· Clinical Research ·

Efficacy of haptic sutured in-the-bag intraocular lens for intraocular lens-capsule complex stability: a comparison of three insertion methods

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Abstract
● **AIM:** To evaluate the efficacy and stability of haptic sutured in-the-bag intraocular lens (IOL) in eyes with zonular instability.
● **METHODS:** A total 60 eyes of 60 patients were included in this retrospective cohort study. Postoperative stability in three groups [haptic sutured IOL in the bag, IOL in the bag insertion with haptics oriented toward areas of zonulysis, IOL with capsular tension ring (CTR) in the bag insertion] were compared according to the IOL insertion methods. To evaluate the IOL stability, the changes of anterior chamber depth (ACD), refraction, contraction of anterior continuous curvilinear capsulotomy (CCC) area, and tilt of IOL were compared.
● **RESULTS:** There was no significant difference in change of ACD (-0.04±0.01 mm in group of haptic sutured IOL, -0.07±0.01 mm in group of CTR insertion) and refraction (0.05±0.05 D in group of haptic sutured IOL, 0.37±015 D in group of CTR insertion) between the group of haptic sutured IOL in the bag and CTR insertion group. But in comparison of CCC contraction and IOL tilt, CTR insertion group showed less contraction (1.00%±0.52%) and less IOL tilt (2.66°±0.11°) than the group of haptic sutured IOL in the bag (6.32%±1.36%, 3.47°±0.11°, respectively). The CTR insertion group showed the least CCC contraction and the least tilt.
● **CONCLUSION:** In eyes with zonular instability, the method of haptic sutured IOL in-the-bag shows comparable stability in ACD and refraction in comparison with IOL with CTR in the bag insertion. The method of IOL only in-the-bag insertion shows the largest contraction of CCC and the largest tilt of IOL.
● **KEYWORDS:** zonular instability; capsular tension ring; haptic sutured in the bag
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INTRODUCTION

In eyes predisposed to intraocular lens (IOL) dislocation due to zonular insufficiency, devices such as standard and modified capsular tension rings (CTR) with transscleral fixation through the ciliary sulcus are used to add stability of IOL-capsule complex during cataract surgery[1-2]. Recently, late in-the-bag IOL subluxation or dislocation due to zonulolysis has been reported with increasing frequency and has been reported as 0.2% to 3%[1,3-10].

Risk factors for postoperative IOL dislocation include pseudoexfoliation syndrome, prior vitreoretinal surgery, history of trauma, long axial length, uveitis, retinitis pigmentosa, and connective tissue disorders, such as Marfan syndrome[11-14]. Certain measures to prevent IOL-bag complex luxation have been proposed in these predisposing eyes: postoperative relaxing cuts of anterior capsulorhexis margin with Nd:YAG laser, intraoperatively, aspiration of cortex directed in a tangential fashion, and preference of a 3-piece hydrophobic acrylic IOL which may reduce continuous curvilinear capsulotomy (CCC) shrinkage through a combination of decreased anterior capsule fibrosis and greater haptic rigidity than a single piece IOL[3-14].

Here, we describe a simple technique involving a modification to the IOL haptic suture fixation locations. The efficacy of this technique to maintain capsular bag stability was then compared with two other traditional methods, namely, in-the-bag IOL insertion with haptics oriented toward areas of zonular dehiscence and in-the-bag IOL insertion with a standard CTR.

SUBJECTS AND METHODS

Ethical Approval Institutional Review Board (IRB)/Ethics Committee approval of St. Vincent's Hospital was obtained (VC21RISI0078). All research was conducted in accordance with the tenets of the Declaration of Helsinki.

Subjects A retrospective cohort study with 60 eyes was performed using records of 60 patients undergoing cataract surgery between January 2015 and May 2020 at St. Vincent's Hospital. Surgeries were performed by one surgeon (Cho YK). Inclusion criteria for patients consisted of 50 or more years of age, clinically significant cataracts with zonular instability, less than 120° (4 clock hours) of zonulolysis, and over 1y of postoperative follow up results. Zonular instability was determined preoperatively by the presence of phacodonesis with or without visible zonular dehiscence in full mydriasis and intraoperatively by marked difficulty in performing the CCC due to lens movement with the presence of zonular dehiscence less than 4 clock hours detected under the operating microscope. Intraoperatively just before IOL insertion, the extent of zonulolysis in clock hours was measured with corneal radial marker with degree gauge. The eyes with phacodonesis in performing the CCC as well as eyes with visible anterior or posterior capsular wrinkling or centripetal movement of anterior capsular margin less than 120° were regarded as eyes with zonulolysis less than 4 clock hours.

Exclusion criteria were congenital zonular laxity (*e.g.*, Marfan syndrome), previous ocular surgery, intraoperative posterior capsule rupture, greater than 2.00 D of corneal cylinder by keratometry, abnormal corneal topographic patterns, and extreme axial length (less than 21.0 mm or longer than 25.0 mm).

Groups Surgical patients underwent one of three techniques for IOL (YA60BBR®, Hoya Corp., Tokyo, Japan) insertion (Figure 1) by surgeon's preference according to the operative situation, such as patient's cooperation including eye movement, hearing ability, availability of CTR, and reimbursement of medical insurance. Group 1 (IOL in the bag) utilized a three-piece IOL inserted in the bag with haptics oriented toward the areas of zonulolysis. Group 2 (IOL with CTR in the bag) had a three-piece IOL inserted after injection of a 12 mm standard CTR (Ophtec, Groningen, The Netherlands). Group 3 (Haptic sutured IOL in the bag) received a three-piece IOL inserted in the bag with novel scleral suture fixation at optic-haptic junction.

Measurements At postoperative 1mo and 1y follow-ups, refractive change, anterior chamber depth (ACD), IOL tilt, and CCC were obtained and compared between groups. Refractive changes (reported as spherical equivalent) were measured using an autorefractor keratometer (RK-F1, Canon, Japan). ACD was measured as the distance between the central corneal anterior surface and the anterior surface of the IOL using A-scan ultrasound (AVISO, Carl Zeiss Meditec Ag, France). Negative and positive values between that of preoperative and postoperative 1-year ACD results indicate forward or backward axial movement of the IOL.

With sufficiently dilated pupils, IOL position was measured using the Oculus Pentacam (Oculus Optikgeräte, Inc., Germany). These measurements were performed by an ophthalmic technician who was blinded to patient IOL insertion method. Two vertical Scheimpflug images of total 25 cross section of the target eye 90° apart were selected, and the mean value of tilt in perpendicular directions was recorded as IOL tilt.

The line between the anterior chamber angle (red line in Figure 2B) and the line between the IOL edges (yellow line in Figure 2B) were marked on imaging. The IOL tilt angle between red line and yellow line was measured using the reference line of Scheimpflug image (dotted line in Figure 2A and 2B).

Two aspects of CCC contraction, shape and area, were measured. The shape was evaluated by calculating the CCC axis balance. An ellipse was drawn from the outer tangent lines of the CCC margin and the shortest axis (X axis) and the vertical, longest axis (Y axis) of the ellipse were measured. The axis balance of CCC was calculated (length of X axis ×100%/length of Y axis) and describes the similarity between axes as a percentage. A percentage of 100% denotes a perfect circle, and a smaller percentage nearing 0 denotes a flatter, ovoid shape due to CCC contraction (Figure 3).

The CCC area was measured using Image J software as the percentage area of the CCC in reference to the total corneal area. The total corneal area was defined as the area contained by the corneal limbus (Figure 4A). CCC contraction was then calculated by subtracting the percentage areas obtained at the two postoperative visits at 1mo and 1y.

The posterior capsular opacity (PCO) at postoperative 1-year follow up were measured using slit lamp microscopic examination according to the grading by Congdon *et al*[15] as follows: absent (Grade 0), no opacity or opacity limited to the peripheral capsule; Grade 1, any wrinkling or opacity of the capsule affecting a circle 4 mm in diameter and centered on the visual axis ; Grade 2, central/paracentral opacity as described above sufficient to degrade details of the macula slightly; Grade 3, central/paracentral opacity as defined above, but sufficient to make ascertainment of the cup/disc ratio difficult; Grade 4, central/paracentral opacity as defined above, but sufficient to make visualization of fundus details difficult or impossible.

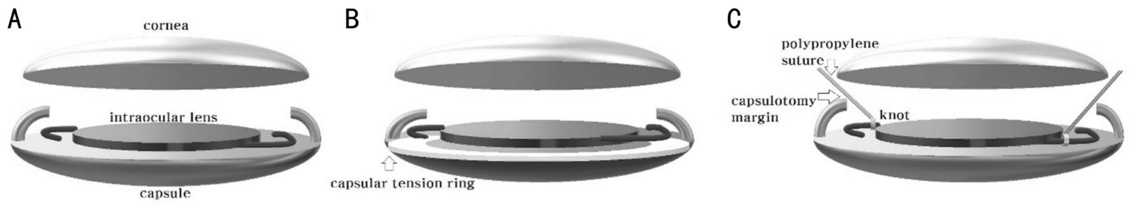

Figure 1 Three techniques for IOL insertion A: Group 1 (IOL in the bag): a three-piece IOL inserted in the bag with the haptic oriented toward the area of zonulysis; B: Group 2 (IOL with CTR in the bag): a three-piece IOL inserted after injection of a 12 mm standard CTR; C: Group 3 (haptic sutured IOL in the bag): three-piece IOL with haptic scleral suture fixated inserted in the bag. Each end of the polypropylene suture was tied near the three-piece IOL optic-haptic junction. The opposite end of the polypropylene suture was placed through a trans-scleral tunnel, tied, and adjusted. CTR: Capsular tension ring; IOL: Intraocular lens.

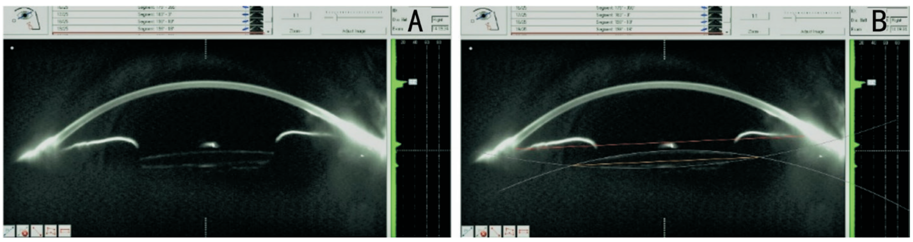

Figure 2 Measurement of IOL tilt A: Original Scheimpflug image at 1-year postoperatively; B: IOL tilt measure by Image J software on edited image (autodesk sketchbook®). The line between the anterior chamber angle (red line in B) and the line between the IOL edges (yellow line in B) were marked. The IOL tilt angle between red line and yellow line was measured using the reference line of Scheimpflug image (dotted line in A and B). IOL: Intraocular lens.

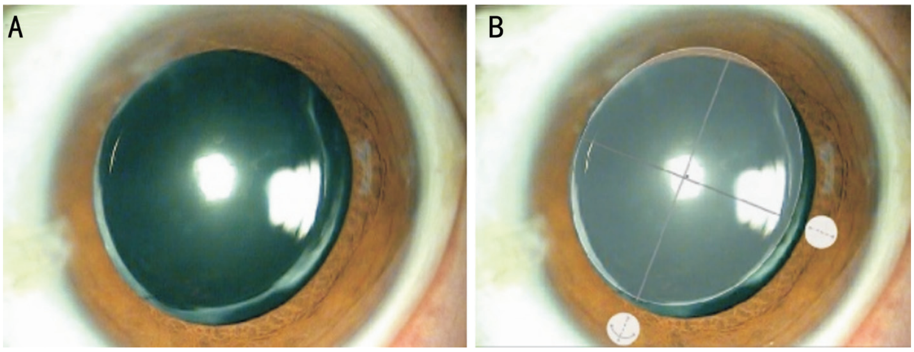

Figure 3 Two aspects of continuous curvilinear capsulotomy contraction, shape and area, were measured A: Original postoperative picture of continuous curvilinear capsulotomy area; B: The difference between the length of longest line and shortest line of two opposite axis in edited image with overlying ellipse (autodesk sketchbook®) of postoperative picture.

The cause of zonular dehiscence was determined by retrospective chart review including history taking, tonometry, slit lamp examination and visual field test.

The primary objective of this study was to evaluate the anatomical stability of IOL capsular bag complex; CCC area contracture, CCC shape and IOL tilt. And the secondary objective was to evaluate the resultant refractive stability, refractive change, and ACD.

Surgical Technique After local anesthetization (sub-tenon injection of lidocaine) and sterile draping, the procedure begins with an anterior CCC approximately 5.0-6.5 mm in diameter using a capsule forcep. In eyes with severe phacodoensis, capsular stability was maintained using disposable iris hook (Synergetics® O'Fallon, MO, USA) placed at the anterior capsular margins. Iris hooks were used in eyes with poor mydriasis. Next, routine phacoemulsification cataract surgery was performed and IOL insertion was accomplished by one of three methods. Group 1 receive a three-piece IOL alone with haptics oriented toward areas of zonulolysis, and Group 2 received CTR coimplantation. The novel method used in Group 3 was performed as follows: After irrigation and aspiration and injection of viscoelastics into the capsular bag and prior to IOL insertion, a 10-0 polypropylene double-armed suture was inserted at the 2 and 8 o'clock position (or the 4 and 10 o'clock position) according to the direction of zonulolysis, about 2 mm from the limbus, and docked in a 30-gauge needle in the anterior chamber. The 10-0 polypropylene suture was retrieved through the main incision and cut in half. Next, each

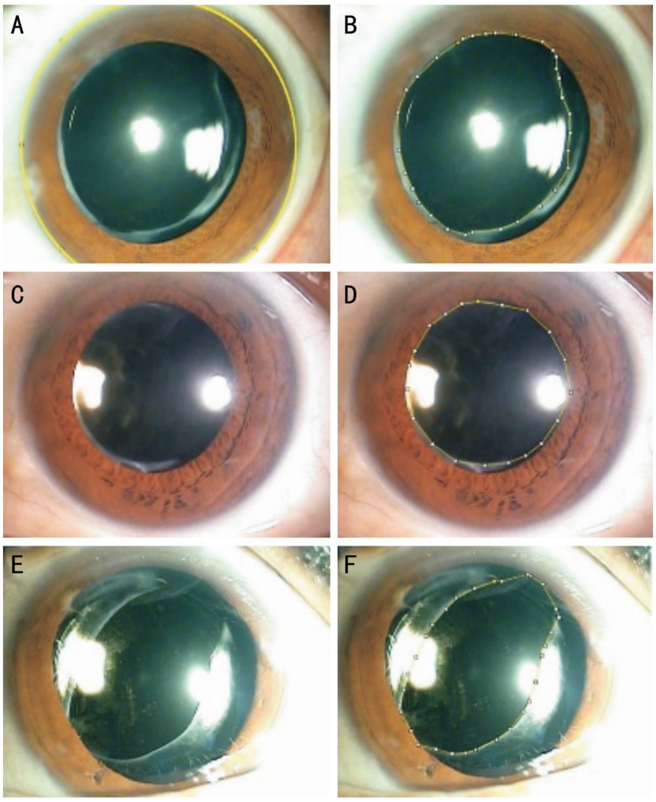

Figure 4 The CCC area was measured using Image J software A, B: Group 1 (IOL in the bag) examples. The outermost yellow line in A marks the corneal limbus, and the area enclosed was measured with Image J software and used as the reference area. The yellow line in B marks the CCC margin and encloses the CCC area measured by image J. C, D: Postoperative picture of CCC area in Group 2 (IOL with CTR in the bag). E, F: Postoperative picture of CCC area in Group 3 (haptic sutured IOL in the bag). In each eye, the CCC area inside of capsulotomy margin was calculated as a percentage area of the total corneal area. The percentage area difference between postoperative 1 and 12mo was then calculated and recorded as CCC contracture. CCC: Continuous curvilinear capsulotomy; CTR: Capsular tension ring.

end of the polypropylene suture was tied near the three-piece IOL optic-haptic junction. The IOL, now with both haptics tied with polypropylene sutures, was then inserted into the capsular bag. The opposite end of the polypropylene suture was placed through a trans-scleral tunnel, tied, and adjusted (Video 1, online supplementary).

Statistical Analysis SPSS Statistics for Windows software (version 11.5, SPSS Inc, Chicago, IL, USA) was used for the statistical analysis. An analysis of variance test was applied to compare data between Groups, and a post hoc analysis was performed when statistical differences were noted between visits. To compare the causes of zonular dehiscence and postoperative 1-year PCO according to each group, the Chi-square test and Fisher exact test were used, respectively. In all cases, a *P* value less than 0.05 was considered statistically significant.

RESULTS

Table 1 shows the preoperative demographics of three groups. At postoperative 1mo, there was no difference between groups in comparison of IOL tilt, axis balance of anterior capsulotomy area and the percentage area of anterior capsulotomy compared with total corneal area (Figure 5).

The refractive change between 1mo and 1y for Group 1 was 0.71±0.02 D and showed significant hyperopic change compared to 0.37±0.15 D for Group 2 (*P*=0.009), and 0.05±0.05 D for Group 3 (*P*=0.007). There was no significant difference in refractive stability between Groups 2 and 3 (Figure 6A).

For ACD changes between 1mo and 1y, Group 1 (0.40±0.05 mm) showed a significant ACD increase compared to Group 3 (-0.04±0.01 mm, *P*=0.005). There was no significant difference in ACD change between Group 2 (-0.07±0.01 mm) and Group 3 (Figure 6B).

As for IOL tilt, Group 2 (2.66°±0.11°) showed significantly less IOL tilting than Group 1 (6.35°±0.28°, *P*=0.005) and Group 3 (3.47°±0.11°, *P*=0.006). Group 3 showed significantly less tilt than the Group 1 (*P*=0.007; Figure 6C).

Comparing of shapes of CCC, Group 2 (93.13%±1.00%) showed the largest axis balance (the least disparity), and Group 3 (64.13%±0.55%) showed the largest disparity between X and Y axis (Figure 6D). For change in area due to CCC contraction, Group 1 (21.62%±1.06%) showed significant CCC contraction compared to the Group 2 (1.00%±0.52%, *P*=0.005) and Group 3 (6.32%±1.36%, *P*=0.007). Group 2 showed less CCC contraction than Group 3 (*P*=0.010; Figure 6E).

Comparing of PCO, there was no eye with PCO Grade 3 or above. There was no difference of PCO incidence between groups (Table 2).

As a result, Group 3 showed the superior anatomical (CCC area, IOL tilt) and refractive stability (ACD, refraction) to Group 1 and showed superior anatomical stability (CCC area, CCC shape, and IOL tilt) to Group 2.

DISCUSSION

Given the rising prevalence of pseudophakia due to increased life expectancy and earlier surgical intervention for cataracts, the incidence of late in-the-bag IOL dislocation may increase over time[12,16]. Surgeons need to consider preoperative risk factors and various surgical techniques to prevent this dangerous complication.

At risk eyes with zonular insufficiency may require transscleral suture fixation which is utilized for both transscleral fixation of IOLs as well as endocapsular supporting devices, such as modified CTR and capsular anchoring devices[1,10].

Cataract surgery in the presence of zonulysis can make the surgery difficult, and it is not uncommon for surgeons to miss zonulysis less than 4 clock hours preoperatively due to

Table 1 Preoperative demographics of three groups according to IOL insertion methods mean±SEM

Demographics	Group 1 (21 eyes)	Croup 2 (18 eyes)	Group 3 (21 eyes)	*P*
Age (y)	71.04±2.35	71.72±2.15	70.47±2.10	>0.05
Nucleosclerosis (LOCS III)	3.90±0.13	4.11±0.11	4.14±0.15	>0.05
Cause of zonulysis, *n* (%)				>0.05
Pseudoexfoliation	5 (23.8)	6 (33.3)	6 (28.57)	
Old age	4 (19.0)	5 (27.8)	6 (28.57)	
Blunt trauma	5 (23.8)	3 (16.7)	5 (23.80)	
Unknown	7 (33.3)	4 (22.2)	4 (19.04)	

IOL: Intraocular lens; LOCS: Lens Opacities Classification System; SEM: Standard error of mean.

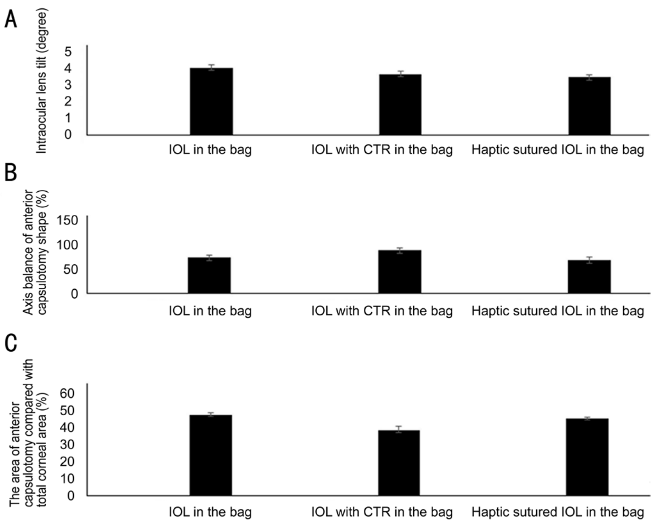

Figure 5 Comparison of IOL tilt (A), axis balance of anterior capsulotomy area (B), and the percentage area of anterior capsulotomy compared with total corneal area (C) in three groups at 1mo postoperatively CTR: Capsular tension ring; IOL: Intraocular lens.

Table 2 Comparison of incidence of posterior capsule opacity at postoperative 1y *n* (%)

Grade	Group 1 (21 eyes)	Croup 2 (18 eyes)	Group 3 (21 eyes)	*P*
Grade 0	7 (33.33)	6 (33.33)	7 (33.33)	>0.05
Grade 1	6 (28.57)	6 (33.33)	7 (33.33)	
Grade 2	8 (38.09)	6 (33.33)	7 (33.33)	

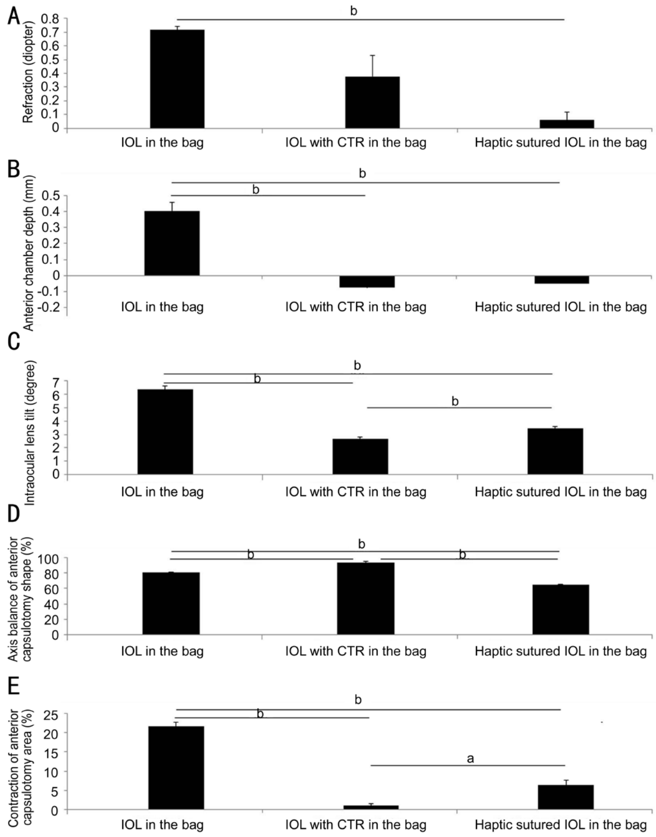

Figure 6 Comparison of changes in refractive change (A), anterior chamber depth (B), intraocular lens tilt (C), axis balance of the anterior capsulotomy shape (D), contraction of anterior capsulotomy area (E) in three groups between 1mo and 1y postoperatively CTR: Capsular tension ring; IOL: Intraocular lens. $^{a}P<0.05$, $^{b}P<0.01$.

poorly dilated pupil or a subtle phacodonesis. In eyes with microscopically visible zonulysis found during surgery, surgeons must determine the appropriate location and IOL insertion methods according to the extent of zonulysis.

CTRs can serve to support the capsular bag during surgery and provide long-term IOL stabilization[1]. The centrifugal force that CTR creates at capsule equator can maintain tension and the circular contour of the capsular bag[1]. However, CTRs carry a risk for iatrogenic damage to capsular bag with insertion[17].

Typically, CTRs are utilized in cases of mild, diffuse zonular weakness or small, localized zonular dialysis (*i.e.*, less than 4 clock hours). When the degree of zonular dehiscence is 120° or greater, however, the stability of IOL-capsule-CTR complex cannot be guaranteed[1].

For large areas of zonulysis, surgeons generally cannot insert IOLs without special devices with sutured fixation, such as modified CTRs or capsular tension segments. In situations where special devices are lacking, insertion of IOL into the sulcus with scleral fixation is the traditional approach to zonulysis confronted during cataract surgery.

With respect to refractive stability, Group 1 (IOL in the bag) showed significant hyperopic changes compared to Group 2 (IOL with CTR in the bag) (*P*<0.01) and Group 3 (haptic sutured IOL in the bag) (P<0.01). This finding signifies greater ACD deepening from capsular contracture and subsequent posterior movement of the IOL in Group 1. In our study, Group 2 showed superior stability in all parameters (refraction, anterior chamber depth, CCC contracture, and IOL tilt) than Group 1.

In contrast to our results, one study on co-implantation of CTR showed hyperopic change in eyes with CTR compared with eyes without CTR[18]. Belov *et al*[19] compared refractive outcomes in myopic eyes between IOL implantation with and without a CTR, and found no statistically significant difference in the mean absolute refractive prediction error between the CTR group and controls. These results may be due to differences in the total follow up period and inclusion criteria of each study as our study included eyes with zonulysis of less than 120°. The capsular contraction syndrome itself can cause postoperative hyperopic change, due to posterior bowing of IOL-capsule complex[20].

But we assume that the difference in refractive changes in each study depends on the degree of zonular weakness with accompanying progressive changes with time. Moreover, CTR cannot entirely prevent capsule contraction[21-22].

When considering IOL tilt, Group 2 showed less tilt than Group 1. These results concur with a study by Lee *et al*[4], who evaluated the impact of the CTR on postoperative IOL position using Scheimpflug imaging and found that eyes with both an IOL and a CTR had significantly lower anatomic IOL decentration and physical tilt than eyes with IOLs alone.

However, the opposite was reported. Page *et al*[17] found the use of CTRs caused an increase in tilt aberration after cataract surgery and does not seem to improve the optical performance of conventional IOL after uneventful cataract surgery. In a study of Takimoto *et al*[23], there was no reported difference in IOL tilt between the CTR group and control at 6mo postoperatively. The observation period of these two studies were different from ours, so further long-term study may provide a better understanding of postoperative IOL tilt.

Group 3 showed comparable ACD and refractive stability to Group 2. This is notable because an effective sutured haptic technique may offer additional advantages over CTR-based methods as this novel technique can be done without special devices, such as the modified CTR. Sutured haptic IOLs would also resist late IOL-capsular bag dislocation that pose a risk to standard CTR co-implantation.

Considering the significant complication such as extension of a zonular dialysis, violation of the capsular bag, displacement of the CTR into the vitreous, misplacement into the sulcus, or the anterior chamber which might occur during CTR implanatation, this novel technique can be an alternative choice for eyes with zonular insufficiency[17,23-26].

When using CTR, if the zonulopathy is a non-progressive zonulopathy, such as traumatic or iatrogenic zonular dialysis, these cases are well suited for standard CTR, as the remaining zonules are typically of normal tension. In cases of progressive or advanced zonulopathy, such as advanced pseudoexfoliation syndrome, a standard CTR is unlikely to provide the capsular support needed, and will most likely allow the IOL to dislocate postoperatively[24-26]. The modified Cionni CTR can prevent the late IOL-capsular bag dislocation, but this Cionni CTR needs scleral fixation, too. So with suture related problems and iris chafing exist with using the Cionni rings[17,23]. This novel, haptic sutured in the bag IOL technique can be used safely in progressive zonulopathy.

In all postoperative values (ACD, refraction, CCC area, IOL tilt) except CCC shape, Group 3 showed significantly superior stability than Group 1. When analyzing Group 3's CCC shape (axis balance), we found the suture point of optic-haptic junction has the potential to elongate the long axis (Y axis), creating a CCC shape that may be more ovoid than those of the other groups.

A well-known technique for IOL insertion in the setting of zonular dehiscence is orienting IOL haptics toward the area of zonulysis. The IOL haptics will extend the capsule in the direction of zonulysis and help maintain the CCC shape. In our study Group 1 was shown to maintain a more circular shape than Group 3. However, using an IOL alone appeared to poorly resist CCC contraction as the CCC contraction was highest in this group.

This novel technique we introduce here involves a modification to the IOL fixation location. Historically, scleral suture fixation[27] of IOLs is accomplished by suturing IOL haptics at one-third from each end (or through premade holes in the haptics) followed by insertion into the sulcus with or without optic capture. In this novel technique, we modified the location of sutures in the IOL haptic to be nearer to the optic-haptic junction to facilitate insertion of the IOL easily into the bag[28]. Additionally, the CCC was made larger than the usual optic size of a commercial three-piece IOL (typically 6.0 mm or less), so the fixation knot point on the haptic will be minimally affected by the capsulorhexis margin.

Because we included only cases of less than 4 clock hours of zonulysis, we did not perform or include cases of traditional scleral sulcus fixation, which is more appropriate for case of larger zonulysis. This study was further limited by its retrospective nature and lack of randomization in choice of IOL insertion methods.

Although the traditional scleral sulcus fixation technique with or without optic capture was not included, we believe this novel technique of in-the-bag haptic sutured IOL will prove to be superior in several regards (a manuscript in preparation).

Our approach preserves anatomical stability of the IOL-capsular bag complex with both optic and haptics in the bag. Retaining the haptics in the bag can stretch the capsular bag (especially toward the direction of zonulysis) according to the total length of the planned IOL. In traditional sulcus scleral fixation methods, total capsular phimosis or bag shrinkage or bag distortion can be caused by an absence of the IOL haptics in the bag[29-31]. This technique can also prevent total capsular phimosis or bag shrinkage due to an absence of the IOL haptics as seen in traditional scleral sulcus fixation.

In conclusion, the in-the-bag haptic sutured IOL technique can improve the IOL-capsular bag complex stability without additional devices. This easy and simple technique we introduce here has the potential to play an effective role in preventing late IOL decentration in eyes at risk, such as those with partial zonulysis or phacodonesis.

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