

The AkkoLens Accommodating Intraocular Lens

a report by

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Cataracts cloud the natural lens and eventually make sufferers blind. Every year over 10 million people have surgery to replace their lenses as a result of cataracts, and the number of cases is increasing by approximately 15% each year, in step with aging populations. In a simple, 20-minute outpatient surgery, the original lens is replaced by an intraocular lens (IOL) made of plastic, and sight is almost miraculously restored. However, unlike the natural lens, the IOL cannot be voluntarily brought into focus; while patients can see perfectly in the distance, they must wear glasses to read. The 'holy grail' of IOL development has always been a lens that can both restore sight and allow the patient to focus without glasses: an accommodating intraocular lens (AIOL).

Presbyopia is a condition in which billions of people lose their ability to focus on nearby objects (such as computer screens or newspapers). Most sufferers are over the age of 40 years. With cataracts, lens replacement is required to restore sight; with presbyopia, lens replacement is an option rather than a necessity. For cataracts, the modern-day monofocal IOL is a simple and safe solution to the catastrophe of blindness; an IOL that accommodates would be a wonderful bonus. For presbyopes, however, there is absolutely no point in removing a healthy but inadequate natural lens by clear lens extraction if it cannot be replaced by a far superior IOL that accommodates. A truly accommodating IOL would improve treatment for cataracts and offer the possibility of restoring focal accommodation to presbyopes. Once an AIOL has been proved to work in cataract patients, the potential for treating presbyopes will represent a potentially vast unexploited opportunity in the healthcare market. Consequently, AIOLs are being pursued intensely by both academia and industry.



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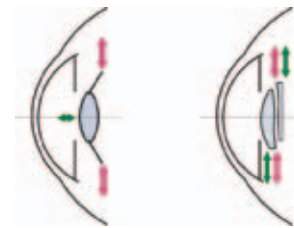
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Figure 1: Comparison of Current and AkkoLens Accommodating Intraocular Lenses



Current accommodating intraocular lenses (AIOLs) (left) are moved along the optical axis (green) by the ciliary muscle (red); the AkkoLens AIOL (right) uses the same muscle, but is moved perpendicularly.

One approach to 'accommodation' taken by some companies is the multifocal lens. However, this does not truly accommodate, but rather presents the eye with multiple focused images from various distances simultaneously. Multifocal IOLs share several advantages with standard monofocal IOLs, such as fixed positioning in the eye and alignment using proven surgical procedures. However, multifocal IOLs improve uncorrected near vision at the expense of overall sharpness, and also significantly reduce contrast.

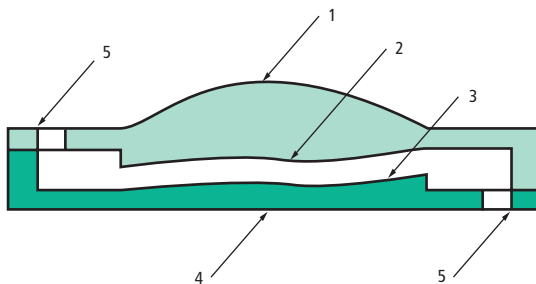
In order to restore sight and allow patients to focus without glasses, the lens has to move or change its refraction index. Most of the designs to date have achieved some limited lens movement along the optical axis, allowing focal change over a short distance—perhaps 0.5–1 diopter (D). The AkkoLens solves this problem with a unique design that magnifies the focal change by moving perpendicularly to the optical axis, resulting in true and clear spectacle-free vision (see Figure 1).

The Design of Accommodating Intraocular Lenses

The pseudophakic eye (an eye with an IOL implant) can achieve limited accommodation by shifting a single lens along the optical axis. Most current AIOL designs are based on this type of shift, which alters the overall refractive power of the eye to produce a variable focal plane. However, the magnitude of movement is relatively small, resulting in accommodation of <0.5D in most patients and up to 1D at best.^{1,2} In order to be able to read clearly, approximately 3D of accommodation is required. Most current lens designs require more ciliary movement than actually occurs (as shown in recent ultrasound studies³) and, possibly, more space in the eye than is actually available. In effect, the ciliary muscle works properly, but current lens designs do not translate such movement into a sufficient change in optical power. For example, in theory a 1mm movement along the optical axis of a 19D IOL will produce a change in optical power of <1.2D,¹ while a highly unlikely shift of >2mm is required

Figure 2: AkkoLens Accommodating Intraocular Lenses

Clear (left) and with a blue blocking filter (right). Note the stripes at the rim of the optics, which assist quality control during manufacturing, positioning during surgery, and evaluation of accommodation once in the eye.

Figure 3: Schematic Representation (side view) of the Basic AkkoLens Accommodating Intraocular Lens

1. Spherical lens to correct the overall refraction of the eye. 2. First cubic surface for varifocal effect. 3. Second cubic surface. 4. Flat posterior surface. 5. The haptics.

to produce 3D accommodation.² The addition of a second lens at a distance of, say, 2–3mm from the first lens increases the hypothetical range; for example, an IOL with a 32D posterior lens shifted 1mm forwards can achieve <math><2.6D</math>.¹ Continuous very precise alignment of both lenses relative to the optical axis is necessary to prevent undesired aberrations. However, in practice, and as measured in actual human eyes, single-optic AIOLs move only <math><0.5mm</math>^{4,5}—not significantly different from the movements observed in standard, non-accommodating IOLs³—which significantly reduces the accommodation that can be achieved by these lenses to approximately 0.5D.

When accommodating, the elastic natural lens flattens due to the stretching of the capsular bag that envelops the lens; this stretching is caused by the relaxation of the ciliary muscle. The eye is focused at a distance. When the ciliary muscle contracts, the capsular bag relaxes, the natural lens regains its natural, more spherical, shape, and the eye becomes focused nearby, for example at reading distance. The natural lens in humans is extremely efficient at converting small movements of approximately 0.5mm of the ciliary muscle⁶ into large changes in focal length. In current single-optic AIOLs, these small ciliary movements are converted mechanically by hinges into even smaller lens movements along the optical axis (see *Figure 1*, left image), producing little change in focal length. In contrast, the AkkoLens AIOL yields large variations in

optical power from tiny movements by using unique cubic optical elements. It has two optical elements that move relative to each other perpendicularly to the optical axis, in the same plane as the movement of the ciliary muscle (see *Figure 1*, right image). Based on successful results over the past two years—which are detailed below—AkkoLens International will be in clinical trials in 2008 with true pseudophakic AIOL (see *Figure 2*) for cataracts and, later, for presbyopia.

The AkkoLens Accommodating Intraocular Lens

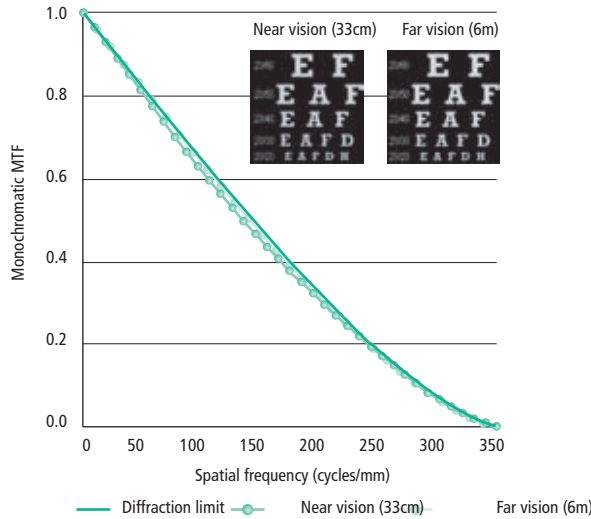
The AkkoLens AIOL is based on cubic optical elements^{7,8} that are fitted by spring-like haptics fused at the rim to allow movement.

Optics and Haptics

The AkkoLens AIOL has, in its basic configuration, an anterior element with a spherical lens to correct the overall refraction of the eye, and a cubic optical surface for varifocal effect. The posterior element carries the second cubic surface (see *Figure 3*).

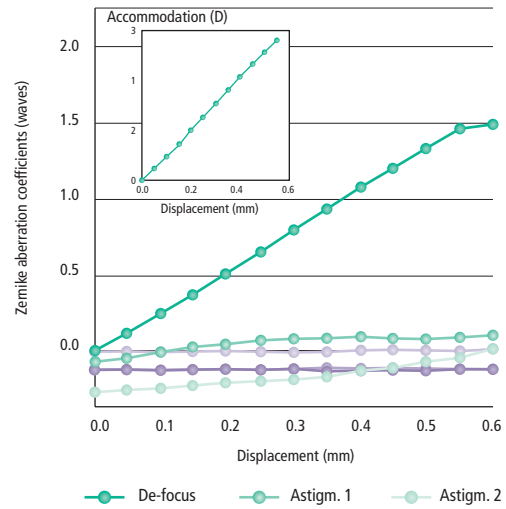
In computer simulations, the optics of the AIOL perform close to its theoretical diffraction limit (see *Figure 4*), and the optics and the sensitivity to tilt are comparable to those of standard monofocal IOLs. In practice on the optical bench, undesired aberrations were virtually absent over the complete range of accommodation (see *Figure 5*). As discussed above, in order to read clearly approximately 3D of accommodation is required. To be sure of achieving 3D in the eye, the AkkoLens AIOL is designed to provide accommodation of 5–6D, leaving a substantial ‘buffer’ for variations in practice. If required, accommodation of 8–10D can be obtained without reducing optical quality. In addition, the AkkoLens AIOL can correct spherical aberrations, astigmatisms, comas, and higher order aberrations, for example those caused by the cornea. Uniquely, the AkkoLens AIOL can correct ‘variable aberrations’ of the eye—i.e. those aberrations, for example astigmatism,⁹ that vary in severity with the degree of contraction of the ciliary muscle. The correction of variable aberrations is an as yet unexplored niche market. The haptics, which hold the lens within the lens capsule, comprise an elastic component for movement and a rim. The rim covers approximately half the circumference of the capsular bag, thus ensuring an even distribution of pressure (see *Figure 6*).

Figure 4: Optical Performance of the AkkoLens Accommodating Intraocular Lens—Spatial Frequency



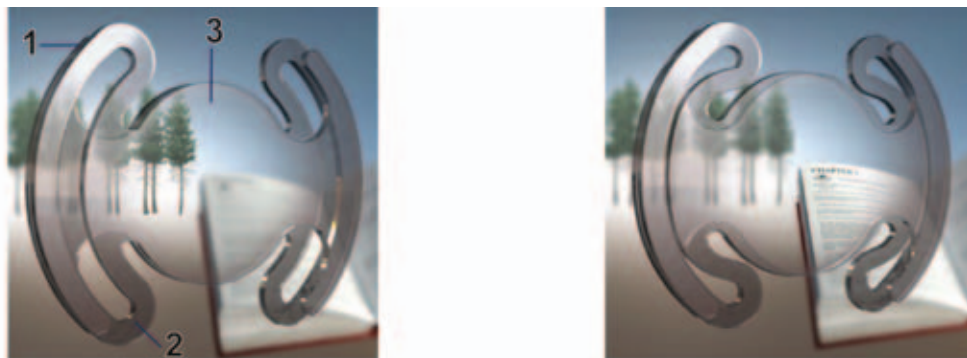
In computer simulations, the AkkoLens accommodating intraocular lens performs close to its theoretical diffraction limit, resulting in high optical quality both nearby and at a distance (inset).

Figure 5: Optical Performance of the AkkoLens Accommodating Intraocular Len—As Measured on the Optical Bench



Optical power ('de-focus') increases during the movement of the optical elements, while undesired aberrations remain negligible over the complete range.

Figure 6: The AkkoLens Accommodating Intraocular Lens in the Unaccommodated State (left) and During Accommodation (right)



1. The rim of the haptic. 2. The elastic section of the haptic. 3. The optics.

Materials and Manufacturing

The AkkoLens AIOL is manufactured by conventional lathing and milling of standard hydrophilic acrylate materials. The haptics are fused at their rims for alignment and stability of construction. The cubic optical surfaces were visualized using interferometry, and the final manufactured product conformed well with the simulated design (see Figure 7). A computer program driving manufacturing machines was developed to customize AIOLs for individual eyes using standard information on required optics—such as axial length and lens thickness—as well as information on required dimensions as measured by partial coherence interference or ultrasound.

Pre-clinical Trials

The performance of the AkkoLens AIOL was studied in artificial capsular bags, as well as in rabbit eyes.^{10,11} The optical elements remain well aligned during simulated accommodation in the artificial capsular bag (see Figure 8). The lens, made of hydrophilic acrylate, is fully biocompatible, with virtually no incidence of posterior capsular opacification (PCO) even after 10 months in rabbit eyes (see Figure 9).

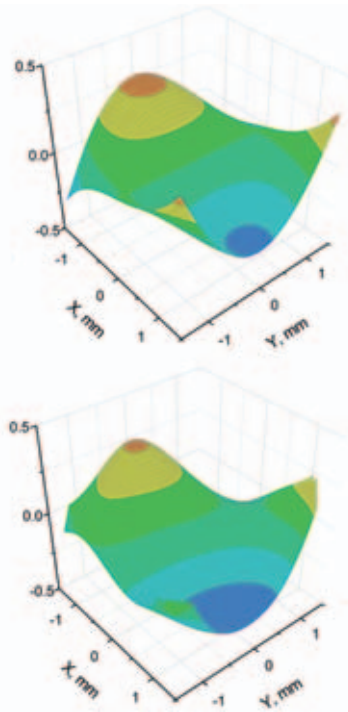
Surgical Measurements and Procedures

Before surgery, the refractive power of the eye must be measured by standard optical techniques to determine the power of the lens. In addition, dimensions inside the eye such as the inter-ciliary or inter-sulcus distance must be measured by, for example, ultrasound biomicroscopy or anterior segment optical coherence tomography (OCT) for proper sizing of the AIOL.

The implantation of the AkkoLens AIOL in the eye follows well-established procedures for cataract surgery. A proprietary disposable injector with an adapted butterfly cartridge is already available. Specially designed proprietary AIOLs for sulcus implantation have been developed to avoid the undesirable effects of capsular bag shrinkage and stiffening of the capsular bag.

Post-operative care is unlikely to differ from that currently given to those with standard monofocal IOLs. PCO, although thus far not observed in animal trials, is likely to be treatable by standard yttrium aluminum garnet (YAG) laser procedures when it occurs in humans.

Figure 7: Wave Front of an AkkoLens Accommodating Intraocular Lens Manufactured Cubic Element



Respective design (left) and measured by interferometry (right). This also illustrates the basic shape of a cubic surface.

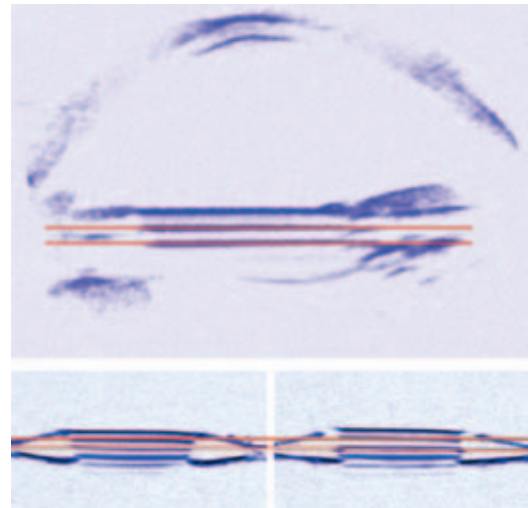
In a recent review, Findl and Leydolt found that the efficacy of AIOLs has generally been evaluated by reading charts. They conclude: "Psychophysical evaluation of true pseudophakic accommodation by optic shift of an accommodating IOL is therefore problematic since outcomes are mainly dependent on pseudo-accommodation. Thus, the need for a biometric method that assesses IOL shift during ciliary muscle contraction is obvious."²

AkkoLens plans to evaluate the efficacy of its AIOL in humans using advanced aberrometers specifically adapted for the measurement of accommodation, in combination with ultrasound measurements of the movement of optical elements. This should provide a true objective measurement of lens performance. AkkoLens plans to begin human trials in early 2008. ■

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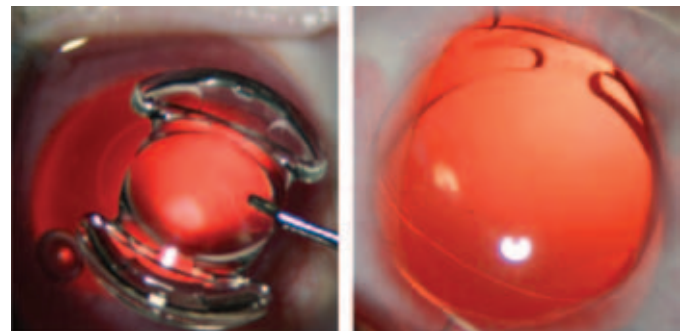
AkkoLens International is a medical device start-up company based in The Netherlands that develops ophthalmic products, including

Figure 8: Ultrasound Images of the AkkoLens Accommodating Intraocular Lens



Taken after 10 months in a rabbit eye (top) and during simulated accommodation in an artificial capsular bag (bottom: left = accommodated; right = unaccommodated). Red lines indicate positioning of optical elements. Courtesy of Dr O Stachs, University of Rostock.

Figure 9: The AkkoLens Accommodating Intraocular Lens Prior to Implantation in a Rabbit Eye (left) and After 10 Months in the Same Rabbit Eye (right)



Courtesy of Dr O Stachs, University of Rostock.

the AIOL described in this article (for further information visit www.akkolens.com). AkkoLens holds a number of patents on ocular optics and surgical equipment. It develops its products in close collaboration with various technology and medical partners in Europe and abroad.

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