

Visual and Refractive Outcomes of Phacoemulsification with Implantation of Accommodating versus Standard Monofocal Intraocular Lenses

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Abstract

Purpose: To compare distant and near visual function after cataract surgery with implantation of Crystalens HD or Tek-Clear as accommodating intraocular lenses (IOLs), versus SA60AT as a standard IOL.

Methods: The study included 62 eyes of 58 patients divided into three groups using three different IOLs: Crystalens HD (Bausch and Lomb, NY, USA), Tek-Clear (Tekia, CA, USA) and SA60AT (Alcon, TX, USA) were implanted in 23, 14 and 25 eyes, respectively. Corrected distant visual acuity (CDVA), uncorrected and distance corrected near visual acuities (UCNVA and DCNVA), near point of accommodation (NPA), spectacle freedom and patient satisfaction were assessed six months postoperatively and compared between the three groups.

Results: After 6 months, all patients showed significant improvement in CDVA with no significant difference among the study groups. However, UCNVA and DCNVA were significantly better in patients implanted with accommodating IOLs. NPA was closest in the Crystalens HD group, followed by Tek-Clear and monofocal SA60AT ($P < 0.001$). Patients with accommodating IOLs were more likely to become spectacle free and satisfied with their near vision as compared to subjects receiving a monofocal IOL.

Conclusions: Accommodating IOLs (Crystalens HD and Tek-Clear) effectively reduce the necessity for spectacles after cataract surgery.

Keywords: Accommodation; Cataract Extraction; Intraocular Lenses; Pseudophakia

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INTRODUCTION

Since the implantation of the first intraocular lens (IOL), attempts have been directed toward improvement of visual

outcomes of cataract surgery. Loss of accommodation is inevitable with conventional monofocal IOLs and the first attempt to overcome this limitation was pseudophakic monovision.^[1] Despite some reports of acceptable spectacle-free near and far visual acuity in more than half of the patients with monovision, this method may be associated with problems in stereoacuity, contrast sensitivity and dominance.^[2]

Multifocal IOLs were designed to overcome the lack of accommodation in pseudophakic patients.^[3] However,

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optical side effects, such as decreased contrast sensitivity, glare disability, and halos, have been reported in eyes with these IOLs.^[4]

In order to avoid the optical side effects of multifocal IOLs, accommodating IOLs were designed. The first developed and marketed accommodating IOLs were positional and had two main types; single optic and dual optic. Single optic IOLs are based on axial (backward and forward) movement of the optic resulting from contraction and relaxation of the ciliary muscle, increasing the effective power of the IOL and thereby providing near focus.^[5]

Several single-optic IOL models have been developed, such as the Crystalens (Bausch and Lomb, NY, USA), 1 CU (HumanOptics AG, Erlangen, Germany) Tetraflex (Lenstec, FL, USA), and Tek-Clear (Tekia, CA, USA). The plate style single optic accommodating IOL Crystalens HD is designed to be implanted within the capsular bag and is made from third generation silicone (Biosil) which unlike other IOL materials does not have internal reflectivity. It has a central bi-aspheric modification to increase depth of focus and provide better intermediate and near vision.^[6] According to the manufacturer, the IOL has a double mechanism to improve near visual function; first, axial movement of the optic which occurs with ciliary muscle changes and second, the radius of curvature of the anterior surface (arching optic) which varies with accommodative effort. A number of studies have shown better visual and accommodative results with this lens as compared to standard monofocal IOLs.^[7,8]

Tekia Tek-Clear is another single optic accommodating hydrophilic acrylic IOL with symmetric optic design, ultraviolet blocker and square edge design which has been approved for treatment of presbyopia by the European Commission since 2006. Near focus is achieved by anterior movement of the optic by ciliary muscle contraction during accommodative effort.^[6]

In the current study, we assessed the visual outcomes and amplitude of accommodation with these two types of monofocal accommodating IOLs, and compared them with a closely age-matched group of patients who received standard monofocal IOLs.

METHODS

In this prospective consecutive interventional clinical study, we evaluated patients with unilateral or bilateral cataracts who had cataract surgery and were implanted with either of two types of single-optic accommodative IOLs (Crystalens HD or Tek-Clear) or a standard monofocal IOL SA60AT (Alcon, TX, USA).

We enrolled 58 subjects (62 eyes) with no preexisting ocular pathology except senile cataracts. The eyes were implanted with the Crystalens HD accommodative IOL (23 eyes of 21 patients), Tek-Clear accommodative IOL (14 eyes of 12 patients) or SA60AT monofocal IOL (25

eyes of 25 patients). Four patients were implanted bilaterally with accommodating IOL (2 subjects with Crystalens HD and 2 with Tek-Clear). None of the patients received simultaneous accommodating and non-accommodating IOL implantation.

Informed consent was obtained from all patients after explaining the advantages and disadvantages of each IOL. This study was approved by the Ethics Committee at the Ophthalmic Research Center, Shahid Beheshti University of Medical Sciences.

Inclusion criteria were age from 40 to 80 years, unilateral or bilateral senile cataracts and minimum level of education (literacy). Exclusion criteria included more than one diopter (D) of keratometric astigmatism, incomplete or damaged zonules, any anterior segment pathology (e.g., chronic uveitis, rubeosis iridis, corneal dystrophy), controlled or undertreated glaucoma, retinal pathologies or history of retinal detachment, age-related macular degeneration, diabetic retinopathy, congenital cataracts, monocular status or previous ocular surgery in either eye.

Preoperative evaluations included refraction, distance and near visual acuity measurements, slit lamp examination, applanation tonometry, dilated fundus examination, standard ultrasonic biometric measurements using A-scan (immersion technique) and LenStar LS900 (Haag-Streit, Bern, Switzerland). IOL power was calculated using the SRK/T formula in all cases.

All procedures were performed by one experienced surgeon. Local anesthesia (either topical or peribulbar lidocaine 2%) was administered. A clear corneal incision (2.8 mm) was made, preferably on the steep corneal axis. Anterior curvilinear capsulorrhexis (approximately 5.5 mm in diameter for monofocal IOLs and 6.0 mm for accommodative IOLs) was performed. Maximal care was taken to achieve a central opening. Phacoemulsification employing standard techniques was performed. In eyes implanted with accommodative IOLs, one drop of atropine 1% was applied at the end of surgery and 24 hours later.

Effectiveness of the IOLs was assessed by measuring uncorrected distance acuity, best corrected distance visual acuity, uncorrected intermediate visual acuity at 80 cm, intermediate visual acuity at 80 cm through the distance correction, uncorrected near visual acuity (UCNVA) at 40 cm, and near visual acuity at 40 cm through the distance correction. Measurements of near and intermediate vision were made through the distance correction to eliminate potential pseudo-accommodation effects due to residual myopia and corneal cylinder.

Accommodative range was defined as the range of lens power allowing best corrected near visual acuity. The areas of interest (near and intermediate) were analyzed using the appropriate levels of defocus. A questionnaire was answered by patients to determine

patient satisfaction, subjective vision quality, and occurrence of visual disturbances.

All data were presented as mean \pm standard deviation and analyzed using SPSS software version 20 (SPSS Inc., Chicago, IL, USA). Distant and near visual acuity was expressed in LogMAR notations. Pre- and postoperative data were compared in each IOL group using paired *t*-test. Analysis of Variance was performed followed by Bonferroni correction to compare data among the IOL groups. *P* Values less than 0.05 were considered as statistically significant.

RESULTS

Sixty-two eyes of 58 patients with mean age of 63.4 ± 9.9 (range, 42-80) years were operated which included the standard monofocal IOL group (25 eyes), the Crystalens HD group (23 eyes) and the Tek-Clear group (14 eyes). Patients with postoperative ametropia more than -0.50 D were excluded from the study, because of possible pseudoaccommodation. There was no significant difference in demographic characteristics and preoperative measurements, including sphere, cylinder, mean keratometry, axial length, uncorrected distance visual acuity (UCDVA), corrected distance visual acuity (CDVA), UCNVA and distance corrected near visual acuity (DCNVA) among the three groups.

Postoperative UCDVA and CDVA were significantly better than corresponding preoperative values in all study groups and there was no significant difference among the groups regarding postoperative CDVA [Table 1]. Uncorrected and distance corrected intermediate and near visual acuities were significantly better in the Tek-Clear and Crystalens HD groups as compared to the monofocal IOL group. Complementary data are shown in Table 2.

Accommodation amplitude was also determined subjectively with the distance correction in place by the Royal Air Force (RAF) rule. The reading text was slowly moved toward the eye from a distance of 50 cm until the patient noted blurring of the N12 optotype. The near point was then converted to diopters. Near point of accommodation (NPA) was the closest in Crystalens HD group, followed by Tek-Clear and monofocal IOL groups [Table 3].

Overall, 89% of patients with unilateral and all patients with bilateral implantation of both accommodating IOLs were satisfied with their quality of near vision. Patients with accommodating IOL were more satisfied with near tasks (93 and 70% for Crystalens HD and Tek-Clear, respectively) and were more spectacle free (71 and 70% for Crystalens HD and Tek-Clear, respectively) as compared to patients with non-accommodating monofocal IOLs (40 and 24% satisfaction for near tasks and being spectacle free, respectively). All patients with monofocal IOLs were satisfied with their quality of vision for day-time and night-time driving, while day-time and night-time driving

Table 1. Refractive outcomes and distant visual acuity in Crystalens HD, Tek-Clear and SA60AT groups six months postoperatively

Parameter	Crystalens HD	Tek-Clear	SA60AT
Sphere (D)	0.17 \pm 1	-0.14 \pm 1.13	-0.11 \pm 0.7
Cylinder (D)	-0.67 \pm 0.39	-1 \pm 0.38*	-0.68 \pm 0.33
UCDVA (logMAR)	0.1 \pm 0.14†	0.22 \pm 0.15	0.23 \pm 0.15
CDVA (logMAR)	0.04 \pm 0.09	0.08 \pm 0.09	0.08 \pm 0.07

Data are presented as mean \pm SD. *Significant as compared with Crystalens HD and SA60AT (*P*<0.05); †Significant as compared to SA60AT (*P*<0.01). SD, standard deviation; UCDVA, uncorrected distant visual acuity; CDVA, corrected distant visual acuity; D, diopters

Table 2. Intermediate and near visual acuities (logMAR) in Crystalens HD, Tek-Clear and SA60AT groups 6 months postoperatively

Parameter	Crystalens HD	Tek-Clear†	SA60AT
UCIVA	0.14 \pm 0.14	0.22 \pm 0.15	0.38 \pm 0.14*
DCIVA	0.13 \pm 0.14	0.22 \pm 0.14	0.51 \pm 0.1*
UCNVA	0.12 \pm 0.16	0.18 \pm 0.17	0.32 \pm 0.13*
DCNVA	0.15 \pm 0.16	0.25 \pm 0.23	0.49 \pm 0.1*

Data are shown as mean \pm SD. *Significant as compared to both Crystalens HD and Tek-Clear groups (*P*<0.001); †No significant difference between Crystalens HD and Tek-Clear groups. SD, standard deviation; UCIVA, uncorrected intermediate visual acuity; DCIVA, distant corrected intermediate visual acuity; UCNVA, uncorrected near visual acuity; DCNVA, distant corrected near visual acuity

Table 3. Near point of accommodation in Crystalens HD, Tek-Clear and SA60AT groups

Parameter	Crystalens HD	Tek-Clear§	SA60AT
NPA monocular (cm)§	34.35 \pm 4.18	56.07 \pm 4.87	94.64 \pm 8.09†
Range	25-40	50-65	85-110
NPA monocular (D)§	2.96 \pm 0.39	1.8 \pm 0.16	1.06 \pm 0.09†
Range	2.5-4	1.54-2	0.91-1.18

Data presented as mean \pm SD. †Significant as compared with Crystalens HD and Tek-Clear groups (*P*<0.001); §No significant difference between Crystalens HD and Tek-Clear groups. cm, centimeters; D, diopters; NPA, Near point of accommodation; SD, standard deviation

satisfaction were both 64% in the Crystalens group, and 74 and 68%, respectively, in the Tek-Clear group.

Regarding complications, patients with Crystalens HD showed the highest rate of posterior capsule opacification (PCO) which occurred in 7 (30%) out of 23 eyes, whereas one (7%) eye in Tek-Clear group and 4 (16%) eyes in SA60AT group developed PCO 6 months after implantation. None of the cases required posterior capsulotomy during the period of the study. Other complications such as uveitis, IOL decentration or IOL tilt were not observed in any group.

DISCUSSION

Functional near vision is indispensable due to the necessity of several near tasks in ordinary life. Loss of

reading ability can greatly reduce quality of life. Thus, providing good near vision after cataract surgery is an important goal in modern cataract surgery.

The present study compared the visual outcomes of two new generation single-optic monofocal accommodating IOLs, namely the Crystalens HD and Tek-Clear with those of a standard monofocal IOL. The aim was to determine which IOL provides the greatest spectacle freedom and the relationship between optical performance and clinical visual outcomes for each IOL.

There was a significant improvement in distance vision after IOL implantation in all groups [Table 1]. This is consistent with findings in previous studies on other positional accommodating IOLs as well as with cataract surgery expectations, and it confirms the safety of both accommodating IOLs used herein.^[9,10] There were also no statistically significant difference between the three IOL groups in terms of postoperative CDVA [Table 1]. However, night vision and glare complaints were more frequently reported in eyes implanted with accommodating IOLs than with monofocal IOLs, but the difference was not significant. These findings indicate that both accommodating IOLs had similar capacity to successfully restore distance visual function after cataract surgery.

Uncorrected near acuity values were best with the Crystalens HD. We observed that 55.6% of eyes with Crystalens HD, 33.3% of eyes with Tek-Clear and none of the eyes with SA60AT Monofocal IOL had uncorrected near acuity of 20/25 (J1) or better.

DCNVA improved significantly with both accommodating IOL groups in our study. Surprisingly, UCNVA and DCNVA also improved in the monofocal IOL group. A previous study demonstrated that the monofocal IOL we used in our study has some pseudo-accommodative ability, although the mechanism was not clearly understood.^[11]

The difference in DCNVA between the monofocal group (J6) and accommodating IOL groups, (Crystalens [J1 to J2]; Tek-Clear [J2 to J3]) was statistically significant, and the best DCNVA occurred in eyes implanted with the Crystalens HD [Table 2].

In most reports, accommodating IOLs were associated with significant improvement in near visual acuity.^[8,12-16] Alió et al^[7] reported significant improvement in uncorrected and corrected near visual acuity with Crystalens HD as compared to a monofocal IOL. However, accommodating IOLs did not show any superiority to monovision or multifocal IOLs in some other studies.^[17,18] In one study, a dual optic accommodating IOL (Synchrony; AMO, CA, USA) showed better distant visual acuity and contrast sensitivity as compared to Crystalens HD; furthermore PCO and higher order aberrations were more common with the single optic Crystalens HD.^[19]

Takakura et al,^[20] performed a meta-analysis on 12 randomized controlled studies (a total of 727 eyes) and

found no clear evidence of near acuity improvement with accommodating IOLs, while they were associated with higher rates of PCO. Saiki et al^[21] evaluated the long-term outcomes of the 1CU accommodating IOL. After 4 years, they found no significant change in CDVA, UCNVA, DCNVA, and subjective and objective accommodation amplitudes.

Near point measurements using the RAF rule (or accommodometer) are simple to perform, but may overestimate true accommodative amplitude due to pupillary miosis and depth of focus.^[22]

Focal point changes, through accommodation, were significantly higher with accommodating IOLs using the monocular NPA measurement method. In unilaterally implanted patients who completed the survey, 89, 90 and 92% of subjects with Crystalens, Tek-Clear and monofocal IOLs, reported improvement in their quality of vision at six months, respectively. All of the patients bilaterally implanted with accommodating IOLs (Crystalens or Tek-Clear) reported that they were very satisfied with their visual outcomes.

In the current series, 100% of cases with bilateral accommodating IOLs, 79% of cases with unilateral Crystalens IOLs, 80% of subjects with unilateral Tek-Clear IOLs and 24% of unilateral monofocal IOL patients did not wear glasses. Spectacle freedom was also greater in patients with accommodating IOLs as compared to monofocal IOLs in a study by Sanders et al.^[23]

The incidence of PCO in the Crystalens HD group (30%) was higher than the two other IOL groups. This finding is in agreement with previous reports.^[19,20] The square edge on the Crystalens IOL extends for only 240°; there is no square edge where the optic abuts the plates, while Tek-Clear and SA60AT both have 360°square edge design.

Capsule fibrosis can be a long-term detrimental factor for accommodating IOLs; capsular bag rigidity limits axial movement of the lens and therefore reduces accommodative capacity; follow-up period in our study was not long enough to evaluate such changes. Longer follow-up is required to confirm stability of near-vision function with these types of accommodating IOLs.

In summary, both monofocal and accommodating IOLs in the present study restored distance visual function after cataract surgery. Both accommodating IOLs employed in this series yielded more ideal UCNVA and DCNVA than the monofocal IOL. The Crystalens HD showed better results than Tek-Clear.

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Conflicts of Interest

There are no conflicts of interest.

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