EXTENDED REPORT

Potential of the 1 CU accommodative intraocular lens

G Sauder, R F Degenring, B Kamppeter, P Hugger

Br J Ophthalmol 2005;**89**:1289–1292. doi: 10.1136/bjo.2005.068056

See end of article for authors' affiliations

Correspondence to: Dr G Sauder, Universitäts-Augenklinik, Theodor-Kutzer-Ufer 1-3, 68167 Mannheim, Germany; gangolf.sauder@augen.ma.uni-heidelberg.de

Accepted for publication 1 June 2005

Aim: To assess the accommodative power of a new foldable monofocal intraocular lens.
Method: A prospective randomised non-masked clinical interventional study. The study included 40 patients attending the hospital for cataract surgery and who were randomly distributed into a study group receiving a new foldable monofocal intraocular lens with flexible haptics, and a control group receiving a standard foldable intraocular lens. Mean follow up period was 8.51 (SD 1.34) months (range 4–11 months) Standard cataract surgery consisted of clear cornea incision, capsulorrhexis, phacoemulsification, and intraocular lens implantation, with topical anaesthesia. The main outcome measures were preoperative and postoperative visual acuity for near and distance; range of accommodation; change in anterior chamber depth.
Results: In the study group compared with the control group, range of accommodation was significantly ($p=0.01$) higher (1.01 (SD 0.4) dioptres versus 0.50 (0.11) dioptres) and change in anterior chamber depth was significantly more pronounced (0.82 (0.30) versus 0.40 (0.32), $p=0.01$). Both groups did not vary significantly in best corrected vision (0.94 (0.12) versus 0.93 (0.18); $p=0.74$).
Conclusion: During a mean follow up period of 8 months after implantation, the new foldable monofocal intraocular lens with flexible haptics showed an accommodative power of about 1 dioptre, which was significantly higher than the accommodative power of a conventional monofocal flexible intraocular lens. The difference in the accommodative power between the two intraocular lenses was paralleled by a difference in the change of the anterior chamber depth.

Treatment of cataract as the most common surgically treatable reason for decreased vision in the elderly population has almost been perfected by phacoemulsification and implantation of intraocular lenses using local anaesthesia. All functions of the natural lens remaining in the elderly patient can be restored such as transparency, refraction, compartmentalisation of the eye into a posterior segment and an anterior segment, and inner stabilisation of the eye. The only remaining function that has generally not yet been restored by surgery on its way to a ''restitutio ad integrum'' or functional rejuvenation of the eye, is accommodation. It was, therefore, the aim of thsi study to evaluate the accommodative power of a new foldable monofocal intraocular lens with flexible haptics, which may allow some degree of accommodation.

PATIENTS AND METHODS

The prospective randomised, non-masked clinical interventional study included 80 eyes of 40 consecutive patients in each group who presented with advanced cataract for routine cataract surgery. Exclusion criteria were age of less than 40 years or higher than 80 years, diabetes mellitus, glaucoma, exudative age related macular degeneration, non-exudative age related macular degeneration with large soft drusen, history of ocular trauma, or previous ocular surgery. The total study population was randomised into a study group consisting of 40 patients undergoing standard cataract surgery with implantation of the new foldable monofocal intraocular lens with flexible haptics (IOL 1 CU; Human Optics AG, Erlangen, Germany) in both eyes, and a control group consisting of 40 patients who underwent standard cataract surgery with implantation of a conventional foldable monofocal intraocular lens (IOL AR 40e Sensar, Allergan, Irvine, CA, USA) in both eyes. For all patients included in the study, the density of cataract was estimated using a relative scale ranging from 0 for clear lens to 4 for mature cataract. Additonally, the duration of surgery, the width of the clear cornea incision, and the diameter of the capsulorhexis were determined. Mean age was 73.29 (SD 5.89) years (range 62–82) in the study group, and 72.66 (4.78) years (range 59–80 years) in the control group. Mean axial length measured 22.87 (0.62) mm in the study group and 23.01 (0.47) mm in the control group. Both groups did not vary significantly ($p>0.40$) in age, refractive error, axial length, anterior chamber depth, and anterior corneal curvature radius (table 1).

Both intraocular lenses carrying the CE mark were certified for intraocular implantation in the European Union. Informed consent was obtained from all patients before enrolment into the study. All patients were fully informed about the new intraocular lens. Institutional ethics committee approved that the methods applied in the study adhered to the tenets of the declaration of Helsinki for the use of human subjects in biomedical research.

The surgical procedure included a paracentesis performed at the 10 o'clock position and the 1 o'clock position, a clear cornea incision in the horizontal meridian (nasal for right eyes, temporal for left eyes), injection of a viscoelastic substance into the anterior chamber, a continuous curve lined capsulorrhexis, phacoemulsification in the chop technique, injection of a viscoelastic substance into the anterior chamber and the capsular bag, endocapsular implantation of the intraocular lens, aspiration of the remaining viscoelastic substance, and injection of Ringer's solution through the paracentesis into the anterior chamber to increase the intraocular pressure to normal values. The new intraocular lens was implanted either with the help of an implantation forceps or with a shooter. The conventional intraocular lens in the control group was inserted using a shooter. All surgeries were performed by the same surgeon (GS) with topical anaesthesia using oxybuprocaine 0.4%.

The study and control groups did not vary significantly in intraoperative data such as duration of surgery, size of the corneal incision, and diameter of the curvilinear capsulorrhexis (table 2).

Table 1 Preoperative data of the study group and the control group (mean (SD))

	Study group (range)	Control group (range)	p Value
Number	40	40	
Age (years)	73.29 (5.89) (62–82)	72.66 (4.78) (59–80)	0.58
Far vision			
Best corrected	0.38 (0.17) (0.01–0.6)	0.33 (0.23)	0.62
Near vision			
Best corrected	0.35 (0.16) (0.01–0.6)	0.30 (1.45) (0.01–0.5)	0.54
Axial length (mm)	22.87 (0.3) (21.62–23.55)	22.59 (0.28) (21.97–24.0)	0.71
Intraocular pressure (mm Hg)	16.7 (3.32) (10–24)	15.9 (4.31) (11–20)	0.43

All patients were examined preoperatively, and 1 month and 6 months after surgery. The examination included slit lamp biomicroscopy of the anterior and posterior segment of the eye, gonioscopy, applanation tonometry. keratometry, optical interferometry (IOL Master, Zeiss-Humphrey, San Leandro, CA, USA) , and visual acuity measurements. At the visit 6 months after surgery, one patient in each group was lost to follow up.

Accommodation was measured in five ways. Firstly, using distance correction, visual acuity was determined for the near at a distance of 30 cm using Nieden and Jaeger charts. Secondly, using distance correction and determining distant visual acuity, minus lenses were added to the correction until one Snellen line in visual acuity was lost. Thirdly, defocusing curves were measured. With best corrected glasses for distance, lenses ranging from +3.0 dioptres to −3.0 dioptres were added in 0.5 dioptre steps. The best visual acuity with each spherical addition was recorded. Fourthly, using optical interferometry (IOL Master, Zeiss-Humphrey, San Leandro, CA, USA), the change in anterior chamber depth was measured during intended accommodation. Fifthly, using optical interferometry the anterior chamber depth was measured in medical mydriasis using tropicamide 0.5% eye drops (four times), and in medical miosis after installation of pilocarpine 2% eye drops four times. Visual acuity was measured using Snellen lines at a distance of 5 metres. Using Nieden and Jaeger charts held in a distance of 35 cm in front of the patient and illuminated from above (about 70 cd/m^2), near vision was assessed with best correction for the distance without added glasses, and with added glasses of 3 dioptres. For statistical analysis, the Mann-Whitney test was applied to test the significance of differences between the groups.

RESULTS

At the end of the follow up period, best corrected visual acuity in the distance measured in the study group 0.94 (0.12) and 0.93 (0.18) in the control group with no significant ($p = 0.74$) difference between the two groups (table 3). Correspondingly, best corrected visual acuity at near did not vary significantly ($p = 0.34$) between the two groups

Accommodative power measured as visual acuity in the near with glasses of the best correction for the distance, accommodative power measured as the power of minus lenses added to the best correction for the distance until at least one Snellen line was lost for the distance vision, and accommodative power measured by the position of the apex of the accommodation curves, was significantly ($p<0.01$) higher in the study group than in the control group (table 3). Additionally, the change in the anterior chamber depth associated with accommodation was significantly ($p = 0.01$) more marked in the study group than in the control group (table 3). The difference between distance corrected near vision and uncorrected near vision was statistically significant in both groups ($p<0.05$). Especially in the 1 CU group there was no dependency of the accommodative power and the spherical power of the Intraocular lens.

Anterior chamber haemorrhage originating from the anterior chamber angle was the only complication observed intraoperatively (one patient in the study group). No other complication such as rupture of the posterior lens capsule, vitreous prolapse, postoperative decentration of the intraocular lens, shallowing of the anterior chamber, and optically significant secondary cataract were detected in any group.

DISCUSSION

Accommodation is a delicate process leading to a change in the focus of the eye by alternating the shape of the lens and, thus, the position of the anterior and posterior lens surface. It is bound to the elasticity of the lens. The accommodative power is strongly associated with age, being about 20 dioptres in a 10 year old subject, decreasing to 10 dioptres in a 20 year old subject, and eventually decreasing to 4 dioptres or less in the age beyond 40 years. Attempts to restore accommodation with cataract surgery have been focused on several mechanisms so far. For all eyes with intraocular lenses, pseudoaccommodation caused by the miosis in association with the convergence reaction has been known for years.[1 2] It usually measures about 0.5 dioptres, a figure also found in the present study for patients in the control group (table 3). Methods specifically associated with cataract surgery to restore accommodation have been the implantation of bifocal or multifocal intraocular lenses, and in bilateral cataract surgery, the implantation of monofocal intraocular lenses with induced anisometropia to achieve so called monovision.[3–6] Independent of cataract surgery, anisometropia, and by that ''monovision,'' was induced by a laser assisted in situ keratomileusis.[7] Additionally, experimental procedures have

Table 2 Intraoperative data of the study and the control groups (mean (SD))

Measurements	Duration of surgery (minutes)	Density of cataract (0–4)	Size of corneal incision (mm)	Rhexis diameter (mm)	Complications
Study group	11.17 (2.85) (8–20)	2.27 (0.82) (1–4)	3.21 (0.31) (3–3.5)	4.91 (0.21) (4.5–5.3)	AC bleeding n = 1
Control group	9.57 (2.1) (7–15)	2.8 (0.56) (1–4)	3.3 (0.19) (3–3.5)	5.42 (0.18) (5.0–6.0)	—
p Value	0.18 (NS)	0.47 (NS)	0.51 (NS)	0.29 (NS)	—

Mean (SD) and range. NS, statistically not significant.

Table 3 Postoperative results (mean (SD)) in the study and the control groups 6 months after surgery

Measurements	Best corrected visual acuity distance	Near vision with distance correction*	Near vision uncorrected	Near vision best corrected	Range of accommodation (dioptres)	Change of anterior chamber (mm) from mydriasis to miosis (mm)
Study group (n = 38)	0.94 (0.12)	6.53 (0.91) (N)	8.07 (1.58) (N)	2.46 (0.9) (N)	1.01 (0.4)	0.82 (0.30)
Range	0.7–1.25	5–9 (N)	5–10 (N)	1–4 (N)	0.5–1.7	0.41–1.14
		8.53 (1.24) (J)	10.53 (2.45) (J)			
Range		6–12 (J)	6–14 (J)			
Control group (n = 38)	0.93 (0.18)	9.61 (1.75) (N)	7.45 (1.63) (N)	2.01 (0.82) (N)	0.5 (0.11)	0.40 (0.32)
Range	0.8–1.0	7–14 (N)	6–10 (N)	1–4 (N)	0–0.75	0.29–0.63
		11.61 (1.75) (J)	9.73 (1.69) (J)			
Range		8–14 (J)	6–14 (J)			
p Value	0.74 (NS)	0.03	0.29 (NS)	0.34 (NS) (N)	0.01	0.01

*J, Jaeger charts; N, Nieden charts.
Mean (SD) and range. NS, statistically not significant.

been performed, such as the substitution of the lens material inside the lens capsular bag by an elastic substance.[8] All of the clinical methods have had their limitations, such as a lack of binocularity in patients with ''monovision,'' and a possibly reduced quality of the retinal image in patients with bifocal or multifocal intraocular lenses as a result of the multitude of optical foci of intraocular lenses.[9]

The intraocular lens used for patients in the study group in this investigation has flexible haptics theoretically enabling the intraocular lens to move its optical part forward and to change its shape if the ciliary muscle contracts, releases the tension on the zonula fibres of the lens capsular bag, and indirectly relaxes the lens capsular bag. The results of the present study suggest that during the follow up period of 6 months after surgery, a small accommodative effect in addition to the pseudoaccommodative effect of 0.5 dioptres, may be measurable (table 3). The mean range of accommodation measured in the control group of about 0.5 dioptres is in agreement with preceding studies.[10]

The results of the present study are in agreement with previous investigations by Kuechle and colleagues reporting an accommodative effect of about 1.57 dioptres for the new intraocular lens.[11] The change in anterior chamber depth between medical miosis and medical mydriasis was smaller in the study performed by Küchle and co-workers compared to the measurements in this study.

The present investigation has limitations. It has remained unclear, so far, how to measure the range of accommodation in pseudophakic eyes. Using defocusing curves and measuring the difference between the near point and the far point as performed by Kuechle *et al* and as carried out in the present investigation may be one of the techniques to measure the range of accommodation.[11 12] Using the device ''IOL Master'' (Zeiss Company, Oberkochen, Germany) for laser interferomatic measurement of the anterior chamber depth in pseudophakic eyes as performed in the present study may lead to inaccurate results, since the device has not been designed for that purpose. Interestingly, however, the measured range of accommodation of about 1 dioptre parallels the mean change in anterior chamber depth of 0.82 mm between medical mydriasis and medical miosis in the study group. Additionally, the difference in the range of accommodation between the two groups of this study agrees with the difference in the change of the anterior chamber depth measurements between the two groups (table 3).

Recently, laserinterferometric measurements reported an anterior movement of the accommodative 1 CU intraocular lens that would result in a pseudophakic accommodation of 0.5 dioptres if compared to a monofokal intraocular lens,[13] with a great variability of movement during pilocarpine induced ciliary contraction. These findings are comparable to our clinical results concerning both the amount of accommodative power and the great variability. Langenbucher *et al*[14] compared different possibilities for measurement of accommodation, indicating that the lowest fluctuation between the 1 CU intraocular lens and a study group with a monofocal intraocular lens could be achieved by measuring and comparing the subjective near point and by comparing defocusing curves. This may lead to the assuption that subjective measurements are especially suitable for assessing the effect of pseudophakic accommodation.

The amount of the pseudophakic accommodative power of the 1 CU certainly increases with the spherical power of the lens.[15] Both study groups did not differ significantly in axial length of the eye or in the spherical power of the implanted intraocular lens ranging from 18–24 dioptres.

In conclusion, this pilot study may suggest that for a follow up period of 6 months, the new monofocal foldable intraocular lens may offer the possibility of a small range of accommodation, in addition to the pseudoaccommodative effect monofocal intraocular lenses usually have.[1 2] Considering that the study and the control groups did not differ significantly in best corrected visual acuity or in the number of complications, further studies on the accommodative properties of the new intraocular lens may be warranted.

Authors' affiliations

G Sauder, R F Degenring, B Kamppeter, P Hugger, Department of Ophthalmology and Eye Hospital, Faculty of Clinical Medicine Mannheim, University of Heidelberg, 68167 Mannheim, Germany

Competing interests: none declared

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