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Accommodative intraocular lenses: Short-term visual results of two different lens types

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PURPOSE. *To compare the ability of two types of accommodative intraocular lenses (IOLs) to provide uncorrected near and distance visual acuity (VA) after cataract surgery.*
METHODS. *A total of 108 eyes of 75 patients underwent cataract surgery by phacoemulsification and IOL implantation either bilaterally or monocularly with one of two types of accommodative IOLs: the AT-45 lens (69 eyes) or the 1-CU lens (39 eyes). Patients were followed for up to 1 year after cataract surgery. Near VA was measured through the distance correction to obtain the true near vision effect of the accommodating IOL.*
RESULTS. *Uncorrected distance VA of 20/30 or better was achieved by 84.6% of the bilaterally implanted 1-CU patients and 73.6% of the bilaterally implanted AT-45 IOL patients 1 year following surgery. Uncorrected near VA of J1 or better was achieved by 42% of the patients with the bilateral 1-CU implant and 36.8% of the patients with the bilateral AT-45 implant. For J3 or better near acuity, the values were 92.3% for the bilateral 1-CU patients and 84.2% for the bilateral AT-45 patients at 1 year. A total of 54% of the eyes with 1-CU implants underwent a mild myopic shift (<1.0 D), 21% had a mild hyperopic shift, and 45% of the eyes were emmetropic at 1 year.*
CONCLUSIONS. *Both accommodative IOLs provided good near and distance vision postoperatively. The 1-CU IOL appears clinically to provide slightly better uncorrected distance and distance-corrected near VA than the AT-45 lens. (Eur J Ophthalmol 2006; 15: 33-9)*

KEY WORDS. *Accommodating IOL, AT-45, Crystalens, 1-CU IOL*

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INTRODUCTION

Patients usually achieve a predictable refraction and excellent uncorrected distance visual acuity (VA) following modern cataract surgery, mostly due to precise intraocular lens (IOL) power calculations and intra- or postoperative correction of astigmatism. However, because most cataract surgery patients are presbyopic, good near and intermediate vision cannot be achieved without spectacles. Presbyopia results from age-related optical and physical changes in the crystalline lens that lead to the loss of accommodative amplitude (1, 2). At age 8, the average amplitude of accommodation is 14.0 to 16.0 diopters. By age 56, it has dropped to 2.0 ± 1.0 D and, by age 60, it is 1.5 D ± 1.0 D (3).

This near vision problem has only partly been solved by the use of multifocal IOLs, which have zones of different refractive power within the same optic plate to allow vision at varying distances (4-9). Loss of contrast sensitivity at low-light levels with these lenses remains a source of concern (10). An alternative approach to multifocal lenses is a monofocal accommodative IOL, implanted in the posterior chamber to increase the patient's reduced accommodative ability (11-16). This approach relies on the demonstrated ability of the ciliary muscle to retain its function through 80 years of age (17, 18). Small contractions of

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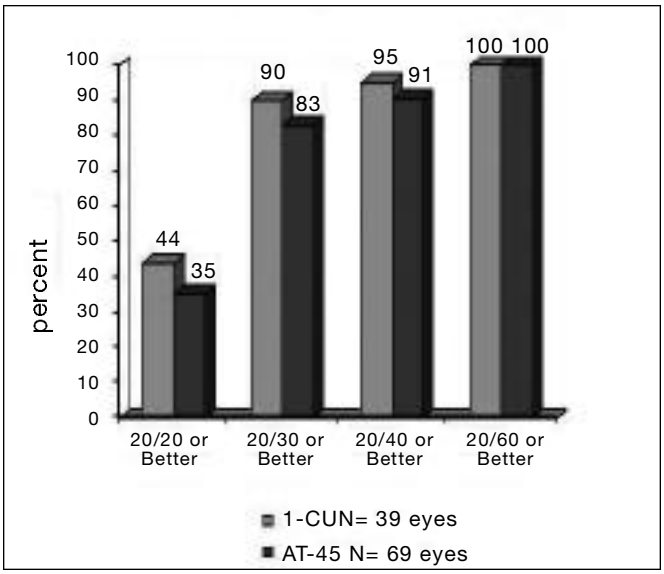

Fig. 1 - *Monocular uncorrected visual acuity (UCVA) – distance at 1 year postoperatively (bilateral and unilateral implants).*

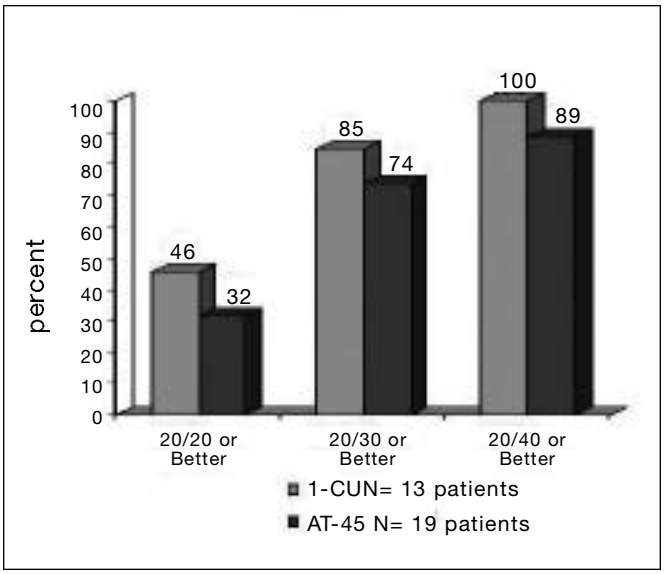

Fig. 2 - *Binocular uncorrected visual acuity (UCVA) –distance at 1 year postoperatively (bilateral implants).*

the ciliary muscle transmitted to the capsular bag allow the monofocal optic plate of the IOL to move forward along the ocular axis and supply sufficient accommodative ability to allow distance and near vision.

In this study, we compared the postoperative visual results following the implantation of two different types of posterior chamber accommodative IOLs: the AT-45 (Crystalens, Eyeonics, Aliso Viejo, CA) and the 1-CU (HumanOptics AG, Erlangen, Germany).

PATIENTS AND METHODS

The AT-45 is a posterior chamber IOL made of third-generation silicone (biosil) with an optic plate diameter of 4.5 mm and two long polyamide loops, 180° to each other, on the end of the plate haptics. The overall length of the lens is 10.5 mm. We began implanting AT-45 lenses in February 2001. The 1-CU is a posterior chamber IOL made of hydrophilic foldable acrylic material with an optic plate diameter of 5.5 mm with four loops positioned at intervals of 90°. The lens has a total diameter of 9.8 mm. We began implanting 1-CU lenses in December 2001.

Patients presenting to our clinic for cataract extraction by phacoemulsification and IOL implantation were considered for study participation.

The nature of the procedure was explained to all participating patients, and they all signed informed consent forms prior to undergoing the procedure.

The surgeon explained the characteristics of standard and accommodative IOLs to presenting patients and asked them to choose their preferred lens type (standard or accommodating). Patients who chose the accommodating lens type were then screened for eligibility and, if eligible, randomly assigned to receive the AT-45 or the 1-CU lens.

To determine study eligibility, patients underwent a complete ocular examination including slit-lamp, immersion biometry, endotheliometry, examination of the fundus oculi, pupillometry, corneal topography, and determination of uncorrected distance VA (UCVA, distance) and near VA through the distance correction (DCNVA) with the Jaeger near vision card. Patients with corneal or retinal pathologies that could compromise postoperative visual results, decompensated glaucoma, previous history of iridocyclitis, or astigmatism greater than 2 D were excluded form study participation. Patients with a mydriatic pupil diameter greater than 5.5 mm in scotopic light were excluded from the AT-45 lens group. In addition, patients who required an IOL of power greater than 27 D or less than 16 D were excluded because these IOL powers are not available. Only patients suitable for bilateral implants were included in the study.

All the surgeries were performed under topical anes-

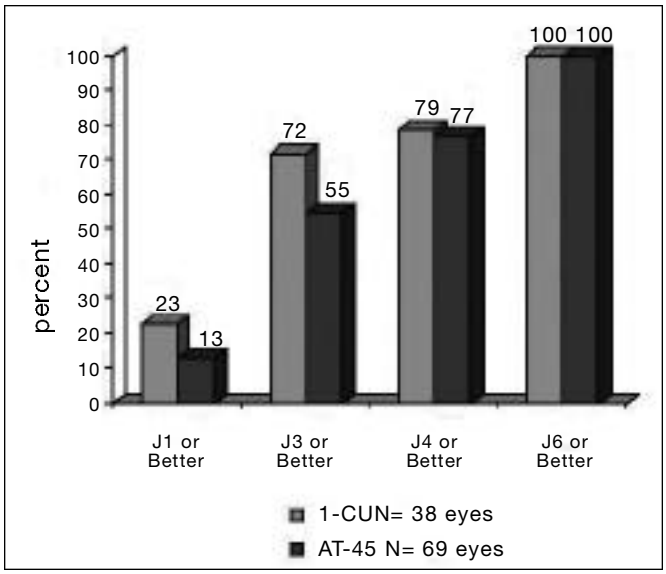

Fig. 3 - *Monocular near visual acuity through distance correction (DCNVA) at 1 year postoperatively (bilateral and unilateral implants).*

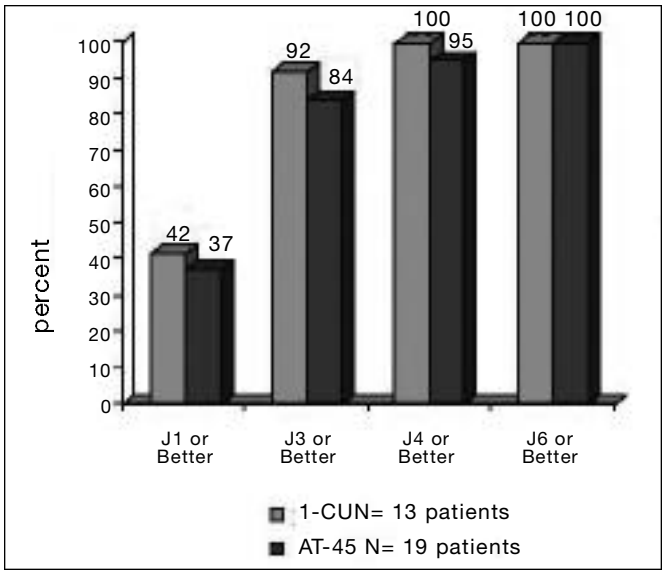

Fig. 4 - *Binocular near visual acuity through distance correction (DCNVA) at 1 year postoperatively (bilateral implants).*

thesia by the same surgeon (L.B.). Following a temporal incision of 3.2 mm with two sideport incisions for the irrigation and aspiration, viscoelastic substance was injected. For a good outcome, the capsulorhexis had to be well-centered, of small diameter (5.5 mm or less because this is important for the function of these lenses), and continuous so that the function of the capsular bag is not compromised. The target correction was -0.50 D for both the AT-45 group and the HumanOptics AG group.

Following a delicate hydrodissection, with injection of a small quantity of balanced salt solution (BSS) below the anterior capsule towards the periphery, the surgeon performed phacoemulsification of the nucleus. For the removal of the cortex, the bimanual method with the assistance of two cannulas, one for irrigation and one for aspiration (Buratto's cannulas), was used. Following the injection of a small quantity of viscoelastic substance and extension of the incision to 3.5 mm, the accommodative IOL AT-45 was inserted by means of special forceps (Buratto's forceps) that permit perfect positioning in the bag without further maneuvers. The 1-CU accommodative IOL was introduced using a special injector and the loops fully opened by means of a special spatula. Finally, the viscoelastic substance was removed and the surgeon proceeded with the hydrosuture.

Atropine was prescribed postoperatively, to be given two times per day for 3 days. Postoperative therapy consisted of tobramycin and betamethasone drops (Tobradex, Alcon, Ft. Worth, TX) three times a day for 2 weeks, followed by diclofenac eyedrops (Voltaren, Novartis Ophthalmics, Duluth, Georgia) three times a day for an additional 2 weeks. Patients were examined 1 day, 1 month, 6 months, and 1 year after surgery. The postoperative examinations included slit-lamp, corneal topography, endotheliometry, examination of the fundus oculi, and determination of the uncorrected and corrected vision with lenses for near and distance vision. Near (35 cm) VA was measured through the distance correction to eliminate the potential pseudo-accommodative effects of residual myopia and astigmatism when trying to determine the extent of IOL movement to provide near vision. Patients who had received bilateral implants had near and distance VA measured monocularly and binocularly.

RESULTS

Patients

A total of 108 eyes of 75 patients were implanted monocularly or bilaterally with either the AT-45 or 1-CU accommodating IOL and were followed postoperatively. The AT-45 lens group began with 51 patients

TABLE I - SUMMARY OF RESULTS WITH THE 1-CU AND THE AT-45 INTRAOCULAR LENSES

	1-CU	AT-45
Monocular UCVA-distance 20/20 or better (bilateral and unilateral implants)		
1 mo	41% (16/39)	33% (23/69)
1 yr	43.6% (17/39)	34.8% (24/69)
Monocular UCVA-distance 20/30 or better (bilateral and unilateral implants)		
1 mo	89.7% (35/39)	82.6% (57/69)
1 yr	89.7% (35/39)	82.6% (57/69)
Binocular UCVA-distance 20/20 or better (bilateral implants)		
1 mo	46.1% (6/13)	31.6% (6/19)
1 yr	46.1% (6/13)	31.6% (6/19)
Binocular UCVA-distance 20/30 or better (bilateral implants)		
1 mo	84.6% (11/13)	68.4% (13/19)
1 yr	84.6% (11/13)	73.6% (14/19)
Monocular UCVA-near J1 or better (bilateral and unilateral implants)		
1 mo	17.9% (7/39)	13% (9/69)
1 yr	23% (8/39)	13% (9/69)
Monocular UCVA-near J3 or better (bilateral and unilateral implants)		
1 mo	76.9% (30/39)	50.7% (35/69)
1 yr	71.7% (28/39)	55% (38/69)
Binocular UCVA-near J1 or better (bilateral implants)		
1 mo	23% (3/13)	31.6% (6/19)
1 yr	42% (6/13)	36.8% (7/19)
Binocular UCVA-near J3 or better (bilateral implants)		
1 mo	92.3% (12/13)	89.5% (17/19)
1 yr	92.3% (12/13)	84.2% (16/19)

UCVA = Uncorrected visual acuity

(70 eyes) with a mean age of 74 years (range 34–87 years). One patient with a monocular cataract and large pupil had to have the AT-45 lens explanted approximately 20 days after surgery because of severe halos. Thus the AT-45 group consisted of 50 patients with 69 implantations; 19 patients were implanted bilaterally for a total of 38 eyes, and 31 patients were implanted monocularly. The 1-CU lens group consisted of 25 patients (39 eyes), with a mean age 62 years (range 25–90 years); 13/25 of the patients were implanted bilaterally and the rest were implanted monocularly. Mean follow-up time for both groups was 15 months.

We attempted to evaluate the movement of the IOL on the ocular axis by measuring the anterior chamber depth with the IOL-Master before and after the instillation of 2% pilocarpine that stimulates the contraction of the ciliary muscle. Both models of IOL showed movement of the optic plate that was sufficient to guarantee good accommodation (1.42 ± 0.51 mm, nearly 3.0 D accommodation for the AT-45; 1.66 ± 0.63 mm, nearly 3.5 D for the 1-CU).

Visual results

Monocular UCVA distance of 20/20 or better was achieved by 41% (16/39) of the 1-CU lens group (monocular and bilateral implants) at 1 month and by 43.6% (17/39) at 1 year. For 20/30 or better monocularly, the percentage was 89.7% (35/39) at both 1 month and 1 year. In comparison, the AT-45 group showed 33% (23/69) with 20/20 or better at 1 month and 34.8% (24/69) at 1 year. For 20/30 or better monocularly with the AT-45, the percentage was 82.6% (57/69) at 1 month and at 1 year. Figure 1 shows the monocular values for the 1-CU and the AT-45 at 1 year.

Of the patients with bilateral implants, 46.1% (6/13) with the 1-CU had uncorrected binocular distance vision of 20/20 or better at 1 month and at 1 year. For 20/30 or better, the percentage was 84.6% (11/13) at 1 month and at 1 year. Figure 2 shows the binocular values for the bilateral 1-CU patients and the bilateral AT-45 patients at 1 year. In comparison, the AT-45 group showed 31.6% (6/19) with uncorrected binocular distance vision of 20/20 or better at 1 month and at 1 year, and 68.4% (13/19) with 20/30 or better at 1 month and 73.6% (14/19) at 1 year.

Monocular distance-corrected near VA of J1 or better was achieved by 17.9% (7/39) of the 1-CU lens group at 1 month and by 20.5% (8/39) at 1 year (Fig. 3). For monocular distance-corrected near VA of J3 or better, the percentage was 76.9% (30/39) at 1 month and 71.7% (28/39) at 1 year. In comparison, the AT-45 lens group showed 13% (9/69) with monocular distance-corrected near VA of J1 or better at 1 month and at 1 year. For monocular distance-corrected near VA of J3 or better, the percentage was 50.7% (36/69) at 1 month and 55% (38/69) at 1 year in the AT-45 group.

Of the patients with bilateral implants, 23% (3/13) with the 1-CU had distance-corrected J1 or better at 1 month and 42% (6/13) had distance-corrected J1 or better at 1 year. For distance-corrected J3 or better, the percentage was 92.3% (12/13) at 1 month and at 1 year. In comparison, the AT-45 group showed 31.6% (6/19) with distance-corrected J1 or better at 1 month and 36.8% (7/19) at 1 year. For J3 or better binocular near acuity in the AT-45 eyes, the values were 89.5% (17/19) at 1 month and 84.2% (16/19) at 1 year (Fig. 4). Table I summarizes all VA results. A total of 34% (13/39) of the eyes with 1-CU implants underwent a mild myopic shift (-0.78 ± 0.22 D; range -1.50 to -0.25 D), 21% (8/39) of the eyes had a mild hyperopic shift (0.71 ± 0.33 D; range +1.50 to +0.25 D), and 45% (18/39) of the eyes were emmetropic at 1 year. Of the AT-45 implanted eyes, 54% (37/69) showed a mild myopic shift (-0.81 ± 0.31 D; range = -1.75 to -0.25 D), 32% (22/69) had a mild hyperopic shift (0.82 ± 0.41 D; range +1.25 to +0.25 D), and 14% (10/69) were emmetropic 1 year after surgery. No patient with a 1-CU implant lost pseudoaccommodation during follow-up.

Complications

No intraoperative complications were observed in any of the surgeries. There were four cases of anterior shift of the optic plate following the implantation of the AT-45 IOL. The plate eventually stabilized in this anterior position with subsequent loss of accommodative ability. One case of anterior shift was encouraged by an excessively wide laser capsulotomy that increased the vitreal thrust towards the IOL. In two cases, a slight ovalization of the capsulorhexis may have encouraged the anterior shift of the loop and consequently the forward displacement of the optic plate. In the fourth case, the IOL gave excellent

results both for distance and near vision until 20 days postoperatively when it became locked in an anterior position. The capsulorhexis was regular, and we have not been able to explain this situation.

Three patients who received the AT-45 implant complained of irritating nighttime halos in the immediate postoperative period. In two cases, the halos diminished over the first 2 weeks postoperatively. The remaining patient had to have the AT-45 lens explanted approximately 20 days after surgery because the halos were severe and prevented normal everyday activities. In 11 cases (16%), a YAG laser capsulotomy was necessary because of the opacification of the posterior capsule postoperatively. Of the patients implanted with the 1-CU lens, a YAG laser capsulotomy was necessary in five cases (13%).

DISCUSSION

The ultimate goal of cataract surgery is to replace the cataractous crystalline lens with a lens that provides a full range of functional vision—distance through near. Modern cataract procedures with monofocal IOL implantation produce excellent uncorrected distance vision; near vision, however, depends on existing accommodative ability, which is usually limited in the age group of most cataract surgery patients. Cumming and Kammann (11) introduced the concept of posterior chamber accommodating IOLs with the aim of allowing pseudophakic accommodation to increase postoperative range of vision. The concept is based on the forward movement of the lens optic from ciliary muscle contraction (focus-shift principle) that results in an increase in lens power. Cumming and Kammann's work resulted in the development of the AT-45 accommodating IOL, a hinged plate haptic silicone lens that received approval from United States FDA in 2004 for the treatment of presbyopia in patients undergoing cataract surgery. The AT-45 provides approximately one diopter of accommodation (19).

The 1-CU accommodating IOL, launched in Europe in 2001 for the treatment of presbyopia following cataract surgery, is also designed to provide pseudoaccommodation using the focus-shift principle (14). The haptics of this IOL, which are thinner near the optic to provide greater flexibility, allow reversible forward movement of the optic following contraction of the ciliary muscle. Mastropasqua and associates achieved a mean amplitude of accommodation of 1.90 ± 0.77 D with the 1CU at 6 months postoperatively and concluded that this lens provided better useful spectacle-free near VA than the conventional monofocal IOL tested as a control (16). A multicenter report showed that refraction, anterior chamber depth, and accommodative range remained stable after implantation of the 1CU for up to 1 year (15).

In this study, we examined VA obtained with these two types of accommodative IOLs that were developed to amplify the residual accommodation in patients subjected to the phacoemulsification procedure with the implantation of an IOL. It was important to obtain good distance as well as good near vision postoperatively with these lenses to be certain that forward and backward lens movement is reversible. We found that uncorrected distance vision measured monocularly was better in the 1-CU lens group eyes than in the AT-45 lens group eyes for all measured acuity levels (20/20 or better, 20/30 or better, and 20/40 or better). Similarly, for patients with bilateral implants, binocular uncorrected distance vision was better in the 1-CU lens group than in the AT-45 group for all measured acuity levels.

We also found better results with the 1-CU lens than for the AT-45 for near vision through the distance correction. Seventy-one percent of the eyes implanted monocularly with the 1-CU had J3 or better monocular near vision through the distance correction compared with 55% in the AT-45 eyes at 1 year. Bilaterally implanted patients showed greatly improved results over those with unilateral implants: 92% with J3 or better near acuity (able to read newspaper without spectacles) in the 1-CU patients compared with 84% in the AT-45 patients at 1 year. In general, results seen at 1 month were similar to those seen at 1 year in both lens groups. Thus visual acuity appeared to be stable after 1 month postoperatively. Refraction, however, changed during follow-up. A total of 55% of 1-CU and 86% of AT-45 implanted eyes underwent a myopic or hyperopic shift at 1 year postoperatively. We were unable to determine a reason for these shifts.

Thus our results showed a greater number of complications, such as anterior displacements, halos, and posterior capsule opacifications, with the AT-45 lens. However, our study was small, and we cannot state for certain that the same incidence of these compli-

cations would occur in a larger study population.

We conclude, from a clinical standpoint, that the results obtained in patients implanted with the 1-CU lenses were slightly better for both efficacy and safety than those obtained in the patients implanted with the AT-45 lenses, even though most patients in both IOL groups did not require correction for near vision except when reading very small print or when performing high-precision work. Since we measured near acuities through the distance correction, our results demonstrate the accommodating function of both lens types without the contribution of pseudoaccommodative factors of myopia and cylinder. A study with a larger number of patients and longer follow-up is needed to determine the benefits of each of these accommodating IOLs for patients undergoing cataract surgery and lens implantation.

Neither Dr. Buratto nor Dr. Di Meglio has any financial interest in the AT-45 lens (Crystalens, Eyeonics Inc., Aliso Viejo, CA) or in the 1-CU lens (HumanOptics AG, Erlangen, Germany).
The nature of the procedure was explained to all partecipating patients, and they all signed informed consent forms prior to undergoing procedure.

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