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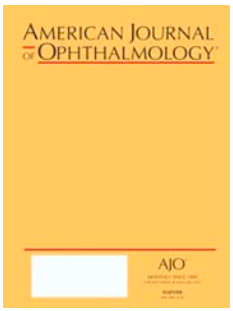

Use of Intraocular Video Endoscopic Examination in the Preoperative Evaluation of Keratoprosthesis Surgery to Asses Visual Potential

Charles C. Farias, MD Hilal E. Ozturk, MD Thomas A. Albini, MD Audina M. Berrocal, MD Guillermo Amescua, MD Carolina Betancurt, OD Jean-Marie Parel, PhD Mary C. Oliveros, MD Allister Gibbons, Jose M. Vargas, MD Victor L. Perez, MD

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Use of Intraocular Video Endoscopic Examination in the Preoperative Evaluation of Keratoprosthesis Surgery to Asses Visual Potential

Charles C. Farias, MD[1,2,3]; Hilal E. Ozturk, MD[1,3]; Thomas A. Albini, MD[1]; Audina M. Berrocal, MD[1]; Guillermo Amescua, MD[1,3]; Carolina Betancurt, OD[1,3]; Jean-Marie Parel, PhD[1,2]; Mary C. Oliveros, MD[4]; Allister Gibbons[1,3]; Jose M. Vargas, MD[4] and Victor L. Perez, MD[1,3]

[1] Department of Ophthalmology, [2]Ophthalmic Biophysics Center and [3]Ocular Surface Center of Excellence, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine; Miami, FL.
[4]Department of Ophthalmology, Cornea Service, Centro Oftalmologico de Valencia; Valencia, Venezuela.

Short title: **Video Endoscopic evaluation before KPro surgery**

Corresponding Author
Victor L. Perez, MD
Director, Ocular Surface Center
Distinguished Walter Ross Chair in Ophthalmic Research
Associate Professor of Ophthalmology, Microbiology and Immunology
University of Miami Miller School of Medicine (UM)
William McKnight Research Building
1638 NW 10th Avenue, #613 Miami – FL 33136, USA
Phone: (305) 326 6302; Fax: (305) 482 4853; Mobile: (786) 390 1292
E-mail: vperez4@med.miami.edu

Abstract

Purpose: To determine the clinical utility of intraocular video endoscopy examination for the evaluation of the retina and optic nerve in patients being considered for a Boston Type I Keratoprosthesis (KPro).

Design: Interventional case series study.

Methods: Ten patients with a history of corneal blindness caused by failed penetrating keratoplasty (PK) and inability to accurately assess visual potential were included in this study. Ophthalmological examination, B-scan ultrasonography and pars- plana video-endoscopy was carried out to assess the retina and optic nerve before KPro.

Results: Posterior segment examination was successfully used to evaluate the retina and optic nerve of all patients with opaque corneas. Out of 10 patients that underwent endoscopic examination, 3 (30%) were considered to be adequate candidates for KPro surgery, and 7 (70%) were not. This was based on visualized retinal disease and/or optic nerve pathology. Of the 3 patients that underwent KPro surgery, all of them had a significant improvement of vision, including: counting finger to 20/100; hand motion to 20/50; light perception to 20/80; as suggested by the endoscopy preoperative exam. No complications of the endoscopy procedure were observed.

Conclusions: This report demonstrates the successful use of intraocular video endoscopy to rule out threats to a good visual outcome of patients being considered candidates for KPro. Direct visualization of the posterior segment can be part of the pre-operative algorithm in the decision process of performing a KPro surgery in patients when visual potential is questionable.

Introduction

Endoscopy, derived from the Greek words endon ("within") and skopein ("to view"), has been widely used for the diagnosis and treatment of disease. The first prototype of an ocular endoscope was reported in 1934 by Thorpe, for removing nonmagnetic of intravitreal foreign bodies. Since then, significant technological advances in microsurgical instrumentation has led to the increased use of endoscopy in ophthalmic surgery. The use of the endoscope in ophthalmology has been mostly used in vitreoretinal surgery.[1, 2] More recently, this technique has proven to be a useful alternative in anterior segment surgery and glaucoma, usually when the image is limited by poor ocular media, such as the presence of corneal opacity.[3, 4]

Corneal disease, characterized by scarring and opacification constitutes the second most common cause of blindness.[5] After the using one or more corneal grafts that may fail in these patients, the use of Boston Type 1 Keratoprosthesis (KPro) has become the next option of therapy for visual rehabilitation.[6] Although published data has demonstrated the successful use of the KPro in the treatment of corneal blindness, the post-operative care of these patients is complex and is associated with significant complications.[7, 8] Mannis et al recently reported that, even though the Boston Type 1 KPro is a viable option after multiple keratoplasty failures; there is a significant number of complications associated with this procedure including glaucoma, retroprosthetic membranes, vitritis and endophthalmitis.[8] Therefore, patient selection is crucial in the decision process during the preoperative assessment of these patients to assure that only patients that will ultimately benefit be considered for KPro surgery.

Nevertheless, the determination of vision potential can be difficult in patients with an opaque corneal. Potential acuity meter, laser interferometry and other techniques usually used in determining potential vision are not very useful in patients with advanced ocular surface disease. In most instances, function is determined by light perception examination; and anatomical normality is determined with ultrasound examination; however this approach has major limitations. In fact, even patients with normal ultrasonography and counting fingers vision may have significant optic nerve or macular pathology that would limit their vision potential. Direct visualization of the posterior segment in these patients could be a major determining factor in the final decision of whether to proceed or not with surgery.

The objective of this study was to determine if the use of intraocular videoendoscopic direct examination of the posterior segment of KPro candidates, with questionable vision potential, could be safely used to predict a good visual outcome after KPro surgery. With this, we aimed to gain a tool to help us in the pre-operative decision process to determine if the placement of a KPro would benefit a certain patient.

Our data demonstrates that the clinical utility of the intraocular videoendoscopy for the evaluation of the retina and optic nerve prior to the placement of a Boston KPro Type 1 is safe and relatively easy to perform. Moreover, the clinical findings obtained by visualization of the posterior segment with intraocular video endoscopy accurately predicted a good surgical outcome in patients in which the endoscopic examination was found to be within normal limits. Therefore, intraocular video endoscopic examination can be major determinant factor in the decision process to perform or to defer KPro surgery in selected patients.

Methods

This study consisted of an interventional case series, of consecutive cases that underwent a diagnostic endoscopic procedure at the Bascom Palmer Eye Institute, Department of Ophthalmology, University of Miami Miller School of Medicine and the Centro Oftalmologico de Valencia during the period of April 2011-April 2012. The protocol was approved by the Institutional Review Board (Medical Science IRB A University of Miami, Nº: 20090935; January 21, 2010). Patient data was collected and maintained in accordance with Health Insurance Portability and Accountability Act guidelines. An institutional review board-approved and Health Insurance Portability and Accountability Act-compliant clinical protocol and surgical consent form for endoscopic procedure were developed and enrollment was initiated for patients with blindness caused by corneal opacity. All patients or their legal representatives signed an informed consent form.

The indication for endoscopic examination was questionable hand motion (HM) to light perception (LP) vision in patients with corneal blindness resulting from severe corneal opacity and vascularization caused mainly by corneal ulcers, ocular trauma, trachoma or anterior segment dysgenesis. All cases had a history of multiple corneal surgeries, corneal grafts or ocular surface transplantation procedures and were deemed high risks for standard keratoplasty. The better or only eye had poor vision, such as LP, HM or at best, counting fingers (CF).

Data from each patient was recorded on the basis of a detailed ocular history and examination. Previous ophthalmologic records were reviewed to identify the reasons for failure of corneal graft or other surgeries. The data collected included age, sex, ocular history, medical history, eye affected, preoperative best-corrected visual acuity, anterior segment examination findings on the slit lamp biomicroscopy, and posterior segment examination findings by B-scan ultrasonography and videoendoscopy. The major determinant whether to perform or withhold KPro surgery were anatomic findings, e.g., status of retina and optic nerve after intraocular videoendoscopic evaluation.

Surgical technique

All the procedures were performed by three surgeons (TAA, AMB and JMV), using peribulbar anesthesia under monitored anesthesia care. The endoscopic system used was an E-4 Microprobe, manufactured by Endo-Optiks, Little Silver, NJ. (**Figure 1).**

A 23-gauge infusion line was placed inferotemporally. A small, localized peritomy was created superotemporally and a 20-gauge sclerotomy was created 4mm posterior to the surgical limbus at that location. The endoscopy probe was checked prior to placing it in the eye and a clinically adequate image was obtained with the probe prior to its insertion into the eye. (**Figure 1).** First, the infusion was checked for correct position through the choroid and in the vitreous cavity, under direct observation with the endoscopy probe the infusion was started. Next, the endoscopy probe was used to perform a systematic examination of the peripheral retina and posterior pole. After the examination, the endoscopy probe was removed from the eye, the sclerotomy was closed with a 7-0 vicryl suture, the overlying conjunctival defect was repaired, the infusion line was removed and it was closed with 7-0 vicryl suture.

Results

A total of ten eyes underwent intraocular videoendoscopic evaluation. The age ranged from 14 to 89 years (median, 47.6 years) **Table 1.** Five patients were male and five were female. The most common cause of corneal blindness was previous corneal ulcer (3 eyes), anterior segment dysgenesis (2 eyes), ocular trauma (2 eyes) and trachoma (1 eye). Of the ten eyes that underwent endoscopic evaluation, one had a history of 3 penetrating keratoplasties (PK), 5 had a history of two prior corneal transplantations, two were cases of retinal detachment with silicone oil and intraocular lens extraction, four cases had previous cataract surgery and one case had glaucoma surgery with a glaucoma drainage implant. All patients had media opacities characterized by the presence of an edematous, vascularized and opacified corneal graft.

The preoperative visual acuity varied between LP (4), HM (4), CF (1) and NLP (1), B-scan ultrasonography was performed in all 10 patients. Three eyes presented with vitreous opacity; one case had diffuse choroidal thickening, another case had changes suggestive of macula edema, one eye had a slightly elevated optic disc and another had silicone oil in the vitreous cavity.

Using videoendoscopy technique, we identified four patients with optic nerve damage **(Figure 2)**; four eyes with retinal detachments, two with proliferative vitreoretinopathy, another three had maculopathy and one had a retinal hemorrhage. According to these findings, 3/10 (30%) were considered to be good candidates for KPro surgery, and 7/10 (70%) were not, **Table 2.** Of the 3 patients that underwent KPro surgery, all of them 3/3 (100%) had a significant improvement of vision (counting finger to 20/100; hand motion to 20/50; light perception to 20/80) (**Figure 3)**. These results confirmed the normal findings observed by the endoscopy preoperative exam. Importantly, none of the patients in our series had a detrimental change of their baseline pre-operative visual acuity and no complications of the endoscopy procedure were observed.

Case 3 was an 85-year-old woman who was referred because of Ocular Surface Disease and presented to the slit-lamp examination with a vascularized and opacified corneal graft after multiple PKs to treat trachoma. She was pseudophakic. On examination, her vision was counting fingers and the endoscopy revealed a healthy optic disc and macula with no sign of retinal pathology (**Figure 4)**. She was considered to be a good candidate for KPro and her visual acuity improved from CF to 20/100.

Case 7 was a 50-year-old male patient with a history of multiple corneal ulcers. At the slit-lamp examination he presented with a vascularized and opacified corneal graft after multiple PKs and aphakia. Fundus examination with videoendoscopy showed a healthy optic disc and macula and was deemed to be a good candidate for KPro surgery. His vision improved from HM to 20/50.

Case 8 was a 14-year-old boy with a history of corneal ulcers. The patient underwent two PKs that evolved with opaque corneal grafts. The endoscopic assessment revealed a healthy optic disc and macula, so he was judged to be good candidate for KPro, and his vision also improved from LP to 20/80.

Discussion

The decision to use a KPro is challenging and important, assessing vision potential is crucial in this process. Visualization of the posterior segment is limited in these patients and in this article we demonstrate that video endoscopy offers an alternative tool in the pre-operative decision process. Our study confirms the usefulness of diagnostic intraocular videoendoscopy when the anterior ocular media are compromised and when it is necessary to examine the anatomical condition of the posterior segment. Moreover, our data showed five different kinds of posterior segment pathology, optic nerve damage, retinal detachments, PVR, retinal hemorrhage and maculopathy. These can now be documented in a safe and conclusive way and KPro surgeries can be deferred or we can better counsel our patient on potential visual outcomes. Videoendoscopy facilitated the view of areas not visible through an operating microscope, like the anterior chamber angle, the retroiridial space, the inside of the capsular bag, the sulcus and the ciliary processes. Additional advantages are: the use of a small gauge and a working channel (for potential laser endodiathermy).

All of the patients in our series that were considered to be good candidates for KPro surgery based on video endoscopic examination experienced a significant vision improvement after placement of Boston Type I KPro. In our case, the major outcome was anatomic, e.g., the status of the retina and optic nerve. Previous studies have also demonstrated the usefulness of videoendoscopic examination in patients with corneal opacities.[1, 4, 9] Volkov et al used three types of flexible ophthalmic endoscopes in patients with opacification of the cornea and lens caused by vitreous hemorrhages, foreign body or retinal detachment.[10]

Our current series of cases did not demonstrate any intra-operative or immediate postoperative complications. Few complications related to the endoscope or the surgical procedures have been observed, such as cataract due to contact with the posterior lens surface.[4] However, complications can occur, Joshua Ben-nun reported five patients that had transient postoperative elevation in intraocular pressure that responded well to oral acetazolamide (Diamox, Lederle Lederle Laboratories, Wayne, NJ).[9]

It is important to take into consideration that electrophysiological functional testing of the retina and optic nerve also play a very important role in the evaluation of patients with corneal blindness. In fact, these tests have been used in the setting of candidates for modified osteo-odonto-keratoprosthesis.[11] Though special considerations must be taken into account, because it is difficult to use a contact lens electrode in severe ocular surface disease. The great value of endoscopic evaluation over electroretinographic studies is that the macula is always hard to isolate with the latter in these cases of great media opacities so specific macular function is very hard to examine with opaque media because a focal (or multifocal) electroretinogram cannot be performed, a healthy macular appearance indicates a positive prognostic indicator. Optic nerve function can be assessed more precisely with other available technologies, like visual evoked potential, which can be correlated to final VA.[11]A patient with a healthy outer retina and optic disk but with a diseased macula could potentially have a close to normal electroretinographic response.

We are unaware of previous reports on the use of endoscopic evaluation prior to surgery and as part of the decision algorithm to place a keratoprosthesis. However, the

use of this technique to assist in the management of patients with other type of KPro has. In fact, recent reports have demonstrated excellent surgical outcomes after combined videoendoscopy-assisted pars plana vitrectomy with placement of a tube shunt in patients with uncontrolled glaucoma and management of advanced glaucoma after osteo-odonto-keratoprosthesis surgery. Similarly, endoscopy has also been used for diagnostic and therapeutic vitrectomy in endophthalmitis; and to control vitreoretinal complications, with retinal detachment associated with a poor prognosis in patients who underwent osteo-odonto-keratoprosthesis surgery.[12-15]

We understand that our study has some limitations, especially considering the small number of cases included, and the fact that only patients that were judged to have good visual potential were finally operated on. However, our data suggests that a clear and direct observation of the retina and optic nerve, in particular, allowed us to avoid complex surgical procedures in patients with poor potential outcome and minimize morbidity.

The eventual finding of macular or optic nerve pathologies in these patients should not constitute an absolute contraindication to receiving a Kpro, but would require specific counseling, depending on the findings encountered and patient expectations. Likewise, a normal endoscopic evaluation could potentially lead an eye to have surgery and not achieve expected vision gain, due to occult and difficult to assess underlying diagnosis as amblyopia or other pathology located posteriorly to the optic nerve.

The use of KPro in visual rehabilitation is not a trivial one as these patients' post-operative care is intense and not free of complications. Therefore, the decision to implant or withhold a KPro should be supported by the use of multiple techniques that can help the physician determine vision potential more accurately.

The use of endoscopy in the evaluation of potential KPro patients is not for every case. Many patients, through their clinical history or other diagnostic methods will give the clinician a good sense as to whether vision can improve or not. To determine if a patient would benefit from surgery, in spite of limited expected success, will depend on a number of factors like visual potential, visual needs, social issues, vision in the contralateral eye, etc. The use of endoscopy should be limited to when there are founded doubts regarding the visual potential of a certain eye, be it that an occult underlying pathology is suspected or that there is no correlation between objective findings and subjective vision testing.

The findings from our study demonstrate that the use of video endoscopy of the posterior segment can be a very useful and safe tool in the pre-operative evaluation of candidates for KPro. Moreover, it can be incorporated as part of the diagnostic algorithm in patients in whom visual prognosis cannot be easily accessed by light perception testing or in other individuals whose B-scan results are not clear or cannot be conclusively interpreted, as direct visualization of the posterior segment by video endoscopy can.

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Dr. Berrocal has served as a consultant for both Thrombogenics and Genentech.

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Contributions to Authors in each of these areas:

Design and conduct of the study: CCF, TA, AB, JMV, AG, JMP, and VLP. Collection of data: CCF, HEO, MVO, TAA, AMB and JMV. Management, analysis, and interpretation of the data: CCF, HEO, GA, CB, JMP, MCO, AG and VLP. Preparation, review, or approval of the manuscript: CCF, HEO, TAA, AMB, GA, CB, JMP, MCO, AG, JMV and VLP.

Other Acknowledgments:

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Figure captions

Figure 1: Video Endoscopic Examination in the Preoperative Evaluation of Keratoprosthesis Surgery. The ophthalmic videoendoscope instrument used in this study (Top left). The position of instruments when the flexible videoendoscope is inserted through the pars plana (Top right).

Figure 2: Anterior segment aspect of case 10 demonstrating an edematous and opacified corneal graft (Second row Left). Posterior segment of revealed optic nerve atrophy (black arrow) and KPro surgery was not performed (Second row Right).

Figure 3: Bar chart showing pre and post-operative best-corrected visual acuity in patients that were considered good candidates for Kpro by video endoscopic findings of the posterior segment: normal appearance of the optic nerve and macula (Third row).

Figure 4: Anterior segment of case 3 demonstrating an edematous vascularized and opacified failed corneal graft (Bottom row left)**.** Posterior segment video endoscopy examination shows a healthy optic nerve disc (black arrow) and macula with signs of myopic degeneration (Bottom row right). This patient underwent KPro surgery and had a significant improvement in vision.

Table 1: Demographic and Clinical Characteristics of patients for the Video Endoscopic Examination in the Preoperative Evaluation of Keratoprosthesis Surgery

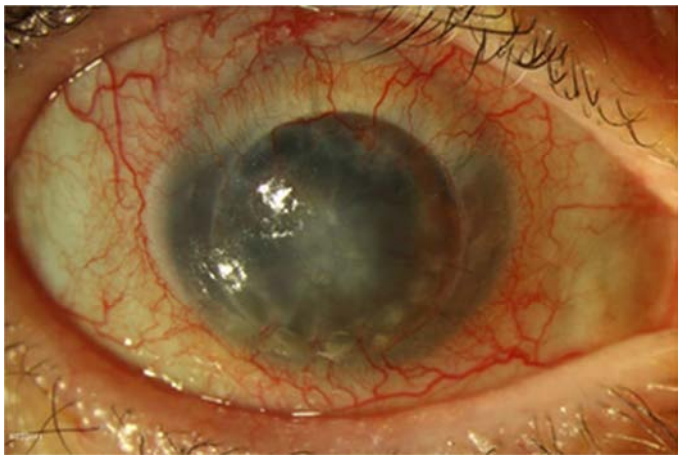
Case	Age [yr]	Sex	Eye	Etiology Cornea Blindness	Previous Surgeries	Anterior Segment Findings
1	14	M	OD	Sclerocornea	PK, PPV, glaucoma tube shunt	Edematous, vascularized, opacified cornea graft
2	22	F	OS	Aniridia	2 PK	Edematous, vascularized, opacified cornea graft
3	85	F	OS	Trachoma	3 PK, cataract surgery	Edematous, vascularized, opacified cornea graft
4	89	F	OD	Failed PK	RD surgery with silicone oil, IOL extraction, PK	Edematous, vascularized, opacified cornea graft; sectoral iris atrophy
5	41	F	OD	Ocular Trauma	PK, cataract surgery	Edematous, opacified cornea graft, calcium deposits
6	52	M	OD	Corneal ulcer	2 PK, cataract surgery	Edematous, vascularized, opacified cornea graft
7	50	M	OD	Corneal ulcer	2 PK, cataract surgery	Edematous, vascularized, opacified cornea graft
8	14	M	OD	Corneal ulcer	2PK	Edematous, vascularized, opacified cornea graft.
9	45	F	OS	Failed PK	2RD surgery with silicone oil, PK	Edematous, vascularized, opacified cornea graft
10	64	M	OS	Chemical burn	ALT, 2PK	Edematous, vascularized, opacified cornea graft

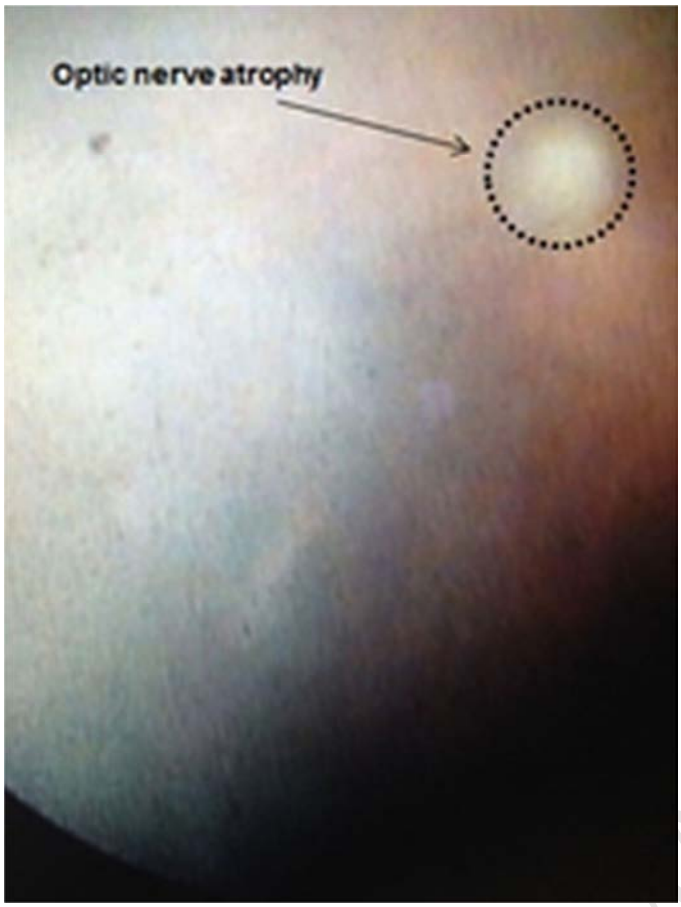
yr=year; M=male; F=female; PK=penetrating keratoplasty; ALT=autologous limbal transplantation; PPV=pars plana vitrectomy; RD= retinal detachment; IOL=intra ocular lens; OS=left eye; OD=right eye

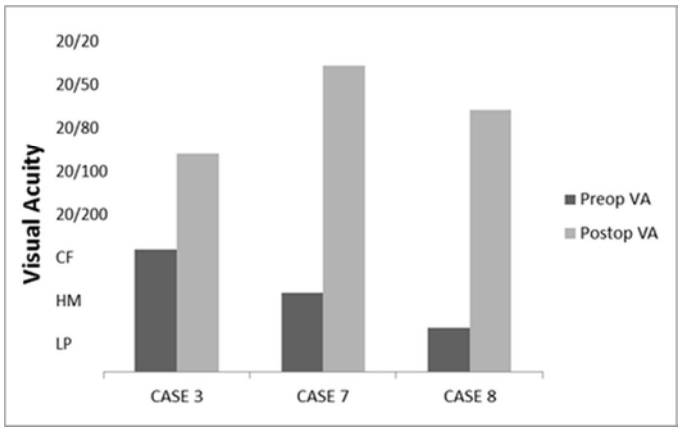
Table 2: Visual acuities and diagnostic imaging technique findings decision base, by which KPro was or nor indicate in patients before and after the Video Endoscopic Examination in the Preoperative Evaluation of Keratoprosthesis Surgery

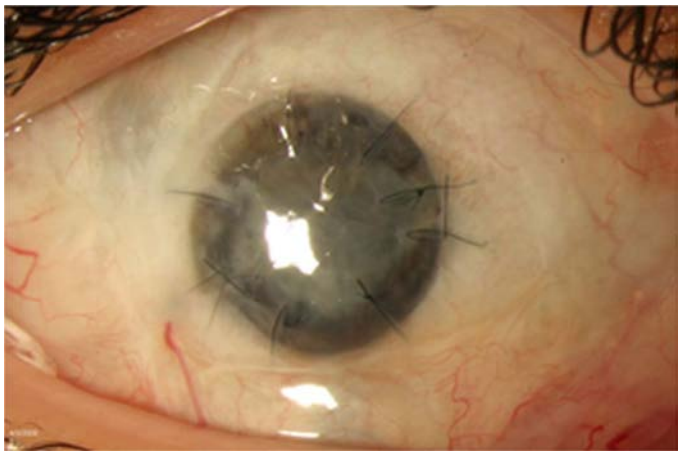
Case	Eye	Pre-op vision	USG findings	Video findings	Post op vision	Decision Based on Endoscopy
1	OD	LP	Vitreous opacities with vitreous membrane, optic disc elevation, no retinal or choroidal detachment, irregular and sloped globe.	Significant maculopathy with RPE atrophy, optic nerve pallor, tractional membranes	LP	no K-Pro Surgery
2	OS	HM	Diffusely choroidal thickened with probable choroidal detachment Probable shallow temporal posterior retinal detachment	Chronic retinal detachment, PVR, preretinal hemorrhage	HM	no K-Pro Surgery
3	OS	CF	Vitreous opacities with a posterior vitreous detachment, macular thickening, posterior staphyloma	Disc and macula appeared healthy (there is only sign of myopic degeneration)	20/100	K-Pro surgery
4	OD	HM	Siliconized eye, no RD but it is not meaningful	Chronic retinal detachment, PVR	HM	no K-Pro Surgery
5	OD	LP	Pseudophakic, Applied retina, PVD	Slight pallor optic nerve, macular hole, PVD	HM	no K-Pro Surgery
6	OD	LP	Aphakia, PVD, Applied retina,	Chronic retinal detachment, PVR	HM	no K-Pro Surgery
7	OD	HM	Aphakia, Vitreous opacity, Applied retina,	Disc and macula appeared healthy	20/50	K-pro Surgery
8	OD	LP	Applied retina	Disc and macula appeared healthy	20/80	K-pro Surgery
9	OS	HM	Aphakia, Macula Edema Retinal detachment	Optic nerve pallor, macular hole, chronic retinal detachment	LP	no K-Pro Surgery
10	OS	NLP	Mild vitreous opacities, no RD, no mass lesion, no obvious cupping	Optic atrophy	NLP	no K-Pro Surgery

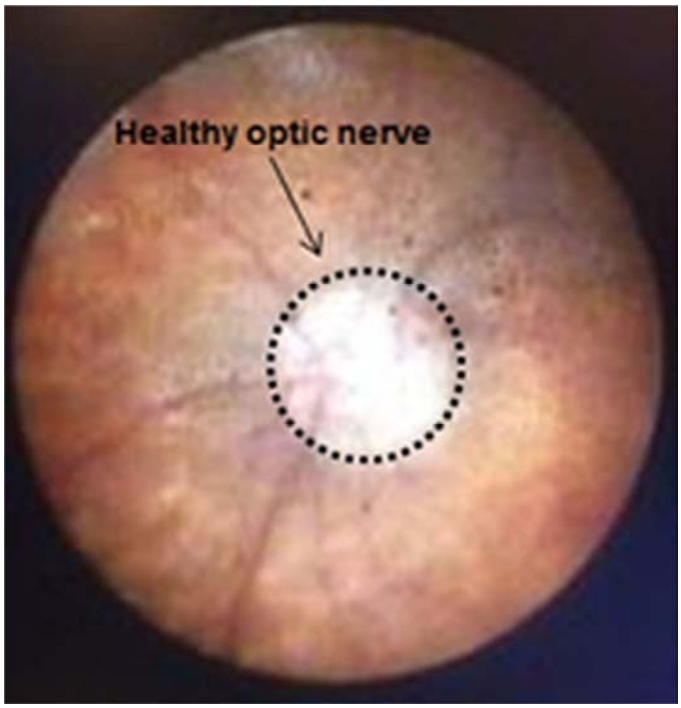
OD=right eye; OS=left eye; NLP=no light perception; HM=hand motion; LP=light perception; CF=count fingers; PVR= proliferative vitreoretinopathy; RPE=retinal pigment epithelium; PVD=posterior vitreous detachment; K-Pro=keratoprosthesis; Pre-op=preoperative; Post-op=postoperative; USG=ultrasonography











Victor L. Perez is the Director of Ocular Surface Center at Bascom Palmer Eye Institute, and Associate Professor of Ophthalmology, Microbiology and Immunology at University of Miami Miller School of Medicine. He also holds the distinguished Walter Ross Chair in Ophthalmic Research. Dr. Perez performed the first Modified Osteo-Odonto Keratoprosthesis procedure in the United States in June 2009, and has published widely on corneal transplantation, ocular immunology and uveitis. He currently performs complex ocular surface surgeries and keratoprosthesis procedures.

Charles C. Farias received his medical degree from the University of Campina Grande, and completed his residency at University of Santo Amaro, Brazil. During his training, Dr Costa undertook different fellowships at the Federal University of Sao Paulo in Brazil where he defended his Doctoral thesis in 2011. He is currently doing a post-doctoral fellow at Bascom Palmer Eye Institute with Dr. Perez. Dr. Costa's research interests pertain to ocular surface, corneal transplantation and keratoprosthesis.

Victor L. Perez is the Director of Ocular Surface Center at Bascom Palmer Eye Institute, and Associate Professor of Ophthalmology, Microbiology and Immunology at University of Miami Miller School of Medicine. He also holds the distinguished Walter Ross Chair in Ophthalmic Research. Dr. Perez performed the first Modified Osteo-Odonto Keratoprosthesis procedure in the United States in June 2009, and has published widely on corneal transplantation, ocular immunology and uveitis. He currently performs complex ocular surface surgeries and keratoprosthesis procedures.