Longterm results of 1 CU® accommodative intraocular lens implantation: 2-year follow-up study

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ABSTRACT.

Purpose: **To evaluate the longterm efficacy of 1 CU® accommodative intraocular lenses (IOLs) to restore near visual performance.**

Methods: **This prospective study comprised 14 eyes previously included in a 6-month, case-control clinical trial, undergoing phacoemulsification and implantation of a 1 CU® accommodative IOL. The main outcome measures were subjective refraction, uncorrected distance visual acuity (UCDVA), best corrected distance VA (BCDVA), distance-corrected near VA (DCNVA), best corrected near VA (BCNVA), and subjective amplitude of accommodation (AA). In addition, anterior and posterior capsule opacification were assessed. Patients were examined over a 2-year follow-up period.**

Results: **Distance and near visual performance worsened after 6 months. Uncorrected DVA and BCDVA were 0.8 ± 2.1 and 1.0 ± 0.8 at 6 months and 0.4 ± 0.1 and 0.6 ± 0.1 at 1 year, respectively ($p = 0.001$). Distance-corrected NVA and BCNVA were 3.7 ± 2.1 Jaeger (J) and 1.0 ± 0.7 J at 6 months and 8.1 ± 0.7 J and 1.5 ± 0.5 J at 1 year, respectively ($p = 0.001$). Anterior and posterior capsule opacification were present, respectively, in 28% and 21% of patients at 6 months and in 100% of patients at 1 and 2 years ($p < 0.001$). After Nd:YAG laser capsulotomy (performed in 100% of patients), UCDVA and BCDVA increased to 0.7 ± 0.2 ($p = 0.007$) and 1.0 ± 0.1 ($p = 0.001$), respectively, at 2 years. Distance-corrected NVA improved to 7.3 ± 0.5 J ($p = 0.006$). Mean AA was 1.9 ± 0.8 D at 6 months, 0.3 ± 0.2 D ($p = 0.004$) at 1 year and 0.3 ± 0.2 D at 2 years.**

Conclusions: **Patients implanted with 1 CU® IOLs lost their accommodation capacities with time because of the high incidence and degree of anterior and posterior capsule opacification. The accommodative lens material and design may have played a role in capsule fibrosis.**

Key words: accommodative IOL – capsule fibrosis – accommodation – presbyopia

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Introduction

The restoration of near functional capacity is one of the main challenges of modern cataract refractive surgery and refractive lens exchange.

Recently, different approaches have attempted to achieve the correction of presbyopia after crystalline lens removal. The monovision-based strategy of implantation of conventional monofocal intraocular lenses (IOLs) has been used by some authors (Claoué & Parmar 2002). However, problems with binocular vision and loss of stereopsis have limited the use of this procedure.

Multifocal IOLs, designed to allow vision for all distances because of the variable number of foci, have been shown to obtain a wide depth of focus (Javitt & Steinert 2000; Kamlesh et al. 2001; Pineda-Fernández et al. 2004).

However, light dispersion due to refractive or diffractive optics leads to undesirable symptoms such as glare, halos and reduction of contrast sensitivity (Schmitz et al. 2000; Montés-Micó et al. 2004; Nida et al. 2004).

Recently, a mechanism that differs from optic multifocality has been made viable by realizing accommodative IOLs that allow near focusing due to the dynamic antero–posterior

shift along the visual axis of the monofocal optic.

Several studies have described a restoration of accommodation in pseudophakic patients by means of accommodative IOLs, with excellent far distance vision and useful near vision and spectacle-independence for several everyday tasks (Küchle et al. 2001, 2004; Langenbucher et al. 2003; Mastropasqua et al. 2003; Claoué 2004; Findl et al. 2004; Heatley et al. 2005; Kriechbaum et al. 2005).

Nevertheless, in the literature there is some disagreement concerning the amount of amplitude of accommodation (AA) provided by these lenses and the related near vision performance. Moreover, there are no published longterm data on these lenses because of the short–intermediate length of most reported clinical trials.

The aim of our study was to evaluate longterm efficacy of 1 CU® accommodative IOLs in the restoration of near vision performance and the influence of late complications of cataract surgery and IOL implantation on the accommodative mechanism.

Materials and Methods

This prospective study comprised 14 eyes of 14 patients implanted with 1-CU® IOLs during a previous 6-month clinical trial. They were recruited during July–September 2001 at the Department of Medicine and Science of Ageing-Section of Ophthalmology, University G. d'Annunzio Chieti-Pescara and were followed for 2 years after surgery.

As already reported (Mastropasqua et al. 2003), inclusion criteria required that patients be 50–75 years of age and have an axial length of 23.0–24.0 mm and a corneal preoperative astigmatism of < 1.00 dioptre (D). Patients were excluded if they had anterior segment pathological alterations (such as chronic uveitis, zonular dialysis, pseudoexfoliation syndrome, glaucoma and diabetes), other ocular pathologies impairing visual function, previous anterior or posterior segment surgery, and intraoperative or postoperative complications.

All 14 patients were implanted with the 1 CU® accommodating IOL (Human Optics AG, Erlangen, Germany). This is a foldable, single-piece IOL with an optic diameter of 5.5 mm and overall length of 9.8 mm. It is made of a hydrophilic acrylic material with an ultraviolet inhibitor and has a refractive index of 1.46. The lens has a biconvex optic and four modified, flexible, square-edged haptics that bend when constricted by the capsular bag after ciliary muscle contraction, allowing anterior displacement of the optic.

In all cases a standardized, uneventful, small-incision phacoemulsification with IOL implantation was performed by a single surgeon (LM). After a 3.2-mm near clear corneal tunnel had been made, a curvilinear capsulorhexis was created. Phacofracture in the capsular bag was followed by automated irrigation/aspiration of the cortical remnants. The IOL was implanted in the capsular bag. The incision was not sutured. Postoperative therapy consisted of ofloxacin 0.3% and dexamethasone 0.2% eyedrops four times daily for 3 weeks.

The mean age of the subjects was 66.9 ± 5.9 years (standard deviation [SD]) (range 52–75 years).

Patients were examined after surgery over a 24-month follow-up period.

The main outcome measures were spherical equivalent (SE) subjective refraction, uncorrected distance visual acuity (UCDVA), best corrected distance visual acuity (BCDVA), distance-corrected near visual acuity (DCNVA) at 40 cm, best corrected near visual acuity (BCNVA) at 40 cm, and subjective AA.

Amplitude of accommodation was evaluated by the near-point procedure as previously described (Mastropasqua et al. 2003).

In addition, at each visit, the anterior and posterior capsules were examined after dilating the pupil to establish the presence of anterior and posterior capsule opacification (ACO and PCO, respectively).

Focal and retroillumination photos were obtained with maximum pupil dilation using a Tomey video slit-lamp in order to evaluate ACO.

Digital retroillumination photographs for PCO assessment were obtained with the same equipment. All digital images were transferred to a personal computer and stored on hard disk for later evaluation.

All examinations were performed by the same investigator (LM).

Anterior capsule opacification was subjectively graded as 0 = none, 1 = moderate (mild opacification not involving the whole capsulorhexis), and 2 = severe (complete whitening of the capsule over the IOL optic).

The intensity of central PCO (behind the IOL optic) was subjectively scored on a 0–4 scale: 0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe.

Scheduled follow-ups of the main parameters evaluated in the study were set at 6, 12 and 24 months postoperatively.

Statistical analysis

Spherical equivalent subjective refraction, uncorrected and best corrected distance VA, distance-corrected near VA and AA were reported as mean ± SD. The variations of these parameters versus those of the previous follow-up visit were statistically evaluated using the non-parametric Wilcoxon *U*-test.

Grades of ACO and PCO were summarized by frequency and percentage. The Sign test was used to assess the statistical significance of differences for the percentage of patients with either ACO or PCO during follow-up.

Statistical analysis was performed using SPSS Version 10.0 (SPSS Inc., Chicago, Illinois, USA).

Results

Visual and refractive parameters at 6 months, 1 year and 2 years after surgery are shown in Table 1.

The SE was -0.1 ± 0.7 at 6 months, -0.2 ± 0.8 at 1 year and -0.2 ± 0.7 2 years postoperatively (p = non-significant [NS], Wilcoxon test).

At 6 months, mean UCDVA and BCDVA were 0.8 ± 2.1 and 1.0 ± 0.8, decreasing at 1 year to 0.4 ± 0.1 ($p = 0.001$) and 0.6 ± 0.1 ($p = 0.001$), respectively.

At 2 years, UCDVA had increased to 0.7 ± 0.2 ($p = 0.007$) and BCDVA to 1.0 ± 0.1 ($p = 0.001$).

Mean DCNVA was 3.7 ± 2.1 Jaeger (J) at 6 months, 8.1 ± 0.7 J at 1 year and 7.3 ± 0.5 J at 2 years after surgery. The differences between findings at 1 year and the previous time-point ($p = 0.001$) and findings at the 2-year and 1-year control visits

Table 1. Mean ± standard deviation of visual and refractive parameters at 6 months, 1 year and 2 years after surgery.

	Follow-up				
Parameters	6 months ($n = 14$)	1 year ($n = 14$)	p-value*	2 years ($n = 14$)	p-value†
SE (D)	− 0.1 ± 0.7	− 0.2 ± 0.8	0.694	− 0.2 ± 0.7	0.785
UCDVA	0.8 ± 2.1	0.4 ± 0.1	0.001	0.7 ± 0.2	0.007
BCDVA	1.0 ± 0.8	0.6 ± 0.1	0.001	1.0 ± 0.1	0.001
DCNVA (J)	3.7 ± 2.1	8.1 ± 0.7	0.001	7.3 ± 0.5	0.006
BCNVA (J)	1.0 ± 0.7	1.5 ± 0.5	0.001	1.0 ± 0.0	0.001
AA (D)	1.9 ± 0.8	0.3 ± 0.2	0.004	0.3 ± 0.2	0.564

* Wilcoxon test versus 6 months; † Wilcoxon test versus 1 year.
SE = spherical equivalent; D = dioptre; UCDVA = uncorrected distance visual acuity; BCDVA = best corrected distance visual acuity; DCNVA = distance-corrected near visual acuity; BCNVA = best corrected near visual acuity; J = Jaeger; AA = amplitude of accommodation.

($p = 0.006$) were statistically significant.

Mean BCNVA was 1.0 ± 0.7 J at 6 months, falling to 1.5 ± 0.5 J at 1 year ($p = 0.001$) and increasing to 1.0 ± 0.0 J at 2 years ($p = 0.001$).

Mean AA was 1.9 ± 0.8 D at 6 months, 0.3 ± 0.2 D at 1 year and 0.3 ± 0.2 D at 2 years.

The difference between findings at 1-year and those at the previous time-point was statistically significant ($p = 0.004$).

The percentage of patients with ACO increased from 28% at 6 months to 100% at 1 year and 2 years ($p = 0.002$, Sign test).

The percentage of patients with grade 1 ACO rose from 14% at 6 months to 29% at 1 and 2 years (Fig. 1A); that for patients with grade 2 ACO rose from 14% to 71%.

The percentage of patients with PCO was 21% at 6 months and 100% at 1 year and 2 years ($p = 0.001$, Sign test). At 6 months only 21% of the patients showed mild PCO, while 36%, 50% and 14% showed mild, moderate and severe PCO, respectively, at both 1 and 2 years (Figs 1B, 2).

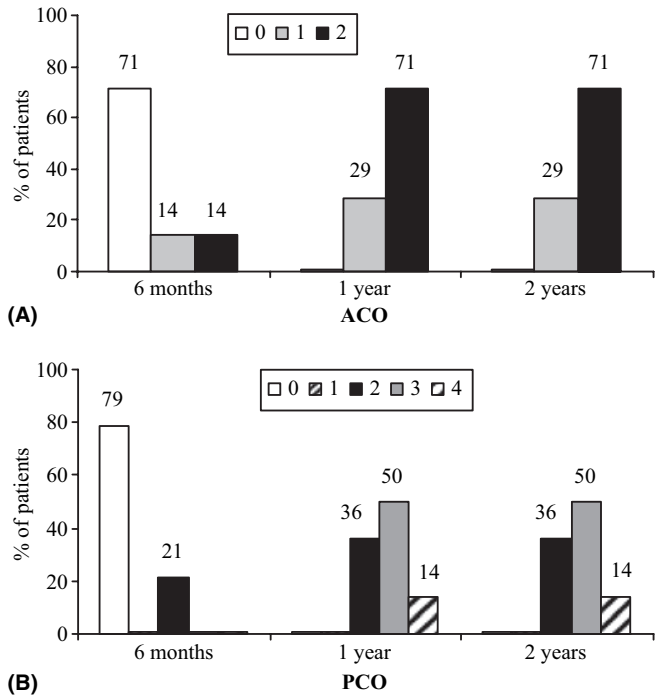

Fig. 1. Grades of (A) anterior capsule opacification (ACO) and (B) posterior capsule opacification (PCO) in patients with accommodating intraocular lenses at different follow-up controls. ACO: 0 = none, 1 = moderate, 2 = severe. PCO: 0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe.

An Nd:YAG laser capsulotomy was performed during the second post-operative year in all eyes (100%) (Fig. 3).

Discussion

Accommodative 1 CU® IOLs have been described as providing useful near vision in the short- and medium-term, while preserving far distance performance.

In analysing the 6-month results, Küchle et al. (2004) showed that 1 CU® IOLs provided higher AA compared with monofocal implantation, ranging from 0.98 D to 1.85 D, according to the different methods of evaluation.

Langenbucher et al. (2003) observed a mean reduction of anterior chamber amplitude of 0.78 mm, corresponding to a mean AA of 1.40 D in patients implanted with accommodative 1 CU® IOLs.

In an 18-month study, Claoué (2004) observed a near UCVA of 20/40 in 76.5% of patients implanted with 1 CU® lenses with a mean AA of 0.44 D.

The results of our initial 6-month study demonstrated the 1 CU® IOL to be effective in near vision restoration, with mean DCNVA of 2.33 J at 3 months and corresponding accommodation of 2.36 D, decreasing, respectively, to 3.66 J and 1.90 D at 6 months (Mastropasqua et al. 2003).

The present study completes the follow-up of the 1 CU® accommodative lens to 2 years, allowing analysis of the longterm results of this accommodative IOL.

At the 1-year follow-up, patients in the study group showed a marked decrease in uncorrected and best corrected VA compared with at 6 months.

Distance-corrected near VA and AA were markedly reduced, considering only the results of the first 6 months. At 1 and 2 years postoperatively, all patients (100%) showed ACO, compared with 28% of patients at the 6-month control visit. At 1 and 2 years, PCO with gross Elschnig pearls that required a posterior YAG laser capsulotomy were present in 100% of patients, 14% of whom had a severe form, while the remaining patients had moderate or mild forms;

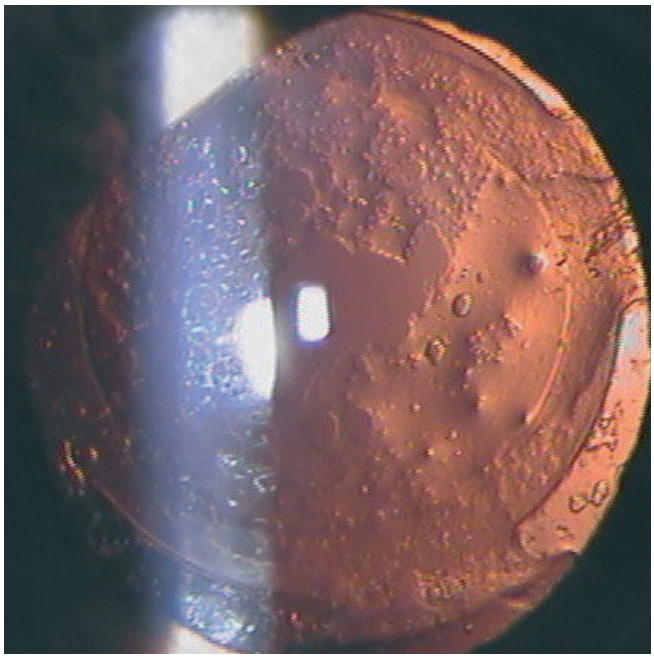

Fig. 2. Retroillumination photograph of a 1 CU® intraocular lens 1 year postoperatively, showing moderate posterior capsule opacification involving the entire posterior capsule.

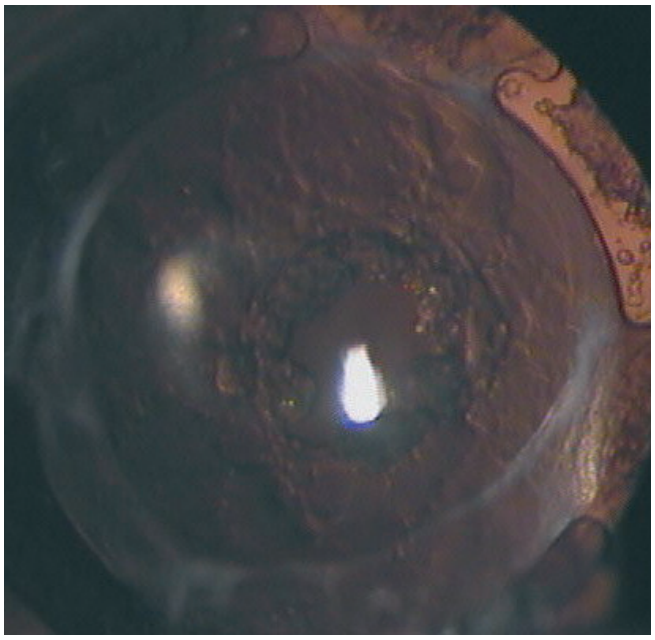

Fig. 3. Retroillumination photograph of a 1 CU® intraocular lens 2 years postoperatively, showing a central Nd:YAG laser capsulotomy and surrounding thickened posterior capsule with severe posterior capsule opacification. On the anterior intraocular lens surface a severe fibrosis of the capsulorhexis edge is visible.

21% of patients had a mild form at the 6-month follow-up. After YAG laser capsulotomy, far distance vision increased in the study group patients, with no improvement of near visual capacities during the remaining follow-up period.

In our previous report, we concluded, in accordance with other authors, that the improved near functional capacities in patients with the 1 CU® IOL could be related to restoration of the accommodating mechanism. This conclusion was supported by our measurements of AA (Mastropasqua et al. 2003).

The 1 CU® lens has modified haptics that bend in the bag after ciliary muscle contraction, causing anterior movement of the lens optic.

Despite the well recognized accommodative mechanism, published studies report different results concerning AA and related near visual performance.

Accommodation ranging between approximately 1.5 D and 3.00 D has been determined by near point and defocusing methods and that between 0.9 D and 1.00 D by streak retinoscopy and video refractometry at 6 months (Langenbucher et al. 2003; Küchle et al. 2004; Heatley et al. 2005).

In accordance with AA evaluated subjectively by other studies, we found accommodation of 1.90 D at the 6-month control using the near point procedure (Mastropasqua et al. 2003).

No agreement between our results and data provided by other authors for longer follow-ups has been found.

Claoue (2004) observed no significant difference between 6- and 12-month AA values, which varied from 1.85 D to 2.02 D, respectively.

The present study showed a decrement in AA to 0.25 ± 0.17 D after 1 year.

The reduction in AA and the related worsening of reading ability at 6 months appear to be associated with the development of ACO and PCO. We hypothesize that the fibrotic capsule may interfere with the accommodating mechanism, preventing IOL movement inside the bag (Mastropasqua et al. 2003).

Anterior and posterior capsule fibrosis are frequently observed after foldable IOL implantation.

Anterior capsule opacification is based on the fibrous metaplasia of residual lens epithelial cells (LECs) attached to the inner surface of the anterior capsule when they come into contact with the IOL.

The IOL material been demonstrated to greatly influence the process of ACO, with higher rates of ACO in patients implanted with silicone and hydrophilic acrylic materials (Tognetto et al. 2002, 2003).

Moreover, it has been suggested that IOL design plays a role in ACO, with higher rates of ACO in plate-haptic silicone IOLs (Werner et al. 2000).

The 1 CU® accommodative IOL is manufactured from hydrophilic acrylic material with four plate-haptics. These

two factors may explain the high percentage of ACO found in patients with this IOL.

Posterior capsule opacification is mainly caused by the migration and proliferation of LECs onto the posterior capsule, forming amorphous layers from epithelial–mesenchymal transition cells or well defined pearls from lenticular fibre regeneration.

Both surface properties and IOL design have been demonstrated to influence PCO (Saika 2004).

Recent comparisons of several IOLs of different materials and design concluded that a sharp edge on the optic is the main factor in preventing PCO (Nishi & Nishi 2002; Nishi et al. 2002, 2004).

Nevertheless, several authors do not negate a role of the IOL material in PCO occurrence (Menapace et al. 1994; Menapace 1996; Hayashi & Hayashi 2004).

Some studies have demonstrated that hydrophilic acrylic IOLs are related to a high incidence and degree of posterior capsule fibrosis, compared with other IOL materials (Menapace et al. 1994; Menapace 1996).

It has been suggested that hydrophilicity leads to weak adhesion of the lens to the capsule, allowing the proliferation of LECs in the retrolental space (Hayashi & Hayashi 2004).

The 1 CU® IOL has a round optic with a sharp edge only at the haptics, thus insufficiently inhibiting LEC migration towards the posterior capsule. Moreover, the hydrophilic acrylic material may have influenced the posterior response.

In addition, it is possible to conjecture that the accommodating mechanism of the 1 CU® lens, characterized by anterior optic shift, may have facilitated the migration of LECs posteriorly against the no space–no cells principle.

A recent study by Nguyen et al. (2005) found no differences in accommodation before and after Nd:YAG laser capsulotomy in patients implanted with 1 CU® IOLs with an AA of approximately 1.9 D 12 months postoperatively.

Moreover, in our series, no differences were present in the accommodative mechanism before and after the capsulotomy, but accommodation was null at that postoperative period. We agree that a central capsulotomy could not limit IOL movement inside the bag, but it is usual for the fibrotic surrounding capsule to hardly contract.

In conclusion, 1 CU® IOLs are related to a high rate of capsule opacification, annulling the accommodative mechanism and necessitating the execution of a posterior capsulotomy to restore far and near distance vision.

The time-dependent loss of accommodation and the alteration in visual performance related to PCO and the possible complications associated with laser capsulotomy should be considered when planning a presbyopia correction with 1 CU® IOLs after crystalline lens removal.

It is probable that refinement of the lens design in order to realize an overall sharp optic edge and the use of a different material may limit the long-term complications encountered in our series.

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