31st Annual International Conference of the IEEE EMBS
Minneapolis, Minnesota, USA, September 2-6, 2009

Design and Fabrication of Accommodating Fluidic Intraocular Lens

Wen Qiao, Daniel Johnson, Frank S. Tsai, *Student Member, IEEE,* Sung Hwan Cho, *Student Member, IEEE,* Yu-Hwa Lo, *Fellow, IEEE*

Abstract— **Intraocular lens (IOL) is a replacement lens for patients with crystalline lens problems. One key problem for today's IOL is its limited ability to retain the original accommodation capability inherent to human eyes. Unlike conventional optical lenses, a bio-inspired fluidic lens changes the curvature of the lens under an external force, resulting in a lens tuning power about 5 times as large as the current devices. By mimicking this desirable feature, a fluidic intraocular lens can achieve a large accommodation range as well. The device is designed that the lens can fully utilize the ciliary muscle force and the deformation of capsular bag during accommodation. Experimental results on fluidic IOL demonstrated a record high 12 Diopter (D) tuning range with a movement around its equator as small as 0.3 mm, achieved under a modest amount of force of 6 grams or 0.06 Newtons. The tuning range of the bio-inspired fluidic lens is comparable to a young, healthy eye, but the force and the movement required for ciliary muscle in order to achieve the wide accommodation range is comparable to an aged eye.**

I. Introduction

An IOL, for the treatment of cataracts and other eye diseases, is an artificial lens to replace the crystalline lens in the capsular bag of a human eye (Fig. 1). An accommodating IOL is designed to change its optical focusing power so that objects may be seen near and far.

Not only helping the cataract inflicted patients, accommodating IOLs can also bring convenience to the daily life of people after their middle age when the accommodation ability of eye decreases substantially due to the combined effects of hardened crystalline lens and thickened capsular bag. The focal distance range of eyes to near and far objects is measured by dioptres. Dioptre is defined as the multiplication of 1000 to the inverse of the focal length in millimeters, and is a direct measure of the focal power of a lens. If an IOL can change its focal length to form clear images on the retina for object distances from infinity to as close to 100 mm, the IOL has an accommodation range of 10 Dioptres. Compared to natural eyes, commercially available accommodating IOLs are limited in optical tuning range [1, 2].

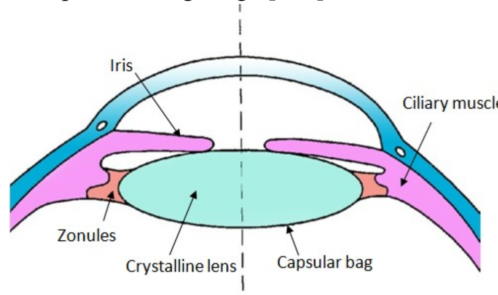

Fig. 1 The structure of a natural eye [3]. An IOL is implanted inside the capsular bag to replace the crystalline lens in a cataract surgery.

Today's IOLs adopt a camera-like working principle: altering the focal distance by moving the lens along the optical axis. The accommodation range of a single-optic IOL varies from 0.3 D to a theoretical maximum of 1.9 D. Concatenating two lenses to form a dual-optic IOL, we can increase the accommodation range to 2.2 D [4], still much lower than the 10-14 D accommodation range of a young eye. The performance of such a dual-optic IOL is limited by the dimension of the capsular bag, which is merely 4 mm [5]. Given the extremely tight spacing available, we need a new mechanism to vary the focal length of the system to acquire the same amount of tuning found in young human eyes. The logical route to search for such "new" mechanism is, obviously, to examine how human eye achieves its tuning range.

Unlike current human made optics, a crystalline lens changes its focal distance by altering its curvature. In this way, an 8-year old eye can achieve a 14 D accommodation range [6]. Utilizing this principle, we and others have developed fluidic lenses that showed an exceedingly high optical tuning range of 200 dioptres [7-9] for imaging devices such as cameras and microscopes. However, the shapes of these "bio-inspired" fluidic lenses have been controlled by external actuators [10, 11]. In this paper, the design and fabrication of a fluidic IOL, which can alter its shape in response to the eye's natural process of accommodation, is described in detail. The device has a proper form factor for implantation in the capsular bag. The mechanical and optical test results show that the fluidic IOL has an accommodation range of 12 D, about 6 times as high as the state-of-the-art IOLs. Furthermore, preliminary

This work was supported in part by the California Institute of Telecommunications and Information Technology (CAL-IT2), in part by the China Scholarship Council, and in part by UCSD Chancellor's Multidisciplinary Research Initiative

W. Qiao, F. S. Tsai and Y.-H. Lo are with the Department of Electrical and Computer Engineering, Jacobs School of Engineering, University of California, San Diego, La Jolla, CA 92093-0407 USA (e-mail: optoqw@gmail.com).

D. Johnson is with the Department of Mechanical and Aerospace Engineering, Jacobs School of Engineering, University of California, San Diego, La Jolla, CA 92093-0411 USA and also with and the California Institute of Telecommunications and Information Technology, University of California, San Diego, La Jolla, CA 92093-0436 USA.

S. H. Cho is with the Materials Science and Engineering Program, Jacobs School of Engineering, University of California, San Diego, La Jolla, CA92093-0418 USA.

measurement showed the fluidic IOL is more robust than a crystalline lens, so post surgery patients are likely to have better vision than before impairment.

II. Structure Design

The fluidic IOL is a disk-like biconvex lens. It consists of two membranes, a support ring as lens holder, and optical fluid (Fig. 2). The circular periphery where the anterior and posterior membranes are joined together forms the equator of the IOL. The diameter of the equator is 12 mm, which is slightly larger than the equator of the capsular bag, the periphery lying between the two layers of the ciliary zonule. When implanted into a natural eye, the fluidic IOL is compressed and fixed by the radial tension. The compression inflates the membranes to form optical power needed to focus on far objects in a relax state.

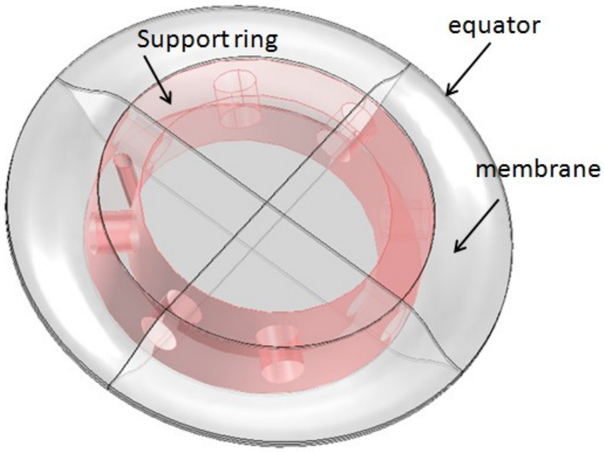

Fig. 2 The structure of fluidic IOL. It is comprised of membranes, support ring and optical fluid. The optical fluid is sealed in the chamber between the membranes.

The membranes are made of Polydimethylsiloxane (PDMS) and its derivatives, and show superior mechanical and optical properties, processibility, and bio-compatability. The membranes are 30 to 50 µm thick and are highly deformable. The membrane/fluid combination is chosen to have no detectable fluid permeation or leakage.

The membrane support ring defines the size of the lens. On the 2mm high side wall of the ring there are 8 through holes connecting the outer reservoir to the lens chamber. A tilted channel, used for injecting optical fluid, connects the inner optical reservoir to the top surface and is angled outward to preserve the integrity of the support ring's inner diameter. The inner and outer diameters of the ring are 6 mm and 8 mm, respectively.

As illustrated in Fig. 2, the optical fluid is sealed inside the chamber by two membranes. To a large extent, the optical fluid determines the IOL's properties such as optical quality, weight, and light transmittance. For aged eyes with thickened capsular bag, a fluid of higher refractive index than the crystalline lens is needed to achieve the desired amount of accommodation. The density of the fluid is another important factor of consideration. A density mismatch between the optical fluid in the IOL and the humor of human eye may result in lens profile distortion and IOL movement in the capsular bag due to the effect of gravity. Therefore, we have chosen a high index (>1.45) optical fluid with a similar density to the humor of a eye as the lens fluid for the IOL.

III. Working Principle

A. Natural eye

During accommodation, the ciliary muscle moves from an unaccommodated state to an accommodated state. This movement decreases tension in the zonules and changes the capsular bag and crystalline lens into a thicker and shorter shape. The change of equatorial diameter of the bag varies from 1 mm for a 21-year old lens to 0.5 mm for a 41-year old lens [12]. The estimated force needed during accommodation is around 6 grams [13].

B. Fluidic IOL

After surgical implantation, the fluidic IOL is placed inside the capsular bag with the equator of the fluidic IOL attached to the capsular bag. To focus on near objects, the capsular bag compresses the equator of fluidic IOL (Fig. 3). This compression forces the optical fluid to move from the outer reservoir to the center lens chamber, which pushes the membranes outward to increase the lens curvature. Conversely, when the ciliary muscle relaxes, the reduced radial tension between the capsular bag and the fluidic IOL decreases the lens curvature and enables the eye to focus on far objects.

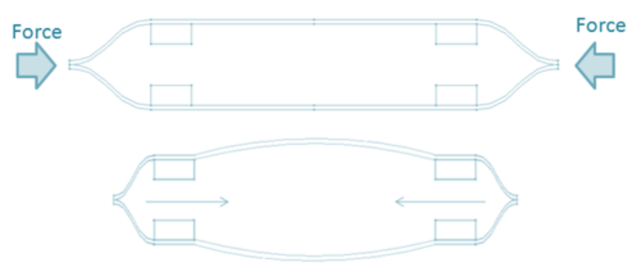

Fig. 3 The working principle of fluidic IOL

IV. Fabrication Process

The fabrication process of an IOL can be divided into four steps (Fig. 4): membrane preparation, support ring preparation, membrane bonding, and fluid filling.

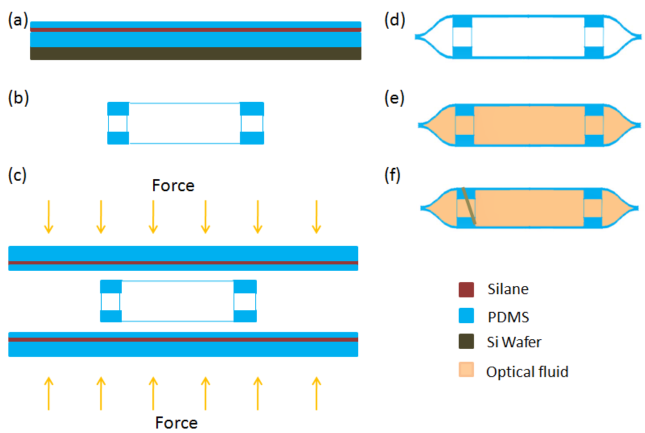

Fig. 4 Fabrication process of a fluidic IOL. (a) membrane preparation; (b) support ring preparation; (c) uniformly force is applied to membranes while bonding; (d) handling layers are peeled off; (e) the device is filled with optical fluid by vacuum; (f) a pin is inserted to seal the IOL

A. Membrane preparation

Considering the limited force provided by the ciliary muscle, a thin elastic membrane is required. To make a smooth membrane of an optical quality surface, uncured PDMS is spun onto a silicon wafer. Desired thickness can be achieved by controlling the spin speed. However, electrostatics makes the thermally cured membrane crumple; hence special care is required to handle the peeled membrane.

As shown in Fig. 4(a), a PDMS (Sylgard 184, Dow Corning) handling layer is formed on a silicon wafer beforehand. Between this handling layer and the thin membrane to be spin-coated later on, a silane coating is employed to create an inert surface, which facilitates membrane peeling after bonding process. The PDMS thin membrane is spun on the silane-treated PDMS/Si wafer at a spinning speed of 1500 rpm for 30 seconds. After placing the sample in a 50 degree Celsius oven for 1 hour, the membrane/handling layer is released from the silicon wafer and diced into 20 mm diameter pieces ready for next steps.

B. Support ring preparation

The support ring is a critical component for IOL. Its circularity affects the optical quality of the lens. Deviation from a circular shape causes astigmatism and degrades the image quality. In addition, the mechanical property of the support ring needs to be meticulously designed so that it can be soft and elastic enough for insertion through a small incision during surgery, and yet, rigid enough not to deform during accommodation.

In order to make a good support ring, an acrylic mold is carefully machined with 25 um precision (Fig. 4 (b)). Prepolymer PDMS mixed at a 1:10 ratio is first poured into the mold. Then the PDMS contained mold is vacuumed in a desiccator for several minutes to remove gas bubbles. After PDMS curing, the PDMS support ring is separated from the acrylic mold. Finally, 8 through holes are formed through the wall of the support ring using needles with 0.8 mm inner diameter and 1.1 mm outer diameter. Another fluid inject channel is carefully drilled through the support ring (see Fig. 2) to form a fluid injection port.

C. Bonding

Two thin membranes and the support ring are UV-ozone treated to activate the surfaces. As shown in Fig. 4 (c), uniform force is applied to sandwich the support ring between the two membranes creating a chamber, as well as to join two membranes along the equator forming a bag. As the force is applied, the device is placed in a 90 degree Celsius oven for at least 8 hours when the membranes are bonded to the top and bottom surfaces of the support ring. After bonding is all completed, the handling layers are peeled off from the two thin membranes (Fig. 4(d)).

D. Filling and sealing

The optical fluid should be filled into the device without leaving bubbles in the chamber (Fig. 4 (e)). To do so, the device is connected to a syringe through the injection channel. The device and the syringe are put in a vacuum chamber during the filling process. When the ambient pressure decreases, the air trapped in the device escapes and the space left is filled with the optical fluid. Finally, the injection channel is tightly sealed with a small pin (Fig. 4(f)).

V. Experiment

The density of the fluidic IOL was 1.12 g/cm^3, similar to the density of aqueous humor and other IOLs [14]. The gravity effect caused by the distortion of the lens membrane is negligible after implantation.

The optical parameters of the fluidic IOL are measured by an optical profiling system (NT1100, Veeco). The mean surface roughness of the fluidic IOL was 2.23 nm, much lower than currently available IOLs [15]. Studies have indicated that a smooth hydrophobic surface can reduce the number of adherent cells and the chance of unexpected inflammatory cell reaction associated with intraocular inflammation [16].

To test the fluidic IOL in conditions that mimic the accommodation process of natural eye, a mechanical actuator was fabricated to produce a similar amount of force and contraction to ciliary muscle. The actuator has a 12 mm diameter cylindrical cavity matching the dimension of the IOL equator to hold the IOL under test. Against the inner wall of the cylindrical cavity of the actuator is a 1.6 mm wide, thin acrylic band. One end of the acrylic band is fixed to the wall of the cavity, and the other end of the band can be pulled to generate a radial compression to the equator of the IOL to change its curvature. This setup simulates the response of the IOL in a capsular bag actuated by ciliary muscle.

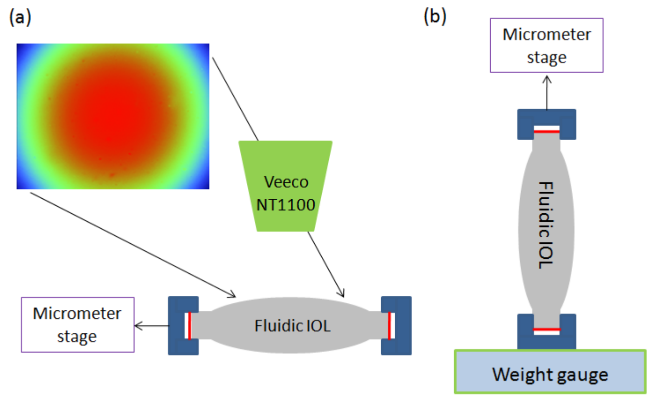

Fig. 5 Schematic diagram of the experimental setup for (a) curvature induced by equatorial diameter changes; (b) force needed for equatorial diameter changes

To measure the accommodation range of the fluidic IOL, a micrometer was connected to the thin acrylic band to obtain the change of the equatorial diameter (Fig. 5). By tuning the micrometer, the band was pulled to a certain distance and the equatorial of the lens was compressed, yielding a larger curvature. The curvature of the lens was measured by an optical profiling system. Results showed the fluidic IOL has a 12 D accommodation amplitude, which corresponds to 0.3 mm displacement of the equatorial radius (Fig. 6). In comparison, the accommodation range obtained from an axial-shift IOL is less than 2.5 D [17]. To our best knowledge, this is the largest accommodation range ever demonstrated for any IOLs. In addition, there is preliminary evidence that the fluidic IOL is more robust than crystalline lens and other IOLs.

The force needed for accommodation of the fluidic IOL has been tested as well. The same lens and the actuator were placed on a strain gauge. The force required to achieve a given amount of equatorial change was measured and plotted in Fig. 6. From Fig. 6, an accommodation range of 12 D can be achieved with 6 grams of force and less than 0.3 mm change in the radius of equator. Both values are consistent with the physiological condition of aged eyes.

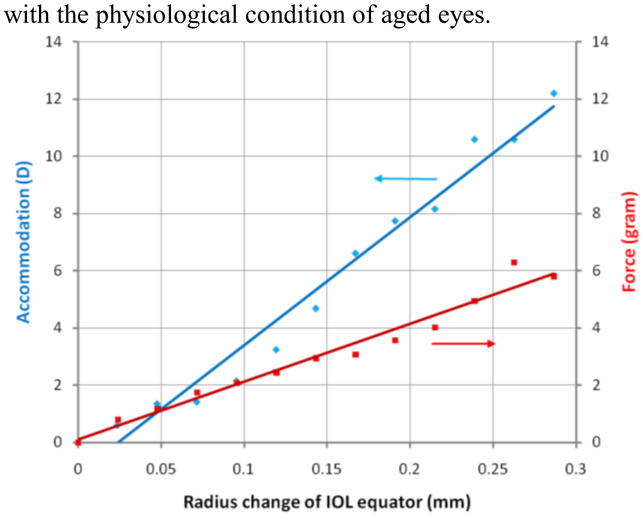

Fig. 6 Force and accommodation as a function of equatorial radius change of the fluidic IOL

VI. Conclusion

An accommodating fluidic IOL has been designed and fabricated. Compared with currently available accommodating IOLs, the fluidic IOL can achieve a much wider accommodation range and holds the promise as the next generation IOL to benefit patients with cataract and other eye diseases.

References

[1] J. S. Cumming, D. M. Colvard, S. J. Dell, J. Doane, I. H. Fine, R. S. Hoffman, M. Packer, and S. G. Slade, "Clinical evaluation of the Crystalens AT-45 accommodating intraocular lens: results of the U.S. Food and Drug Administration clinical trial," *Journal of cataract and refractive surgery*, vol. 32, pp. 812-25, 2006.

[2] A. Galand, "Performance of the 1CU accommodating IOL," *Journal of cataract and refractive surgery*, vol. 32, pp. 3; author reply 3-4, 2006.

[3] H.-M. Pham, T. A. Nguyen, "Accommodating intraocular lens system and method of making same," U.S. Patent 6 818 158, Nov. 16, 2004.

[4] S. D. McLeod, V. Portney, and A. Ting, "A dual optic accommodating foldable intraocular lens," *The British journal of ophthalmology*, vol. 87, pp. 1083-5, 2003.

[5] J. L. Alio, P. Schimchak, H. P. Negri, and R. Montes-Mico, "Crystalline lens optical dysfunction through aging," *Ophthalmology*, vol. 112, pp. 2022-2029, 2005.

[6] A. Duane, "Normal values of the accommodation at all ages," *Journal of the American Medical Association*, vol. 59, pp. 1010-1013, 1912.

[7] F. S. Tsai, S. H. Cho, Y. H. Lo, B. Vasko, and J. Vasko, "Miniaturized universal imaging device using fluidic lens," *Optics Letters*, vol. 33, pp. 291-293, 2008.

[8] D. Y. Zhang, V. Lien, Y. Berdichevsky, J. Choi, and Y. H. Lo, "Fluidic adaptive lens with high focal length tunability," *Applied Physics Letters*, vol. 82, pp. 3171-3172, 2003.

[9] H. W. Ren and S. T. Wu, "Variable-focus liquid lens," *Optics Express*, vol. 15, pp. 5931-5936, 2007.

[10] W. Qiao, F. S. Tsai, S. H. Cho, H. Yan, and Y. H. Lo, "Fluidic intraocular lens with a large accommodation range," *Photonics Technology Letter*, vol. 21, pp. 304-406, 2009.

[11] W. Qiao, F. S. Tsai, S. H. Cho, H. Yan, and Y.-H. Lo, "Tunable Fluidic Intraocular Lens in Human Eye Model," presented at Frontiers in Optics, 2008.

[12] S. A. Strenk, J. L. Semmlow, L. M. Strenk, P. Munoz, J. Gronlund-Jacob, and J. K. DeMarco, "Age-related changes in human ciliary muscle and lens: A magnetic resonance imaging study," *Investigative Ophthalmology & Visual Science*, vol. 40, pp. 1162-1169, 1999.

[13] E. A. Hermans, M. Dubbelman, G. L. van der Heijde, and R. M. Heethaar, "Change in the accommodative force on the lens of the human eye with age," *Vision Research*, vol. 48, pp. 119-126, 2008.

[14] M. Renard, M. Delmelle, and A. Galand, "Buoyancy of Human and Intraocular Lenses in Air and in Aqueous-Humor," *Graefes Archive for Clinical and Experimental Ophthalmology*, vol. 223, pp. 205-206, 1985.

[15] M. Lombardo, M. P. De Santo, G. Lombardo, R. Barberi, and S. Serrao, "Analysis of intraocular lens surface properties with atomic force microscopy," *Journal of Cataract and Refractive Surgery*, vol. 32, pp. 1378-1384, 2006.

[16] T. Tanaka, M. Shigeta, N. Yamakawa, and M. Usui, "Cell adhesion to acrylic intraocular lens associated with lens surface properties," *Journal of Cataract and Refractive Surgery*, vol. 31, pp. 1648-1651, 2005.

[17] S. D. McLeod, L. G. Vargas, V. Portney, and A. Ting, "Synchrony dual-optic accommodating intraocular lens. Part 1: optical and biomechanical principles and design considerations," *Journal of cataract and refractive surgery*, vol. 33, pp. 37-46, 2007.