Original Research Article

Clinical outcomes of Tetraflex accommodative intraocular lens implantation 2 years after cataract surgery for presbyopia

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Abstract

Aims: To evaluate the 24 month visual and accommodative outcomes of Tetraflex accommodative intraocular lens (AIOL).

Study Design: Retrospective, interventional case series.

Place and Duration of the Study: Bakirkoy Training and Research Hospital, Istanbul, Turkey, between December 2011 and April 2012.

Material and Methods: The patients who underwent cataract surgery with phacoemulsification, and in whom Tetraflex AIOL was implanted and who completed the follow-up period of 24 months were included. Uncorrected (UCDVA) and best corrected distance visual acuities (BCDVA) were evaluated pre- and post-operatively, and uncorrected (UCNVA), distance-corrected (DCNVA) and best corrected near visual acuities (BCNVA) and spherical equivalent (SE) refraction errors were evaluated post-operatively only. Accommodative amplitude was measured with a subjective and objective method and at post-operative month 3, 6 and 24.

Results: A total of 16 eyes of 14 patients were included. The mean baseline, month 3, 6 and 24 UCDVA of the patients was 0.95 ± 0.47, 0.11 ± 0.14, 0.14 ± 0.16 and 0.14 ± 0.17 LogMAR, respectively. The mean month 3, 6 and 24 UCNVA was 0.49 ± 0.16, 0.54 ± 0.15 and 0.51 ± 0.16 LogMAR, respectively. The mean amplitude of accommodation by subjective defocus method was -1.06 ± 0.30, -1.14 ± 0.27 and -1.13 ± 0.27 D and the average pilocarpine-induced IOL mobility (∆ ACD) was 0.34 ± 0.16 mm, 0.37 ± 0.16 mm and 0.36 ± 0.15 mm at postoperative month 3, 6 and 24, respectively.

Conclusion: The Tetraflex AIOL implantation seemed a safe and effective treatment option for presbyopia.

Keywords: Accommodation, cataract, intraocular lens, presbyopia.

1. INTRODUCTION

Implantation of accommodative intraocular lenses (AIOL) is theoretically the most physiological treatment option for presbyopia. There are several types of AIOLs such as single optic AIOLs, dual-optic AIOLs, and capsular bag refilling AIOLs [1,2]. Single optic AIOLs work with accommodative effort, while the lens optic of the AIOLs moves forward consequently with the contraction of the ciliary muscle this movement increases the refractive power of the IOL [1,2].

Eyeonics Crystalens (Eyeonics, Inc., Aliso Viejo, CA, USA), the Akkommodative ICU lens (HumanOptics AG, Erlangen, Germany), and the Tetraflex KH-3500 (Lenstec Inc, FL, USA) were the most evaluated AIOLs in the literature [1,3]. The Tetraflex AIOL is a single-piece, spherical optic, acrylic IOL, flexible 5˚ anteriorly angulated, closed-loop haptics which are designed to utilize the two forces activated during accommodation to ensure maximum forward movement for a good near vision. Also, it is designed to move back and forth, as to focus on distant, mid or near objects. It can be inserted through a small (as small as 2.5 mm) clear corneal incision [1,8]. It has a 5.75 mm optic with square edges and overall size of 11.5

mm. This study aimed to evaluate the 24 month visual and accommodative outcomes of Tetraflex AIOL implanted during cataract surgery with phacoemulsification.

2. MATERIAL AND METHODS

The patients who underwent cataract surgery with phacoemulsification, and in whom Tetraflex accommodative intraocular lens (AIOL) was implanted between December 2011 and April 2012, and who completed month 24 follow-up period were included in the study retrospectively. The medical records of the patients were assessed. The patients who were between 40 and 65 years old, had a unilateral or bilateral senile or presenile cataract, had good cooperation, had a minimum level of education (literacy), and did not want to use spectacles post-operatively were included. The patients who had any other ocular disease such as diabetic retinopathy, previous retinal detachment, glaucoma, amblyopia etc., who underwent any intraocular surgery previously, who did not have presbyopia, who had a spherical refractive error > ±6 diopters or cylindrical refractive error > ±1.5 diopters, who suffered from complications such as posterior capsule rupture, iris damage, irregular and large or small capsulerrhexis preoperatively, who had a personality of obsessive, who required very concise near vision (watch repairer, jeweler etc.) were not included. Written informed consent was obtained from all of the patients preoperatively. The study adhered to the tenets of Declaration of Helsinki and local ethical approval was obtained.

2.1 Preoperative assessment

Preoperative assessment involved a complete eye examination including distance and near BCVA, manifest refraction, keratometry (Auto kerato-refracto-tonometer TRK-1P, Topcon, Tokyo, Japan), slit lamp biomicroscopy, intraocular pressure measurement via applanation tonometry, and dilated retinal examination. Biometry was obtained via the Bioline Ultrasound Biometer (Optikon, Roma, Italy). Immersion biometry technique was chosen, and the surgeon calculated the required IOL power with formula of SRK-T. Distance visual acuity was measured via a projection chart from 4 meters and noted in decimals. Near visual acuity was measured via a Turkish near vision chart which was previously described [9]. All examinations were performed by a single ophthalmologist (HNT).

2.2 Surgical Technique

All patients underwent a cataract surgery with a standardized phacoemulsification technique and implantation of Tetraflex AIOL under local anaesthesia. All surgeries were performed by a single surgeon (UY). A 2.8 mm clear corneal incision was placed at the steepest corneal meridian. A continuous curvilinear capsulerrhexis of 5-5.5 mm was created. Phacoemulsification was performed using the Infiniti Vision System (Alcon, Fort Worth, Texas, USA). All AIOLs were implanted into the capsular bag with a single use IOL injector. None of the patients required corneal incision suturation because leakproofing was obtained with only wound hydration. All patients used topical prednisolone acetate and ofloxacin 5 times a day after the surgery. Prednisolone acetate began to be tapered after the first week and was stopped after 4 weeks. Ofloxacin was stopped after 2 weeks post-operatively.

2.3 Postoperative assessment

Postoperative examinations were performed at postoperative day 1, week 1, and month 1, 3, 6, 12, and 24. Each visit included measurement BCVA and manifest refraction, slit-lamp examination of the anterior and posterior segments and intraocular pressure measurement. Full visual assessment and measurement of accommodative amplitude were performed at postoperative month 3, 6 and 24. Accommodative amplitude was evaluated with both subjective and objective methods. Defocus method was chosen as an individual method, and minus lenses were used for the stimulation of the accommodation. Under standard room illumination, the patient was seated with a full distance refractive correction while viewing the smallest letter on the visual acuity chart. Then, minus-power lenses were gradually increased in 0.25 D steps until the visual target was blurred (minus-lenses-to-blur-method) and the added diopter was defined as the amplitude of accommodation [10]. Anterior chamber depth measurement was made via Sirius Scheimpflug-Placido Topographer (Costruzione Strumenti Oftalmici, Florence, Italy) as an objective method [10,11]. The distance between the anterior surface of the IOL and the corneal vertex was accepted as the anterior chamber depth and measured in both unaccommodated and accommodated status. Accommodative status was induced with 2 drops of 2% pilocarpine at 5 minutes interval and the measurements were obtained after 30 minutes from the first drop [12]. Three consecutive measurements were taken and averaged before and after the installation of pilocarpine drops. The difference between the two statuses was calculated and accepted as drug-induced AIOL movement which showed us the accommodation objectively.

2.4 Outcomes Measures

The outcome measures of this study were uncorrected distance visual acuity (UCDVA), best-corrected distance visual acuity (BCDVA), uncorrected near visual acuity (UCNVA),distance-corrected near visual acuity (DCNVA), best corrected near visual acuity (BCNVA) and accommodation amplitude.

2.5 Statistical Methods

All visual acuity measurements were converted to the logarithm of the minimum angle of resolution. Statistical analysis was performed using commercially available software (SPSS for Windows, version 20.0 SPSS Inc., Chicago, IL). Descriptive statistical results were described as the mean, standard deviation (SD), and 95% confidence interval (CI) of the mean. The normality of the data was assessed using the Shapiro-Vilk test. According to the normality results the Mann- Whitney U test or t-test were used for comparing the variables. Wilcoxon test was used for repeated values. Chi-square and Fisher-exact test was used for the analysis of categorical variables. A P value less than 0.05 was considered statistically significant.

3. RESULTS AND DISCUSSION

A total of 16 eyes of 14 patients were included. Mean age was 55.3 ± 7.8 years (range 45-65 years). The baseline demographic features of the included patients were summarised in table 1.

Table 1. Baseline characteristics of the patients

Mean age, years	55.3 ± 7.8 (range 45-65)
Male/Female	9/5
Right/Left	7/9
IOL Power (diopter)	21.0 ±1.3 (range 20.0-22.2)
Axial Length (mm)	23.1 ±0.6 (range 22.2-24.5)

Abbreviations: IOL, intraocular lens

3.1 Visual Outcomes

Visual outcomes were summarized in table 2 and 3. The mean baseline, month 3, 6 and 24 UCDVA of the patients was 0.95 ± 0.47, 0.11 ± 0.14, 0.14 ± 0.16 and 0.14 ± 0.17 LogMAR, respectively ($p<0.0001$ for month 3, $p<0.0001$ for month 6, and $p<0.0001$ for month 24). The mean baseline, month 3, 6 and 24 BCDVA of the patients was 0.73 ± 0.43, -0.02± 0.04, 0.00 ± 0.05 and 0.00 ± 0.05 LogMAR, respectively ($p<0.0001$ for month 3, $p<0.0001$ for month 6, and $p<0.0001$ for month 24). The mean month 3, 6 and 24 UCNVA was 0.49 ± 0.16, 0.54 ± 0.15 and 0.51 ± 0.16 LogMAR, respectively ($p<0.0001$ for month 6 and $p<0.0001$ for month 24). The mean month 3, 6 and 24 DCNVA was 0.59 ± 0.09, 0.62 ± 0.09 and 0.61 ± 0.08 LogMAR, respectively ($p<0.0001$ for month 6 and $p<0.0001$ for month 24). The mean month 3, 6 and 24 BCNVA was 0.04 ± 0.05, 0.08± 0.07 and 0.06 ± 0.06 LogMAR, respectively ($p<0.0001$ for month 6, and $p<0.0001$ for month 24).

Table 2. The distance visual acuity outcomes at different time points.

	Mean ± SD	P value (vs baseline)
UCDVA (LogMAR)		
Baseline	0,95 ± 0,47	-
Month 3	0,11 ± 0,14	0,000
Month 6	0,14 ± 0,16	0,000
Month 24	0,14 ± 0,17	0,001
BCDVA (LogMAR)		
Baseline	0,73 ± 0,43	-
Month 3	-0.02 ± 0,04	0,000
Month 6	0,00 ± 0,05	0,000
Month 24	0,00 ± 0,05	0,001

Abbreviations: UCDVA, uncorrected distance visual acuity; BCDVA, best corrected distance visual acuity; SD, standard deviation; vs, versus.

Table 3. The mean spherical equivalent, near visual acuity, and accommodation amplitude levels at different time points.

	Mean ± SD
SE (D)	
Month 3	-0,27 ± 0,76
Month 6	-0,15 ± 0,78
Month 24	-0,30 ± 0,71
UCNVA (LogMAR)	
Month 3	0,49 ± 0,16
Month 6	0,54 ± 0,15
Month 24	0,51 ± 0,16
DCNVA (LogMAR)	
Month 3	0,59 ± 0,09
Month 6	0,62 ± 0,09
Month 24	0,61 ± 0,08
BCNVA (LogMAR)	
Month 3	0,04 ± 0,05
Month 6	0,08 ± 0,07
Month 24	0,06 ± 0,06
AA(Defocussing, D)	
Month 3	-1,06 ± 0,30
Month 6	-1,14 ± 0,27
Month 24	-1,13 ± 0,27
∆ ACD (mm)	
Month 3	0,34 ± 0,16
Month 6	0,37 ± 0,16
Month 24	0,36 ± 0,15

Abbreviations**:** SE, spherical equivalent; UCNVA, uncorrected near visual acuity; DCNVA, distance-corrected near visual acuity; BCNVA, best corrected near visual acuity; AA, accommodation amplitude; Δ ACD, the difference between before and after pilocarpine induced anterior chamber depth; D, diopter; SD, standard deviation.

3.2 Refractive and Accommodative Outcomes

Refractive and accommodative outcomes were summarized in table 3. The mean spherical equivalent (SE) refraction was -0.27 ± 0.76, -0.15 ± 0.78 and -0.30 ± 0.71 diopters (D) at postoperative month 3, 6 and 24, respectively. The mean amplitude of accommodation via subjective defocus method was -1.06 ± 0.30, -1.14 ± 0.27 and -1.13 ± 0.27 D and the average pilocarpine-induced IOL mobility (∆ ACD) was 0.34 ± 0.16 mm, 0.37 ± 0.16 mm and 0.36 ± 0.15 mm at postoperative month 3, 6 and 24, respectively.

3.3 Complications

No postoperative complications like inflammation, corneal edema, increased intraocular pressure, cystoids macular edema, decentralization or dislocation of the AIOLs were detected in any of patients. Any of patients did not complain about halo or glare during the postoperative follow-up. Posterior capsular opacification was detected in 6 of 16 eyes (37.5%); however only 4 of them required laser capsulotomy.

4. DISCUSSION

We evaluated the clinical and accommodation outcomes of Tetraflex AIOLs over 24 months of follow-up of period in this study. A total of 16 eyes of 14 patients were operated. The mean baseline UCDVA and BCDVA of the included eyes increased significantly at month 24. The near visual acuity levels were also satisfactory at month 24 and the mean UCNVA, DCNVA, BCNVA was 0.51 ± 0.16, 0.61 ± 0.08, 0.06 ± 0.06 LogMAR, respectively. As a daily reading ability parameter; we assessed the percentage of the included eyes which had a UNCVA ≥0.6 LogMAR [13,14]. Because the newspapers or journals usually use a standard writing font of 9.5 Times New Roman and these written letters were found to be equal to 20/80 levels in Snellen chart which is equal to 0.6 LogMAR when converted [13,14]. Also Sanders et al, mentioned that none of the written materials contained any letters which required a visual acuity level of >20/40 [14]. All of the included eyes in our study reached an UNCVA level of at least 0.6 LogMAR at month 24 and gained the ability to read a newspaper or journal without the help of near vision spectacles. The mean spherical equivalent refraction at month 24 was -0.30 D, which was very near to emmotropia. The mean amplitude of accommodation with subjective defocus method was -1.13 D, and pilocarpine-induced IOL mobility was 0.36 mm at month 24. No significant complications were detected during the postoperative period except PCO which occurred in 37.5% of the eyes and this was a quite high rate. Probably this was secondary to the hydrophilic material of the AIOL.
The outcomes of Tetraflex AIOL implantation were assessed in many studies [4-8,13,15-19]. In a study by Sanders et al, the clinical outcomes of Tetraflex AIOL implantation in 95 eyes of 59 patients were evaluated prospectively over a 6 months follow-up period [13]. It was reported that the patients who had BCDVA ≥20/40 was 98.7%, UCDVA ≥20/40 was 92.2%, UCNVA ≥20/40 was 48.1%, DCNVA ≥20/40 was 63%, and who showed an accommodation amplitude ≥1 D was 75.7% at month 6. The only reported postoperative complication was PCO in only one eye at month 3, and significant residual refractive error in one eye. In a comprehensive study in which the outcomes of Tetraflex AIOL implantation was compared with monofocal IOL implantation for a trial for United States Food and Drug Administration [15]. In the prospective, non-randomized study 255 Tetraflex and 101 monofocal IOL control patients were assessed. At month 12 the Tetraflex group of the study showed better outcomes in regards to reading different print size, reading speed, and requirement for glasses. Dong et al, evaluated the safety, distance and near visual acuity, subjective accommodation and IOL mobility of the Tetraflex AIOL implantation in a prospective study [16]. Fifty eyes of 42 patients were included in the study and the outcomes were evaluated at month 3. The UCDVA and BCDVA were reported to be ≥20/40 in 82% and 92% of the operated eyes, respectively; 66% of the eyes had a DCNVA ≥ J4 (approximately 0.25 LogMAR). The mean subjective accommodation with defocus method was 0.94±0.61 D, and pilocarpine induced IOL mobility was 337±124 micrometers. No significant postoperative complications were reported. Wang et al compared the clinical outcomes of Tetraflex AIOL with monofocal IOL implantation over a 1 year period [17]. Twenty-three eyes of 23 Tetraflex and 26 eyes of 26 monofocal IOL implanted patients were included in the study unilaterally. At month 12, UCDVA and UCNVA showed no significant differences between the two groups. Anterior and posterior capsular opacification was detected more frequently the Tetraflex group. They concluded that Tetraflex AIOL had some drawbacks and AIOLs should be implanted prudently. Rahimi et al, compared the near visual acuity outcomes of Tetraflex AIOL and monofocal IOLs in a study [18]. After a follow-up period of 6 months 89% of the Tetraflex implanted eyes achieved a DCNVA ≥20/40. Mean accommodation was measured with near-point of accommodation method and was found to be 3.54 D of the Tetraflex AIOL group and 0.48 in monofocal IOL group. Wolffsohn et al compared the subjective and objective accommodation ability of Tetraflex AIOL with monofocal IOLs and both of them was found to be better in Tetraflex group than monofocal group at postoperative month 6 [19]. Our visual and accommodative results were consistent with the previous literature. The main limitation of our study was low patient number and nearly all of the patients were operated unilaterally. However, all of our patients were over 40 years and therefore all of the included patients formed a homogenous group. Also our prospective study had a quite long follow-up period of 2 years.

4. CONCLUSION

In conclusion, the Tetraflex AIOL implantation seemed to be a safe and effective treatment choice for presbyopia. After a follow-up period of 2 years both distance and visual acuity parameters and also the subjective and objective accommodation amplitudes were very satisfactory with a very low postoperative SE refraction.

COMPETING INTERESTS

None of the authors has conflict of interest with the submission. No financial support was received for this submission. None of the authors has proprietary interest for with the submission

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