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Specialty Contact Lens Travel Grant Application

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## **Correction of Poor Visual Quality Post-Penetrating Keratoplasty with the Ampleye Scleral Contact Lens**

### **Abstract**

Penetrating keratoplasty (PKP), otherwise referred to as a full thickness corneal transplant has solidified itself as one of the gold standard surgical treatments for the correction of advanced stage corneal ectasia complications as well as other various corneal conditions. While this procedure often provides patients with healthy and clear corneal tissue, surface irregularities as well as compounding factors from the original reason for the need of a corneal transplant create visual distortions that result in poor visual quality even through best spectacle correction. To correct these visual distortions scleral lens designs are often utilized to restore functional vision to patients that have undergone a PKP procedure. Post-PKP status is estimated to be responsible for up to 15% of scleral lens fittings.<sup>1</sup> In this case report scleral lenses are employed to correct poor visual quality in a patient that had undergone bilateral corneal transplants secondary to keratoconus complications. Scleral lens intervention was able to restore functional vision while remaining comfortable and stable throughout the day of contact lens wear.

**Keywords: penetrating keratoplasty (PKP), scleral lens, higher order aberrations (HOAs), corneal ectasia, keratoconus**

### **Introduction**

Although recent developments in surgical technology have ushered in corneal cross linking (CXL), intrastromal corneal ring segments (ICRS), and anterior lamellar keratoplasty (ALK) as preferred surgical treatments for keratoconus, penetrating keratoplasty (PKP) has historically proven to be a well-established and successful surgical treatment for advanced stage corneal ectasia.<sup>2</sup> This procedure is especially useful in cases where the cornea has undergone an acute corneal hydrops event with residual corneal scarring and acceptable vision can no longer be achieved with spectacles or contact lenses. Although a penetrating keratoplasty can restore visual function to patients, it also often results in high degrees of irregular astigmatism, anisometropia, higher order aberrations (HOAs), and even recurrent keratoconus where ectatic changes proliferate onto the donor cornea several years after the initial PKP.<sup>3, 5</sup> These factors often leave patients with poor visual quality through spectacles and conventional soft contact lenses even when the corneal graft appears to be clear, healthy, and functional.

Patients that have undergone a penetrating keratoplasty often require specialized rigid contact lenses to provide functional visual quality. These lenses reduce higher order aberrations

created by the irregular corneal surface by effectively creating a topographically regular refractive surface over the cornea. The combination of HOA reduction and refractive correction can often restore functional vision to patients that would otherwise be non-functional in spectacles. Historically, large diameter intra-limbal rigid gas permeable (RGP) lenses have been used to correct these patients' visual ailments as well as minimize interaction with the graft-host junction and maximize oxygen availability. However, issues with intra-limbal lens comfort and stability as well as large irregularities in the corneal surface of post-PKP patients have created a surge in the use of scleral contact lenses. Scleral contact lenses are able to completely vault over the irregular corneal surface and are exceptionally stable due to the lens landing on the sclera, which is generally topographically regular in patients with PKP secondary to corneal ectasias. These lenses are also largely customizable with the ability to finely adjust clearance between the lens and cornea, add stable astigmatic correction, reduce HOAs with wavefront guided and aberration optical design, as well as several other customization techniques that vary by lens manufacturer. These lenses have also proven to be an exceptionally safe treatment option with little association with transplant complications.<sup>4</sup> After a lens is successfully fit and adjusted to specific refractive and visual needs, post-PKP patients often experience exceptional lens comfort with long lens wear time and restore clear and functional vision in their daily lives.

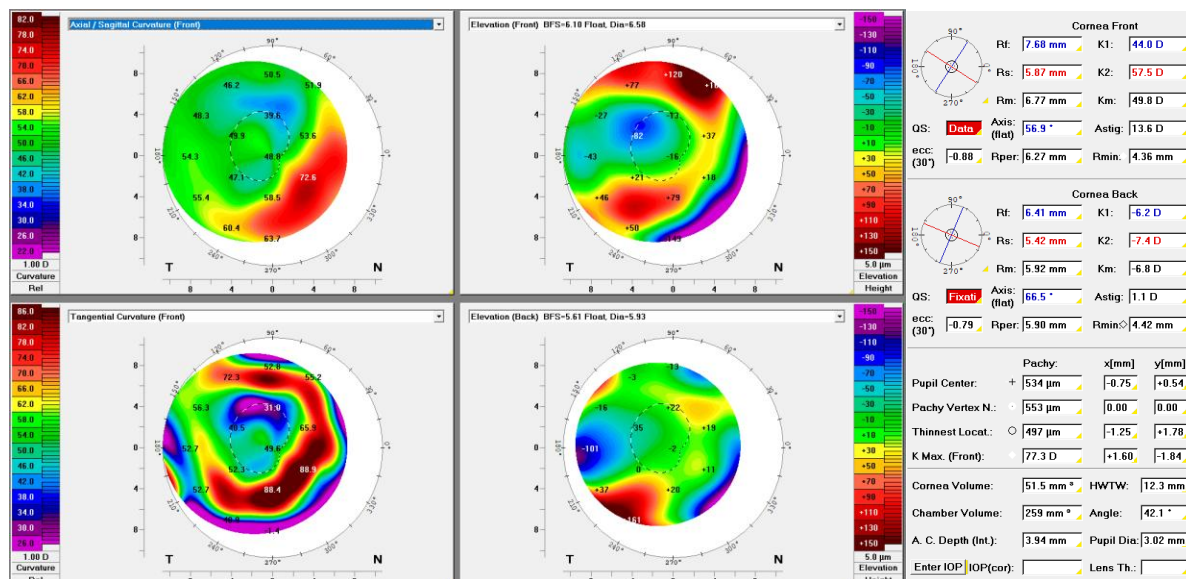
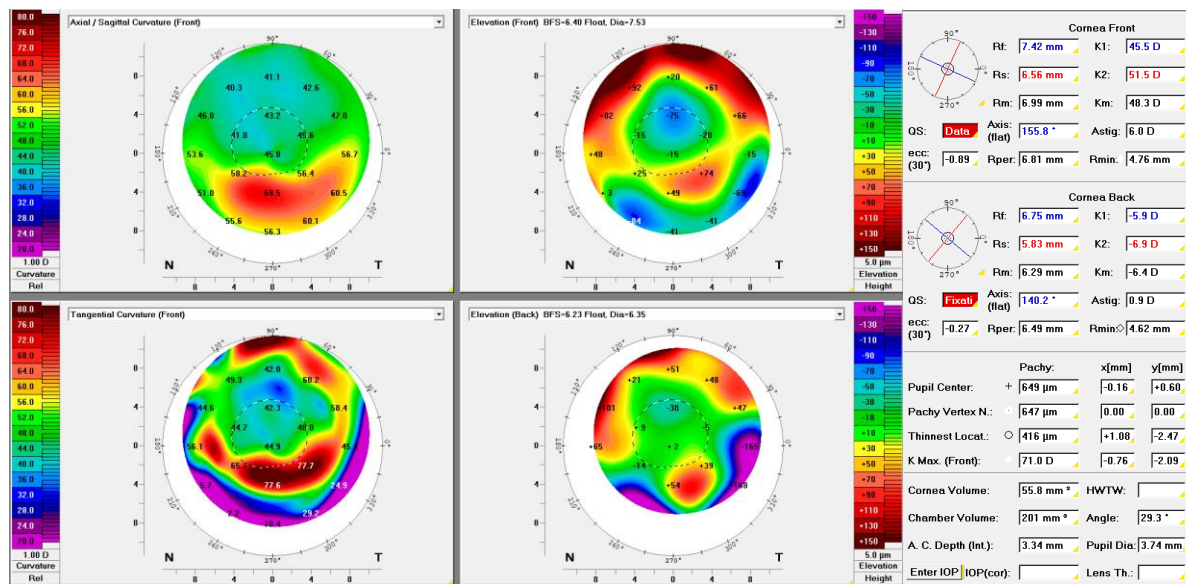
## **Case Report**

A 47-year-old African American male presented to University of Missouri – St. Louis University Eye Center for a scleral contact lens fitting in both eyes secondary to historical penetrating keratoplasty due to keratoconus in both eyes. The patient's chief complaint was very poor vision in spectacles with noted streaks around objects and monocular diplopia. The patient had no pertinent medical history, allergies, or medications and reported a family ocular history of glaucoma in his mother. Entering visual acuity was OD: 20/80-1 PHNI OS: 20/50+2 PHNI OU: 20/40-1 through his habitual spectacles. Lensometry revealed a habitual OD: -5.00 -5.00 x 075 OS: +0.75 -5.50 x 104. All other entrance testing was unremarkable.

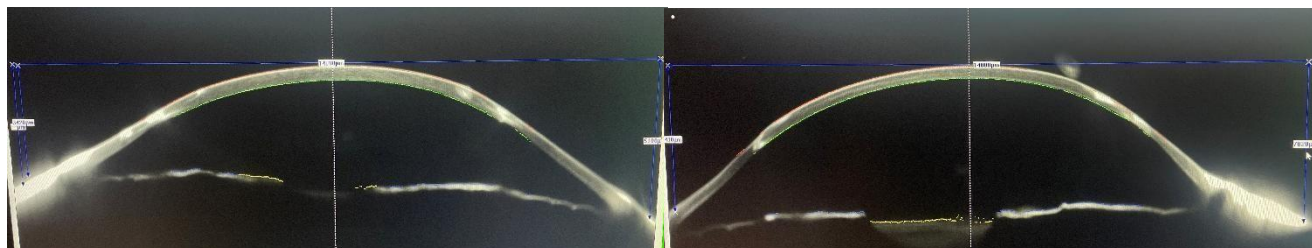
The patient was initially diagnosed with keratoconus in both eyes in 2006 and managed his visual needs with spectacles to maximize vision. The penetrating keratoplasty procedures were performed approximately 1 year apart with OD in 2009 after an acute corneal hydrops event and OS in 2010 secondary to advanced keratoconus and significantly reduced VA. The patient reported no previous contact lens wear history other than an attempted fitting of a piggyback system sometime prior to PKP with a conventional soft contact lens as the base for a corneal GP. This lens suffered from significant stability issues, and the patient reported only being able to wear the lens system for a few hours at a time due to the corneal GP falling out. The patient reported having a period of good visual quality with spectacles immediately after the PKP procedures that gradually declined over the years, and reported that at the time of his scleral fitting visit his vision is the worst it has ever been.

Initial ocular health evaluation revealed approximately 8mm bilateral corneal buttons that were clear with a healthy appearance of the graft-host junction and no remaining sutures.

Specular microscopy revealed an adequate endothelial cell count of the transplants OU. A thin tear meniscus was noted, but otherwise all anterior segment findings were unremarkable on biomicroscopy. Posterior segment evaluation was performed via Optomap photography and revealed no gross abnormalities. With acceptable health of the transplant, anterior segment, and posterior segment, Pentacam tomography was gathered to aid in initial diagnostic lens selection and establish a baseline to monitor yearly for significant topographic changes. Initial diagnostic lenses were selected by utilizing Pentacam generated Scheimpflug Images and measuring the necessary starting sagittal depth using software measurement tools to establish a 15mm line parallel to the limbus and measure approximate sagittal depth. This measurement was adjusted for the increased diameter of the diagnostic lens by incorporating the desired lens central clearance and adding 400 microns for each 1 mm increase in diameter versus the 15 mm initial measurement.



**Image 1 (above):** OD (top image) OS (bottom image). Oculus Pentacam 4 map selectable images with axial curvature and tangential curvature on a 1.00D scale as well as front and back surface elevation maps. Despite difficulties with the scan quality the significant corneal topographical irregularity can be observed. Note K Max OD: 71.0D OS: 77.3D



**Image 2:** Scheimpflug Images from Oculus Pentacam Tomography. OD (Right) and OS (Left) with ruler tool utilized to determine appropriate starting diagnostic lens sagittal depth. Note the areas of hyperfluorescence in the midperipheral cornea highlighting the graft-host junction and the visibly increased anterior chamber depth of the left eye when compared to the right.

The Ampleye Scleral contact lens manufactured by Art Optical was selected for initial fitting. Diagnostic lenses were selected based on Pentacam measurements and were as follows-

OD: BC: 6.04 Diam: 16.5mm Power: -16.00D Sagittal Depth: 4800 microns

OS: BCL 8.04 Diam: 16.5mm Power: -8.00D Sagittal Depth: 5600 microns

Initial diagnostic fitting revealed excessive central clearance (~500 microns) with inferior decentration and good peripheral alignment OD and 350 microns central clearance with inferior decentration and good peripheral alignment OS. Over-refraction was performed through the diagnostic lenses OD: -2.75D 20/20-1 OS: +3.50D 20/20-1. The patient reported great initial contact lens comfort as well as noting that with the over refraction he was overjoyed with the quality of vision. In order to improve lens centration, the lenses were steepened by 50 microns in the steep meridian and flattened by 25 microns in the flat meridian OU. Additionally, the sagittal depth was decreased by 250 microns OD and decreased by 150 microns OS. Lens parameters were calculated with Art Optical consultation and ordered for dispense and insertion and removal training when the lenses arrive.

On the next follow up the lenses demonstrated much better centration OU with approximately 300 microns of clearance OU after 15 minutes of settling. A small over-refraction was noted but vision without over-refraction was 20/25+ OD, OS, OU. The patient completed a successful insertion and removal training, and the lenses were dispensed with instructions to build up total wear time throughout the next week and evaluate his vision in the lenses. The patient was lost to follow-up for 1 month, and at his next appointment noted that he had been having significant difficulty with insertion and removal. A reinstruction was performed, and the lenses were dispensed without adjustment with instructions to wear lenses for several hours

before his next follow-up appointment. At his next follow-up visit he reported wearing the lenses for 5 hours before his appointment time and was very happy with the comfort and vision through the lenses. Approximately 200 microns of central clearance was noted OU with good edge alignment and adequate limbal clearance. Visual acuity was 20/20-2 OD, OS, OU and although there was a mild plus over-refraction, he reported satisfaction with his current lenses and elected to continue with those vs. reordering with the over-refraction incorporated. Due to the excellent fit and vision, the lenses provided he was instructed to return to clinic annually for a comprehensive exam or sooner if any issues arise.

## **Discussion**

Keratoconus is categorized as the most common form of corneal ectasia with a prevalence estimated to be somewhere between 1 in 375 and 1 in 2000 globally.<sup>2</sup> Since the 2000's the approval of new surgical management techniques has prompted a shift in the most commonly performed treatments. Previously, there were no treatment modalities to prevent the progression of keratoconus, and once a keratoconic cornea was scarred or too ectatic to achieve good visual quality with spectacles or contact lenses a corneal transplant was required. Now with the implementation of corneal crosslinking (CXL), intrastromal corneal ring segments (ICRS), and anterior lamellar keratoplasty (ALK) providers have the ability to slow keratoconus progression and have less invasive options for surgical intervention.<sup>2</sup> Despite these significant advances in surgical procedures, patients with keratoconus will often still require specialty contact lens correction to achieve good visual quality.

Patients post-penetrating keratoplasty are estimated to account for approximately 15% of scleral contact lens fittings.<sup>1</sup> Of these fittings, approximately 69% have irregular astigmatism present that will often result in poor visual quality in spectacles and conventional soft contact lenses. Additionally, when a patient undergoes a PKP secondary to keratoconus complications, keratoconic corneal changes to the corneal graft can be observed and is referred to as recurrent keratoconus. These changes can result in significant visual distortion and higher order aberrations that will poorly affect visual quality. While no large-scale studies have estimated the incidence of recurrent keratoconus in post-PKP patients, some small-scale studies have found up to 75% of participants evaluated having 2 diopters or more of Kmax progression as well as other tomographic changes after 5 years post-PKP.<sup>3</sup> Some studies estimate the risk of recurrent keratoconus at 10-30% at 10-20 years after PKP, although this data is from a relatively small sample size.<sup>2</sup> Despite the unrealized risks of recurrent keratoconus, treatment of advanced stages of corneal ectasia with PKP has shown great safety and efficacy. The Australian Corneal Graft Registry reports that of a sample of 4,834 eyes post-PKP had a 89% graft survival rate at 10 years and a 49% graft survival rate at 20 years.<sup>2</sup>

For this case, scleral lens treatment was chosen for a number of reasons. As a first time contact lens wearer contact lens comfort was paramount for our patient to maximize lens wear time. Additionally, the stability of the contact lens was important due to the increased chance of having to implement additional astigmatic correction due to the high degree of corneal and

refractive astigmatism. Although no explicit dry eye complaints were noted during the initial fitting evaluation, the patient presented with a thin tear film with notably short tear break up time. Due to the chance of exacerbating mild dry eye symptoms into more severe complaints with a corneal GP, a scleral lens was chosen as it has the ability to alleviate any potential dry eye complaints.

## **Conclusion**

Despite recent advances in surgical treatment methodology for keratoconus, penetrating keratoplasty still has a place in treating the most severe complications of advanced corneal ectasia and associated corneal scarring. This surgical treatment has proven to be a safe and effective way to restore patients' corneal integrity and visual function that can be further refined via visual rehabilitation with specialty contact lenses such as scleral lenses and intra-limbal rigid gas permeable lenses. Modern scleral lens designs offer immense opportunities for customization to a patient's individual needs and should be regarded as a valuable tool in the restoration of visual function in post-PKP patients as they have been in this case.

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