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Shape optimization of an accommodative intra-ocular lens

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Abstract

Cataract surgery consists in replacing the clouded or opacified crystalline lens by an Intra-Ocular Lens (IOL) having the same mean dioptrical power. Clear vision is then achieved at a given distance and glasses are needed in many situations. A new kind of IOL, potentially accommodative, is proposed. Its design is based on the deep understanding of the accommodation mechanism and on the mathematical modeling and the numerical simulation of the IOL's comportment in vivo. A preliminary version of this IOL is now commercialized by the company HumanOptics under the name '1CU'. In a second phase, shape optimization techniques equipped with strong mechanical and physiological constraints, are used to enhance the IOL performance and build a new design. ***To cite this article: F. Jouve, K. Hanna, C. R. Mecanique 333 (2005).***

Résumé

Optimisation de la forme d'un implant intraoculaire accommodatif. L'opération de la cataracte consiste à remplacer le cristallin naturel devenu opaque par une lentille intraoculaire de même puissance refractive moyenne. Après une telle intervention la vision du patient est nette à une distance fixe et il doit porter des lunettes dans de nombreuses circonstances. Nous proposons un nouvel implant qui permet de préserver au moins en partie sa capacité accommodative. Sa conception repose sur la compréhension des mécanismes de l'accommodation, la modélisation et la simulation numérique du comportement de l'implant in vivo. Une version de cet implant est actuellement fabriquée et commercialisée par la société HumanOptics sous le nom de « 1CU ». Dans une seconde phase, nous décrivons comment les techniques récentes d'optimisation de forme permettent d'améliorer le design initial. ***Pour citer cet article : F. Jouve, K. Hanna, C. R. Mecanique 333 (2005).***

Keywords: Biomechanics; Computational solid mechanics; Shape optimization

Mots-clés : Biomécanique ; Mécanique des solides numérique ; Optimisation de formes

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1. Introduction

This Note is a survey of the successive steps that have been followed to design a new accommodative Intra-Ocular Lens (IOL) for cataract surgery. The classical theory of accommodation is summarized from a mechanical point of view and the cataract surgical techniques are briefly described. Then a mechanical model able to simulate the IOL is proposed. Some clinical studies are cited that demonstrate the clear efficiency of this IOL, although the measured accommodation amplitude is still too small. Finally, up to date shape optimization techniques are introduced to enhance the performances of the initial design.

2. Schematic description of the classical theory of accommodation

From a mechanical point of view, the human crystalline lens can be considered as a thin membrane called *capsular bag* containing a very soft lens. The capsular bag's thickness varies between 5 µm and 20 µm while the central thickness of the total lens is about 4 mm. The mean Young modulus of the capsular bag is roughly 1000 times higher than the Young modulus of the lens (MPa versus kPa, cf. [1,2]). The lens is inhomogeneous and anisotropic. The geometry of the lens and its capsular bag at rest is the 'accommodated' shape, a rounder form adapted to near vision. When the capsular bag is removed, still without external forces, the lens changes its shape to its 'unaccommodated' geometry. Its central part becomes flatter, allowing the eye to focus at far distance [3]. The total system is thus composed of a relatively rigid membrane, containing a much softer material with a *shape disparity*. At rest, the system is pre-stressed and the reference configuration is not a natural state. This pre-stressed character allows the lens to change its geometry up to the unaccommodated state very easily. Moreover, this movement is achieved with small and 'approximative' applied forces: a generic radial traction on the capsular bag is enough to relax the capsular bag tensions and allow the interior part of the lens to reach its own natural state, precisely the unaccommodated state. An homogeneous elastic solid would need much more precision in the forces distribution and directions to control it toward a given geometry. The natural crystalline lens is thus designed to have the apparent comportment of a smart material with shape memory.

The *ciliary muscle* is a part of the *ciliary body*, a wedge-shaped collar anchored to sclera. The lens is suspended to a series of tiny fibers, called *zonular fibers*, attached to the ciliary body. The principle of the accommodation mechanism have been formulated by Von Helmholtz in 1855 [4]: the contraction of the ciliary muscle relaxes the tensions in the zonular fibers and the lens recovers its rounder equilibrium state (accommodated shape). When the ciliary muscle relaxes, it pulls on the suspensory ligaments and on the capsule around its equator, allowing the interior lens to recover its own, flatter, reference state (unaccommodated shape), cf. Fig. 1.

Few quantitative data are available on the forces involved in the accommodation mechanism. The global traction, integrated over all the ciliary muscle and indirectly measured in vitro, is of the order of 10^{-2} N (cf. [5]). This rough estimate does not say anything about the directions and local intensities of the forces, but it will be useful to check whether an IOL is likely to be moved by the forces present in vivo.

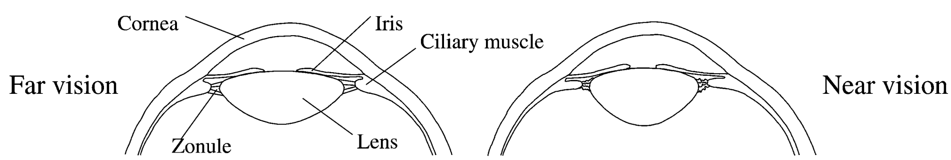


Fig. 1. Classical theory of accommodation: relaxed ciliary muscle and stretched zonule adapted to far vision (left); contracted ciliary muscle and relaxed zonule adapted to near vision (right).

3. Cataract surgery

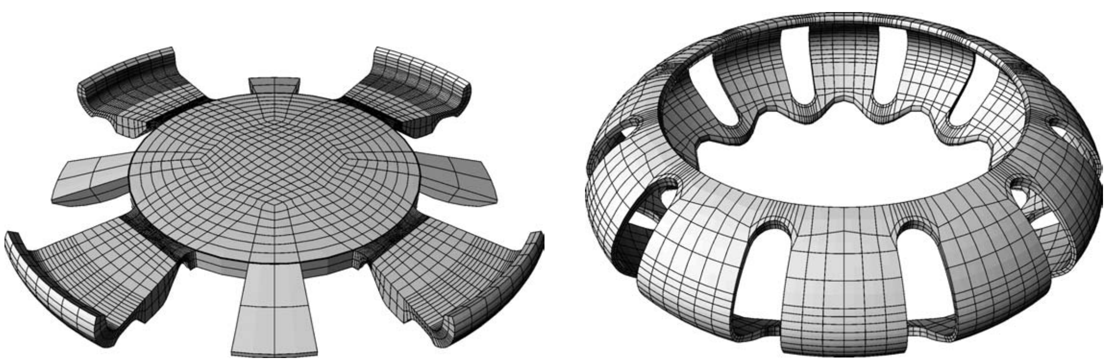
A cataract is a cloudiness or an opacity of the lens. It is the leading cause of blindness worldwide (16 million cases of blindness in 1997 due to cataracts). More than half the people over the age of 65 have some degree of cataract. Most of the time, this is easily treated by surgery, at least in rich countries. Modern surgical techniques involve a small incision (3 mm) made at the periphery of the cornea to insert the surgical tools. A circular cut is made on the capsular bag (*capsulorhexis*), the lens material is emulsified by an ultrasonic handpiece (*phacoemulsification*), aspired and replaced by an IOL of equivalent refractive power. Most of the IOLs are implanted into the capsular bag which remains partially intact after surgery, as well as the rest of the accommodative apparatus (ciliary body and zonule). A traditional IOL is made of PMMA or acrylic. Its refractive power is fixed and clear vision occurs at a given distance. The patient have to wear glasses to focus at different distances.

The goal of this paper is to briefly describe the conception of an accommodative IOL that uses the mechanical action of the ciliary muscle and the zonule to change the refractive power of the eye.

4. Conception of a potentially accommodative IOL

An IOL having an active accommodative capability, i.e. changing the total refractive power of the eye under the action of the ciliary muscle, can be designed using two different principles: (i) it can be a soft lens that is adequately deformed by the zonular fibers action, changing precisely its radii of curvature and thus its own refractive power just like the natural crystalline lens; or (ii) one (or more) rigid lens – with fixed power – moving back and forth along the visual axis. Our IOL belongs to the latter category, as well as all the other existing accommodative IOLs. A calculation with a simple optical model of the eye, such as Gullstrand's model [4], shows that a translation of 1 mm of the lens forwards leads to an accommodation between $+1.2$ Dioptres (D) and $+2$ D. A good comfort of vision is assumed if the total accommodative amplitude is at least 2.5 D, allowing the eye to focus between 40 cm and $+\infty$.

The basic principle of the proposed IOL design is to mimic the natural accommodation mechanism. Our IOL is made of two parts, with a shape disparity between the components to help the system jump smoothly from one position to another. The shape disparity consists of an inner part – supporting the potentially moving optics – having a total diameter larger than the outer part (cf. Fig. 2). This first IOL has been elaborated using successive direct numerical simulations of various candidate designs.



(a) (b)

Fig. 2. Two-components IOL: (a) mesh of the mobile part including the optics and the 4 haptics; (b) the envelope which is in contact with the capsular bag. At rest, the diameter of (b) is smaller than the diameter of the inner part (a).

Two main difficulties arise in the modelling: first, the external forces transmitted to the IOL through the perforated capsular bag are far from being known; second, the numerical simulation of a two-components nonlinear elastic system, with a shape disparity and a contact condition between the components, is not easy to handle.

These two difficulties can be alleviated using the following assumption that leads to an approximate model of the IOL in vivo: since the inner part supporting the optics (Fig. 2(a)) is in contact with the envelope (Fig. 2(b)) through four 'legs' or *haptics*, the contact zone can be roughly guessed. We assume that the global geometry of the contact zone is not modified when the system is deformed, i.e. the extremities of the haptics are not deformed but rather are submitted to a rigid displacement. It is a reasonable approximation since they are very rigid, compared to other regions of the system. It allows us to replace the difficult simulation of the assembled system by two series of independent computations on each subdomain. A one-side contact condition is imposed on each domain and the global position of the system is parameterized with one variable: the total diameter of the IOL. The deformation state of each part is computed for discrete values of this parameter in a given interval (the lower bound corresponds to the reference configuration of the outer part, the upper bound to the reference configuration of the inner part). Large displacements are involved and nonlinear elasticity is used with a St Venant Kirchhoff constitutive law for the material (acrylic). Ω_1 and Ω_2 denote the two components of the IOL, Γ_1^c and Γ_2^c are the two parts of the boundary that can potentially be in contact, and S_λ is a function characterizing the contact surface ($x \in \Gamma_k^c \Rightarrow S_\lambda(x) = 0$). It is parameterized by a real number λ. In our case, S_λ defines a torus of major radius λ because the cross-section of the contact zone is a portion of circle (Fig. 4). If u is the displacement field and $W(I + \nabla u)$ the stored energy function of the hyperelastic material, for a given value of λ we can solve, independently for $k \in \{1, 2\}$, the following minimization problems, where the one-side contact condition have been penalized using a small parameter ε and $(\cdot)^+$ denotes the positive part:

$$I_{\lambda,k} = \inf_{u_{\lambda,k} \in H^1(\Omega_k)} \left\{ \int_{\Omega_k} W(I + \nabla u_{\lambda,k})\,\mathrm{d}x + \frac{1}{\varepsilon} \int_{\Gamma_k^c} \left((-1)^k S_\lambda\big(x + u_{\lambda,k}(x)\big)\right)^+ \mathrm{d}s \right\}$$

Summing the elastic energies obtained in the two domains for each value of λ in a given interval leads to a graph like Fig. 3, where the minimum of the total energy of the system is reached at the equilibrium position of the assembled IOL without applied forces (Fig. 4(a)). The difference between the minimal energy and the energy associated to a given position is the energy needed to move from equilibrium to this position. It can be compared to the energy computed using the rough estimate of the ciliary muscle forces found in [5]. It is thus possible to check if the IOL can potentially be actioned by the ciliary muscle.

In the proposed design, various thicknesses are adjusted so that the equilibrium of the system is close to the reference configuration of the optical part. The envelope has a physiological role too: it maintains the capsular bag in a position close to its shape in the natural lens, avoiding the fibrosis phenomenon (a strong shrink and hardening of the capsular bag) that would ruin all accommodation possibilities.

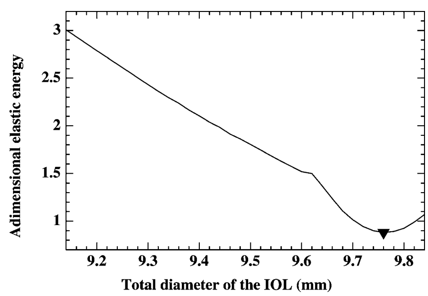


Fig. 3. Two-components IOL: elastic energy of the assembled system function of the total IOL's diameter. Equilibrium is reached when the inner part supporting the optics is close to its reference configuration (unaccommodated state).

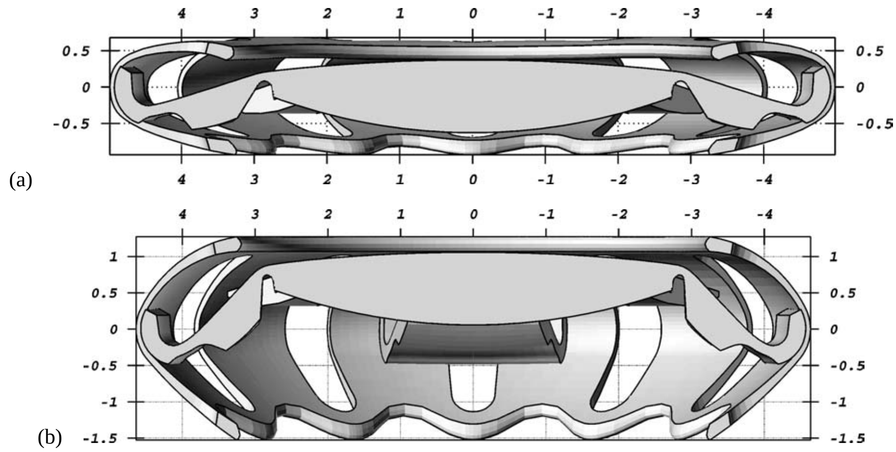


Fig. 4. Cross-section of the two-components IOL: (a) equilibrium position after assembly without applied forces (unaccommodated state); (b) accommodated state.

5. The 1CU

Unfortunately, it has not been possible to manufacture the envelope (Fig. 2(b)) with a good geometrical precision at a reasonable cost. The optical part of the above IOL – hardly modified – have been experimentally implanted *alone* for the first time in June 2000. Since the first clinical studies were very encouraging, this one-component IOL is now commercialized under the name of '1CU' (*I see you*) and has been implanted more than 20 000 times between 2000 and 2004. Clinical studies (for example [6,7]) report that the observed accommodation amplitudes, 6 months after the operation, range from 0.5 D to 2.75 D, with a mean value between 1.7 D and 1.9 D. It may be considered as a good step forward, but still not sufficient for many patients to avoid glasses. It demonstrates the validity of our approach but calls for a new version of the IOL, with increased accommodative capabilities.

6. A new enhanced design

The first version of the 1CU have provided important informations about the comportment in vivo of an accommodative IOL. They can be exploited to enhance the design of the existing 1CU, or to develop new designs. Shape optimization techniques, like the homogenization method [8,9] and the level set method [10], have proved to be very efficient tools to replace the old-style manual 'trial and error' optimization. However, they can have some limitations if a complex modelling is needed, or in presence of strong and hardly quantifiable manufacturing and physiological constraints, like those we are facing in this study. The homogenization method is a true topology optimization method, with rigorous convergence and stability results, but it is limited to linearized elasticity. The level set method is based on the shape sensitivity analysis. It carries part of the flaws of this classical technique, except the numerical instabilities caused by remeshing since the shapes are captured on fixed meshes and described by the zero level set of a scalar field. However, it shares with the classical boundary variation methods many advantages, including their ability to handle complex physical models like nonlinear elasticity. Both of these methods have been applied to the IOL problem. If Ω is the computational domain and $\chi \in L^\infty(\Omega; \{0,1\})$ a characteristic function, a shape is defined as the set $\{x \in \Omega;\ \chi(x) = 1\}$. In the context of IOL optimization, a typical (cf. [11]) objective function to minimize over all the characteristic functions χ is

$$J(\chi) = \int_\Omega \chi(x) C(x) \left|u(x) - u_0(x)\right|^2 \mathrm{d}x$$

where u is a displacement field solution of the – linearized or nonlinear – elasticity system modeling the direct problem, u_0 is a given target displacement and $C(x)$ is a given non-negative weighting factor. If the goal is to maximize the axial displacement of the lens in the x_3 direction, when the haptics are submitted to radial forces in the (x_1, x_2) plane, $C(x)$ will be non-zero only in the central part of the optics, and $u_0 = (0, 0, U)$ with U a large enough positive number.

Since the solutions given by the shape optimization algorithms cannot verify all the constraints involved in the IOL optimization, they are used as preliminary computations to give a rough idea of what kind of design could be efficient. They have then to be 'cleaned', sometimes simplified, through 'manual' expertise, and submitted again to more precise direct numerical computations.

This procedure have been recently applied with success. A new design is about to be finalized following these computations. The mechanical principle used to move the lens is slightly different from the 1CU and its accommodative amplitude could be up to 30% wider under the same external loadings, according to our simulations. It cannot yet be shown here for commercial confidentiality reasons.

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