ARCH SOC ESP OFTALMOL. 2016;xxx(xx):xxx–xxx

ARCHIVOS DE LA SOCIEDAD ESPAÑOLA DE OFTALMOLOGÍA

www.elsevier.es/oftalmologia

Original article

An angle-supported foldable phakic intraocular lens for correction of myopia: A five-year follow-up☆

J.L. Alió[a,b,*], *A.B. Plaza-Puche*[a], *F. Cavas*[c], *P. Yébana Rubio*[a], *E. Sala*[a]

[a] *Vissum Alicante, Departamento de Investigación, Desarrollo e Innovación, Alicante, Spain*
[b] *División de Oftalmología, Departamento de Patología y Cirugía, Universidad Miguel Hernández, Alicante, Spain*
[c] *Departamento de Expresión Gráfica, Universidad Politécnica de Cartagena, Cartagena, Murcia, Spain*

ARTICLE INFO

Article history:
Received 13 April 2016
Accepted 30 May 2016
Available online xxx

Keywords:
Phakic intraocular lens
Long term follow-up
Visual outcomes
Endothelial cell density
Efficacy
Safety

ABSTRACT

Objective: To evaluate the efficacy and safety of an angle-supported foldable phakic intraocular lens (pIOL) for the correction of moderate to high myopia after 5 years follow-up.
Methods: Prospective and retrospective, observational, longitudinal, non-randomised consecutive series of cases conducted on a total of 100 eyes of 67 patients with moderate to high myopia implanted with an Acrysof Cachet pIOL (Alcon Laboratories Inc.) with the aim of minimizing the refractive error. The ages ranged between 18 and 60 years. Uncorrected distance visual acuity (UDVA), manifest refraction, corrected distance visual acuity (CDVA), endothelial cells density, pIOL position, intraocular pressure, and complications were recorded preoperatively and during the 5 year follow-up.
Results: Five years after implantation, the mean manifest spherical equivalent refraction reduced significantly from -11.62 ± 3.35 dioptres (D) to -0.33 ± 0.85 D. UDVA was 20/20 or better in 5 of 25 cases (20%), and 20/40 or better in 22 cases (88%). CDVA was 20/20 or better in 17 cases (68%), and 20/32 or better in 23 cases (92%) of eyes. The residual refractive error was within ±0.50 D of emmetropia in 12 cases (48%), and within ±1.00 D in 19 cases (76%). Mean endothelial cell loss at 5 years was 11.8% central, and 13.7% peripheral. Mean endothelium-pIOL distance was 2.11 ± 0.18 mm, and mean pIOL-crystalline distance was 0.88 ± 0.20 mm.
Conclusions: This angle supported pIOL provided a favorable refractive correction and predictability, as well as acceptable safety in patients with moderate to high myopia. Although endothelial cell density decreased over 5 years, the results are within the range reported in previous studies with other pIOLs.

☆ Please cite this article as: Alió JL, Plaza-Puche AB, Cavas F, Yébana Rubio P, Sala E. Lente intraocular fáquica plegable acrílica de apoyo angular para la corrección de miopía: seguimiento de 5 años. Arch Soc Esp Oftalmol. 2016. http://dx.doi.org/10.1016/j.oftal.2016.05.009

* *Corresponding author.*
E-mail address: jlalio@vissum.com (J.L. Alió).

Lente intraocular fáquica plegable acrílica de apoyo angular para la corrección de miopía: seguimiento de 5 años

Palabras clave:
Lente intraocular fáquica
Seguimiento a largo plazo
Resultados visuales
Densidad de células endoteliales
Eficacia
Seguridad

RESUMEN

Objetivo: Evaluar la eficacia y la seguridad de una lente intraocular (LIO) fáquica plegable de apoyo angular para la corrección de miopía de grado moderado-alto tras 5 años de seguimiento.

Métodos: Análisis prospectivo y retrospectivo, observacional, longitudinal, no aleatorizado de una serie casos que incluye un total de 100 ojos de 67 pacientes con miopía moderada-alta implantados con una LIO fáquica Acrysof Cachet (Alcon Laboratories Inc.) con el objetivo de minimizar el error refractivo. El rango de edad comprende de 18 a 60 años. La agudeza visual sin corrección de lejos (AVsc), la refracción manifiesta, la agudeza visual con corrección de lejos (AVcc), la densidad de células endoteliales, la posición de la LIO fáquica, la presión intraocular y las complicaciones detectadas fueron registradas antes de la operación y durante los 5 años de seguimiento.

Resultados: Cinco años después de la implantación la refracción manifiesta media se redujo de forma significativa de un equivalente esférico de $-11{,}62 \pm 3{,}35$ dioptrías (D) a $-0{,}33 \pm 0{,}85$ D. La AVsc fue de 20/20 o mejor en 5 de los 25 casos (20%) y 20/40 o mejor en 22 casos (88%). La AVcc fue de 20/20 o mejor en 17 casos (68%) y 20/32 o mejor en 23 casos (92% de los ojos). El error refractivo residual presentaba un valor entre $\pm 0{,}50$ D y emetropía en 12 casos (48%) y entre $\pm 1{,}00$ D en 19 casos (76%). La media de pérdida de células endoteliales en los 5 años fue del 11,8% en la región central y del 13,7% en la periferia. La distancia media entre endotelio-LIO fáquica fue de $2{,}11 \pm 0{,}18$ mm y la distancia media LIO fáquica-cristalino, de $0{,}88 \pm 0{,}20$ mm.

Conclusiones: Esta LIO fáquica de apoyo angular proporciona una corrección refractiva y una predictibilidad favorables, así como una seguridad aceptable en pacientes con un grado de miopía moderado-alto. A pesar de que la densidad de células endoteliales disminuyó durante los 5 años de seguimiento, los resultados están dentro del rango reportado en estudios anteriores con otras LIO fáquicas.

Introduction

It has been demonstrated that phakic intraocular lens (IOL) implants are an alternative for optical compensation in young patients with moderate to high myopia (from −8 to −23.00 D) and who are contraindicated for refractive corneal surgery.[1–9] It has also been demonstrated that phakic lenses exhibit several potential advantages[10]: excellent refractive results, refractive stability, fast visual recovery, good visual quality and preservation of accommodation. Additional advantages are that this surgery is well known to anterior segment surgeons involving lens explants, it is possible to combine this surgery with other corneal refractive surgery methods and its low cost in comparison to corneal laser surgery.[10–13]

Intraocular lenses can be classified in 3 categories on the basis of their position in the eye or fixation mechanism, i.e., anterior chamber angle support, iris fixation in anterior chamber and posterior chamber lenses. The main advantages of angle support phakic IOLs is the ease of insertion and simplicity of extraction if necessary, in addition to being fully visible in the anterior chamber so that any complication can be detected at an early stage. However, phakic IOLs—particularly anterior chamber angle support models—can be associated to numerous complications after implantation[11–14] such as corneal decompensation, pupil ovalization, glaucoma, angle closure, formation of cataracts and endophthalmitis.

In 1954, Benedetti Strampelli designed the first anterior chamber biconcave phakic IOL with angle support. The use of this IOL was discontinued due to associated complications.[15] Four decades later, new phakic IOL designs were successfully applied for correcting high myopia.[16–18] Since then, ophthalmologists have not observed significant changes in the IOL implant concept for correcting high refractive defects, excepting the improvements achieved in biocompatibility of materials and lens flexibility as well as the biomechanical performance of the lens in the anterior segment. Despite said improvements, the angle support phakic IOL still associated complications, particularly high loss of endothelial cells and pupil ovalization.[19,20] Some of its disadvantages were related to rigid polymethacrylate methyl (PMMA) that requires large incisions—at least the size of the lens optic—which in some cases required sutures. This limitation was overcome with new flexible models that can be inserted through 3.0 mm incision or less, thus reducing the possibility of producing induced astigmatism and obtaining good results as reported in various clinic studies.[1–3,21,22]