Intraocular Lenses for Restoring Accommodation: Hope and Reality

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One of the most challenging tasks of modern cataract and refractive surgery is restoration of the accommodative ability in pseudophakic patients. Various attempts have been made to solve the problem of presbyopia after cataract or refractive lens exchange surgery, enabling patients to have satisfactory distance and near vision without spectacles. One example is multifocal intraocular lenses (IOL) that provide improved uncorrected near vision, but at the expense of reduced contrast sensitivity and disturbing optical phenomena. Another attempt is refilling the capsule bag with an elastic copolymer, named lens refilling or "phakoversatz," but this remains experimental and is confronted with problems such as compromised optical quality and posterior capsule opacification. A third attempt to restore accommodation has been the introduction of accommodating IOLs. Several manufacturers have launched products within the past 5 years. The accommodating IOLs currently available are designed to transform forces of the ciliary muscle into a forward movement of the IOL optic (optic-shift concept) by anterior flexing of the optic in relation to the haptics. A prerequisite for the performance of accommodating IOLs is a functioning ciliary muscle in the presbyopic eye. Evidence from magnetic resonance and ultrasound biomicroscope studies show that the ciliary muscle continues to contract as individuals age, but the amplitude of the ciliary muscle apex movement under contraction seems to be smaller than in the young eye.

A forward shift of a single IOL optic induces an increase in overall refractive power of the eye; a shift of approximately 0.60 mm would cause 1.0 diopter (D) of accommodation in the spectacle plane for an eye of normal dimensions. To attain an accommodative amplitude of 3.0 D to enable reading at the customary distance of 33 cm (13 in), an IOL movement of 1.8 mm is needed. This amount of shift seems unrealistic in a pseudophakic eye, considering that the IOL optic would need to strongly anteriorly displace the iris. On the other hand, an accommodative effect of an IOL by movement of the optic would be supported by the apparent accommodation, which is determined by the depth of focus of the eye, which is always present. The amplitude of apparent accommodation is in the order of 1.0 to 2.0 D depending on which method of assessment is used. Therefore, if an "accommodative" IOL would cause at least 1.0 D of true pseudophakic accommodation by moving at least 0.6 mm, then most patients should be able to read without near spectacle addition.

Unfortunately, the evidence that accommodating IOLs work is still sparse.

APPARENT ACCOMMODATION AND DEPTH OF FOCUS

Several factors such as small pupil size, myopic astigmatism, corneal aberrations, corneal multifocality, and good visual perception allow some pseudophakic patients to have an adequate depth of focus, so they can reach satisfying far and near visual acuity without any correction. This clinical phenomenon is referred to as apparent accommodation or pseudoaccommodation, and varies greatly among patients. Apparent accommodation causes subjective tests such as the push-up method to overestimate accommodative amplitude when compared to objective measurements. However, it has been difficult to achieve reproducible objective measurements of refraction and its change with attempted accommodation in pseudophakic eyes using automated photorefractometry due to the bright Purkinje reflexes and small pupil size.

Therefore, most clinical studies use psychophysical methods such as near visual acuity with distance spectacle correction for assessing the accommodative effect of accommodating IOLs. Patient compliance and observer bias are confounding factors in such subjective

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testing. Differences in optotype size among different reading charts makes comparisons among studies difficult. For these reasons, psychophysical assessment is not adequate to prove that an IOL actually causes accommodation. Biometric measurement of the change in IOL position is the most direct way of proving that an IOL has accommodative potential.

**BIOMETRIC MEASUREMENT OF IOL OPTIC MOVEMENT**

In the January/February 2005 issue of the *Journal of Refractive Surgery*, Stach et al. evaluated four patients with an accommodating IOL using a dedicated three-dimensional ultrasound biomicroscope setup. Pilocarpine and cyclopentolate eye drops were used to stimulate and relax the ciliary muscle, respectively. Measurements showed minimal optic shift and change in haptic angulation. These results are consistent with other biometric studies using partial coherence interferometry. But a paradox exists: the biometric data that show minimal IOL shift in most eyes do not explain the exceptionally good near visual function found in some clinical studies. How can we explain the discrepancy between minimal IOL shift in biometric studies and good near acuity in clinical studies?

There are two possibilities. 1) The apparent accommodation predominantly determines the near vision ability and the IOL shift adds little to this effect. Factors such as highly selective inclusion criteria, high patient- and/or examiner-motivation, and “optimized” near acuity testing conditions can improve the outcome, namely good reading acuity. Therefore, a prospective randomized clinical trial with a control group with standard multifocal IOLs, masked observers measuring the visual function, and a sufficient number of patients to achieve statistical power is mandatory for a study with near visual acuity as the main outcome measure.

2) The other possibility is that the stimulus conditions during biometric measurements are less effective than under actual reading conditions. Maintaining near-point induced accommodation during biometric measurements is difficult, especially for elderly pseudophakic patients. Therefore, most studies use pilocarpine as the stimulus for ciliary muscle contraction, and cyclopentolate as the stimulus for ciliary muscle relaxation; the difference between IOL position under maximum stimulation and relaxation of the ciliary muscle is this maximum amplitude of IOL movement—an indicator of the accommodative potential of an IOL design. Although it is possible that pilocarpine is an insufficient stimulus and not comparable to near-point stimulated ciliary muscle contraction that occurs when a person attempts to read, comparison of pilocarpine stimulation with near-point stimulation in phakic eyes has shown that pilocarpine seems to be a superstimulus in humans and monkeys. Therefore, we may be overestimating pseudophakic accommodation when assessing IOL shift under pilocarpine stimulation.

The paradox persists. It is still not clear why the biometric outcomes differ from the clinical near acuity outcomes. The most likely explanation is that the non-controlled studies of near visual acuity assess primarily apparent accommodation and not the actual effect of the accommodating IOL.

**COMPROMISED CAPSULE BAG PERFORMANCE**

Current accommodating IOLs are made of well-known materials, but have an altered haptic design compared to conventional open loop or plate haptics, which are intended to allow optic movement during ciliary muscle contraction. Such design alterations also carry the risk of a compromised capsule bag performance by deviating from the well-tested conventional IOL designs. Therefore, meticulous evaluation of the safety of such new IOLs is of clinical importance. The main variables concerning capsule bag performance are lens centration and tilt, resulting from fibrotic changes of the capsule and posterior capsule opacification.

From clinical data with the accommodating IOLs currently available, posterior capsule opacification seems to be significantly increased compared to modern hydrophobic, sharp optic edge IOLs, resulting in Nd:YAG capsulotomy rates of ≥40% 2 years after surgery. Also, haptic infolding with resulting optic tilt and axial displacement has necessitated IOL explantation in a few cases. Overall, the capsule bag performance of the accommodating IOLs seems to be worse than that of the standard IOLs.

**THE FUTURE OF IOLs**

A widespread and strong interest in accommodating IOLs is present among cataract and refractive surgeons, as illustrated by the most recent American Society of Cataract and Refractive Surgery survey of practice styles and preferences. Clinical studies are needed to evaluate the action method of these IOLs. The study design should incorporate objective methods of assessment of IOL position. If this is not possible and psychophysical methods are used, the studies should be performed in a prospective, randomized trial with examiner masking with a control group of age- and sex-matched patients with normal retinal and corneal function who receive standard multifocal IOLs. This would reduce the risk of selection and evaluation bias.

Concerning new approaches, it will be interesting...
to see how the new dual-optic IOL designs perform, because theoretically they need much less IOL shift to result in the accommodative amplitude necessary for reading without near addition.

REFERENCES