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Permavision intracorneal inlay after sixteen years. Regression of initial refractive hyperopia

José-María Sánchez-González[a,b,*], Jonatan Amián-Cordero[b], Federico Alonso-Aliste[b]

[a] Department of Physics of Condensed Matter, Optics Area, University of Seville, Reina Mercedes, Seville, Spain
[b] Department of Ophthalmology and Optometry, Tecnolaser Clinic Vision Centre, Juan Antonio Cavestany, 14, Seville, Spain

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ABSTRACT

According to the available scientific literature, 77 patients underwent Permavision inlay worldwide, between 2004 and 2007. This study reported about the use of Permavision intracorneal inlay to increase the central corneal curvature and to correct hyperopia. A 32-year-old male patient went to the Tecnolaser Clinic Vision ® facilities for a refractive study. Preoperative refraction without cycloplegia was +6.00 D in the right eye (RE) and +4.00 in the left eye (LE). The surgery was performed for both eyes on December 2, 2003. The Carriazo-Barraquer mechanical microkeratome (Moria) was used to create a 180 µm-thick corneal flap with a diameter of 8.5 mm. After lifting the flap, the corneal inlay was placed centrally above the pupil and the flap was re-positioned. In this case report, the patient reverted to the initial refractive situation. The first refractive regression appeared at twelve-month follow-up. After sixteen years, it was found a decrease in maximum corneal curvature, an increase in mean corneal densitometry percentage, and no important changes in the central corneal thickness. In the reported case, the cornea reverted to its original shape. In the scientific literature, this is the first case report of a non-explanted Permavision inlay after sixteen years.

Intracorneal lens implant was first defined in 1949 [1]. It was described as refractive keratoplasty in rabbits [2]. Hydrogel lenticules Permalens (Perfilcon A, Cooper Vision Laboratories, Düsseldorf, Germany) were implanted within an intralamellar pocket in the cornea [2]. Two years later, other materials such as Sauflon (American Medical Optics) and Vistamarc (Vistakon) demonstrated short-term biocompatibility in animal models [3]. In subsequent studies, long-term biocompatibility of Permalens was demonstrated in monkey models [4]. Barraquer et al. [5] reported initial human experience with Permalens. They obtained good corneal tolerance in aphakic and high myopic eyes.

Safety and efficacy of Permavision intracorneal lenses (Anamed Inc / Revision Optics, Lakeforest, California) was reported by Ismail [6] in rabbits and firstly in humans by Michielleto et al. [7], wherein only the cases of six patients with six-month follow-up period were described. Güell et al. [8] showed low predictability in uncorrected visual acuity (UCVA). According to the available scientific literature, 77 patients [7–13] underwent Permavision inlay worldwide, between 2004 and 2007. The purpose of the corneal inlay is to increase the central corneal curvature and to correct hyperopia [14]. The maximum available inlay power by the manufacturer was + 6.00 diopters (D). Permavision implant ceased to be used due to poor refractive predictability [8,12], inlay decentration [7,9,10,12], or haze [7–13]. Herein, a report of Permavision Inlay after 16 years of follow-up were presented.

1. Case report

Before the Permavision inlay implantation (Anamed Inc / Revision Optics, Lakeforest, California), the 32-year-old patient visited the Tecnolaser Clinic Vision ® facilities for a preoperative refractive study. A statement of consent to publish this case was gathered from the patient. This statement of consent specifies that consent to publish these images was gathered. The examination was performed by a licensed and an expert optometrist, and it included (1) uncorrected and corrected visual acuity measurement in distance and near (Snellen scale) and (2) manifest refraction without and with cycloplegia (refraction method of the first and second maximum positive).

Astigmatism was assessed by the Jackson cross cylinder method. These data were checked with a wavefront-supported custom ablation (WASCA) and an autorefractor/aberrometer (Carl Zeiss Meditec AG, Jena, Germany). Corneal topography (including maximum curvature, mean densitometry, and central corneal thickness [CCT]) were measured with the Pentacam single rotation Scheimpflug camera (Oculus Optikgeräte GmbH, Wetzlar, Germany). Preoperative intraocular

* Corresponding author at: University of Seville, Reina Mercedes St., Physic Faculty, Seville, Spain.
E-mail address: jsanchez80@us.es (J.-M. Sánchez-González).

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Table 1
Uncorrected distance visual acuity (UDVA) and residual refractive error changes thought different appointments.

Appointment date	UDVA (Snellen)		Refractive error (sphere, cylinder and axis	
	Right	Left	Right	Left
December 2003	20/40	20/25	+0.00 + 1.00 × 155°	+0.50 + 0.75 × 100°
January 2004	20/40	20/25	+2.00 + 1.00 × 155°	+0.50 + 0.75 × 100°
March 2004	20/40	20/25	+2.00 + 1.00 × 155°	+0.50 + 0.75 × 100°
December 2005	20/40	20/25	+2.00 + 1.00 × 155°	+0.50 + 0.75 × 100°
September 2006	20/63	20/32	+4.00 + 1.00 × 155°	+0.50 + 1.00 × 100°
November 2009	20/63	20/32	+4.25 + 0.75 × 155°	+1.75 + 1.00 × 100°
May 2016	20/100	20/50	+6.00 + 0.75 × 155°	+3.00 + 0.75 × 100°
February 2019	20/200	20/100	+6.25 + 0.75 × 155°	+3.25 + 0.75 × 100°

pressure was assessed with a manual tonometer Perkins (Kowa Company, Aichi, Japan). After sixteen years, postoperative intraocular pressure was measured with CORVIS ST (Oculus Optikgeräte GmbH, Wetzlar, Germany). The study of epithelial thickness, retinal optical coherence tomography was measured with the spectral domain optical coherence tomography (SD-OCT) (Optovue Inc., Fremont, CA). The Carriazo-Barraquer mechanical microkeratome (Moria) was used to create a 180 µm-thick corneal flap with a diameter of 8.5 mm. After lifting the flap, the corneal inlay was placed centrally above the pupil and the flap was re-positioned.

Preoperative refraction without cycloplegia was +6.00 D in the right eye (RE) and +4.00 in the left eye (LE). Preoperative refraction with cycloplegia was +6.50 D in RE and +4.50 in LE. Corrected distance visual acuity (CDVA) was 20/32 in RE and 20/20 in LE. Preoperative CCT was 580 µm in RE and 575 µm in LE. Preoperative IOP was 17 mmHg in RE and 18 mmHg in LE. The surgery was performed for both eyes on December 2, 2003. During the postoperative appointment on the next day, the lenses were found to be centered, and a moderate edema was observed through the slit lamp. Patient progress in terms of visual acuity and residual refractive error are described in Table 1. Maximum corneal curvature, corneal densitometry percentage, and CCT changes are described in Table 2.

2. Discussion

First long-term Permavision-reported results were described by Ismail et al. [10]. They observed stromal opacification, induced astigmatism, night halos, glare, and decentration in a significant number of eyes. Alió et al. [9] showed diffuse peri-lenticular opacity of varying intensity that was unresponsive to steroids; this case report showed similar results Fig. 1. The reason for this event was the keratocyte activation during corneal wound healing [13]. This fact was reported by Lindsey et al. [11] using confocal microscopy, who found significant postoperative inlay haze.

Previous studies reported a high rate of inlay removal. Alió et al. [9] explanted 5 of 11 inlay implants, Mulet et al. [12] removed 20 of 34 implants, and Verity et al. [13] explanted 18 of 30 inlay implants.

Table 2
Maximum corneal curvature, mean corneal densitometry and central corneal thickness changes thought appointments.

Appointment date	Max. corneal curvature (D)		Mean corneal densitometry (%)		Central corneal thickness (µm)	
	Right	Left	Right	Left	Right	Left
Preoperative	42.6	42.8	7.8	8.2	580	575
January 2004	51.8	52.4	12.1	13.6	630	640
September 2006	50.3	52.0	17.7	18.3	636	632
November 2009	49.0	51.1	20.3	20.6	624	645
May 2016	46.2	46.7	20.9	19.5	636	639
February 2019	46.1	46.8	22.3	21.44	636	628

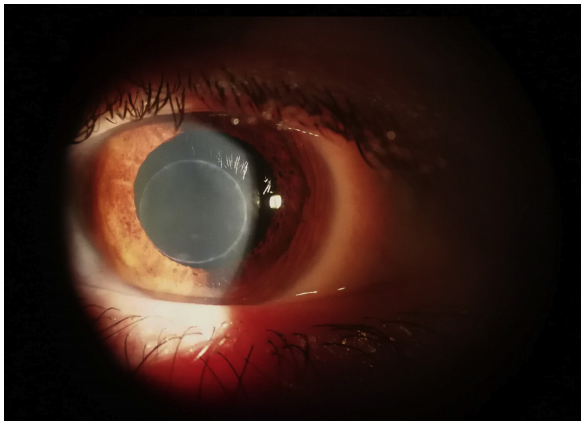

Fig. 1. Right eye Permavision inlay photograph taken by slit-lamp biomicroscope (SL-D701, TOPCON, Tokyo, Japan) attached with a smartphone camera (20-megapixel camera, Huawei Mate 9, Longgang, Shenzhen, China) in February 2019. Corneal opacification can be observed at the Permavision inlay edges.

Taneri et al. [15] recently reported a case of corneal melting after Permavision inlay procedure. Ismail et al. [10] suggested that the depth of the implant indicates the removal rate. They suggested deep flat cuts. In this case, it was performed a deep flat cut of 180 µm thickness Fig. 2 for both eyes. Verity et al. [13] used a 120 µm corneal flap and obtained a high removal rate.

3. Conclusions

Finally, it was observed a complete refractive regression and the patient reverted to the initial refractive situation. Ismail et al. [10] reported one diopter of hyperopia regression after 24 months. It was noticed a decrease in maximum corneal curvature after sixteen years and no important changes in the CCT. In the reported case, the cornea reverted to its original shape. The inlay was not removed due to its stable situation and to avoid additional complications. In the scientific literature, this is the first case report of a non-explanted Permavision inlay after sixteen years. The patient was offered the use of spectacles and annual controls.

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Declaration of Competing Interest

The Authors declare that there is no conflict of interest.

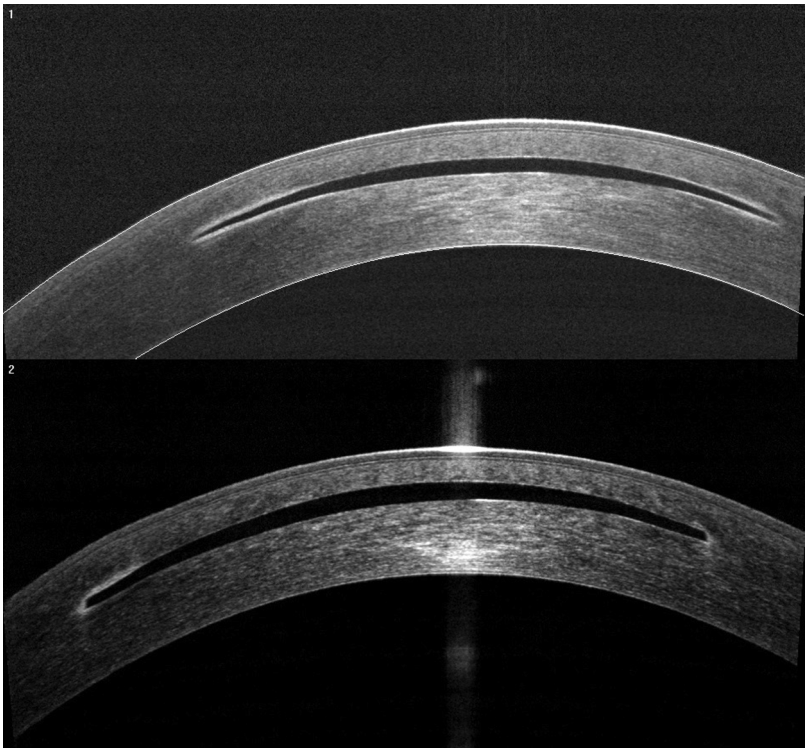

Fig. 2. Anterior segment optical coherence tomography was measured with the spectral domain optical coherence tomography (SD-OCT) (Optovue Inc., Fremont, CA). Measured with CAM L lens. Right eye on the top and left eye on bottom. Corneal opacification can be observed at the Permavision inlay edges.

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