LABORATORY SCIENCE

Rotational stability of toric intraocular lenses with a newly modified capsular tension ring

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Purpose: To determine whether a newly modified capsular tension ring (CTR) is effective at preventing toric intraocular lens (TIOL) rotation and misalignment.

Setting: John A. Moran Eye Center, University of Utah, Salt Lake City, Utah, USA.

Design: Experimental study.

Methods: Ten human cadaver eyes were used to test the ease or difficulty of TIOL rotation in the capsular bag under 3 experimental conditions: a TIOL alone, a TIOL with a standard CTR, or a TIOL with a newly modified CTR with indentations in a sinusoidal pattern. Scores for the ease of IOL rotation were compared by using the nonparametric Friedman analysis of variance test. In addition, both anterior and posterior Miyake-Apple views were filmed to observe the rotational stability of TIOLs in the capsular bag under the 3 test conditions.

Results: In the ten eyes of five patients, the rotational stability improved with a standard CTR, but further improvement was statistically observed ($P < .05$) with the newly modified CTR under all test conditions. This was true for both IOLs used (AcrySof and TECNIS toric IOLs), with or without ophthalmic viscosurgical device, and for either clockwise or counterclockwise rotations.

Conclusions: A newly designed CTR prototype represents a new technology for improving the rotational stability of a TIOL in the capsular bag. Under all test conditions, the prototype performed significantly better than a standard CTR. The results support the use of this new CTR design to improve the accuracy and refractive success of TIOLs.

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The accurate positioning of a toric intraocular lens (TIOL) at the intended axis is critical for the successful correction of astigmatism.[1] Toric IOLs have been shown to rotate out of their intended position postoperatively in a small but significant number of cases; the incidence of toric IOL rotations of greater than 10 degrees has been reported to range from 2.8% to 6.7% of all surgeries.[2–5] Visser et al. reported that rotation greater than 10 degrees occurred 11.3% of the time when averaging 4 different types of TIOLs.[1]

A rotation of greater than 10 degrees will reduce the intended astigmatism correction by approximately 33% and, more importantly, will generally require surgical repositioning.[1,6,7–11] In a recently reported retrospective study of 1273 toric paitents receiving the most widely used TIOLS in the United States (Acrysof Toric, Alcon Laboratories, Inc. and Tecnis Toric, Johnson & Johnson Vision, Inc.), it was found that surgical realignment was required in 1.6% and 3/1% cases, respectively.[12]

Previous authors have provided anecdotal evidence that a capsular tension ring (CTR) may limit the rotation of a TIOL, and 2 prospective studies have also concluded that a CTR can effectively increase the rotational stability of a toric IOL.[13–18] A modified CTR with indentations was introduced in 2007 (Henderson CTR type 10C; Morcher GmbH) for the purpose of improving the ease of cortical removal.[19] However, surgeons noted an incidental finding that this modified CTR was associated with decreased TIOL rotation.[20] Because of this finding, we developed additional modifications to this modified CTR type 10C to stabilize and hinder the movement of the TIOL in the capsular bag.

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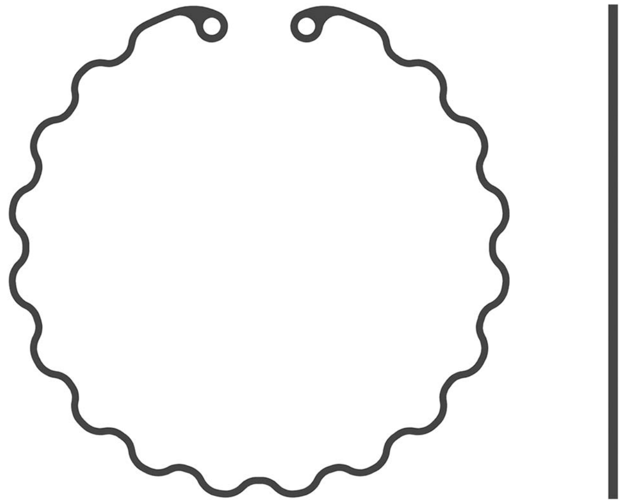

Figure 1. Schematic drawing showing the modified PMMA capsular tension ring evaluated in this study. It features 17 indentations in a sinusoidal pattern. The total outer diameter of the ring (uncompressed) is 12.01 mm.

We present a new design for a CTR, a prototype with an open modified C-shape, made of polymethylmethacrylate, and 17 indentations in a sinusoidal pattern (Zdral-Henderson CTR type 20C; Morcher GmbH) (Figure 1). The indentations approximate the size of the haptic terminal bulbs of a TIOL. Experiments were performed to test the ease of rotation under 3 conditions; a TIOL with no CTR, with a standard nonindented CTR, or with the newly modified sinusoidal pattern CTR. Miyake-Apple videography was performed under each test condition to view the interactions of the modified CTR with the IOL haptics and study how it may prevent rotational movements in the capsular bag.

METHODS

This study was performed in collaboration with eye banks nationwide within the United States. Five pairs of fresh, phakic human eyes obtained postmortem (N = 10 eyes) within 72 hours of death/enucleation were used. The following TIOLs and CTRs were used in this study: AcrySof IQ Toric, model SN6AT5, power of +21 D and 3.00 cyl; SN: 21161594020; expiration date: May 31, 2021 (Alcon Laboratories, Inc.; N = 1) and TECNIS Toric, model ZCT300, power of +21 D and 3.00 cyl; SN: 8052221309; expiration date: August 2017 (Abbott Medical Optics, Inc.; N = 1), standard preloaded Eyejet CTR type 14C RIGHT (Morcher GmbH; N = 10), and modified preloaded CTR type 20C (Morcher GmbH; N = 10) (Figure 2). The total outer diameter uncompressed is 13 mm in type 14C CTR and 12.01 mm in type 20C CTR. The total outer diameter compressed is 11.0 mm in both types of CTR.

Once available in our laboratory, gross measurements of each eye were obtained by using a digital metric ruler (model Absolute Digimatic; Mitutoyo Corp.), including anterior-posterior length, equatorial diameter, and corneal diameter. The eyes were then bisected coronally just anterior to the equator. The anterior segment of each eye was then glued to a glass slide according to the Miyake-Apple technique for experimental surgery.[21]

All subsequent surgeries were performed by the same surgeon (NM). The capsulorhexis was performed, and its diameter was measured in the horizontal and vertical meridians with surgical calipers, followed by hydrodissection and phacoemulsification. Both anterior and posterior Miyake-Apple views were filmed to observe the rotational stability of TIOLs in the capsular bag under

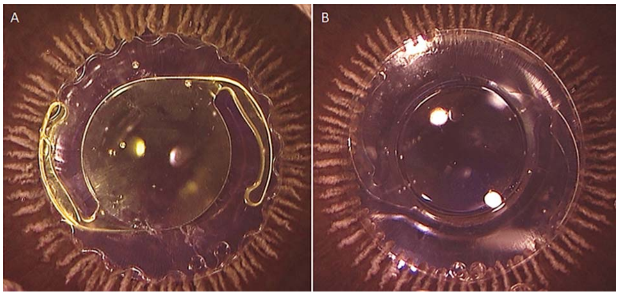

Figure 2. Gross photographs (Miyake-Apple view) of human eyes obtained postmortem implanted with the devices used in this study. *A*: AcrySof IQ toric IOL and modified CTR type 20C. *B*: TECNIS toric IOL and standard CTR type 14C. CTR = capsular tension ring

the 3 test conditions: a toric IOL alone, a toric IOL with a standard CTR, and a toric IOL with the newly modified CTR. In each eye, an ophthalmic viscosurgical device (OVD) was injected within the empty capsular bag, followed by the insertion of the IOL. Clockwise and counterclockwise rotations of the IOL were attempted with a collar button hook and scored with an OVD in place and after irrigation-aspiration of the OVD. The tip of the hook was placed in the concavity of the optic–haptic junction for the clockwise rotation and exactly on the other side of the junction for the counterclockwise rotation. After removal of the IOL, more OVD was injected, followed by the insertion of the first CTR and the IOL. Clockwise and counterclockwise rotations of the IOL were again attempted and scored with an OVD in place and after irrigation-aspiration of the OVD. Finally, the IOL and the first CTR were removed, and the OVD was again injected into the bag. The second CTR and the IOL were inserted, and clockwise and counterclockwise rotations of the IOL were attempted and scored, before and after OVD irrigation-aspiration. Each eye was tested with the same IOL type and with both CTR types. The same 2 IOLs were used throughout the study, whereas new CTRs were used for each eye. The behavior of the capsular bag and zonular fibers during insertion of both types of CTR was also qualitatively evaluated. Table 1 summarizes the overall design of the study, the IOL used in each eye, and the order of CTR evaluation in each eye.

The experiments were designed to test ease or difficulty of rotation of a toric IOL in the capsular bag and were graded by ease of rotation in the clockwise (CW) and counterclockwise (CCW) directions. A grading scale from (1) very easy, (2) easy, (3) difficult, and (4) very difficult was used. Of note, the surgeries, rotations, and initial rating of the results were performed independently by a different surgeon than the 2 creators (J.Z., B.A.A.) of the newly modified CTR type 20C to avoid any bias. The initial rating was done by the surgeon (N.M.) based on his ability to rotate the IOL. Three independent coinvestigators (L.W., S.B., and S.K.) observed all surgical procedures through the video monitors, particularly focusing on the posterior or Miyake-Apple view (not accessible to the surgeon during surgery), and the final score for each maneuver was based on the agreement among the 4 participants.

Scores for ease of IOL rotation were obtained in the 10 eyes and compared among the 3 device implantation scenarios (IOL alone, standard CTR/IOL, and modified CTR/IOL) by using the nonparametric Friedman analysis of variance test for repeated measures. A P value less than 0.05 was considered statistically significant. For the significant overall comparisons among the 3 device scenarios using the Friedman test, a post hoc comparison between the standard CTR/IOL scores and the modified CTR/IOL was performed using the nonparametric Wilcoxon signed-rank test.

RESULTS

Table 2 summarizes the characteristics of the eyes included in the study. There were 3 male and 2 female donors aged

Table 1. Overall Design of the Study.

Eye#	RE/LE	IOL	Devices
1	RE	AcrySof	(1) IOL alone; (2) standard CTR/IOL; (3) modified CTR/IOL
2	LE	TECNIS	(1) IOL alone; (2) standard CTR/IOL; (3) modified CTR/IOL
3	RE	AcrySof	(1) IOL alone; (2) modified CTR/IOL; (3) standard CTR/IOL
4	LE	TECNIS	(1) IOL alone; (2) modified CTR/IOL; (3) standard CTR/IOL
5	RE	TECNIS	(1) IOL alone; (2) standard CTR/IOL; (3) modified CTR/IOL
6	LE	AcrySof	(1) IOL alone; (2) standard CTR/IOL; (3) modified CTR/IOL
7	RE	TECNIS	(1) IOL alone; (2) modified CTR/IOL; (3) standard CTR/IOL
8	LE	AcrySof	(1) IOL alone; (2) modified CTR/IOL; (3) standard CTR/IOL
9	RE	AcrySof	(1) IOL alone; (2) standard CTR/IOL; (3) modified CTR/IOL
10	LE	TECNIS	(1) IOL alone; (2) standard CTR/IOL; (3) modified CTR/IOL

CTR = capsular tension ring; LE = left eye; RE = right eye
After implantation of the devices in the order shown in 1, 2, and 3 for each eye, clockwise and counterclockwise rotation of the IOL was attempted with and then without ophthalmic viscosurgical device (12 IOL rotations attempted in each eye)

63 ± 20 years (range: 31 to 81 years). All tests were performed between 1 to 3 days after death/enucleation. Anterior-posterior length was 24.97 ± 0.98 mm (range: 24.03 to 26.72 mm), equatorial diameter was 24.34 ± 0.9 mm (range: 22.75 to 25.87 mm), and corneal diameter was 11.89 ± 0.38 mm (range: 11.3 to 12.06 mm). The horizontal diameter of the capsulorhexis ranged from 4.75 to 5.5 mm, and the vertical diameter ranged from 4.75 to 5.25 mm.

Tables 3–5 show the scores for ease of CW and CCW rotation of each IOL type in the absence of a CTR, in the presence of a standard CTR, and in the presence of a modified CTR, respectively. Table 6 shows the statistical analyses comparing scores for the 3 scenarios (IOL alone vs standard CTR/IOL vs modified CTR/IOL), as well as post hoc comparisons of the standard CTR/IOL scenario vs the modified CTR/IOL scenario. For the 10 eyes studied, rotational stability was improved with the standard CTR, and further improvement was statistically observed with the newly modified CTR under all test conditions. This was true for both the AcrySof and TECNIS IOLs, with or without OVD, and for either CW or CCW rotations. Under all conditions, the results remained statistically significant ($P < .05$). The injections of both types of CTRs were overall smooth and uneventful, without any undue stress on the capsular bag or the zonular apparatus observed through the posterior or Miyake-Apple view. In all eyes, there was generally an overlapping of one of the haptics of the IOL over the sinusoidal indentations of the new CTR, as appreciated through the Miyake-Apple view. No efforts were made to change this, as the surgeon would normally not have access to the view of the equatorial region of the bag, due to the iris. This had no effect on the centering of the IOL, as the haptics of these single-piece IOLs adapt well to the capsular bag configuration.

DISCUSSION

A major requisite for toric IOLs is rotational stability.[22,23] The most common complication associated with TIOLs is postoperative rotation leading to misalignment.[23] Rotation usually occurs within the first 24 hours postoperatively and is uncommon after the first week, at which point capsular shrinkage and bioadhesion have likely occurred.[7,22]

In a retrospective analysis of over 12,000 eyes, Kramer et al. concluded that 90% of TIOLs were not at the ideal orientation, and repositioning would be of some benefit.[24] In the initial clinical evaluation of the TECNIS toric IOL by Waltz et al., a rotation greater than 10 degrees occurred in 2.87% of cases and reoperations in 2.3% of all patients.[2] In a large retrospective study of 1273 patients, Lee and Chang

Table 2. Characteristics of Eyes Used in This Study.

Donor	Age (y)	M/F	Eye#	RE/LE	Days to test	AP	ED	WW	Capsulorhexis diameter horizontal/vertical
1	77	M	1	RE	2	24.2	24	11.5	4.75/5
			2	LE	2	24.3	24.1	11.3	4.75/4.75
2	57	M	3	RE	1	24.03	23.42	12.04	5.25/5
			4	LE	1	24.27	22.75	12	5.25/5
3	81	M	5	RE	3	24.26	24.16	11.69	5/5.25
			6	LE	3	24.41	24.26	11.99	5.25/5.25
4	69	F	7	RE	3	26.15	25.23	12.31	5.25/5
			8	LE	3	26.72	25.87	12.6	5.25/5
5	31	F	9	RE	2	25.9	24.64	11.74	5.5/5.25
			10	LE	2	25.46	25.04	11.76	5/5.25

AP = anterior-posterior length; ED = equatorial diameter; LE = left eye; RE = right eye; WW = white to white
Eye measurements done with a digital caliper (millimeters). Capsulorhexis diameter measured with a surgical caliper with steps of 0.25 mm.

Table 3. Scores for Ease of CW and CCW Rotations of the IOL in the Absence of Any Capsular Tension Ring.

Eye#	CW with OVD	CCW with OVD	CW without OVD	CCW without OVD
AcrySof				
1	1	2	2	3
3	1	2	2	2
6	1	2	2	2
8	1	2	2	2
9	1	2	2	2
Mean	1	2	2	2.2
SD	0	0	0	0.4
TECNIS				
2	1	1	1	2
4	1	1	1	1
5	1	2	1	2
7	1	2	1	2
10	1	2	2	2
Mean	1	1.6	1.2	1.8
SD	0	0.5	0.4	0.4

1 = very easy; 2 = easy; 3 = difficult; 4 = very difficult; CCW = counterclockwise; CW = clockwise; OVD = ophthalmic viscosurgical device

reported surgical reoperation rates of 3.1% for the TECNIS toric and 1.6% for the AcrySof toric IOLs.[12] Four patients also required a second surgical repositioning. Many factors can contribute to the instability of a TIOL, including longer axial length, large capsular bag diameter, size of the capsulorhexis, and IOL material and design.[25–30]

Multiple authors have provided anecdotal support for a CTR providing stability for the toric IOL platform. Safran, Wiley, Sagiv and Sachs, and Tataru et al. have all reported improved rotational stability with various types of CTRs coimplanted into the capsular bag, without any complications.[13–16] Similarly, 2 prospective studies by Rastogi et al. and Zhao et al. concluded that a CTR can enhance rotational stability for patients with TIOL implants, achieving improvement in the overall visual acuity.[17,18]

One of the main drawbacks of a standard smooth CTR is that the ring compresses the residual cortical material against the capsular bag, hindering its removal. The modified Henderson type 10C CTR was created with indentations to allow gap areas between the CTR and capsular bag. In these gap areas, the cortex is not trapped between the ring and the bag and therefore is removed more easily.[19] Anecdotally, surgeons have been using this modified CTR to help prevent rotation of TIOLs. It is hypothesized that the indentations may offer additional resistance against rotation compared with the nonmodified smooth C-shaped design. To our knowledge, this hypothesis has not been tested in a prospective study.

Therefore, we decided to enhance the design of the modified type 10C with additional indentations for further resistance and investigate the efficacy of this new modification in inhibiting the rotation of TIOLs. The number of indentations was increased to 17 while maintaining the sinusoidal pattern of indentations of 0.15 mm. The total external diameter is 12.01 mm (uncompressed). The results clearly demonstrate that the newly modified type 20C CTR is effective in restricting the mobility of both brands of commonly implanted TIOLs. Whether the rotation was clockwise or counterclockwise, with or without OVD, the new CTR was better at locking in the IOL in every situation.

Both the AcrySof and TECNIS IOLs are made of hydrophobic acrylic material and have similar dimensions with a 6 mm optic and an overall length of 13 mm. Miyake-Apple

Table 4. Scores for Ease of CW and Counterclockwise CCW Rotation of the IOL in the Presence of a Standard Capsular Tension Ring.

Eye#	CW with OVD	CCW with OVD	CW without OVD	CCW without OVD
AcrySof				
1	1	2	2	2
3	2	2	2	2
6	2	3	2	3
8	2	3	2	3
9	2	2	2	2
Mean	1.8	2.4	2	2.4
SD	0.4	0.5	0	0.5
TECNIS				
2	1	2	2	2
4	1	2	1	2
5	2	2	2	2
7	2	2	2	2
10	2	2	2	3
Mean	1.6	2	1.8	2.2
SD	0.5	0	0.4	0.4

1 = very easy; 2 = easy; 3 = difficult; 4 = very difficult; CCW = counterclockwise; CW = clockwise; OVD = ophthalmic viscosurgical device

Table 5. Scores for Ease of CW and Counterclockwise CCW Rotation of the IOL in the Presence of a Modified Capsular Tension Ring.

Eye#	CW with OVD	CCW with OVD	CW without OVD	CCW without OVD
AcrySof				
1	2	4	3	4
3	3	4	4	4
6	3	4	3	4
8	3	3	3	4
9	3	3	3	4
Mean	2.8	3.6	3.2	4
SD	0.4	0.5	0.4	0
TECNIS				
2	2	4	4	4
4	2	3	3	4
5	3	4	3	4
7	2	2	2	3
10	3	4	3	4
Mean	2.4	3.4	3	3.8
SD	0.5	0.8	0.7	0.4

1 = very easy; 2 = easy; 3 = difficult; 4 = very difficult; CCW = counterclockwise; CW = clockwise; OVD = ophthalmic viscosurgical device

Table 6. Statistical Analysis for the Comparison of the Scores for Ease of CW and CCW Rotation of the IOL.

Comparison	Test	CW with OVD	CCW with OVD	CW without OVD	CCW without OVD
IOL alone vs standard CTR/IOL vs modified CTR/IOL	Nonparametric Friedman ANOVA test for repeated measures	P = .00028	P = .00267	P = .00085	P = .00044
Standard CTR/IOL vs modified CTR/IOL	Two-tail, nonparametric Wilcoxon signed-rank test	P < .05	P < .05	P < .05	P < .05

ANOVA = analysis of variance; CCW = counterclockwise; CTR = capsular tension ring; CW = clockwise; OVD = ophthalmic viscosurgical device

videography provided evidence that both IOLs were effectively held in place by the newly modified CTR, which significantly impeded any movement of the IOL on attempted rotations. Although not the objective of this study, our results suggest that rotation of the AcrySof IOL was overall more difficult than the TECNIS IOL. The high bioadhesivity of the AcrySof material, as well as the design of the haptics of this IOL with a bulb at the tip, may at least in part explain this finding.

In addition, the newly modified type 20C CTR was compared with a standard smooth type 14C CTR to investigate the possibility that the restriction to rotation was due purely to the presence of a ring. In these direct comparisons, the newly modified CTR obstructed the movement of the TIOL better than the standard CTR (P < .05). Limitations of the study include the fact that the Miyake-Apple technique is an open-sky system, only one type of OVD was available for the study (a dispersive OVD, although many surgeons would prefer a cohesive OVD to inflate the capsular bag), and only one type of IOL material and overall design was represented (hydrophobic acrylic, single-piece with loops). In addition, to further standardize the procedures, it would have been interesting to mark an axis of intended alignment on the surface of each eye, with the IOL placed at the same axis before the rotation tests. The degree of difficulty of rotation in this study may not represent what actually happens when the IOL rotates in vivo in the postoperative state. However, the surgical videos demonstrate the enhanced difficulty of rotating the IOL with the new CTR even in an open-sky system with direct, forceful, and purposeful attempted rotation with a lens manipulator. If the IOL barely rotates in this exaggerated experimental in vitro setup, it can be extrapolated that in a normal postoperative eye, even in the presence of a wound leak or nudge on the eye, it seems unlikely that there would be sufficient force to push the IOL out of place.

The limitations of the newly modified CTR include the same limitations of any CTR, namely, difficulty of removing any compressed cortical material against the capsular bag, possible improper insertion with the trailing haptic inadvertently released in the sulcus, rupture of the capsular bag, and inability to use a CTR without an intact capsule or capsulorhexis. In addition, because the modified CTR increases the difficulty of rotating the IOL, it may affect the ease of the initial positioning and alignment.

In conclusion, the newly designed CTR in our study represents a new technology to cumber the movement of a TIOL. By locking the IOL into place, it is hoped that the TIOL will remain at the intended target axis, until capsular shrinkage and bioadhesion can take permanent effect. By measuring the rotational tendency of a TIOL in a series of human cadaver eyes, we were able to verify that this new design drastically improved the rotational stability of a TIOL in the capsular bag and performed significantly better than a standard CTR.

Because there are both risks and costs to performing lens repositioning surgery, by reducing the tendency for rotation, it is hoped that this new CTR modification will lower misalignments and reoperation rates in patients receiving TIOLs. The new CTR design may represent an option surgeons use in the future to improve both the accuracy and stability of TIOL alignment, resulting in improved refractive success.

WHAT WAS KNOWN

- A toric IOL (TIOL) may rotate out of position, requiring surgical repositioning, in a small but significant number of cases.
- A standard capsular tension ring (CTR) may impede the rotational movements of a TIOL in the capsular bag, helping stabilize the IOL.

WHAT THIS PAPER ADDS

- In comparison with a TIOL alone, or with a standard smooth CTR, a modified CTR with indentations in a sinusoidal pattern dramatically improves the rotational stability of a TIOL in the capsular bag.

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