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Soft Contact Lenses for Keratoconus: Case Report

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Purpose. Contact lenses have assisted the refractive correction of keratoconus since the 19th century. In these case reports, the authors describe their experience with a new soft contact lens design. **Methods.** The Soft K is a new soft lens comprising a thick fenestrated design to fit in patients with mild to moderate corneal distortion and fitting problems or physical intolerance to rigid gas-permeable (RGP) contact lenses. Three eyes with mild keratoconus from two 25-year-old patients (one man and one woman) were fitted with the Soft K contact lens. Both patients had previously worn other contact lens types. **Results.** Improvements in comfort and quality of vision compared with previously worn RGP or soft toric contact lenses were the most remarkable advantages objectively observed and subjectively described by both patients. For one patient, a professional soccer player, the benefits were also important in terms of compatibility with the dynamic environment of his activity, satisfying the need for stable correction and constant full field-of-view demand without spectacles. No physiologic complications such as edema or neovascularization were observed during the follow-up period. **Conclusions.** This new soft lens design for irregular corneas is especially indicated for those with intolerance to RGP or other contact lenses and for patients for whom RGP lenses do not satisfy the dynamic environment inherent to some professional or leisure activities, particularly sport activity. This is a good option to consider in patients with mild to moderate keratoconus and good correction of slight or moderate irregular corneal astigmatism with good tolerance. Aftercare implications are also discussed.
Key Words: Comfort—Moderate keratoconus—Soft K—Thick fenestrated soft contact lens.

Keratoconus is a progressive, asymmetric, noninflammatory dystrophy of the cornea characterized by steepening and distortion of the cornea, apical thinning, and central scarring. More complete descriptions of the condition and its signs and symptoms are available in the strong body of literature surrounding this topic.

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The contact lenses most frequently used to correct irregular astigmatism are currently made of rigid gas-permeable (RGP) materials of conventional spherical, aspheric designs, and other unconventional designs.[1,2] These materials provide the best visual performance for patients with keratoconus.[3]

Nevertheless, corneal lenses made of polymethylmethacrylate or RGP materials are frequently difficult to fit for a cornea with keratoconus, even with the variety of designs currently available. Problems with tolerance are common, and mechanical friction with the apex of the cone can affect the quality of vision.[4] When a highly irregular corneal surface makes an RGP lens fitting less than optimal as a consequence of poor stabilization and mechanical relationship with the anterior corneal surface, other modalities must be considered. These modalities use different designs or combinations of RGP and hydrophilic materials to offer the patient with keratoconus a comfortable, safe, and effective mode of vision correction.

Hybrid lenses, such as SoftPerm (CIBA Vision, Duluth, GA), have been associated with edema,[5] decreased endothelial cell density,[6] increased risk of neovascularization, and other issues regarding lens resistance to handling. Conversely, piggyback systems seem to be effective and have been shown to provide enough oxygen to fulfill corneal needs during daily wear, even when conventional lenses are used.[7] However, handling and cleaning two different lenses are major inconveniences for many patients.

The application of conventional soft contact lenses for keratoconus is limited to the initial stages of the dystrophy, even with lenses as thick as 0.2 mm.[3] Other special designs made of soft materials included the Freflex and Flexlens (Optech, Englewood, CO), which combine materials with a high water content (55% and 45%, respectively) and a thick (0.3–0.5 mm) optic zone.[8] The Keratosoft lens (Ultravision International Ltd., Beds, UK) has also been used in a low proportion of patients.[2]

To optimize quality of life in patients with keratoconus, many different designs have been marketed in the last few years. One of these designs is made of a thick hydrophilic material that neutralizes the irregularity of the corneal surface through a thick optic zone and a system of peripheral fenestrations or pressure-balancing holes to prevent negative pressure behind the lens. The first lens, initially named Soft K, gained U.S. Food and Drug Administration approval in 2002 and has been marketed in Europe since 2002 under the name Soft K (Soflex Contact Lens Industries Ltd., Misgav, Israel).

Barequet et al.[9] evaluated the use of the Soft K lens in patients with irregular astigmatism who were unable to wear RGP contact lenses. Their study involved 57 eyes of 32 patients and assessed visual acuity and lens tolerability for up to 1 year of use. They

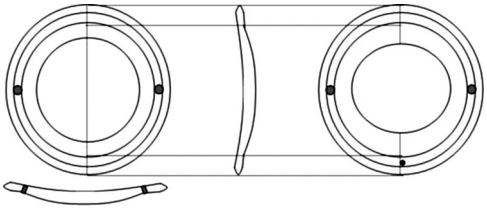

FIG. 1. Approximate graphical representation of the Soft K soft contact lens. Peripheral fenestrations are identified as filled gray circles. The figure on the right corresponds to the toric design with the axis reference mark at the 6-o'clock position.

concluded that the Soft K lens can serve as a viable option in keratoconus patients with intolerance of RGP contact lenses.

This article describes two typically eligible patients for this fitting approach. With the exception of the study by Barequet et al., to the best of the authors' knowledge, this is the first clinical report on the use of this soft contact lens design for keratoconus.

MATERIALS AND METHODS

The Soft K soft contact lens is made of a nonionic material with a high water content (58%) under the generic name GM3, which is a copolymer of glycerol monomethacrylate and vinyl pyrrolidone. The United States Adopted Names Council attributed the nonproprietary name acofilcon A to this material in 2002.[10] As described by the manufacturer, this design is available in two different materials: Eni-Eye Soft K and Eni-Eye Soft K Toric made of a copolymer of N-vinyl pyrrolidone, methyl methacrylate and cyclohexyl methacrylate 2-ethoxyethyl methacrylate cross-linked with allyl monomethacrylate (33% xylofilcon A and 67% water at 20°C); and Soflex Soft K and Soflex Soft K Toric made of a copolymer of glycerol methacrylate and vinyl pyrrolidone (42% acofilcon A and 58% water at 20°C). The main differences between the two designs are the higher permeability of xylofilcon A (29 barrer [$cm^3O_2 \cdot cm^2/cm^3$ $_{material} \cdot$ seg $\cdot$ mm Hg] vs. 21.5 barrer of acofilcon A), the extended refractive range of Soflex Soft K from +10.00 to –20.00 diopters (D), and the slightly thicker center thickness of Eni-Eye Soft K (0.38 mm vs. 0.36 mm of Soflex Soft K).

The novel design of this lens comprises spherical base curve geometry and an aspheric periphery. The front curve has three zones: a thick optic zone to improve the optic quality, a special lenticular zone for structural stabilization, and the edge (Figs. 1 and 2). Two fenestrations act as pressure-balancing holes to equalize the pressure between the front and the back of the lens. The goal of this design is to center over the irregular cornea and minimize material deformation to allow partial correction of the irregular cornea with maximum comfort for the patient. Technical and fitting details are shown in Tables 1 and 2, respectively.

RESULTS

Patient 1

A 25-year-old man had a chief complaint of poor visual acuity and ghost images surrounding objects, mainly at night with his current soft toric contact lenses. Keratoconus had been diagnosed 6 months before by another practitioner. After a first attempt to fit an RGP lens, which was described as "very uncomfortable" and "drop down after blink," soft toric lenses had been prescribed by

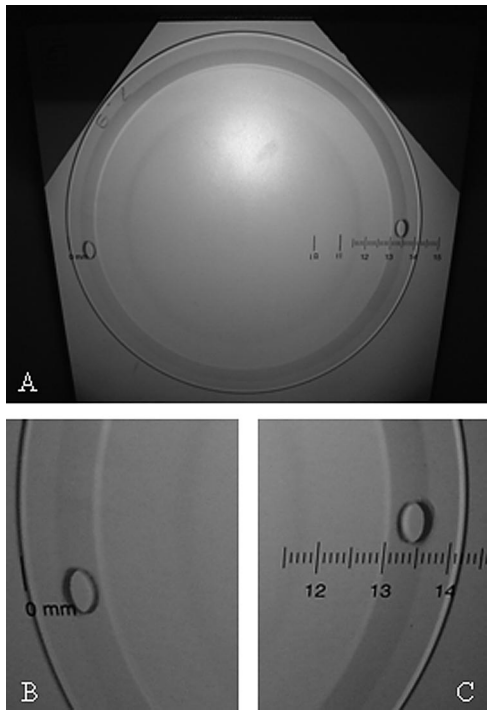

FIG. 2. (A) Magnified view of the lens. (B and C) Pressure balancing holes and thickness transition zones.

the same practitioner. On examination, uncorrected visual acuity (20/25 with both eyes) was better than that achieved with his contact lenses. At this first examination, the subjective refraction (–1.75 ×60 [20/15⁻] in the right eye and +0.50 –1.50 ×105 [20/15⁻] in the left eye) did not agree with objective refraction nor with the current spectacle and soft toric contact lens prescription (–3.50 –1.00 ×10 [20/30] in the right eye and –1.50 –1.00 ×10 [20/30] in the left eye). During objective and subjective refraction,

TABLE 1. *Technical Parameters of the Soft K Contact Lens as Indicated by the Manufacturer*

Material	GM3 (glycerol monomethacrylate and vinyl pyrrolidone) (acofilcon A)
Water content	58% in saline at 20°C
Food and Drug Administration classification	Group II: nonionic, high water content
Dk (Fatt method)	21.5×10^{-11} barrer at 35°C
Central thickness (–3.00 D)	0.32 mm
Edge thickness (–3.00 D)	0.11 mm
Front surface geometry	Thick optic zone Lenticular mid peripheral zone Edge zone
Back surface geometry	Spheric optic zone Aspheric periphery
Special design features	Two pressure-balancing holes
Manufacture	Lathe-cut

TABLE 2. *Fitting Parameters of the Soft K Contact Lens as Indicated by the Manufacturer*

Base curve radius	7.30, 7.60, 7.90, and 8.20 mm
Total diameter	14.2 mm
Optic zone diameter	8.30 mm
Power range for trial	+10.00 to –20.00 D
Toric design	Back toric –0.50 to –2.00 D of cylinder at any axis
Handling tint	Light blue
Cleaning	Hydrogen peroxide recommended
Wearing schedule	Daily wear

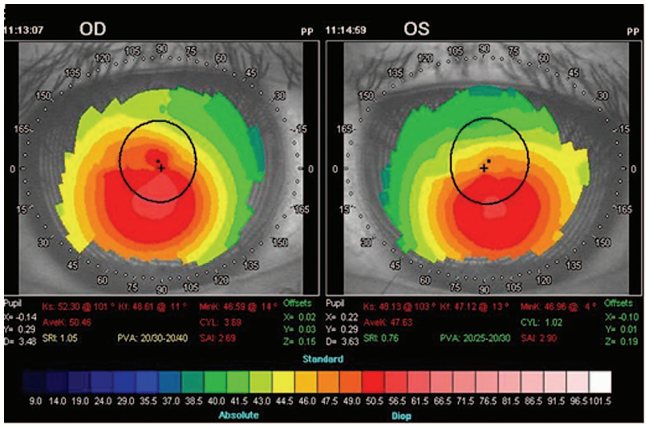

FIG. 3. Corneal topography of the right and left eyes of patient 1 showing keratoconus in both eyes. Despite the large extension of the affected area, the irregular astigmatism is moderate.

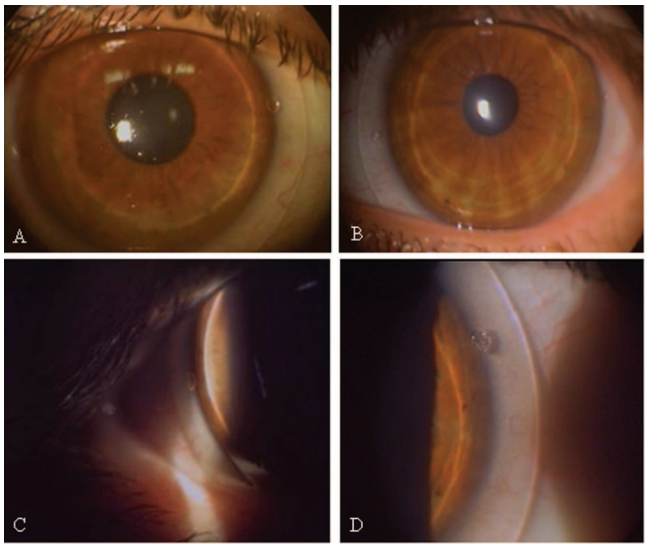

FIG. 4. On-eye performance of patient 1 with the 7.60 base curve lens in the right eye (A) and the 7.90 base curve lens in the left eye (B) slightly decentered inferiorly and nasally. Lens design on the left eye of patient 2 is shown under medium magnification (C) and air bubbles leaving the postlens space in the same eye (D).

a clear endpoint could not be found. Typical signs of keratoconus were found during retinoscopy, but no other signs were evidenced by slitlamp examination. Before considering any other fitting strategy, the patient was advised not to wear the lenses, and a follow-up examination was scheduled a fortnight later to rule out a molding effect on the cornea.

During the second examination after 2 weeks without contact lenses, uncorrected visual acuity decreased to 20/30$^-$ in the right eye and 20/25$^-$ in the left eye. The refractive error by subjective refraction was –1.00 –4.00 ×70 (20/15) in the right eye and –2.25 × 110 (20/15) in the left eye at this second visit. Corneal topography by videokeratoscopy confirmed the presence of keratoconus in both eyes, more advanced in the right eye (Fig. 3). Simulated keratometric readings obtained with videokeratoscope were 48.61 D @ 11 / 52.30 @ 101 in the right eye and 47.12 @ 13 / 48.13 @ 103 in the left eye.

One of the patient's main concerns was the interference between his prescription, either RGP lenses or spectacles, and his activity as a professional soccer player, which was the reason why an RGP lens fitting, our first choice for keratoconus, was not considered.

After discussion of the pros (comfort, stability, and visual compensation), cons, and limitations of the Soft K contact lens with the patient, including a strong recommendation to limit wearing time until more experience is available with this thick design, a complete examination was performed to evaluate patient characteristics and suitability for this new fitting. Trial lenses sent by the manufacturer were placed in both eyes –5.00 D/7.60 base curve in the right eye and –5.00 D/7.90 base curve in the left eye. After 10 minutes of initial slight discomfort with blinking, the lenses became comfortable. This sensation could be justified by the thick design of the optical zone or could be caused by trapped debris at first insertion. Nevertheless, this fact seems not to be a rule because it was not present on successive experiences. On-eye performance was satisfactory for the right eye with good movement and centration (Fig. 4A) but was too loose for the left eye (Fig. 4B). Overrefraction was neutral in right eye to achieve 20/15. A second test was performed in the left eye with the base curve of 7.60, which performed significantly better in terms of centration; overrefraction was +2.25 D to achieve 20/15.

Instructions were given to the patient to wear his lenses on a daily-wear basis and to use one-step hydrogen peroxide for disinfection every night. A progressive adaptation period during the first week was prescribed, up to a maximum of 8 hours a day for 7 days a week. After 4 months of satisfactory wear, the patient showed some signs of ocular irritation after lens insertion, apparently because of deposits as dehydration areas over the anterior lens surface after blinking were observed. At this point, a daily cleaner and weekly protein removal were prescribed and solved the problem. At the writing of this article, the patient had been wearing the lenses 8 hours a day, 7 days a week for 11 months with no mention of an adverse reaction or a noticeable physiologic interaction with the ocular surface. Nevertheless, at the last visit (9 months), the patient was advised not to wear the lenses more than 8 hours a day and to adapt insertion and removal to his variable professional calendar. This means that he could adapt the hour of insertion and removal accordingly to his sport activity (training and matches), without exceeding the 8 hours of maximum wearing time.

Patient 2

A 25-year-old woman with a history of bilateral keratoconus underwent penetrating keratoplasty on the right eye 5 years before. Uncorrected visual acuity was counting fingers at 1.5 meters in the right eye and 20/30 in the left eye. Best spectacle refraction was +4.00 –7.00 ×130 (20/60) in the right eye and +1.25 –2.00 ×100 (20/25) in the left eye. Videokeratographic evaluation (Fig. 5) showed a typical tilted graft with high astigmatism in the right eye and a typical pattern of keratoconus in the left eye. Simulated keratometric readings obtained from the videokeratoscope were 38.63 @ 129 / 48.04 @ 39 in the right eye and 43.71 @ 120 / 47.00 @ 30 in the left eye.

A piggyback system with a hyper permeable soft left and a back-toric RGP lens was fitted to the right eye to obtain a visual acuity of 20/30 with a slight sensation of ghost images because of the astigmatism induced by the back toricity of the RGP lens. This sensation was not felt by the patient in binocular conditions, which

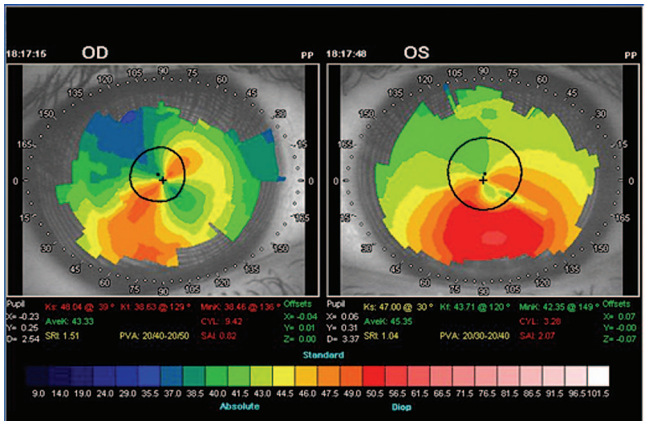

FIG. 5. Corneal topography of the right and left eyes of patient 2.

is normal because this eye is not the dominant one because of the reduced visual acuity after surgery.

Despite the visual acuity of the left eye being slightly improved with spectacles, the patient complained of a sensation of shadows around letters or ghost images, even with the better spectacle refraction given earlier. This was attributed to the irregular astigmatism not fully correctable with spectacles, so a contact lens fitting was considered. The option of RGP lenses was presented to the patient as the best possibility to obtain full correction of the corneal irregularity. However, the patient was reluctant to try this possibility because of experiences of discomfort with this type of lens; additionally, the patient referred to some recurrent episodes of corneal scarring and temporary vision loss with her previous left RGP lens, which was attributed to epithelial compromise. Considering this patient's observations and the moderate evolution of the keratoconus, the Soft K lens was suggested as another option, and the pros and cons were discussed. These include the benefits of the fitting in comfort and vision, with the limitations of wearing period to 8 hours, at least as a prophylactic recommendation, given the thick design of the lens and the unknown contribution of pressure-balancing holes in oxygen availability to the cornea.

The median base curve lens (7.60 mm) was inserted in the left eye and showed good comfort, movement, and centration. Overrefraction with the trial lens of –5.00 D was +4.50 D to achieve 20/15. Figures 4C and 4D highlight the particular aspects of lens design observed under slitlamp biomicroscopy. Figure 4D shows a common situation in which air bubbles trapped behind the lens during insertion are removed from the postlens tear layer through the pressure-balancing holes.

A hydrogen peroxide care system was prescribed with weekly protein removal. At the time of this writing, the patient had been wearing the lens 8 hours per day, on average, for 9 months with no physiologic compromise. Artificial tear instillation was recommended before lens insertion in the back lens surface to avoid bubble formation and before removal to facilitate the extraction of the lens.

DISCUSSION

From the first historic notes on the correction of keratoconus with contact lenses made of glass, numerous approaches have been considered for the correction of the irregular astigmatism present in the keratoconic corneal surface. Among the currently available contact lens materials, RGP lenses provide the best visual performance for patients with keratoconus.[3] RGP lenses are sometimes difficult to fit on the keratoconic cornea; the patient may experience intolerance, or the lenses simply may not be the best option for some situations, including the activity of dynamic sports.

The lens described herein has shown performance superior to that of conventional hydrogel lenses in several respects, when fitted to a mild keratoconic cornea without the initial discomfort and trouble with centration associated with RGP lenses. Absence of negative pressure behind the lens to improve movement and astigmatism masking, good resistance to on-eye flexure by a thick optic zone improving vision over the irregular cornea, a lenticular peripheral zone improving comfort, and the presence of air bubbles leaving the postlens space through pressure-balancing holes are evidence of the effectiveness of this device in improving tear exchange.

Another important feature of this lens is the possibility of incorporating an astigmatic correction by a back toric surface to correct residual astigmatism up to –2.00 D. However, additional astigmatic correction was not necessary in the patients described herein.

Additional explanations should be provided to the patient to facilitate the manipulation of this thick contact lens. Such difficulties are present not only at insertion because of the central thick design of the lens, which complicates the insertion of the lens, but also during removal because of the difficulties in bending the central zone of the lens with the fingers, as conventional soft contact lenses are frequently removed. Application of artificial tears or saline solution and a suction cup should be suggested to remove the lens without damage to the delicate cornea.

The case of reaction to deposits with patient 1 deserves some attention. Although the source of the deposition could not be identified, various authors conclude that the presence of vinyl pyrrolidone is the main factor for the adhesion of lipid deposition on group II soft contact lens materials.[11,12] Zhou et al.[13] found a higher incidence of meibomian gland dysfunction, tarsal hypertrophy in the form of papillae, mucus, soiled lenses, and allergic conjunctivitis in patients with keratoconus compared to healthy eyes.

Both factors could place the patient with keratoconus at higher risk for allergic deposit-mediated reactions by using this kind of lens. Hence, additional care should be emphasized. However, the need for a more intensive cleaning regimen involving different active components could induce allergic reactions because patients with keratoconus have reported significantly higher levels of atopy.[14,15] This is particularly important with soft contact lenses because of the ability of these materials to absorb the molecules of cleaners, preservatives, and so forth. From the authors' experience, a care system typical of a conventional soft contact lens consisting of hydrogen peroxide, daily cleaning before disinfection, and weekly or biweekly protein removal prevent deposit formation. Rinsing could be of major importance to prevent the contact of residual preservatives and active compounds within the eye.

Significant improvements in vision have been described by the two patients when compared with their prescription in spectacles or soft toric contact lenses. From these results, it may be speculated that the correction of the aberrations of the anterior surface of the cornea with mild keratoconus could be responsible for such improvements.

Corneal surface aberration correction with RGP contact lenses through the postlens tear meniscus is responsible for the improvement of vision in keratoconus.[16] However, several investigators support the idea that additional aberration correction over a customized anterior surface of the lens will contribute to improvements in vision.[17] Aberration-free soft contact lenses may or may not improve vision for the general population, depending on the previous condition of the eye for the general population.[18] However, higher-order aberration correction will be certainly of invaluable interest for eyes with corneal irregularities, such as keratoconus. By now, several factors that are difficult to predict influence the effectiveness of customized contact lenses. Variability in pupil aperture size, the role of the tear film and its changes during blinking,[19] and the eye aberration structure make the prediction of the ideal design difficult for each patient. Additionally, lens parameter stability and lens centration over the entrance pupil of the eye seem to be critical for effective aberration correction. RGP contact lenses warrant proper stability against flexure, whereas soft contact lenses improve centration. Whereas hybrid contact lenses do not ensure adequate oxygen transmissibility, it is difficult to consider an aberration-free solution with the parameter stability of a central RGP material and the centration given by the hydrophilic periphery. Perhaps lenses like this with good centration and parameter stability from its thick design will play a role in the future for higher-order aberration correction. By now, the improved centration obtained with this lens can reduce coma aberration responsible for the sensation of shadows around letters, a common complaint in patients with keratoconus who are fitted with poorly centered RGP lenses.

Despite the design of the lens and the reported exchange of air bubbles, the peripheral localization of the fenestrated area could still induce some tear stagnation. Although the impact of pressure-balancing holes on corneal oxygenation is not known, the thick design that significantly reduces oxygen transmissibility through the lens material should make practitioners aware of potential hypoxia by searching for signs of corneal vascularization and other evidence of corneal compromise, including limbal hyperemia and corneal microcysts, haze, folds, and striae. Such situations have the potential to compromise the viability of a future corneal transplant if needed. When fitting these lenses, limitations to the wearing schedule must be discussed with the patient to prevent corneal compromise and make him or her aware of the importance of being compliant with the care schedule.

Some questions arise from this study and must be clarified in the future to better understand the visual improvements and ideal fitting conditions of new soft lens designs for the correction of irregular astigmatism. What is the limit for acceptable correction of irregular astigmatism with this lens? What is the long-term physiologic response of the cornea to this new design, considering the thick optic zone and how the pressure-balancing hole system effectively compensates for such an effect? Is tear exchange through the pressure-balancing holes high enough to compensate for tear stagnation and hypoxia induced by such a thick design? What is the long-term impact of such a thick contact lens on its mechanical relationship with the ocular surface? What is the actual impact of lens deposits over hydrogel materials on the long-term tolerance of the patient with keratoconus to this kind of lens, and what is the ideal maintenance regimen to minimize the risk of sensitivity reactions? It would be interesting to study the aberration profile of eyes with keratoconus while wearing this kind of lens to better understand the patient's subjective response. Could this lens be used as the hydrophilic base for a piggyback system in patients with serious corneal irregularity?

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