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Fabrication and analyses of bionic intraocular lens with meniscus polymer layer and porous structure

Dan Liang *, Dong Tai Liang, Ping Li

Ningbo University, Faculty of Mechanical Engineering and Mechanics, 818 Fenghua Rd., Ningbo City, Zhejiang Province, 315211, PR China

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ABSTRACT

This paper proposes an accommodating IOL with meniscus polymer membrane and porous structure based on the optical structure and focusing mechanism of the human eye. The fabrication procedure and forming characteristics of the meniscus membrane based on thermal and gravity assisting method are also presented. The proposed IOL mainly consists of two soft meniscus polymer layers, a porous support ring and optical liquid, which can be fixed in the capsular bag and adjusted by the ciliary muscle to change the focus. The structure and regulating principle of the IOL are presented, as well as the lens fabrication process. Additionally, the lens adjusting properties, imaging quality, surface roughness and physical density are also measured and analyzed. Under the radial pressure of 92.3 mN, the designed IOL can achieve a 13.5 D accommodating range. The presented IOL shows good accordance with the regulating process of the human eye, which can be used for the visual disturbance therapy and various optical zooming systems.

1. Introduction

The intraocular lens (IOL) is widely used in ophthalmic surgery which can help the cataract patients partly recover visual accommodation capability. Compared with the medicinal therapy, lens implantation surgery is an effective way to treat cataract [1]. During the operation, the impaired crystalline lens is taken out and replaced by the implanted IOL. As the cataract generally has a high incidence rate among the elderly, the need for IOLs with good adjustability and biological compatibility has become more and more urgent with the increasingly aging of the population.

The traditional monofocal IOL has little adjustability and can only help the patients get clear vision from a specific distance [2], which brings much inconvenience for the postoperative life of the patients. Different from the monofocal IOLs, the accommodating IOLs have adjustable optical focus which has attracted much attention in the decades [3–7]. According to the adjusting principles, the accommodating IOLs can be mainly divided into two kinds: the position-based IOL and the deformation-based IOL. The position-based IOL adjusts the diopter by changing the lens position, such as the single-optic and dual-optic accommodating IOLs, which is widely used in clinic applications [8]. The single-optic IOL is mainly composed of a biconvex lens and two antennae, and adjust the focus through the movement of the biconvex lens under the deformation of the capsular bag [9]. The dual-optic IOL generally consists of two lenses which are connected through a spring, and changes the diopter by the spacing alteration between the two lenses [10]. Limited by the thickness of the capsular bag, the actual adjusting ability of the single-optic and dual-optic IOLs is relatively small (<3.5D) after the implanting operation.

Different from the position-based IOLs, the deformation-based IOLs alter the diopter through the lens surface deformation [11]. This kind of IOLs generally consists of thin elastic membrane and optical liquid, fixed in the capsular bag and can be adjusted by the ciliary muscle flexibly. The deformation-based IOL has large adjustability and high integration, showing the potential to help the cataract patients fully recover the visual accommodating capability. A bionic IOL with thin elastic film and rigid lens has been presented in our previous study [7]. However, using the thin film and liquid as the main refractive units makes the IOL vulnerable to the effects of gravity and external vibration, and the lens structure and optical properties remain to be improved. The rigid lens in the IOL also leads to a larger implantation wound which increases the risk of potential postoperative complications. There are also some other accommodating IOLs such as the liquid crystal IOL, electrowetting IOL, and magnetic IOL [12–17], but these IOLs generally need external power supply and electrical driving modules, making the whole lens system rather complicated and affecting the clinical applications. In short, it

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* Corresponding author.
E-mail address: ldldld7777@163.com (D. Liang).

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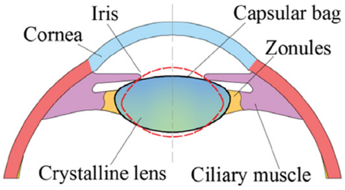

Fig. 1. The schematic diagram of human eye. The red curve shows the shape of the deformed crystalline lens.

is still a pressing issue to develop the accommodating IOL with large adjustability, good stability and biocompatibility.

In this paper, we have proposed an accommodating IOL with meniscus polymer membrane and porous structure based on the optical structure and focusing mechanism of human eye. The fabrication procedure and forming characteristics of the meniscus membrane based on thermal and gravity assisting method are also presented. The proposed IOL mainly consists of two soft meniscus polymer layers, a porous support ring and optical liquid, which can be fixed in the capsular bag and adjusted by the ciliary muscle to change the focus. Different from the previous deformation-based IOL, the proposed IOL utilizes two meniscus membranes rather than a thin membrane as the deforming surface, offering more freedoms for the optical design. Besides, the solid–liquid mixed porous structure of the IOL also helps to reduce the liquid proportion and improve the lens stability. Both the membrane and porous support ring are made from soft material with good biocompatibility and foldability, which is beneficial for the lens implanting process. In the following sections, the structure and regulating principle of the IOL are presented, as well as the lens fabrication process. Additionally, the lens adjusting properties, imaging quality, surface roughness and physical density are also measured and analyzed.

2. Design and fabrication process

2.1. Design concept

The crystalline lens is an elastic biconvex lens with a diameter of about 9 mm, which is the key optical regulation unit of human eye. As is shown in Fig. 1, the crystalline lens is located in front of the vitreous body, and enveloped by the elastic capsular bag which is connected with the zonules and ciliary muscle. Inside the crystalline lens are layers of fibers, showing a gradient refractive index from the lens marginal areas to the central zones. The diopter of the crystalline lens is about 19 D, which takes almost 1/3 of the total diopter of eye [18]. When looking at objects from different distances, the surface shape of the crystalline lens would get deformed by the ciliary muscle to alter the lens diopter, so that the objects can image onto the retina clearly. With the aging of human eye, the elasticity and transparency of the crystalline lens decrease gradually, which would evidently reduce the lens adjustability and impact the vision acuity.

Inspired by the physiological structure and regulating mechanism of human eye, we have designed an accommodating IOL which mainly consists of two meniscus membranes, a porous support ring and optical liquid, as is shown in Fig. 2. The lens outer diameter is about 9.6 mm, a little larger than the capsular bag, in order to get fixed by the capsular radial pressure. There are 8 slime holes in the sidewall of the supporting ring, and the optical liquid can flow through the holes flexibly. Both the meniscus membrane and support ring are made from PDMS (Polydimethylsiloxane) material, which is widely used in the contact lenses and has good biocompatibility and optical transparency. The optical liquid has direct influence on the lens diopter and optical properties, and we choose a commercial optical liquid with a refractive index of 1.52 for the design of the prototype lens. During the ophthalmic surgery, the IOL can be implanted into the capsular bag to replace the impaired crystalline lens. When the ciliary muscles contract to reduce the diameter of the capsular bag during the visual regulation process, the optical liquid inside the IOL would get squeezed to the lens surface, thus increasing the lens curvature and diopter.

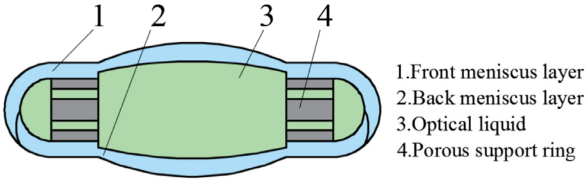

Fig. 2. The structure diagram of the designed artificial intraocular lens.

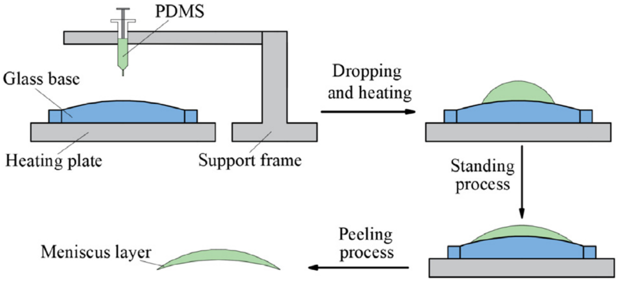

Fig. 3. The fabrication process of the meniscus lens.

The traditional deformation-based IOLs usually utilize thin film as the elastic surface, which are always faced with the spherical aberration and distortion problems. Previous study shows that using the meniscus membrane would help to reduce the aberrations of the optical system through the non-spherically deformation of the membrane [19]. Therefore, we make use of two symmetrical meniscus membranes as the deformable parts, which offers more freedoms for the optical design and has the potential to achieve a good optical properties. The designed IOL also has a solid–liquid mixed porous structure including the meniscus membrane, support ring and optical liquid, which helps to enhance the lens resistance to gravity and stability by reducing the liquid proportion and increasing the porous damping force. During the ocular surgery, the optical liquid of the IOL can also be injected and sealed after the implantation operation, which would help to reduce the surgical site and postoperative complications. The optimization of the lens optical structure, aberration analyses, and animal implantation experiment would be considered in future work according to actual requirement.

2.2. Fabrication and formation characteristics of the meniscus layer

2.2.1. Fabrication process of the meniscus layer

The meniscus layer is the key part of the proposed IOL, which has direct effect on the lens adjusting process. In this section, we present a simple and feasible fabrication process using the PDMS material based on heating and gravity assisting method. The PDMS material is a kind of thermally curable polymer and has good elasticity, chemical stability and optical transparency. When the PDMS drops onto a smooth surface, the droplet would gradually spread and transform into a dioptric lens under the interaction force between the interior tension and the gravity. By adjusting the heating temperature and dropping volume of the PDMS, we can control the final shape and curing time of the PDMS lens.

The designed meniscus layer can be divided into to two parts: the meniscus lens and the connecting membrane. Fig. 3 shows the fabrication process of the meniscus lens. Firstly, the PDMS prepolymer and curing agent is mixed at a volume proportion of 8:1, and gets degassed process through a vacuum pump for 30 min. Secondly, extracting the PDMS mixture (40 ml) using a micro-syringe, then dropping the PDMS onto a round glass base quickly at a fixed height of 15 mm. During