• Clinical Research •

Effect of capsular tension ring implantation on predicted refractive error after cataract surgery in patients with pseudoexfoliation syndrome

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Abstract

● **AIM:** To investigate the effect of capsular tension ring (CTR) implantation on predicted refractive error after cataract surgery in patients with pseudoexfoliation (PEX) syndrome.

● **METHODS:** This double-blind randomized clinical trial was conducted on 60 patients with PEX syndrome referring to Imam Khomeini Hospital affiliated to Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran, for undergoing cataract surgery. The study population was divided into two groups, namely CTR group (*n*=30) and non-CTR group (control group; *n*=30). The refractive error and anterior chamber depth (ACD) were measured 1wk, 1mo, and 3mo after phacoemulsification (PE) surgery.

● **RESULTS:** The results indicated no statistically significant difference between the two groups in terms of predicted refractive error (obtained by subtracting preoperative predicted refractive error from actual postoperative refractive error) 1wk (*P*=0.47), 1mo (*P*=0.30), and 3mo (*P*=0.06) after the PE surgery. Regarding the CTR group, the changes of ACD was statistically significant 1 and 3mo after the PE surgery, compared to those obtained 1wk post-surgery (*P*=0.005).

● **CONCLUSION:** The CTR implantation in PEX cataractous patients without zonulysis has no statistically significant effect on the predicted refraction and ACD changes after PE. The predicted refraction error has a hyperopic shift in both groups. The results reveal the unnecessary of calculating modified IOL in CTR implantation.

● **KEYWORDS:** pseudoexfoliation syndrome; capsular tension ring; refraction error; anterior chamber

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INTRODUCTION

Pseudoexfoliation (PEX) syndrome is a systemic degenerative disease that is accompanied with many intraocular complications and characterized with meshwork eosinophilic fibrillary material in the anterior segment[1]. The poor pupil dilation and zonular weakness in PEX syndrome increase the risk of intraoperative complications during the cataract surgery[2]. Intraocular pressure, glaucoma, mydriasis, zonular weakness, corneal neuropathy, and vitreous loss during the cataract surgery are the main complications of PEX syndrome[3].

The most common prospective complications of PEX syndrome include capsular phimosis, capsule opacification, increased postoperative inflammation (*i.e.*, enhancement of the cells and flare in the anterior chamber), fibrinous reaction, and posterior adhesion[4]. This syndrome is also accompanied with nuclear cataract (more dense cataract) and zonular dehiscence and/or crystalline lens subluxation[2]. Previously, the complications of cataract surgery in the patients with PEX syndrome were 5-10 folds higher than those in the patients without such syndrome; nevertheless, this rate has decreased recently[5].

Commonly, the use of capsular tension ring (CTR) is suggested for preventing postoperative complications due to zonular weakness[6]. The CTRs are adopted in about 1% of all complicated cataract surgeries[7]. These devices can facilitate the maintenance of intraocular lens (IOL) centration through expanding the capsular bag and contribute to the equal distribution of the load and stress to the remaining intact zonules[8]. Use of CTR during phacoemulsification (PE) makes all maneuvers safer. The CTRs prevent from collapsing the equatorial capsule and decrease the postoperative capsular phimosis[9]. However, they cannot prevent the postoperative

displacement of IOLs, which may shift posteriorly after CTR implantation. The implanted IOL should have more dioptric power than the one calculated preoperatively[10]. This concept may result in the variation of predicted refractive error.

Although there is limited evidence supporting the effectiveness of CTRs in the postoperative prediction of refractive error, they are recommended as a proper and safe approach in the literature[6]. With this background in mind, the present study was conducted to investigate the effect of CTR on predicted refractive error. This study also involved the evaluation of the changes of anterior chamber depth (ACD) after PE surgery.

SBJECTS AND METHODS

Ethical Approval The study protocol was agreed with the Declaration of Helsinki. This study was registered at the Iranian Registry for Clinical Trials (code: IRCT2017010431771N1). In this study, the participation was on a voluntary basis. In this regard, the objectives of the study were explained to the subjects, and informed consent was obtained prior to enrollment. Furthermore, the patients were assured that their information will remain confidential. The study proposal was approved by the Ethics Committee of the Research Deputy of Ahvaz Jundishapur University of Medical Science, Ahvaz, Iran. This double-blind randomized clinical trial was conducted on patients with PEX syndrome referring to Imam Khomeini Hospital affiliated to Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran, for undergoing cataract surgery.

Inclusion and Exclusion Criteria The inclusion criteria were candidacy for cataract surgery and affliction with PEX syndrome. The exclusion criteria were zonulysis, subluxated crystalline lens, and measureless keratometry due to corneal disorders, glaucoma, history of a previous procedure (*e.g.*, buckle and trauma), capsulorhexis extension, vitreous loss, corneal suture for the prevention of wound leakage, corneal edema, and anterior chamber cellular reaction.

Study Design In this study, the eligible patients with PEX syndrome were selected based on the clinical criteria of PEX material on the pupillary margin or anterior capsule. The study population corresponded to a group of 60 cataractous patients with PEX syndrome without zonulysis that were operated with one surgeon for PE. The participants were randomly divided into two groups, namely intervention (co-implantation of IOL and CTR; n=30) and control (implantation of IOL alone; n=30) groups. The PE surgery was performed for the two groups using a standard method.

After preparation and drape under general or local anesthesia, all patients were subjected to cataract surgery. To this end, the patients' eyes were washed by betadine 5% solution and normal saline 10% three times. Then, the main incision of 2.8 mm was made on the clear cornea by a 2.8-mm keratome knife. Another incision was created in the limbus with a distance of 70°-80° from the main incision by a Sideport 15 degree blade. Subsequently, 2% epinephrine and 1.2% sodium hyaluronate viscoelastic solution (Bausch and Lomb, Germany) were used, and continuous curvilinear capsulorhexis of 5.5 mm and hydrodissection were performed. In the next step, the PE was carried out in the bag space.

In the CTR group, after the irrigation and aspiration of the cortical material, a Morcher CTR proportional to the axial length (AL) of the globe (AL<22 mm: CTR-11; 22 mm ≤AL<25 mm: CTR-12 mm; and AL≥25 mm: CTR-13) was implanted in a capsular bag using a CTR injector. The AL was measured by means of ZEISS IOL Master 500 (Carl Zeiss Meditec AG, Jena, Germany). In both groups, a foldable ALCON Acrysof (R) Single-piece SA60AT or SN60AT IOL was used, which was implanted in a capsular bag with IOL forceps. Finally, viscoelastic materials were washed out, and the cut was closed with balanced salt solution hydration.

One day post-surgery, the patients were examined in terms of uncorrected visual acuity, corneal edema, leakage, apparent ACD, amount of cell in the anterior chamber, intraocular pressure, centration of IOLs, and red reflex. All patients were visited on the same day and followed up 1wk, 1mo, and 3mo after the operation. The postoperative manifest refractive error and ACD in the follow-up period were measured by means of the RM-800 Topcon auto refractometer (Topcon RM.800 Hasunuma_cho. Itabashi_KU, Tokyo, Japan) and ZEISS IOL Master 500, respectively.

The preoperative predicted refraction, which was subtracted from the manifest postoperative refractive error, was used to calculate arithmetic refraction (ArRef). For example, if the predicted refraction was 0.09 diopter (D), and the measured refraction was -0.5 D, the ArRef was calculated as 0.59 D. Accordingly, a positive value of predicted refraction indicated a hyperopic shift. The depth of the anterior chamber was also measured using the IOL Master device.

Statistical Analysis Descriptive statistics, including frequency, percentage, mean, and standard deviation, were used to express data. Normality of the quantitative variables was assessed through Kolmogorov-Smirnov test and histograms. The comparison of the effect of CTR between the two groups during different times was accomplished using repeated measures ANOVA. Statistical analysis was performed in SPSS software (version 22, International Business Machines Crop.). P-value less than 0.05 was considered statistically significant.

RESULTS

In general, 58.3% (n=35) of the patients were male. The CTR group was comprised of 15 males and 15 females with a mean age of 69.4±9.4y. The control group entailed 20 males and 10 females with a mean age of 64.7y. The mean scores of AL in the CTR and control groups were 23.17±0.56 (range: 21.97-

24.03 mm) and 22.78±0.94 mm (range: 21.12-24.54 mm), respectively. Furthermore, the mean values of IOL power were obtained as 21.31±1.64 and 22.61±2.27 D in the CTR and control groups, respectively.

The results indicated a significant difference between the two groups in terms of IOL power (P=0.014). There was no statistically significant difference between the two groups regarding the mean ArRef.

The ACD in the CTR group was obtained as 4.01 mm 1wk post-surgery, which increased to 4.10 mm 1mo after the surgery. Regarding the control group, this value was estimated as 4.09 mm 1wk after the PE surgery that elevated to 4.19 mm 3mo post operation. However, this difference was statistically significant only in the CTR group. The ACD changes from 1 to 3mo post-surgery were 1 and 2 mm in the CTR and control groups, respectively, which were not statistically significant (P=0.54 *vs* P=0.12). Evaluation of ACD in both groups preoperatively showed statistically insignificant difference between the two groups (P=0.68). There was no statistically significant difference between the two groups in terms of ACD measurement at the follow-up period.

DISCUSSION

This study was targeted toward the evaluation of the effect of CTR implantation on predicted refractive error after PE surgery in patients with PEX syndrome. In the current study, the implantation of CTR did not induce a higher hyperopic or myopic shift in the patients with PEX syndrome, compared to the control group in which no CTR was implanted. Consequently, in CTR implantation, the calculation of modified IOL may not be required.

This finding is consistent with the results obtained by Schild *et al*[11] evaluating the effect of CTR implantation on refractive outcomes in patients with high myopia. To this end, they implanted CTR in 16 eyes of 31 high myopic patients undergoing PE surgery; however, they observed no statistically significant difference between the patients with and without CTR. Accordingly, they reported that the implantation of a CTR has no consistent effect on refractive outcomes.

One of the common side effects of cataract surgery is subluxation[9]. The accumulation of PEX material on the zonular fibers in patients with PEX syndrome leads to the reduction of the tensile strength of the zonule. Recently, CTR is increasingly used to prevent the postoperative side effects caused by zonular weakness[6]. The growing use of CTRs in PEX syndrome patients is accompanied with an increase in the atypical angle closure[12]. Zonular weakness and anterior dislocation of the IOLs, followed by angle closure glaucoma, have been also reported in the literature[13].

Laser peripheral iridotomy is suggested for the management of pupillary block due to zonular weakness causing the anterior dislocation of the IOL. The CTR is applied to maintain the shape and centration of the capsular bag; however, it may lead to postoperative side effects. The disk-shaped capsular bag-CTR-IOL complex may be accompanied with generalized zonular weakness. The instability of the capsular bag-CTR-IOL complex in the anterior posterior direction may lead to angle closure even with a slight anterior movement of the capsular bag-CTR-IOL. Therefore, to rule out the other possible mechanisms of angle closure in the pseudophakic eyes, ultrasound biomicroscopy examination should be carried out, along with gonioscopy[6].

Based on our findings, the predicted refraction did not change in the CTR group across the three research exam stages (*i.e.*, 1wk, 1, and 3mo after the PE surgery). Nonetheless, this value was different across the three stages in the control group. Moreover, the predicted refraction in the third month of operation had a hyperopic shift in comparison to that obtained in the first month; however, the myopic shift was not different between the first month and first week of PE surgery.

In the study by Schild *et al*[11], the amount of refraction was myopic (-0.12 D), but the refractive shift 3mo postoperation was hyperopic. Baranwal *et al*[10] implanted CTR with IOL in patients without hyperopia or myopia, but with a zonular dialysis of 2-5h. They showed that patients with CTR had a hyperopic shift of +0.5 to 2.0 D due to the posterior shift of IOL 45d after the surgery. Therefore, they suggested that IOL implantation should be +1.0 to 1.5 D higher than the preoperative calculation. They also used polymethylmethacrylate IOL and limited vitrectomy if vitreous presented.

Based on a study carried out by Takimoto *et al*[14], refractive prediction error and ACD were not different in patients with and without CTR, which was confirmed by other studies as well[15]. Furthermore, Alió *et al*[16] showed that the results of postoperation refraction were closer to the expected values using CTR in combination with multifocal lens. In another study, the refraction rate in implant design was reported to have a high accuracy when measured with modern methods[17].

In a retrospective study performed by Boomer and Jackson[18] on patients with zonular instability, no difference was observed in ArRef error after a month. They obtained more accurate refraction findings in the CTR group although myopic or hyperopic shift was not observed in this group. Fallah Tafti *et al*[19] also showed a hyperopic shift in the refraction of PEX syndrome patients with a normal AL without CTR.

In our study, ACD change was not different between the patients with and without CTR in the first week, first month, and third month of PE surgery. In the CTR group, the amount of change in the third month was different with that obtained in the first week. Our findings are in line with those of other similar studies[18-19]. In a study conducted by Weber *et al*[20],

ACD was not different in patients with and without CTR. This was also confirmed by the results of another study carried out by Gür Güngör *et al*[15].

In a study performed by Baranwal *et al*[10], the ACD was deepened 0.15-0.5 mm; however, in the current study, limited vitrectomy was performed for some patients. In our study, the predicted refractive error was closer to the target point in the patients with CTR implantation. One of the limitations of this study is that the duration of follow-up was short with regard to the sample size and issue under investigation. Future studies are suggested to adopt a larger sample size and implement a longer follow-up.

In conclusion, as the results of our study indicated, the PEX syndrome patients without a remarkable zonulysis who were managed with CTR demonstrated myopic changes as a result of refraction 1wk and 1mo after the operation. However, this change was not observed in the patients subjected to the cataract surgery without CTR; therefore, it is not necessary to modify IOL power. Moreover, the changes in the depth of the anterior chamber in the CTR group were not significantly different from those in the control group.

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