Near Visual Performance Results of the Accommodating Intraocular Lens (Tetraflex)® in Comparison to Monofocal Foldable Intraocular Lens

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Abstract

Purpose: To evaluate the near visual performance of an accommodative intraocular lens (IOL); Tetraflex, in comparison to a standard monofocal foldable IOL in cataract surgery.

Setting: Eye Research Center, Farabi Eye Hospital, Department of Ophthalmology, Tehran University of Medical Sciences, Iran.

Methods: Forty six eyes of 23 patients with cataract underwent phacoemulsification and accommodative IOL (Tetraflex) implantation bilaterally (case group). The same number of age-matched control group were implanted a foldable monofocal IOL bilaterally (control group). Outcome measures were uncorrected distance visual acuity (UCDVA), uncorrected near visual acuity (UCNVA), manifest refraction, best corrected distance visual acuity (BCDVA), distance corrected near visual acuity (DCNVA), and the amplitude of accommodation up to 6 months after surgery.

Results: The final BCDVA was better than $^{20}/_{25}$ in all eyes. Mean±standard deviation (SD) DCNVA in the accommodative IOL group (0.69±0.25) was significantly higher than monofocal foldable IOL (0.18±0.09) six months following surgery (P<0.001). Eighty nine percent (41 eyes of 46) of the accommodative IOL group achieved DCNVA of $^{20}/_{40}$ or better 6 months after surgery. At 1 month after surgery, mean±SD accommodation in the case group was 3.86±1.11 D compared to 0.27±0.18 D in the control group (P<0.001). Six months after operation, 95.7% of the patients in the case group had 2.5 D or more accommodation compared to a mean of 0.48 D in the control group.

Conclusion: The accommodative IOL provides both enhanced near vision and good distance vision 6 month after surgery. It seems that patient's dependence to near add will be decreased and they can have a good range of clear vision.

Keywords: Accommodative Intraocular Lens, Accommodation, Tetraflex, Cataract Surgery

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Introduction

Surgery of cataract, as the most common surgically treatable reason for decreased vision in the elderly population, has been perfected by phacoemulsification and implantation of intraocular lenses (IOLs). With this method all functions of the natural lens remaining in the elderly patient such as transparency, refraction, compartmentalization of the eye, and inner stabilization of the eye can be restored. The only remaining function that has generally not yet been restored by surgery to functional rejuvenation of the eye is accommodation.[1] So, postoperative presbyopia remains as an unsolved challenge. Numerous techniques to overcome this problem exist: spectacle, contact lenses or IOLs using monovision technique, refractive procedures, and multifocal or accommodative IOLs.[2] It is well known that the quality of vision obtained with multifocal lenses is compromised with problems of decreased contrast sensitivity, halos, and night glare.[3-5] Accommodative IOLs are monofocals with accommodative abilities that lead to superior vision quality without the inherent optic problems of the multifocal IOLs.

The Tetraflex® (Lenstec, St. Petersburg, Florida) IOL is currently CE marked in Europe, and is under clinical trial with the United State's Food and Drug Administration (FDA). In this randomized clinical study, we assessed 6 months visual and accommodative changes after accommodative IOL implantation and compared its result with monofocal foldable IOL.

Methods

Patients

This prospective randomized clinical study included 92 eyes from 46 patients who presented with senile cataract for routine cataract surgery from September 2005 to July 2007. The cases divided into two groups: accommodative IOL (Tetraflex) as the case group and standard monofocal foldable IOL as the control group. Each group included 46 eyes from 23 patients. All patients who underwent implantation of the accommodative IOL had prior informed consent and the ethics committee of Tehran University of Medical Science approved the study.

Exclusion criteria included any subject with an uncontrolled systemic disorder like diabetes mellitus or hypertension, age less than forty years, glaucoma, age-related macular degeneration, history of ocular trauma or previous ocular surgery, corneal astigmatism more than 1 D or those who required corneal relaxing incisions for the treatment of astigmatism, amblyopia, and any intraoperative complications such as capsulorrhexis diameter less than 5 mm, posterior capsular rupture or vitreous loss.

Tetraflex® accommodating intraocular lens

Tetraflex® is an acrylic single-piece IOL, 5° anteriorly angulated, closed-loop haptics which are claimed by the manufacturer that has been designed to utilize the two forces activated during accommodation -vitreous movement and ciliary swelling- to ensure maximum forward movement for clear near vision. The Tetraflex® is designed to move back and forth, as to focus on distant, mid or near objects, allowing the patients to once again "accommodate". It can be inserted through a small (2.5-3 mm) clear corneal incision. It has a 5.75 mm optic with square edges and overall length of 11 mm. The Tetraflex® is not currently FDA approved.

Softec foldable monofocal intraocular lens

The Softec is a one-piece acrylic IOL with 0-degree angulation. It has 5.75 mm optic size and 12 mm length.

Surgical technique

The power of the lenses were calculated by using IOL Master (Zeiss–Humphrey CA, USA) with postoperative refractive target of less than -0.5 D. The surgeries were performed using topical anesthesia following instillation of one drop of tetracaine 5 minutes before initiation of the surgery. Intracameral injection of lidocaine 1% was used if necessary through the operation. The surgical method was standard phacoemulsification with clear corneal incision. The lens was inserted through cartridges using standard technique. Postoperatively, all eyes received topical betamethasone eye drop, six times daily tapering over four weeks and chloramphenicol eye drop for four times daily for one week

after surgery. Two of authors; F.R. and M.N.H. performed all the surgeries.

Outcomes measures

The preoperative assessment included slit-lamp examination, intraocular pressure (IOP) measurement with applanation tonometer, funduscopy, and best corrected vision of distance and near. Postoperative assessments were performed at 1 day, 1 week, and 1, 3, and 6 months after surgery. The examination at day 1 included a slit-lamp examination along with uncorrected distance visual acuity (UCDVA) testing. At 1 week and 1, 3, and 6 months refraction, best corrected distance visual acuity (BCDVA), distance corrected near visual acuity (DCNVA), and the amplitude of accommodation were also tested. Near visual acuity was measured by a Jaeger reading chart held 40 cm from the eye in good lighting condition. For measuring accommodation, the patient was asked to fixate on a movable target of a minimum angle of resolution of 5' of arc, with best distance correction in place for elimination of potential pseudoaccommodative effects of residual myopia or corneal cylinder. The target was moved toward the eye until the patient reported it to be blurred. The distance to the eye was recorded and the inverse distance in meter was the amplitude of accommodation.

Statistical analysis

For data analysis, unpaired T-tests were used. All statistics were two tailed. LogMAR visual acuity values were used for calculations. The paired T-test compared differences between values at baseline and those at one week and 1, 3, and 6 months after surgery. A finding was considered statistically significant at $P<0.05$. Statistical analyses were performed using the SPSS software version 14.5 (SPSS Inc., Chicago, IL, USA).

Results

Table 1 summarizes preoperative data of both groups. Mean±standard deviation (SD) spherical equivalent (SE) 6 months after the surgery was -0.08±0.28 D in eyes with the accommodative IOL and -0.05±0.22 D in the control group. There were no statistically significant differences between the mean SE scores of the two studied groups at any examination point ($P>0.05$). The final BCDVA was $^{20}/_{25}$ or better in all eyes with the accommodative IOL and the monofocal groups. There were no statistically significant differences between the mean UCDVA and BCDVA scores at any examination ($P>0.05$) (Table 2).

Table 1. Characteristics of groups by treatment, Group 1= Accomodative group, Group 2= Softec Group

	Group 1 (N=46)	Group 2 (N=46)	P-value
Sex (F/M)	14/32	24/22	
Age (years)	59.06±9.45	59.06±9.45	0.939
Axial length (mm)	22.35±1.14	22.59±1.08	0.311
IOP (mmHg)	16.52±2.90	16.15±3.36	0.574
Keratometry	44.34±1.23	43.52±1.67	0.326

Values show means ±SD.

Table 2. UCDVA (logMAR) of groups by duration after surgery

Time after surgery	Group 1 (N=46)	Group 2 (N=46)	P-value
1 week	0.12±0.07	0.14±0.06	0.166
1 month	0.04±0.05	0.04±0.04	0.703
3 months	0.04±0.05	0.02±0.03	0.066
6 months	0.04±0.04	0.03±0.03	0.160

Values show means ± standard deviation.

Mean values of UCNVA were significantly better in the accommodative IOL group at 1 week, and 1, 3, and 6 months postoperatively ($P<0.001$). Mean values of DCNVA were significantly better in eyes implanted by accommodative IOL ($P<0.001$) (Table 3). Mean±SD DCNVA values 6 months after surgery were 0.66±0.13 in the accommodative IOL group and 0.23±0.12 in the Softec group. At 1 month after surgery, 50% of cases in the case group had achieved $^{20}/_{40}$ or better DCNVA, and by 6 months 89.1% (41 of the 43) had achieved $^{20}/_{40}$ or better DCNVA. The change over time in the DCNVA in the

accommodative IOL group was analyzed by Wilcoxon Signed Ranks test. We observed an improvement in DCNVA at 1 month (P<0.001) and 3 months (P<0.001) in comparison to DCNVA values at week 1 (P<0.001). There was no change thereafter (Figure 1).

There were statistically significant decrease at 6 month in comparison to 1 month (P=0.003) in the accommodative group, but 95.7% of cases at 6 months after surgery had an accommodative amplitude of 2.5D or more (Figure 2).

Table 3. DCNVA (logMAR) of groups by duration after surgery

Time after surgery	Group 1 (N=46)	Group 2 (N=46)	P-value
1 week	0.78±0.29	0.35±0.13	<0.001
1 month	0.68±0.25	0.22±0.11	<0.001
3 months	0.70±0.28	0.19±0.09	<0.001
6 months	0.69±0.25	0.18±0.09	<0.001

Values show means ± standard deviation.

Table 4. Add (diopter) required for each groups by duration after surgery

Time after surgery	Group 1 (N=46)	Group 2 (N=46)	P-value
1 week	1.47±0.51	2.59±0.63	<0.001
1 month	1.32±0.54	2.57±0.63	<0.001
3 months	1.21±0.49	2.55±0.67	<0.001
6 months	1.20±0.50	2.94±0.25	<0.001

Values show means ± standard deviation.

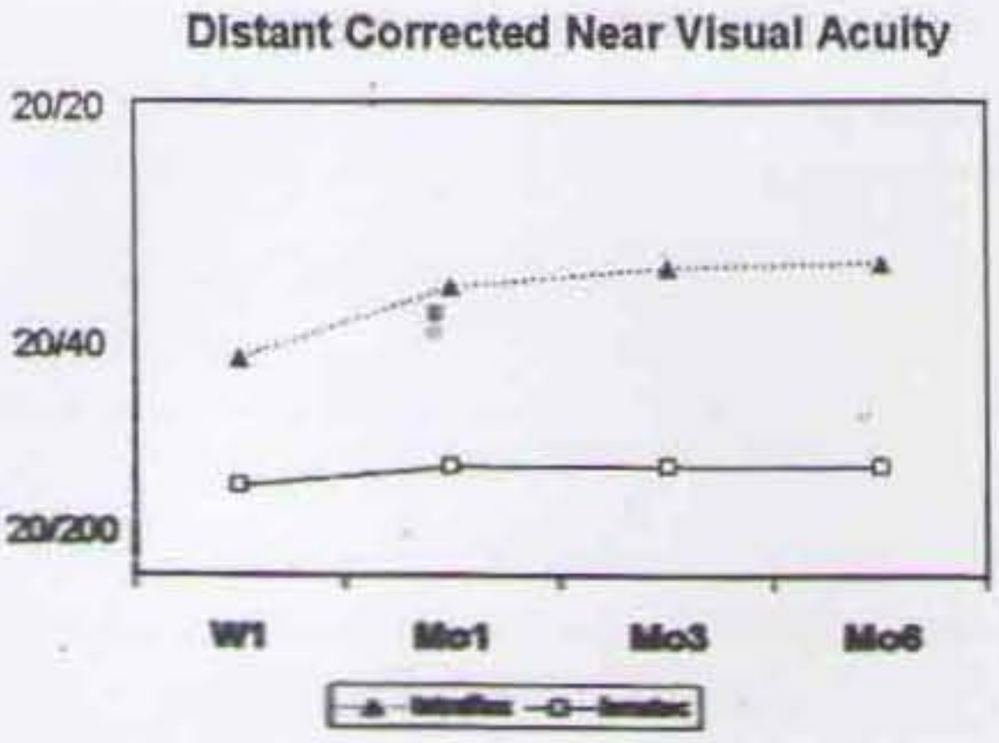

Figure 1. Change of DCNVA with time in both groups (W1= Week 1, Mo1=Month 1, Mo3= Month 3, Mo6= Month 6)

Table 5. Accommodation (diopter) of groups by duration after surgery

Time after surgery	Group 1 (N=46)	Group 2 (N=46)	P-value
1 week	3.58±1.22	0.25±0.20	<0.001
1 month	3.86±1.11	0.27±0.18	<0.001
3 months	3.68±0.93	0.39±0.16	<0.001
6 months	3.54±0.89	0.48±0.20	<0.001

Values show means ± standard deviation.

There was significant difference in the amount of add required to achieve BCNVA in the two groups (P<0.001) (Table 4). Mean±SD add requirements 6 months after surgery were 1.20±0.50 D in the accommodative IOL group and 2.94±0.25 D in the Softec group. Mean±SD amplitudes of accommodation were 3.58±1.2 D at 1 week, 3.86±1.11 D at 1 month, 3.68±0.93 D at 3 months, and 3.54±0.89 D at 6 months in the accommodative IOL group (Table 5). In the control group corresponding amounts were 0.22±0.22, 0.48±0.19, 0.51±0.25, and 0.51±0.25 (Table 5). The change over time in amplitude of accommodation was analyzed.

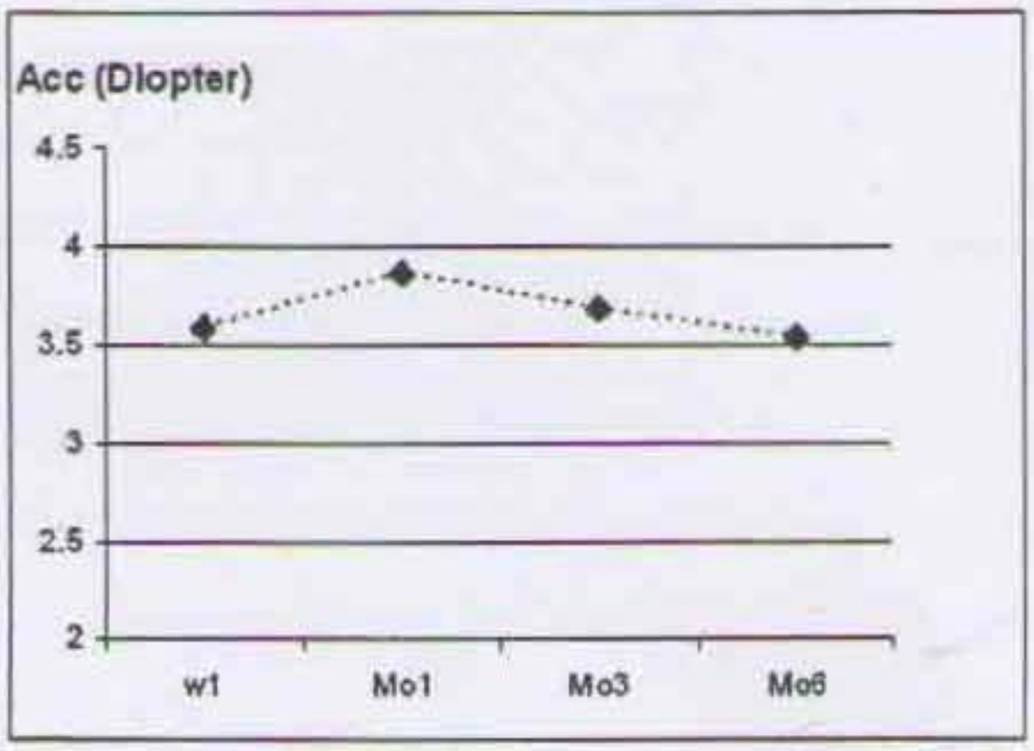

Figure 2. Change of amplitude of accommodation with time in the Tetraflex group (Acc= accommodation, W 1= Week 1, Mo 1=Month 1, Mo 3= Month 3, Mo 6= Month 6)

No intraoperative complications were observed. Only one patient had mild uveitis at 1 month that cleared with a brief period of topical corticosteroid.

Discussion

The restoration of near visual function in patients with senile cataract having cataract surgery with IOL implantation remains a challenging problem of modern cataract surgery.

Conventional monofocal IOLs offer excellent distance visual rehabilitation; however, most patients require reading glasses for near tasks. Implantation of multifocal IOLs provides an alternative to patients seeking both pseudophakic distance and near vision. However, multifocal IOLs can lead to symptoms of glare, halos, and a reduction in contrast sensitivity.[6-8] In a prospective study of the Array IOL (Advanced Medical Optics, Santa Ana, CA, USA), 34% of eyes had severe glare and approximately 20% of patients were very dissatisfied with their visions.[9] But in the study of Chiam et al,[10] there was a high level of satisfaction in both multifocal IOL groups; ReSTOR and ReZoom (Advanced Medical Optics, Santa Ana, CA, USA), despite the finding that most patients experienced various degrees of halos and glare. There are, in addition similar findings in other papers in the peer reviewed literature.[11-13] Such loss of image quality can affect visual performance and has led to interest in alternative methods of providing both distance and near vision in pseudophakic eyes.

The primary objective of this study was to determine and quantify any accommodative effect produced by Kellan Tetraflex KH-3500 lens in patients undergoing cataract surgery. In this study, we had no complaints of halo, glare or other visual disturbances and all of our patients had high levels of satisfaction.

As mentioned previously, the level of accommodative ability measured by DCNVA and accommodative amplitude by subjective method. The mean range of DCNVA at 6 months was $^{20}/_{32}$ - $^{20}/_{30}$ (J3-J4) which means satisfactory for social performance.[14] All of our patients in the case group had BCNVA of better than $^{20}/_{25}$. Our findings are comparable to the report of Cumming et al[15] who implanted the AT-45 IOL (Eyeonics Inc., Aliso Viejo, CA, USA) in 76 eyes of 62 patients and found that 92% of them achieved a DCNVA of $^{20}/_{30}$ or better. Higher DCNVA has also been reported by Dogru et al[3] with 1CU IOL (HumanOptics, Erlangen, Germany) at 3, 6, and 12 months too.

It has been calculated that 2 D of accommodation is sufficient to enable most subjects to function without reading glasses for almost all near and intermediate vision tasks.[14] We had maximum mean accommodation at 1 month (3.86±1.11 D), but it decreased to 3.68±0.93 D at 3 months, however this decrease was not statistically significant. Accommodative amplitude was stable from 3 to 6 months with almost 96% of patients demonstrating 2.5 D or more accommodation. This finding is great because one of the most important concerns about these lenses is diminishing of accommodative ability over the course of time. The 1CU accommodative IOL, also provided improved near acuity, but the benefit disappeared at 12 months with concomitant decrease in accommodation amplitude owing to an increase in capsular opacification and fibrosis.[3]

Accommodative IOLs can yield good intermediate vision which is critical for those people who work with computers and the ones who have to work within intermediate distances. It is better to consider individual patient's expectation. For someone expecting to read very small printed scripts without glasses, this may not be achieved but we can offer them freedom from glasses for 95% of their daily activities.[14]

We did not find any significant difference between the two IOLs groups related to SE values and postoperative astigmatism at our follow-up examinations.

The main limitation of our study was the limited follow-up time. A 6 months follow-up might be too short to demonstrate the clinical efficacy of accommodative lenses, specially since the functional results at 6 months are somewhat inferior as compared to the earlier performance. On the other hand, it should not be forgotten the important characteristic of this study from those previously published by emphasizing the bilateral simultaneous implantation of the IOLs as well as the use of a control group.

Conclusion

In conclusion, the Tetraflex IOL seems to restore accommodation and provide additional near visual acuity postoperatively. Although accommodation decreased 6 months after surgery, significant number of people had at least 2.5 D of accommodation which is sufficient for most of humans' near tasks.

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