"PRESBYCUSTOM" NEW CUSTOMIZABLE CONTACT LENSES TO CORRECT PRESBYOPIA

PATENTED TECHNOLOGY

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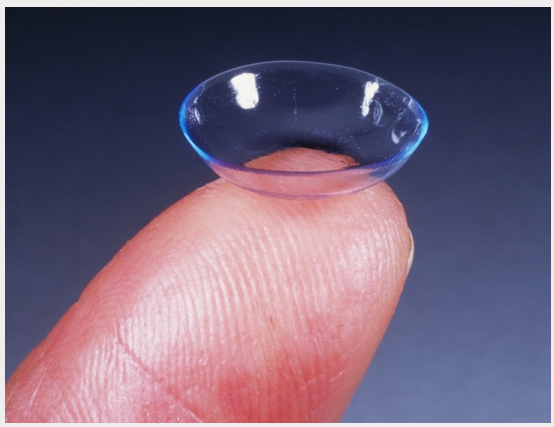
ABSTRACT

The research group of Optics and Visual Perception of the UNIVERSITY OF ALICANTE, with the collaboration of the company LABORATORIOS LENTICON SA, has developed a new multifocal scleral contact lens to compensate presbyopia (age-related near vision deterioration) which has the peculiarity of being optically customizable according to the specific needs of each patient.

The new contact lens has been developed combining different types of stable optical aberrations that have allowed us to optimize the depth of focus, providing excellent levels of visual quality as well as very comfort wear, easy fitting process and greater stability than current multifocal contact lenses. Some prototypes have been manufactured at laboratory level and they have been validated successfully in patients. Currently, CE marking is being processed which will allow its international commercialization. We are looking for companies interested in acquiring this technology for commercial exploitation.



INTRODUCTION

Presbyopia is an age-associated ocular defect that usually appears between 40-45 years old and causes difficulty in seeing up close.
It is due to the reduction of the accommodation ability of the eye, which causes decreased ability to sharply focus nearby objects.
At present, there is a wide variety of multifocal contact lenses designs to compensate the presbyopia, both in hydrogel material

and oxygen permeable rigid material.
All of these designs are based on the induction of fixed amounts of primary spherical aberration for different levels of near vision.
Spherical aberration is an optical aberration in which rays parallel to the optical axis, but at a certain distance from it, are brought to a different focus than those rays close to it.
The induction of this aberration allows increasing the depth of the focus, and therefore provides to the patient the ability of seeing clearly at different distances.

Among the main limitations of multifocal contact lenses that are currently available on the market, we have found the following:

1. The induction of spherical aberration is fixed and it does not take into account the specific aberrometric defects inherent to each patient's eye.

2. The fitting guides are empirical and do not always operate properly.

3. In most of these fitting guides, refraction is used as the only selection criterion for the selection of the trial lens.

4. These types of lenses experience decentrations, which minimize the increase in depth of focus.

5. Corneal multifocal contact lenses only induce different levels of positive primary spherical aberration without the possibility of modifying it according to specific peculiarities of the patient's eye. Likewise, rigid lenses cause discomfort during the beginning of the contact lens wearing, which can lead to its rejection.

6. Practically all current multifocal contact lenses induce primary spherical aberration, but do not consider the combination of other types of optical aberrations that have been shown to be highly effective to induce significant increases in depth of focus without deteriorating the visual quality.

TECHNICAL DESCRIPTION

Presbyopia is a widespread problem in the population over 45 years, so it is especially relevant to develop a new multifocal contact lenses based on the optimization of depth of focus through combining different types of optical aberrations, with an easy fitting, with significant positional stability, and customizable according to the specific needs of each patient.

The present invention solves technical problems described above.

In this case, a **new multifocal contact lenses** has been developed to compensate **presbyopia**. It is made of oxygen permeable rigid material, with scleral bearing (that is, the outermost and white layer of the eyeball), which is fully customizable according to the specific anatomical properties of the eye of each patient, such as:

- Zernike's third to sixth order aberrations.
- Pupil dynamics.
- Position of the visual axis with respect to the pupillary center.

This novel contact lens, which allows an aligned and adequate fitting to the corneal-conjunctival profile of the patient, comprise **three different areas**: corneal, limbar and scleral. In turn, each of these areas has **two surfaces**: anterior (which is in contact with the environment), and posterior (which is the one that configures the tear meniscus retained between the cornea and the contact lens). See Figures 1 and 2.

1. **Corneal area** (3): it has a variable diameter with a fixed rear surface geometry (3a) and an anterior surface shape (3b) which is modified during the manufacturing process according to the specific needs of the patient (according to the refractive error to correct) and the aberrometric induction required. For such purpose, the radius of the central curvature and the asphericity are modified.

2. **Limbar area** (2): it has both a diameter and a variable asphericity (a total of 8 options of asphericity are offered to facilitate the fitting of this zone to the cornea-conjunctival transition of each patient). Also, this area is the responsible for the control of the sagittal height of the contact lens.

3. **Scleral area** (1): it is the area of the contact lens that rests on conjunctiva. It has a spherical geometry and a variable diameter. The radius of curvature of the temporal portion and the nasal portion is different to consider the naso-temporal asymmetry of the corneo-scleral profile.

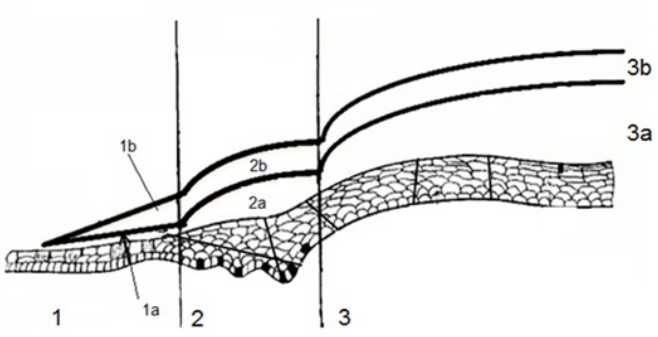


Figure 1: Cross section image showing the profile of the contact lens and how it rests on the different structures of the eye: corneal (3), limb (2) and scleral (1). In addition, the posterior (a) and anterior (b) surfaces of each of these areas can be seen.

The contact lenses are made of a **gas permeable material** (with high **oxygen** transmissibility) and with a variable overall diameter

depending on the iris of the patient.

For the **fitting** of the contact lens, the following variables (calculated according to the post-lens tear meniscus) should be considered:

a. Refraction of the patient.

b. Near addition.

c. Level of primary and secondary ocular spherical aberration.

d. Pupil dynamics pattern.

e. Kappa angle magnitude.

Different simulations were carried out using the standard ray tracing procedure and assuming different model eyes with different magnitudes of primary spherical aberration, which allowed us to define the most suitable aberrometric profile for the contact lens, providing **optimized visual quality** and depth of the desired focus, for different eye optical combinations.

A classification has also been made with different levels of decentration of the optical center at the nasal level, depending on the magnitude of the patient's kappa angle.

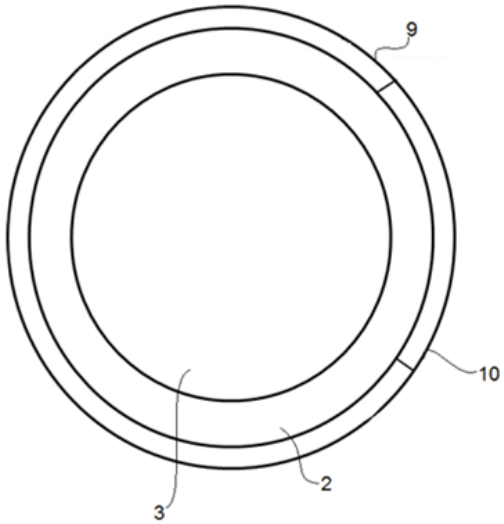


Figure 2: Frontal profile of the contact lens showing the different areas: corneal area (3), limbar area (2), temporal scleral area (9) and nasal scleral area (10).

TECHNOLOGY ADVANTAGES AND INNOVATIVE ASPECTS

ADVANTAGES OF THE TECHNOLOGY

The new multifocal scleral contact lens made of oxygen permeable rigid material and with optical personalization for each patient, offers the following **advantages** over the designs currently on the market:

1. It rests only on the conjunctival-scleral surface (this lens *does not bear at any point on the surface of the cornea*), minimizing the risk for continuous friction between the lens and the cornea, allowing a fitting providing maximum comfort.

2. It presents a great variety of options to induce stable optical aberrations according to the needs and the optical peculiarities of the patient's eye.

3. It allows an optimization of the depth of focus leading to excellent levels of visual quality.

4. In the case of patients with a peculiar pupil dynamics or a very marked kappa angle, the contact lens can be modified to adapt it to these factors, thus achieving an even greater optimization of the results.

5. The scleral support in the 360° confers a greater stability to the lens, minimizing the movement and the decentration, and therefore contributing to an optimum vision for both near and far.

6. It takes into account the naso-temporal asymmetry of the profile of the corneo-scleral junction, which minimizes both the decentration and the movement of the lens.

7. The fitting of the contact lens is easy, personalized and specific for each patient, providing great levels of comfort and excellent visual quality.

8. The high failure rates provided of current multifocal contact lenses are overcome with this lens.

INNOVATIVE ASPECTS OF THE TECHNOLOGY

A multifocal scleral contact lens has been developed to compensate presbyopia, which is optically customizable according to the specific needs of each patient's eye.

Its development has been based on the optimization of depth of focus by combining different types of optical aberrations that are

stable as no decentrations of the lens are expected due to the high stability of the bearing of the lens.

For such purpose, a wide variety of Zernike third to sixth order optical aberration induction options has been used not only according to the patient's near addition, but also according to the patient's kappa angle as well as the pupil size under different lighting conditions.

Therefore, the design has been managed to optimize the depth of focus while maintaining excellent levels of visual quality.

This novel contact lens is easily fitted, even in those patients who have a peculiar pupil dynamics or a marked kappa angle.

In addition, the optical center of this lens can be decentrated as a function of the kappa angle of the patient, thereby preventing high levels of comatic aberration in patients with a large kappa angle (for instance, in nearsighted patients).

Unlike virtually all current multifocal contact lenses, which work with induction of primary spherical aberration, it has been shown that the combination of other types of optical aberrations may induce significant increases in depth of focus without significant deterioration of the visual quality.

CURRENT STATE OF DEVELOPMENT

This novel multifocal scleral contact lens to compensate presbyopia (eyestrain) has been d**eveloped on a laboratory scale**.

A batch of prototypes has been manufactured and **successfully validated in different patients**. The manufacturing process is reliable and reproducible.

Currently, the **CE marking** is being processed, which will allow its commercialization at international level.

MARKET APPLICATIONS

The present invention is framed in the field of Optics. In particular, it relates to a multifocal scleral contact lens to compensate presbyopia. It is optically customizable according to the specific needs of each patient.

COLLABORATION SOUGHT

It is looking for companies interested in acquiring this invention for commercial exploitation through:

- License agreement.
- Development of new applications.
- Technology and knowledge transfer agreements.
- Carry out technical reports and scientific advice for companies.
- Provide specific training tailored to the needs of the company.Provide technological support in those techniques that require high training or sophisticated instruments that are not available to the requesting company.
- Exchange of personnel for defined periods of time (for learning a technique, etc.).
- Rental of internal equipment to clients who wish to carry out their own tests (own infrastructure of the Department of Optics, Pharmacology and Anatomy, or Technical Research Services (SSTTI) of the University of Alicante).

INTELLECTUAL PROPERTY RIGHTS

The present invention is protected through **granted patent** :

- *Title of the patent: "Lente de contacto multifocal escleral".*
- *Application number: P201631236.*
- *Application date: 21th September 2016.*

MARKET APPLICATION (3)

Pharmacology, Cosmetics and Ophthalmology
Materials and Nanotechnology
Medicine and Health