Introduction of the use of -PresbyMax®- A new Application for the correction of Presbyopia with Excimer Laser Surgery

SCHWIND eye-tech-solutions Lunch Symposium

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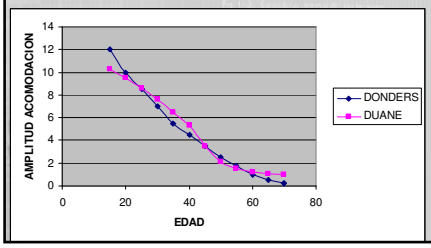
VISSUM
INSTITUTO OFTALMOLÓGICO DE ALICANTE SPAIN

XXVII Congress of the ESCRS
12 -16 September 2009
Barcelona, Spain

PRESBYOPIA

Progressive disability for near vision performance related to the ageing process

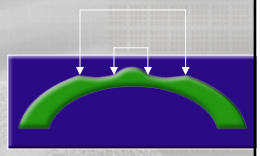


PRINCIPLES FOR PRESBYOPIA CORRECTION

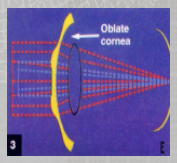
- Simple and effective restoration of near and intermediate vision
- Binocular
- Fast recovery
- Safe, not at the cost of bcva
- Stable
- Fast postoperative recovery
- With very few complications , minimal collateral symptoms

Modern PresbyLasik

1. **CENTER FOR NEAR : Central hyperpositive multifocal area (Central Presbylasik).**



1. **CENTER FOR FAR: Peripheral multifocal area (Peripheral Presbylasik).**



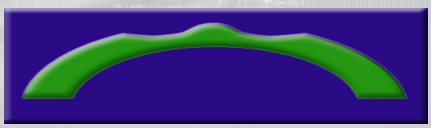
CENTRAL Vs PERIPHERAL PRESBYLASIK

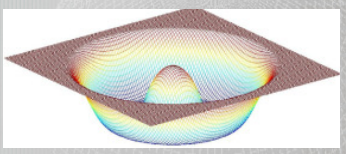
Differences in tissue removal :

- HYPEROP +3: (with +2 near ADD)

Central: 4 micron more

Peripheral:150 micron more for **-0.5** asphericity





- MYOP -3:

Central: 4 micron more

Peripheral: 200 micron more for **-0.25** asphericity

> 270 micron more for **-0.5** asphericity

CENTER FOR NEAR IS BETTER

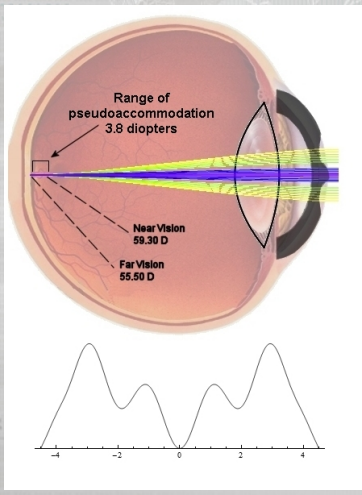
- Synergistic with convergence myosis
- Synergistic with the line of sight
- Minimal tissue ablation added to the correction of the main defect
- Minimal neuroadaptation , immediate outcome
- Focus dominance FAR/NEAR depending on pupil size
- Minimal induction of HOA / minimal or no degradation of the quality of the retinal image

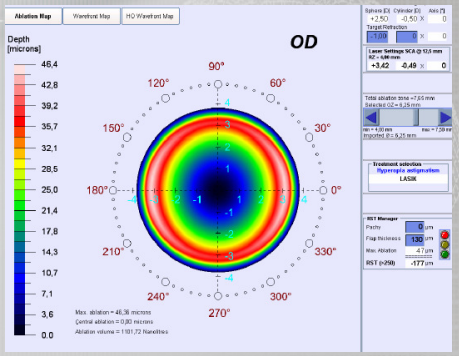
PresbyMax®

- A Presbylasik method patented by VISSUM INSTITUTO OFTALMOLOGICO DE ALICANTE.
- Uses the AMARIS SCHWIND Platform.
- Biaspheric central Presbylasik.
- Predicts visual outcome for for and near in every patient by using a predictive software based on the use of a propietary Gaussian light propagation Algorithm.

PRESBYMAX®

- Multifocality is created with a biaspheric ablation profile based on optimized mathematic curves, providing adequate transitions between distance and near vision





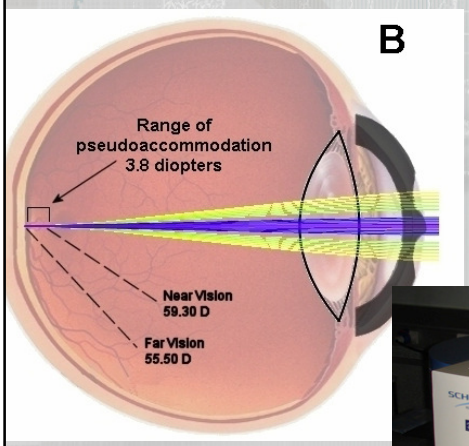
PRESBYMAX® FACTS

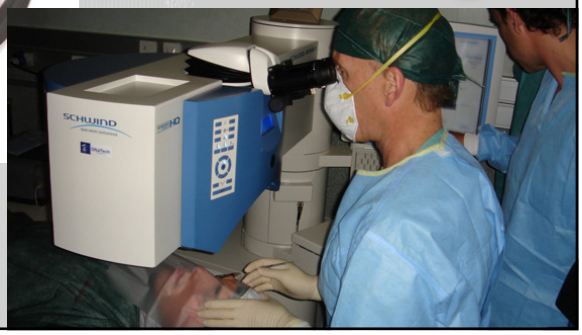
- Achieves spectacle independence by excimer laser surgery
- Uses corneal multifocality as the main approach
- Minimally invasive
- Personalized for each patient
- Useful in all types of refractive errors, to correct them simultaneously
- Useful in all degrees of presbyopia
- Useful in pseudophakic patients
- Useful in cases with previous Lasik
- Predictable / predictive

PresbyMax® OFFERS TO THE REFRACTIVE SURGEON…

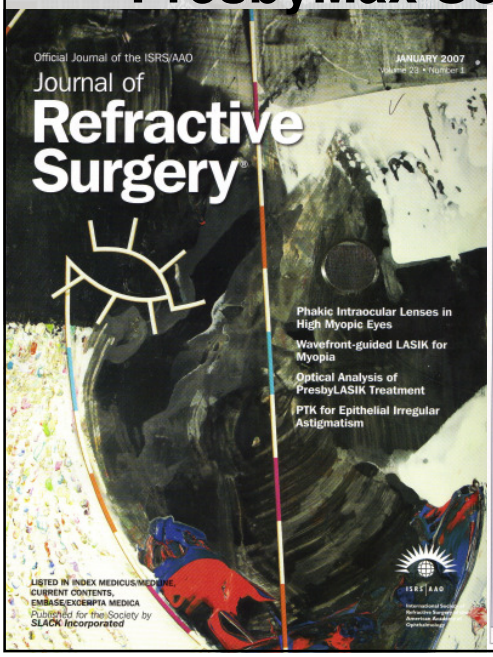
1. Predictive model of Presbylasik based on robust scientific basis.
2. Near vision effect up tp +3D.
3. Pupil dependent, BUT pupil predictive.
4. Very good near vision quality.
5. Works in hyperopes , myopes, emmetrops and previous lasik cases
6. Compensates age-related positive asphericity of the adult's eye (Bi-Aspheric profile).
7. Centration optimised.
8. Customised to patient´s preop. eye aberrations
9. It is a NEAR vision dominant procedure when pupil is constricted and FAR dominant when dilated

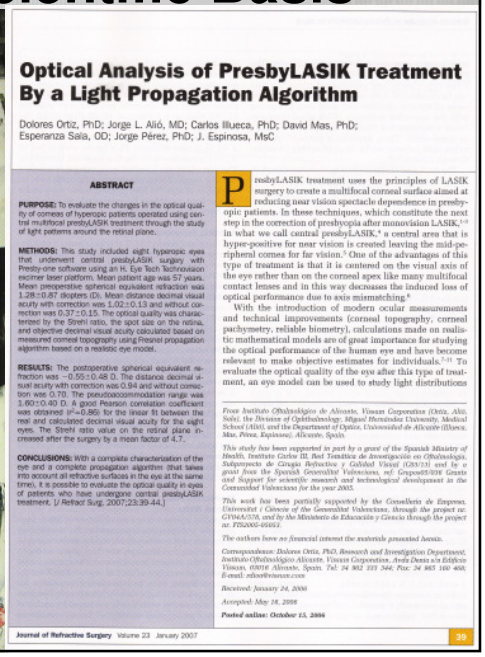
PresbyMax® Scientific basis





PresbyMax® Scientific Basis





Optical Analysis of PresbyLASIK Treatment By a Light Propagation Algorithm

Dolores Ortiz, PhD; Jorge L. Alió, MD; Carlos Illueca, PhD; David Mas, PhD; Esperanza Sala, OD; Jorge Pérez, PhD; J. Espinosa, MsC

ABSTRACT

PURPOSE: To evaluate the changes in the optical quality of corneas of hyperopic patients operated using central multifocal presbyLASIK treatment through the study of light patterns around the retinal plane.

METHODS: This study included eight hyperopic eyes that underwent central presbyLASIK surgery with Presby-one software using an H. Eye Tech Technovision excimer laser platform. Mean patient age was 57 years. Mean preoperative spherical equivalent refraction was 1.28±0.87 diopters (D). Mean distance decimal visual acuity with correction was 1.02±0.13 and without correction was 0.37±0.15. The optical quality was characterized by the Strehl ratio, the spot size on the retina, and objective decimal visual acuity calculated based on measured corneal topography using Fresnel propagation algorithm based on a realistic eye model.

RESULTS: The postoperative spherical equivalent refraction was −0.55±0.48 D. The distance decimal visual acuity with correction was 0.94 and without correction was 0.70. The pseudoaccommodation range was 1.60±0.40 D. A good Pearson correlation coefficient was obtained (r^2=0.86) for the linear fit between the real and calculated decimal visual acuity for the eight eyes. The Strehl ratio value on the retinal plane increased after the surgery by a mean factor of 4.7.

CONCLUSIONS: With a complete characterization of the eye and a complete propagation algorithm (that takes into account all refractive surfaces in the eye at the same time), it is possible to evaluate the optical quality in eyes of patients who have undergone central presbyLASIK treatment. [J Refract Surg. 2007;23:39-44.]

PresbyLASIK treatment uses the principles of LASIK surgery to create a multifocal corneal surface aimed at reducing near vision spectacle dependence in presbyopic patients. In these techniques, which constitute the next step in the correction of presbyopia after monovision LASIK,[7-11] in what we call central presbyLASIK,[4] a central area that is hyper-positive for near vision is created leaving the mid-peripheral cornea for far vision.[5] One of the advantages of this type of treatment is that it is centered on the visual axis of the eye rather than on the corneal apex like many multifocal contact lenses and in this way decreases the induced loss of optical performance due to axis mismatching.[4]

With the introduction of modern ocular measurements and technical improvements (corneal topography, corneal pachymetry, reliable biometry), calculations made on realistic mathematical models are of great importance for studying the optical performance of the human eye and have become relevant to make objective estimates for individuals.[7-11] To evaluate the optical quality of the eye after this type of treatment, an eye model can be used to study light distributions

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This study has been supported in part by a grant of the Spanish Ministry of Health, Instituto Carlos III, Red Temática de Investigación en Oftalmología, Subproyecto de Cirugía Refractiva y Calidad Visual (C03/13) and by a grant from the Spanish Generalitat Valenciana, ref: Grupos03/038 Grants and Support for scientific research and technological development in the Comunidad Valenciana for the year 2003.

This work has been partially supported by the Conselleria de Empresa, Universitat i Ciència of the Generalitat Valenciana, through the project nr. GV04A/576, and by the Ministerio de Educación y Ciencia through the project nr. FIS2005-05693.

The authors have no financial interest the materials presented herein.

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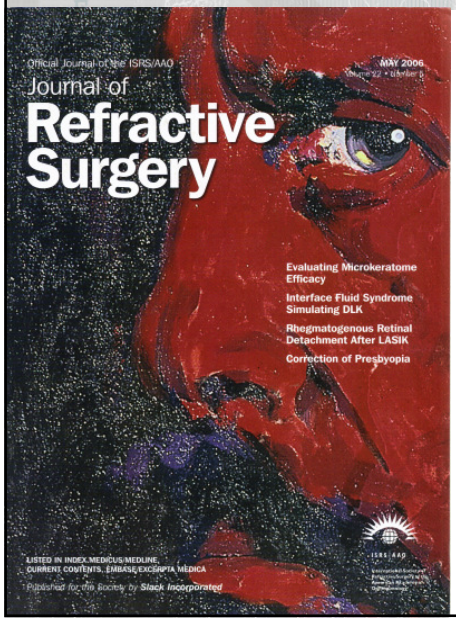
Received: January 24, 2006

Accepted: May 18, 2006

Posted online: October 13, 2006

PresbyMax® Scientific Basis



Correction of Presbyopia by Technovision Central Multifocal LASIK (PresbyLASIK)

Jorge L. Alió, MD, PhD; Jean Jacques Chaubard, MD; Araceli Caliz, PhD; Esperanza Sala, OA; Sudi Patel, PhD, FCOptom

ABSTRACT

PURPOSE: To investigate central multifocal presbyLASIK based on the creation of a central hypepositive area.

METHODS: Twenty-five patients (50 eyes) underwent presbyLASIK in an open-label, prospective, non-comparative pilot study. Mean patient age was 58 years (range: 51 to 68 years), mean preoperative spherical equivalent refraction was +1.6±0.63 diopters (D) (range: +0.50 to +3.00 D), and mean spectacle near addition was +2.27±0.37 D (range: +1.75 to +3.00 D). The ablation pattern was performed with proprietary software from Technovision using an H. Eye Tech. excimer laser platform.

RESULTS: Mean postoperative spherical equivalent refraction was −0.37±0.55 D (range: −1.50 to +1.00 D) and mean spectacle near addition was +1.72±0.34 D (range: +1.25 to +2.25 D). After 6 months, 16 (64%) patients achieved a distance uncorrected visual acuity (UCVA) of >20/20 and 18 (72%) patients achieved a near UCVA of >20/40. Seven (28%) patients lost a maximum of 2 lines of best spectacle-corrected visual acuity (BSCVA). The safety index for distance was 0.98 binocular and for near was 0.99 binocular. After 6 months, no significant change was noted in contrast sensitivity at 1.5 cycles/degree. A significant mean reduction was found at spatial frequencies of 3, 6, 12, and 18 cycles/degree ($P<.001$). There was a significant change in corneal aberrations after surgery. The coefficients for coma increased and the coefficients for spherical aberrations decreased. A significant decrease was noted in point spread function values ($P=.0018$).

CONCLUSIONS: Central presbyLASIK may be used to provide improvement in functional near vision in patients with presbyopia associated with low and moderate hyperopia. However, factors involved in the loss of BSCVA in some cases and loss in vision quality should be further studied prior to its general use. [J Refract Surg. 2006;22:453-460.]

With the term presbyLASIK, we can group a series of corneal surgical techniques based on the principles of LASIK to create a multifocal corneal surface aimed to reduce near vision spectacle dependency in presbyopic patients. In such techniques, either a central area hyperpositive for near vision is created, leaving the mid-peripheral cornea for far vision[1] (central presbyLASIK) or a central area for distance vision is created with a mid-peripheral corneal area for near vision[2] (peripheral presbyLASIK). Essentially, both groups of techniques create a multifocal corneal surface and so the term "multifocal presbyLASIK" is preferred to differentiate this from other photoablative surgical alternatives developed to reduce spectacle dependence for near vision by increasing the depth of focus based on modifications of the peripheral corneal ablation profile.[3]

The concept of multifocal presbyLASIK is attractive as it uses a well-known surgical technique, LASIK. Also the use and acceptance of multifocal intraocular lenses for the correction of aphakia with partial near vision restoration has reinforced the knowledge and clinical potential of multifocal optics for the purpose of near vision spectacle-free improvement. Multifocal presbyLASIK also has the advantage of being centered on the visual axis of the eye rather than on the corneal apex like many multifocal contact lenses, thereby eliminating the induced decrease of optical performance due to axis mismatching.[4] However, despite the increasing inter-

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This study was supported in part by a grant from the Spanish Ministry of Health (Red Tematica de Investigación en Oftalmología, subproyecto de Cirugía y Refractiva y Calidad Visual C30/12) and by an unrestricted grant from Technovision GmbH, Munich, Germany

Dr Chaubard has a financial interest in Presby-One software (Technovision, Munich, Germany). The remaining authors have no financial or proprietary interests in the materials presented herein.

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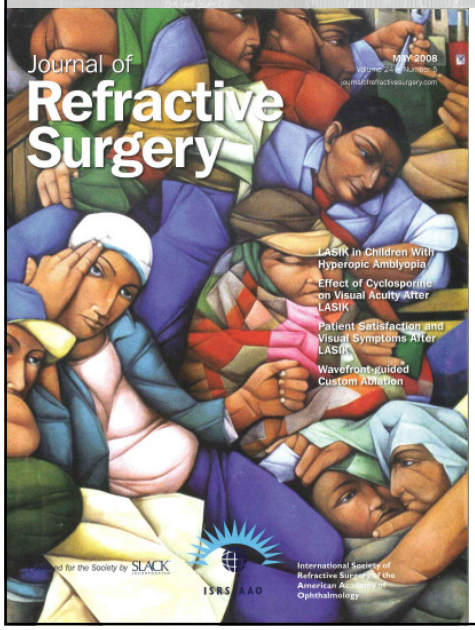
Received: May 4, 2005

Accepted: November 15, 2005

PresbyMax® Scientific Basis



Correction of Presbyopia in Hyperopia With a Center-distance, Paracentral-near Technique Using the Technolas 217z Platform

Roberto Pinelli, MD; Dolores Ortiz, PhD; Anna Simonetto, MA; Cristian Bacchi, OD; Esperanza Sala, OD; Jorge L. Alió, MD, PhD

ABSTRACT

PURPOSE: To analyze the results of hyperopic patients treated with a peripheral presbyLASIK algorithm for the correction of presbyopia.

METHODS: The study included 44 eyes of 22 hyperopic patients treated with a peripheral presbyLASIK technique using a Technolas 217z excimer laser. Mean patient age was 56 years (range: 47 to 72 years), mean preoperative spherical equivalent refraction was +1.21±0.77 diopters (D) (range: +0.50 to +4.00 D), and mean spectacle near addition was +1.76±0.42 D (range: +1.00 to +2.75 D). The Peripheral Multifocal LASIK (PML) ablation pattern creates a multifocal corneal profile over a 6.5-mm diameter, performing the distance correction first in a 6-mm optical zone and then near correction in a 6.5-mm zone. Main outcome measures were uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BSCVA) for near and distance, spherical equivalent refraction, contrast sensitivity, and corneal aberrations.

RESULTS: Six months postoperatively, mean binocular UCVA was 1.06±0.13 for distance and 0.84±0.14 for near. Mean postoperative spherical equivalent refraction was −0.42 D (range: −1.12 to +0.87 D). Two (4.5%) eyes lost 1 line of BSCVA for distance and near vision, and 20 (45%) eyes gained 1 line of distance BSCVA. Contrast sensitivity decreased for 3, 6, 12, and 18 cycles/degree. Corneal aberration analysis showed a slight increase in coma and decrease in spherical aberration.

CONCLUSIONS: The peripheral presbyLASIK technique used in this study is a safe and efficient treatment that may improve functional near vision in presbyopic patients with low and moderate hyperopia (from +0.50 to +3.00 D). [J Refract Surg. 2008;24:494-500.]

The refractive correction of presbyopia is one of the most frequently discussed topics in refractive surgery today, generating curiosity and great interest throughout the world among surgeons and the ophthalmic industry. There are several surgical approaches to the correction of presbyopia: conductive keratoplasty, presbyLASIK, monovision correction, scleral expansion, and phakic and multifocal intraocular lens (IOL) implantation. Conductive keratoplasty is an effective and safe procedure for the treatment of presbyopia,[1] but it is limited by its monocular application. Monovision correction (by corneal refractive surgery or refractive lens exchange), is a surgical strategy for those patients who need distance and near vision with realistic expectations, but it has some disadvantages, such as the decrease in contrast sensitivity.[2] Accurate patient selection is also crucial for this strategy because monovision is not well tolerated by all patients. Scleral expansion is another surgical approach to correct presbyopic symptoms but is prone to regression.[3] The performance of different types of IOLs (refractive, diffractive, pseudoaccommodating, and multifocal) is constantly being improved,[4,5] but the IOLs cause a decrease in near vision contrast sensitivity.[6]

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This study was supported in part by a grant of the Spanish Ministry of Health, Instituto Carlos III, Red Tematica de Investigación en Oftalmología, Subproyecto de Cirugía Refractiva y Calidad Visual (C30/12) and by a grant from the Spanish Generalitat Valenciana, ref. GrupoeAMA08 Grants and Support for scientific research and technological development in the Comunidad Valenciana for the year 2005.

Dr Pinelli has a proprietary interest in the PML software. The remaining authors have no proprietary interest in the materials presented herein.

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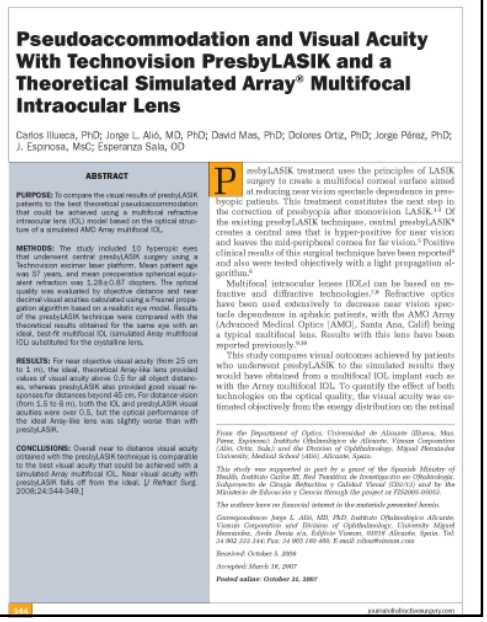
Received: September 11, 2006

Accepted: March 18, 2007

Posted online: October 31, 2007

PresbyMax® Scientific Basis



Pseudoaccommodation and Visual Acuity With Technovision PresbyLASIK and a Theoretical Simulated Array® Multifocal Intraocular Lens

Carlos Illueca, PhD; Jorge L. Alió, MD, PhD; David Mas, PhD; Dolores Ortiz, PhD; Jorge Pérez, PhD; J. Espinosa, MsC; Esperanza Sala, OD

ABSTRACT

PURPOSE: To compare the visual results of presbyLASIK patients to the best theoretical pseudoaccommodation that could be achieved using a multifocal refractive intraocular lens (IOL) model based on the optical structure of a simulated AMO Array multifocal IOL.

METHODS: The study included 10 hyperopic eyes that underwent central presbyLASIK surgery using a Technovision excimer laser platform. Mean patient age was 57 years, and mean preoperative spherical equivalent refraction was 1.28±0.87 diopters. The optical quality was evaluated by objective distance and near decimal visual acuities calculated using a Fresnel propagation algorithm based on a realistic eye model. Results of the presbyLASIK technique were compared with the theoretical results obtained for the same eye with an ideal, best-fit multifocal IOL (simulated Array multifocal IOL) substituted for the crystalline lens.

RESULTS: For near objective visual acuity (from 25 cm to 1 m), the ideal, theoretical Array-like lens provided values of visual acuity above 0.5 for all object distances, whereas presbyLASIK also provided good visual responses for distances beyond 40 cm. For distance vision (from 1.5 to 6 m), both the IOL and presbyLASIK visual acuities were over 0.5, but the optical performance of the ideal Array-like lens was slightly worse than with presbyLASIK.

CONCLUSIONS: Overall near to distance visual acuity obtained with the presbyLASIK technique is comparable to the best visual acuity that could be achieved with a simulated Array multifocal IOL. Near visual acuity with presbyLASIK falls off from the ideal. [*J Refract Surg.* 2008;24:344-349.]

PresbyLASIK treatment uses the principles of LASIK surgery to create a multifocal corneal surface aimed at reducing near vision spectacle dependence in presbyopic patients. This treatment constitutes the next step in the correction of presbyopia after monovision LASIK.[1,2] Of the existing presbyLASIK techniques, central presbyLASIK[3] creates a central area that is hyper-positive for near vision and leaves the mid-peripheral cornea for far vision.[4] Positive clinical results of this surgical technique have been reported[3] and also were tested objectively with a light propagation algorithm.[5]

Multifocal intraocular lenses (IOLs) can be based on refractive and diffractive technologies.[7,8] Refractive optics have been used extensively to decrease near vision spectacle dependence in aphakic patients, with the AMO Array (Advanced Medical Optics [AMO], Santa Ana, Calif) being a typical multifocal lens. Results with this lens have been reported previously.[9,10]

This study compares visual outcomes achieved by patients who underwent presbyLASIK to the simulated results they would have obtained from a multifocal IOL implant such as with the Array multifocal IOL. To quantify the effect of both technologies on the optical quality, the visual acuity was estimated objectively from the energy distribution on the retinal

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This study was supported in part by a grant of the Spanish Ministry of Health, Instituto Carlos III, Red Temática de Investigación en Oftalmología, Subproyecto de Cirugía Refractiva y Calidad Visual (C03/13) and by the Ministerio de Educación y Ciencia through the project nr FIS2005-00602.

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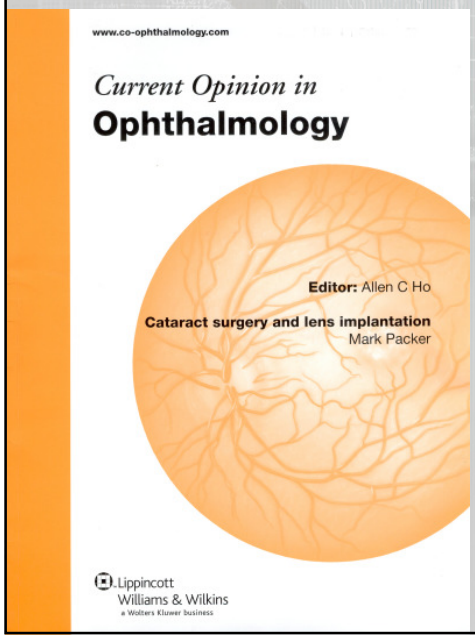
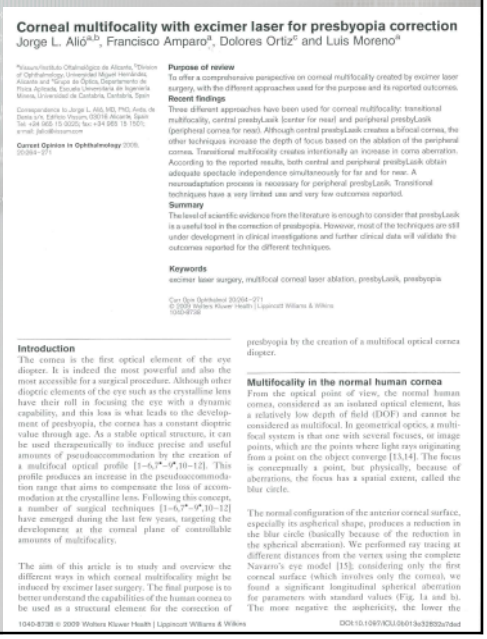
Received: October 5, 2006

Accepted: March 16, 2007

Posted online: October 31, 2007

PresbyMax® Scientific Basis





Corneal multifocality with excimer laser for presbyopia correction

Jorge L. Alió[a,b], Francisco Amparo[a], Dolores Ortiz[c] and Luis Moreno[a]

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Current Opinion in Ophthalmology 2008, 20:264–271

Purpose of review

To offer a comprehensive perspective on corneal multifocality created by excimer laser surgery, with the different approaches used for the purpose and its reported outcomes.

Recent findings

Three different approaches have been used for corneal multifocality: transitional multifocality, central presbyLasik (center for near) and peripheral presbyLasik (peripheral cornea for near). Although central presbyLasik creates a bifocal cornea, the other techniques increase the depth of focus based on the ablation of the peripheral cornea. Transitional multifocality creates intentionally an increase in corna aberration. According to the reported results, both central and peripheral presbyLasik obtain adequate spectacle independence simultaneously for far and for near. A neuroadaptation process is necessary for peripheral presbyLasik. Transitional techniques have a very limited use and very few outcomes reported.

Summary

The level of scientific evidence from the literature is enough to consider that presbyLasik is a useful tool in the correction of presbyopia. However, most of the techniques are still under development in clinical investigations and further clinical data will validate the outcomes reported for the different techniques.

Keywords

excimer laser surgery, multifocal corneal laser ablation, presbyLasik, presbyopia

Curr Opin Ophthalmol 20:264–271
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1040-8738

Introduction

The cornea is the first optical element of the eye diopter. It is indeed the most powerful and also the most accessible for a surgical procedure. Although other dioptric elements of the eye such as the crystalline lens have their roll in focusing the eye with a dynamic capability, and this loss is what leads to the development of presbyopia, the cornea has a constant dioptric value through age. As a stable optical structure, it can be used therapeutically to induce precise and useful amounts of pseudoaccommodation by the creation of a multifocal optical profile [1–6,7*–9*,10–12]. This profile produces an increase in the pseudoaccommodation range that aims to compensate the loss of accommodation at the crystalline lens. Following this concept, a number of surgical techniques [1–6,7*–9*,10–12] have emerged during the last few years, targeting the development at the corneal plane of controllable amounts of multifocality.

The aim of this article is to study and overview the different ways in which corneal multifocality might be induced by excimer laser surgery. The final purpose is to better understand the capabilities of the human cornea to be used as a structural element for the correction of presbyopia by the creation of a multifocal optical cornea diopter.

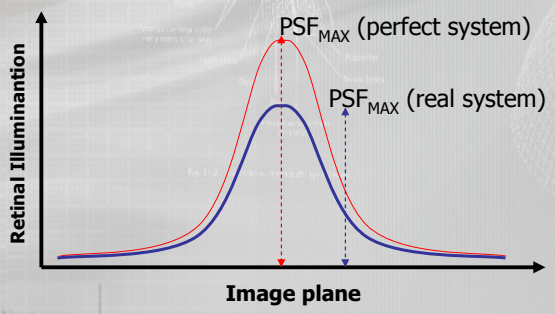
Multifocality in the normal human cornea

From the optical point of view, the normal human cornea, considered as an isolated optical element, has a relatively low depth of field (DOF) and cannot be considered as multifocal. In geometrical optics, a multifocal system is that one with several focuses, or image points, which are the points where light rays originating from a point on the object converge [13,14]. The focus is conceptually a point, but physically, because of aberrations, the focus has a spatial extent, called the blur circle.

The normal configuration of the anterior corneal surface, especially its aspherical shape, produces a reduction in the blur circle (basically because of the reduction in the spherical aberration). We performed ray tracing at different distances from the vertex using the complete Navarro's eye model [15]; considering only the first corneal surface (which involves only the cornea), we found a significant longitudinal spherical aberration for parameters with standard values (Fig. 1a and b). The more negative the asphericity, the lower the

Optical quality: Strehl Ratio

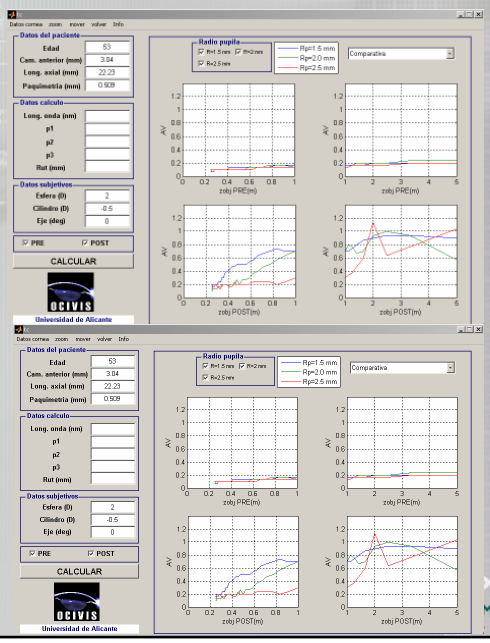
The <u>Strehl ratio</u> is the ratio of peak focal intensities in the aberrated and ideal point spread functions

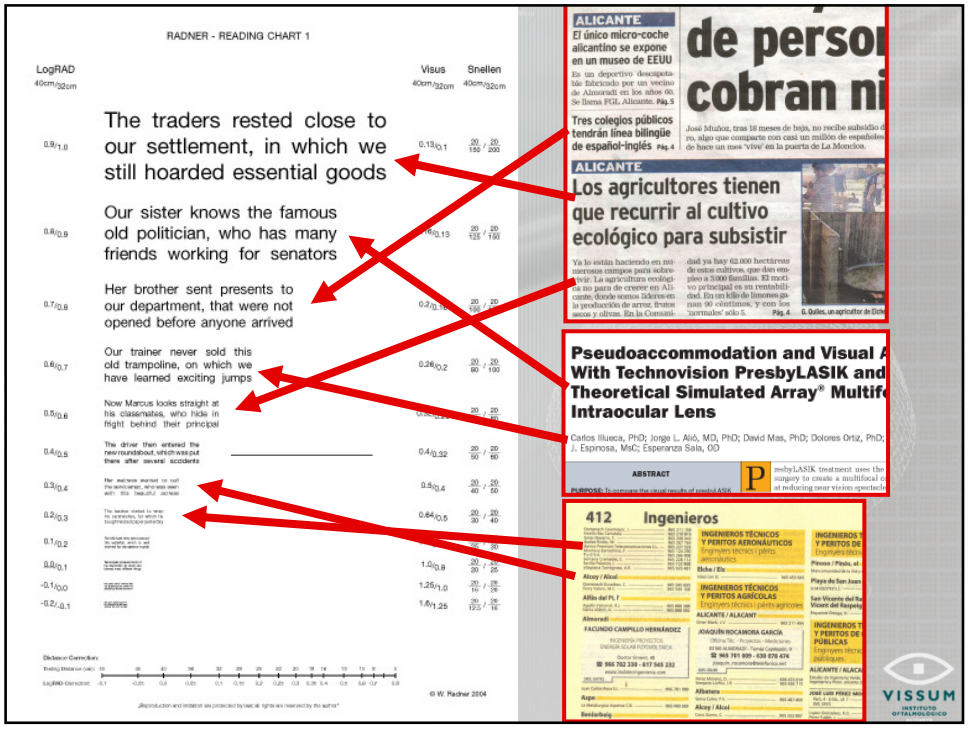


$$SR = \frac{PSF_{MAX}(RealSystem)}{PSF_{MAX}(PerfectSystem)}$$

PRESBYMAX®

- Second-generation presbyLASIK technique patented by Vissum Alicante (Spain)
- SCHWIND EXCIMER LASER Platform
- Prediction of visual outcome for distance and near conditions in every patient by using a predictive software based on the use of a proprietary Gaussian light propagation algorithm (University of Alicante model)





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