characteristics prior to contact lens fitting [11,12]. Edmonds, et al.[11] have shown that limited oxygen transmissibility through a contact lens, regardless of type (soft and RGP), was correlated to increased polymegathism and polymorphism in Keratoconic patients in the area of greatest thinning (cone). These observations suggest that sampling errors are likely unless multiple areas are measured.

With regard to our patient, several scans were taken with a specular microscope at the time of the visit to establish a baseline for future comparison. Unfortunately, few endothelial cells were identified by the specular microscope which rendered subsequent analyses (HEX, CD and CV) inconclusive. These results may be explained by the pre-existing central/pericentral corneal opacities in both eyes. While difficult to interpret, these results are illustrative of the current clinical challenges. Without the ability to sample multiple off-axis areas of the cornea, more reliable data could not be obtained.

## Discussion & Conclusion

As clinicians, we must incorporate objective measures of corneal health when fitting scleral contact lenses. Overestimation of the oxygen transmissibility of scleral lens made with high Dk materials may subject patients to hypoxia that compromises long-term corneal health [1,6,2,9]. This risk of hypoxia increases with scleral lens fitting characteristics. Subclinical edema may lead to permanent damage more commonly than previously thought [1,2]. Furthermore, with increased reliance on scleral lenses in a variety of situations, clinicians need to be well versed in the potential long-term consequences of their use [1,3]. Currently, the decision to fit keratoconic patients with scleral lenses is largely based on patient vision, comfort and quality of life with few objective measures of long term corneal health routinely done. Serial objective measures such as corneal pachymetry, specular microscopy, and anterior segment Ocular Coherence Topography (OCT) could afford the clinician the tools he needs to track corneal health. Utilization of anterior segment OCT can give an exact measurement of the scleralvault, eliminating clinician's error of estimation. Understanding the relationship between tear film thickness, oxygen transmissibility, and their effect on the cornea is crucial to the appropriate usage of scleral contact lenses and how they are fit. If we can be sure the scleralvaultis narrow by anterior segment OCT and that corneal endothelial cells are not lost as measured by specular microscopy, then scleral lens fittings presumably could be done safely

At the time of this writing there are no evidence-based guidelines or a consensus regarding optimal fitting of scleral lenses. Additional studies are needed to:

- Elucidate optimal fitting characteristics.
- Establish specular microscopy normative database(s).
- Determine the optimally efficient number area(s) of objective measurements needed to follow patients, and
- Determine guidelines for considering a change of treatment regimen(s).

In conclusion, for those patients with corneal compromise, scleral lenses may be the best option for visual rehabilitation when fit optimally and monitored closely using both clinical and objective measures.

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