

The Outcomes of Asthenopia after ICL Implantation and Its Related Factors

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ABSTRACT

Objective: To evaluate the changes of visual fatigue symptoms, accommodative functions, ocular surface conditions, and high-order aberrations (HOA) after implantation of Implantable Collamer Lens (ICL), and explore their effects on asthenopia. **Methods:** Design: prospective observational case series. Patients with ametropia who underwent ICL surgeries and completed 3-month follow-up periods in our hospital were enrolled. Asthenopia degrees, amplitude of accommodation (AA), positive/negative relative accommodation (PRA/NRA), accommodative facility (AF), the ratio of accommodative convergence and accommodation (AC/A), Schirmer I test, noninvasive breakup time (NBUT), and HOA were examined and analyzed preoperatively and at 1 week, 1 month and 3 months postoperatively. **Results:** Symptoms of asthenopia: the symptoms of asthenopia were significantly worse at 1 week after ICL surgeries than those before surgeries but increased gradually as time went by. The asthenopia scores 1 month after surgeries were still higher than those before ICL surgeries, eventually recovered at 3 months postoperatively. AA, AF, AC/A decreased 1 week postoperatively, returned to the baseline at 1 month and were higher at 3 months after surgeries. NBUT at 1 week, 1 month and 3 months after surgeries were significantly decreased and was the lowest at 1 week postoperatively. PRA, NRA, Schiermer values and HOA had no significant change. 3. Correlation analysis showed that the worse AF and NBUT, the more severe the symptoms of asthenopia. **Conclusion:** The symptoms of asthenopia aggravate transiently after ICL implantation surgeries, but improved gradually with time. AF and NBUT were important factors affecting the changes of asthenopia.

Keywords: Implantable Collamer Lens, implantation, Asthenopia, Accommodation, Dry eye.

ABBREVIATIONS

ICL: Implantable Collamer Lens; HOA: High-Order Aberrations; AA: Amplitude of Accommodation; PRA: Positive Relative Accommodation; NRA: Negative Relative Accommodation; AF: Accommodative Facility; AC:

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Accommodative Convergence; NBUT: Noninvasive Breakup Time.

INTRODUCTION

The Visian Implantable Collamer Lens (ICL; STAAR Surgical Co., CA, USA) implantation has been proved to be effective and safe in the treatment of ametropia, with the advantages of wide correction, good visual acuity and reversibility [1-3]. However, many patients suffered from postoperative asthenopia, such as unclear close work, vision fluctuation and intermittent pain. It is known that corneal refractive surgeries are often followed by asthenopia related to changes in accommodative functions [4]. Do the same mechanisms exist after ICL surgeries? Therefore, we measured visual fatigue symptoms and accommodative functions, ocular surface conditions, visual quality parameters before and after ICL implantation, in order to identify risk factors and improve patients' satisfaction.

MATERIALS AND METHODS

Population enrollment

This prospective observational trial was performed in the Ophthalmological Institute of Cangzhou Central Hospital (Hebei, China). The study was approved by Cangzhou Central Hospital Ethics Committee and registered at Chinese Clinical Trial Registry (ChiCTR2100047020). Ametropia patients who planned to undergo ICL V4c implantations were continuously collected from May 2021 to May 2022, following these inclusion criteria: ① Age \geq 18 years had reasonable surgical expectations, agreed to participate in this study and signed informed consent; ② Meet the ICL implantation criteria; ③ No drugs affecting tear secretion or tear film stability have been used in the past year. The exclusion criteria were as follows: ① Patients not suitable for ICL implantations; ② Patients with serious complications such as intraocular lens displacement; ③ Patients who did not agree to participate in the study nor had poor compliance.

PREOPERATIVE EXAMINATION

Routine examinations

All patients received preoperative examinations for ICL surgeries, including uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), optometry, intraocular pressure (CT-800 non-contact tonometer; Topukang YM0021338, Japan), corneal topography and wavefront aberration (OPD-ScanIII corneal/refractive analyzer, NIDEK, Japan), anterior chamber depth and angle (ultrasonic biological microscope, Md-300I, Tianjin Magda,

China), slit lamp and fundus examinations.

Visual fatigue questionnaires

The visual fatigue questionnaire designed by Lv Fan's team from Wenzhou Medical University Affiliated Optometry Hospital was selected in this study and filled by subjects according to their eyes in the past week. The questionnaire covers frequent clinical symptoms which can quantify the severity of visual fatigue and assist in the diagnosis of causes (details showed in "Attachment file"). Its Cronbach α was 0.90, and retest reliability coefficient was 0.965, showing good reliability and validity [5].

Measurements of accommodation

After refractive errors corrected by comprehensive refractometer (Japan's Dirx RT - 3100), the subject was instructed to look at an optotype at 0.4m distance under indoor illumination. The optotype was moved constantly until the subject first felt sustained blur. The reciprocal of distance between the optotype and glasses was monocular amplitude of accommodation (AA). Returning to initial settings, the subjects saw the optotype clearly through +2.00D lens, and then flipped it to the -2.00D lens. This circuit would repeat within 1 minute, and the number of circuits was recorded as accommodative facility (AF). When +0.25D lens were added gradually until the subject reported persistent blurred vision, the sum of positive diopters was the negative relative accommodation (NRA). While -0.25D lens was gradually increased until the optotype became blurred, sum of the negative diopters was the positive relative accommodation (PRA). At last, the horizontal phoria (A) at 0.4m was measured by Von Graefe method, and phoria (B) was measured after adding +1.00D spherical lens. $(AC/A) = (A-B) / +1.00D$.

Ocular surface examinations

The noninvasive breakup time (NBUT) was measured by a Keratograph 5M (OCULUS, Germany). Schirmer tests were performed with sterile strips (Eagle Vision, Memphis, USA).

ICL selection and implantation

Appropriate V4c ICL or TICL were calculated by professional computing software on STAAR'S ICL customization website. Pupil was dilated 30 minutes before surgery. Temporal transparent limbus incision was made under topical anesthesia, ICL was inserted and placed in the posterior chamber. All surgeries were performed by the same chief physician.

Postoperative follow-up and evaluation

All patients were followed up at 1 day, 1 week, 2 weeks, 1 month and 3 months after surgeries, including routine postoperative examinations: UDVA, CDVA, optometry, intraocular pressures, aberrations, ICL vaults (Heidelberg OCT, Germany). In addition, the visual fatigue questionnaires, accommodation and ocular surface examinations were repeated 1 week, 1 month and 3 months after operations. All the examinations were performed by the same skilled physician.

Statistical analysis

Data were analyzed using SPSS software (version 19.0; SPSS, Inc, Chicago, IL). The results are expressed as mean±standard deviation. Visual acuity results before and after surgeries were converted to LogMAR value= $\lg(1/\text{fractional vision})$ and compared by Wilcoxon rank sum test while the other data at different time points were analyzed by one-way repeated ANOVA with Bonferroni's test. Furthermore, Spearman correlation test was used to analyze the relationship between postoperative visual fatigue questionnaire scores and various factors such as genders, ages, diopters, visual acuity, AA, AF, PRA, NRA, AC/A, tear secretion volume, NBUT, HOA. Multiple stepwise regression analysis (significance level $\alpha=0.05$) was used to further explore the influence of related factors on early postoperative visual fatigue symptoms. A value of $P<0.05$ was considered statistically significant.

RESULTS

Demographics

A total of 66 patients (66 right eyes were selected for analysis) were enrolled in the study, including 32 males and 34 females. 6 patients were lost within 3 months, and 60 patients (60 eyes) completed the follow-up finally, including 28 males and 32 females.

Visual acuity and refraction

The mean UDVA and CDVA (LogMAR) of 1 week, 1 month and 3 months after surgery were significantly improved compared with those before surgery ($P_{\text{UDVA}}=0.000, 0.000, 0.000$; $P_{\text{CDVA}}=0.030, 0.001, 0.000$). At 3 months postoperatively, UDVA of 60 eyes (100%) ≥ 0.6 , 54 eyes (90.0%) ≥ 0.8 , and 50 eyes (83.3%) ≥ 1.0 . The CDVA of all eyes ≥ 0.8 .

Changes of asthenopia symptoms before and after ICL surgery

The average score of visual fatigue questionnaires before ICL implantation was (24.3±10.2), which significantly rose 1 week after surgeries ($P=0.000$), and then decreased slowly.

It was still higher than that before surgeries at 1 month postoperatively ($P=0.000$), and recovered to the preoperative level 3 months after surgeries with a slight decrease, which was not statistically significant ($P=1.000$).

Changes of accommodation and convergent function

AA decreased at 1 week postoperatively ($P=0.000$), but was significantly higher at 1 month and 3 months after surgeries ($P=0.000, 0.000$), with statistical differences at each time point ($P=0.000$). The AF was the lowest at 1 week after surgery than baseline ($P=0.000$), slightly better at 1 month postoperatively ($P=0.010$), and peaked at 3 months after surgeries ($P=0.000$). AC/A reduced at 1 week postoperatively ($P=0.000$), had no significant difference at 1 month postoperatively ($P=1.000$), and increased 3 months postoperatively ($P=0.000$). There was no significant difference in PRA at 1 week, 1 month and 3 months after operations ($P=1.000, 0.398, 0.152$), Neither in NRA ($P=0.276, 0.708, 1.000$).

Changes of tear and meibomian gland function

Postoperative NBUT values declined obviously. NBUT at 1 week postoperatively was minimum, which was less than half of preoperative line. Though NBUT at 3 months postoperatively rebounded, there was a gap compared with those before surgeries ($P = 0.000$). The changes of NBUT were most obvious, which had obvious differences between each time point ($P = 0.000$). Schiermer values decreased at 1 week after surgeries ($P=0.000$), basically returned to the preoperative level 1 month after surgeries ($P=0.055$), and continued to improve 3 months after surgeries, with no significant differences ($P=0.929$).

Change of high-order aberrations (HOA)

The total HOA at 1 week, 1 month and 3 months after surgeries increased compared with those before surgeries ($P=0.000$), but there was no significant changes at each postoperative time point ($P_{1\text{w vs.1m}}=0.0482$; $P_{1\text{w vs.3m}}=0.535$; $P_{1\text{m vs.3m}}=1.000$).

Effects of various parameters on visual fatigue scores

Since the visual fatigue scores increased significantly 1 week after ICL implantation, this study chose this time point to evaluate each parameter which may affect asthenopia, including AA, AF, PRA, NRA, AC/A, tear secretion, NBUT, HOA, age and gender. Only NBUT and AF were negatively correlated with visual fatigue scores. Multiple stepwise regression analysis (significance level $\alpha=0.05$) was used to investigate the effect of NBUT(X1), AF (X2) on visual fatigue

symptoms (Y) 1 week after surgeries. The linear regression equation was obtained as $Y = -0.444X_1 - 0.308X_2$ ($R^2 = 0.307$, $F = 14.057$, $P = 0.000$), that is, the worse AF, the lower NBUT and the more severe the visual fatigue symptoms.

DISCUSSION

With improving requirements of visual quality, postoperative asthenopia after ICL has received more and more attention. Asthenopia is a group of various subjective symptoms of eye discomforts, visual impairments, or systemic upsets when or after using eyes [6]. Experts noted that different degrees of asthenopia symptoms may occur in the early stage after all kinds of eye surgeries. In this study, questionnaires were chosen to evaluate the visual fatigue severity. Results showed that visual fatigue symptoms aggravated ICL at 1 week after surgeries, gradually eased at 1 month, then returned to preoperative baseline or even slightly better 3 months after ICL implantation, which were similar to other refractive operation researches such as laser in situ keratomileusis (LASIK) and femtosecond laser in situ keratomileusis (FS-LASIK) [7,8].

Accommodation and convergence

At present, many experts believed that the imbalance between accommodation and convergence was one of the main reasons of asthenopia. In this study, AA decreased 1 week after ICL implantation, then gradually increased, and was higher 1 month and 3 months after surgeries compared with that before surgeries, which were consistent with visual fatigue degrees. This results of Fu Jing', Ma Ke' and Chen' studies [9-11] are the same as this study, except the observation at 1 week postoperatively and the temporary reduction of AA. Due to less use of accommodation, the function of ciliary muscles weakened in nearsighted patients. Meanwhile, because of surgical traumas, inflammatory reactions and optical interface addition, the clarity of retinal imaging was affected and reduced AA ulteriorly [12]. Moreover, the disappearance of glasses increased the need for accommodation at the same distance, resulting in the aggravation of early postoperative visual fatigue symptoms. After 3 months of intensive exercises, accommodating functions improved greatly, forming a new balance and relieving asthenopia, which was equally reflected in other research results [13].

AF measures the reaction speed of accommodating changes [14], which decreased 1 week after surgeries, exceed the preoperative level at 1 month and was much higher at 3 months after surgeries in this study. Other researches of ICL [9,10] and corneal refractive surgeries [13,15,16] showed

similar results. They believed that AF declined related to contrast sensitivity transient reduction, and gradually increased with the recovery of visual clarity and the accommodative increasing needs. In this study, correlation and regression analysis also showed that AF was significantly negatively correlated with visual fatigue symptoms, which were consistent with the results of Zhou Shaobo' research [16]. Although AA had the same trend as AF, it was not so closely correlated with asthenopia, probably because AA was a static indicator and could not fully reflect the functional changes of accommodation.

In addition to accommodation, insufficient binocular convergence function leads to difficulty in image fusion, while excessive convergence leads to excessive tension, both of which could cause asthenopia. AC/A value reflect the interaction between accommodation and convergence [17]. In this study, AC/A reduced 1 week after surgeries, recovered to the preoperative level at 1 month, and continued to increase significantly at 3 months postoperatively. These results were consistent with Fu Jing' study [11]. However, some scholars [18] pointed out that there was no statistical difference in AC/A 3 and 6 months after ICL implantation. Thus it can be seen the poor repeatability of AC/A because it may be influenced by age, preoperative level, postoperative residual diopters and other factors.

Dry eye

Dry eye is closely related to visual fatigue symptoms. The protective effect of tear film on the eye surface reduces, and discomfort symptoms are more likely to occur. Unstable tear film also causes light scattering, reducing visual quality, and causing asthenopia [19]. There were many related parameters of dry eye, and the most obvious change in this study was BUT, which was also most closely related to visual fatigue symptoms. Therefore, for patients with dry eye symptoms before surgeries, the risk of visual fatigue should be explained in time, so as to establish reasonable expectations. And the most important thing is preoperative treatment of dry eye.

Visual quality

The increase of optical aberration may cause various discomforts such as blurred vision, halo, glare and diplopia [20], which may emphasize visual fatigue. However, in this study, the increase of HOA after ICL was small and relatively stable, and there was no significant correlation with asthenopia.

In summary, through the analysis of postoperative visual

fatigue symptoms and changes in accommodation, ocular surface and refractive conditions after ICL implantation, this study preliminarily concluded that the main reasons for the aggravation of postoperative visual fatigue symptoms were the change of accommodating function and the decline of tear film stability. Therefore, it is recommended to perform routine preoperative functional examination of accommodation and NBUT to identify risk factors, and design personalized treatment plans to minimize postoperative visual fatigue symptoms and optimize surgical effects.

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CONFLICT OF INTERESTS

The authors declare that there is no conflict of interests regarding the publication of this paper.

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