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Long – term clinical outcomes after implantation of Tetraflex accommodative intraocular lens

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Tetraflex 可调节人工晶状体远期临床效果观察

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摘要

目的:评价 Tetraflex 可调节人工晶状体植入术后 1a 的临床效果。

方法:纳入研究组 23 例,均为老年性白内障患者,所有患者均在我院确诊并行白内障超声乳化摘除联合 Tetraflex 可调节人工晶状体植入术。术后 12mo 复诊时,分别记录患者的裸眼远视力、裸眼近视力、脱镜率、患者满意度以及异常视觉出现情况。另外,重点记录前、后囊膜的混浊情况。对照组为同期在我院行白内障手术并植入单焦点人工晶状体(SN60AT, Alcon)的患者共 26 例。

结果:12mo 复诊时,Tetraflex 组相较对照组拥有更好的裸眼远视力和裸眼近视力,但两者相比差异无统计学差异。两组的脱镜率分别为 34.7% 和 26.9%,两者相比差异亦无统计学差异($\chi^2=0.355$, $P=0.551$)。满意度调查显示两者之间无明显差异($\chi^2=2.367$, $P=0.124$)。前、后囊膜的混浊情况出现比率分别为 34.8% 和 7.7% ($\chi^2=3.972$, $P=0.046$),Tetraflex 组明显高于对照组。另外,Tetraflex 组有 2 例出现人工晶状体偏位,对照组无出现人工晶状体偏位现象($\chi^2=0.659$, $P=0.417$)。两组患者均未诉异常视觉出现。

结论:长期来看,Tetraflex 可调节人工晶状体并不能提供足够的裸眼远、近视力,而且发生囊膜混浊的比率高于普通单焦点人工晶状体。调查研究发现,患者的满意度较低,最主要的原因是昂贵的人工晶状体未能达到术前期待的足够调节力。所以,Tetraflex 可调节人工晶状体应该谨慎植入,尤其是对于有可能发生囊袋混浊、收缩的患者。

关键词:Tetraflex 可调节人工晶状体;远期;临床效果

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Abstract

• AIM: To evaluate the clinical gains 1 year after implantation of Tetraflex accommodative intraocular lens (IOLs).

• METHODS: This study comprised 23 patients (23 eyes) with cataract and undergone phacoemulsification and implantation of a Tetraflex accommodative IOL. At the 12-month follow-up visit, uncorrected distance visual acuity (UCDVA) and uncorrected near visual acuity (UCNVA) were measured to determine the efficacy of the IOL. Incidence of spectacle independence, patients' satisfaction and presence of visual disturbances were investigated. In addition, anterior and posterior capsule opacification were assessed. Twenty-six patients (26 eyes) with implantation of monofocal IOLs (SN60AT, Alcon) were recruited as control group.

• RESULTS: At the 12-month follow-up visit, the patients in Tetraflex accommodative IOLs group had better UCDVA and UCNVA than those in control group, but no significant difference was found ($P>0.05$). There were 34.7% patients of Tetraflex accommodative IOLs group and 26.9% patients of control group achieving total spectacle independence, and no significant difference was found ($\chi^2=0.355$, $P=0.551$). Patients' satisfaction rates with two groups did not differ significantly too ($\chi^2=2.367$, $P=0.124$). Anterior and posterior capsule opacification were present, respectively, in 34.8% and 7.7% of patients ($\chi^2=3.972$, $P=0.046$). Two cases of accommodative IOLs displacement were discovered ($\chi^2=0.659$, $P=0.417$). No visual disturbances were mentioned in both groups.

• CONCLUSION: In the long run, compared with monofocal IOLs, Tetraflex accommodative IOLs can not provide efficient uncorrected visual acuity and had higher incidence and degree of anterior and posterior capsule opacification. Patients implanted have lower satisfaction rate due to poor accommodative ability versus expensive material. So, accommodative IOL should be implanted prudently, especially to the patients with high risk factors for capsule fibrosis.

• KEYWORDS: Tetraflex accommodative intraocular lens; long-term; clinical outcomes
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INTRODUCTION

It is widespread known that near vision ability of pseudophakic patients decreases proportionally with age[1]. Although the refractive results of cataract surgery with monofocal intraocular lens (IOL) implantation are excellent, the concomitant correction of unaided far and near vision is not satisfactory. Therefore, in the attempt to manage presbyopia, different intraocular lens designs have been proposed such as accommodative intraocular lens, which were designed to provide satisfactory vision for all distances by restoring some degree of "pseudoaccommodation" by implementing several designs of the haptic and the optic part of the intraocular lens[2-4].

Existed researches demonstrate that with the implantation ofaccommodative IOLs, subjective accommodative amplitudes of up to 2.0D and spectacle independence have been reported in most patients. However, most of the studies are short-term[4-6], which still lack adequate evidences to demonstrate the long-term effects of accommodative IOLs. A small number of researches consider that the positive near vision effects achieved with accommodative intraocular lenses are due rather to pseudoaccommodative effects than to accommodative ones and the accommodation capacities will lost with time due to high incidence and degree of anterior and posterior capsule opacification and the other researches maintain that the accommodative IOLs resulted in fewer favorable visual acuities and contrast sensitivities (CS) than diffractive multifocal IOL[7]. Tetraflex IOL (KH-3500, Lenstec, America), the most studied and currently clinically available accommodative IOLs, is under clinical trial with the United States Food and Drug Administration in 2007. Through the movement of the ciliary muscle and the vitreous change of position and shape, It could offer a change of the overall dioptric power of the eye and the facilitation of near vision. In the present international data collection, we evaluated our clinical experience with the Tetraflex accommodative IOLs and assessed the uncorrected distance visual acuity (UCDVA), uncorrected near visual acuity (UCNVA), patients' satisfaction and capsule opacification after implantation at 1 year.

SUBJECTS AND METHODS

Subjects The studied sample involved 23 eyes of 23 patients with implantation of Tetraflex accommodative IOLs and the control group included 26 eyes of 26 patients with implantation of monofocal IOLs (SN60AT, Alcon). All the cases with age-related cataract undergone phacoemulsification and implantation of IOLs and were recruited during March 2010 and September 2010 at Ophthalmic Center of Chancheng Affiliated Hospital of Guangdong Medical College. This study was performed in accordance with the ethical standards laid down in the Declaration of Helsinki.

All the surgeries was done by one ophthalmologist. The operation started as a routine phacoemulsification under sub-Tenon's anesthesia with a 2.8-mm slit knife incision and a CCC of 5.0mm-6.0mm diameter was performed, followed by hydrodissection and pachoemulsification, the processes were smooth and no complications occurred. At the end, IOLs were well placed.

The ages of studied sample were between 53 and 77 years, The mean age ± standard deviation was (55.9±10.5) years, and there were 13 males and 10 females. The ages of control group were between 50 and 80 years, The mean age ± standard deviation was (53.7±11.07) years, and 12 males and 14 females were reckoned in. No significant difference was found ($t=5.329$, $P>0.05$). Subjects included in this study have an axial length of 23.0mm-24.0mm and a corneal preoperative astigmatism of <1.00 dioptre (D) as already reported. Those who with vision impairing retinal or corneal diseases, optic neuropathies, chronic or relapsing uveitis, biomicroscopically detectable zonular defects were excluded. All the patients could cooperate and tolerate the operation and without serious illness.

At the 12-month follow-up visit, UCDVA, UCNVA, incidence of spectacle independence, patients' satisfaction and presence of visual disturbances were investigated. In addition, anterior and posterior capsule opacification were assessed specially by mydriatic. 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 posterior capsule opacification (PCO) was subjectively scored on a 0-4 scale: 0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe.

Statistical Analysis Statistical analysis was performed using commercially available software (SPSS for Windows, version 13.0, SPSS Inc., Chicago, IL). The data were confirmed to distribute normally and therefore are presented as the $\bar{x} \pm s$ deviation. To compare the two groups, t-test for paired samples and χ^2 were performed. The level of significance was <0.05 (two-sided) for all statistical tests.

RESULTS

At the 12-month follow-up visit, mean UCDVA of Tetraflex accommodative IOLs group and control group were (0.5±0.1) and (0.4±0.2), respectively. Mean UCNVA of two groups were (7.1±0.5) J and (6.8±1.0) J. The patients in Tetraflex accommodative IOLs group had better UCDVA and UCNVA than those in control group, but no significant difference was found ($t=1.257$, 5.017; $P=0.150$, 0.428).

There were 34.7% patients of Tetraflex accommodative IOLs group and 26.9% patients of control group achieving total spectacle independence, and no significant difference was found ($\chi^2=0.355$, $P=0.551$). Patients' satisfaction rates with two groups did not differ significantly too ($\chi^2=2.367$, $P=0.124$) and only 43.5% (10/23) patients of Tetraflex accommodative IOLs group showed satisfaction. Causes of discontent included expensive IOLs versus not conformed desired effect (69.2%, 9/13), decreasing visual acuity (23.1%,3/13), eye pain (7.7%, 1/13). Capsule opacification were present, respectively, in 34.8% and 7.7% of patients ($\chi^2=3.972$, $P=0.046$).

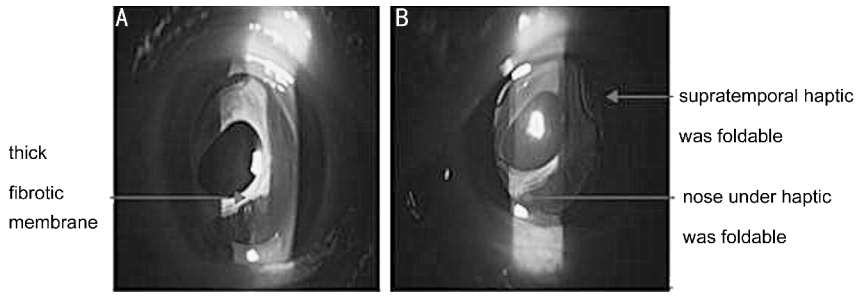

Figure 1 A: Thick fibrotic membrane was noted with extremely anterior capsule contraction; B: IOL was in a sloping position and nose under and supratemporal haptics were foldable.

Two cases of severe ACO and accommodative IOLs displacement were discovered ($\chi^2 = 0.659$, $P = 0.417$). Thick fibrotic membrane was noted with extremely anterior capsule contraction and IOL was in a sloping position and nose under and supratemporal haptics were foldable in one patient (Figure 1). No visual disturbances were mentioned in both groups.

DISCUSSION

Accommodative intraocular lens (KH-3500, Tetraflex™, Lenstec, America), currently under trial for FDA approval, is a foldable single-piece IOL that has an optic diameter of 5.5mm and overall length of 9.8mm. It is of a hydrophilic acrylic with an ultraviolet inhibitor and has a refractive index of 1.46. The lens has a biconvex square-edged optic and 4 modified flexible haptics that are designed in order to bend when constricted by the capsular bag after ciliary muscle contraction. This allows anterior displacement of the optic resulting to refractive power increase[8,9].

Different methods show different results[4,10-12]. A numbers of researches show increased accommodative range and better near visual acuity than a control group. However, other studies found that long-term clinical outcomes after implantation of accommodative intraocular lens were limited and could not provide efficient uncorrected visual acuity because of the high incidence and degree of anterior and posterior capsule opacification and resulted in fewer contrast sensitivities (CS).

In order to evaluate the long-term outcomes of Tetraflex accommodative IOL directly, we choose UCDVA and UCNVA as main measures because many elderly people are reluctant to wear glasses. In our study, we found mean UCDVA and UCNVA of Tetraflex accommodative IOLs group had better UCDVA and UCNVA than those in control group, but no significant difference was found ($P>0.05$) at the 12-month follow-up visit. Accommodation ranging was not considered because there were no classical methods to measure accommodation amplitude until now[13,14].

What we were interested most were spectacle independence and patients' satisfaction rates, However, the results were disappointing. Total spectacle independence and patients' satisfaction rates with two groups did not differ significantly and only 43.5% patients of Tetraflex accommodative IOLs group showed satisfaction, which made an unexpected comeback. So, we made further investigation of causes of discontent. Investigation showed that the principal cause of discontent was expensive IOLs versus not conformed desired effect.

Compared with SN60AT IOL, Tetraflex accommodative IOL was more expensive. Generally, the patients with Tetraflex IOL needed pay more than 6000RMB for the operation.

In our investigation, we also noticed one interesting phenomenon that Tetraflex accommodative IOLs seemed have higher incidence and degree of capsule opacification. As we all kown, once capsule opacification happens, it can compromise visual acuity severely, which may be the reason why the patients with Tetraflex accommodative IOLs complain eyesight becoming progressively worse as time prolonging.

Hence, it is indispensable to carry out the following methods to acquire satisfactory results. A high level of surgical skill is required. Central continuous circular capsulorhexis (CCCC) is important and diameter should be between 5.5mm and 6.0mm. The lens must be implanted in the capsular bag, and if sterile packaging has been damaged or there are traces of leakage on the bottle or pouch, the accommodative IOLs should not be implanted. In addition, suitable patients are critical. Those who suffering from presence of an ocular infection, RP, diabetic retinopathy, axial length >25mm, patients aged 80 and over or with chronic diseases or chronically take any medicine that affect accommodation should be prudent.

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Dear Professor Xiu-Wen Hu,

I want to add my thanks for the generous contribution from the International Journal of Ophthalmology to the ICOFoundation.

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We very much look forward to working with you and the IJO in the future to contribute to ophthalmic education in China and around the world.

We are deeply appreciative of your support and wish you a productive and healthy 2013.

Best regards,

Bill
William C. Felch, Jr.

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