

Rotational stability of a toric intraocular lens: Influence of axial length and alignment in the capsular bag

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PURPOSE: To evaluate the rotational stability of a toric intraocular lens (IOL) using purpose-designed software and to determine the influence of axial length (AL) and in-the-bag IOL alignment on IOL rotation.

SETTING: Iladevi Cataract & IOL Research Centre, Ahmedabad, India.

DESIGN: Prospective observational case series.

METHODS: This study enrolled eyes that had AcrySof toric IOL implantation. The AL was measured using optical coherence biometry or immersion A-scan biometry. Corneal astigmatism was determined by manual keratometry and topography. The IOL alignment was vertical, horizontal, or oblique. Rotational stability was measured using the purpose-designed software, and the mean absolute difference was determined. The effect of AL and IOL alignment on rotational stability was determined 6 months postoperatively.

RESULTS: The study evaluated 168 eyes (168 patients). The mean AL was 23.86 mm $\pm$ 1.63 (SD), (range 19.50 to 29.03 mm). The median IOL rotation was 0.3 degree from baseline to 1 week, 1.0 degree from 1 week to 1 month, 0.2 degree from 1 to 3 months, and 0.1 degree from 3 to 6 months. The maximum rotation occurred between 1 week and 1 month. There was a strong correlation between AL and IOL rotation at 6 months ($r = 0.93$, $P < .001$). The mean absolute difference at 6 months was not significantly different between the 3 axis placement categories when correlated with the rotation ($P = .102$, analysis of variance).

CONCLUSIONS: Toric IOL rotation was greater in eyes with a longer AL. Alignment of the IOL in the capsular bag had no influence on rotation.

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Claim: Mean rotation $<5^\circ$ observed across more than 1,750 patients. (This study adds 168 patients toward that total)

Toric intraocular lens (IOL) implantation is a relatively new option for astigmatism correction in cataract patients. It has been shown conclusively that accurate rotational stability and axial alignment of toric IOLs are critical to the efficacy of surgery. Furthermore, some studies^{1–5} established risk factors affecting the rotational stability of toric IOLs, such as IOL design (plate haptic) and material, axial length (AL), axis of IOL alignment, capsulorhexis size, capsular bag diameter, capsular bag shrinkage, and overall haptic diameter.

Initial studies^{1,6–11} were performed to evaluate the rotational stability of IOLs using methods such as slit-lamp examination, digital photography, conventional

slide photography with the digital overlay technique, and fundus and bifocal photography. Accurate measurement of IOL rotation is, however, dependent on factors such as cyclorotation, head position, and the assessment technique.¹² Some authors propose that digital photography might eliminate the intrinsic errors of standard fundus photography.⁹

In our previous study,¹³ we developed and validated a software-based technique with a purpose-designed grid for determining toric IOL alignment. In the present study, we used the findings in our previous study and our software to assess whether established risk factors (ie, AL and IOL alignment) have an effect on the rotational stability of a toric IOL 6 months

postoperatively. Because our software can measure rotation to a precise point (1 degree of movement), we believed its use would help us achieve the goals of this study.

PATIENTS AND METHODS

This prospective clinical trial performed at the Iladevi Cataract and IOL Research Centre enrolled eyes having phacoemulsification with implantation of an Acrysof toric IOL (Alcon Laboratories, Inc.). Recruitment began in January 2008 and ended in December 2008. All patients provided informed consent preoperatively.

Inclusion criteria were as follows: preoperative regular corneal astigmatism more than 1.00 diopter, adequate pupil dilation to visualize the innermost toric axis marks at all follow-ups, at least 1 prominent episcleral vessel around the limbus to act as a reference mark for aligning all follow-up images, and total capsulorhexis coverage of the IOL optic. Patients with irregular corneal astigmatism, a history of intraocular surgery or keratorefractive procedures, glaucoma, uveitis, coexisting corneal pathology, or macular disease were excluded from the study. Patients with intraoperative complications, such as wound-site thermal injury, incisions requiring suturing, posterior capsule rupture, and Descemet membrane detachment, were also excluded from the final analysis.

Preoperative Assessment

All the patients had a routine slitlamp examination with the pupils completely dilated. Axial length was measured using optical coherence interferometry (IOLMaster, Carl Zeiss Meditec AG). Immersion A-scan biometry (Ocuscan, Alcon Laboratories, Inc.) was used in cases in which the AL could not be measured with the IOLMaster device. Corneal astigmatism was determined by manual keratometry (Ophthalmometer OM-4, Topcon Corp.) and by topography (Atlas topographer, Carl Zeiss Meditec AG). The spherical power of the IOL was then calculated using the SRK/T formula, targeting emmetropia. The cylindrical power and the axis of toric IOL placement were calculated using an online calculator provided by the IOL manufacturer.^A

Intraocular Lens

The toric IOL design is based on the 1-piece Acrysof platform. The overall haptic length is 13.0 mm and the optic diameter, 6.0 mm.

Surgical Technique

For preoperative corneal marking, the eye was anesthetized with a single drop of proparacaine. With the patient sitting upright and with the head carefully aligned, the patient was asked to fixate straight ahead on a distant target with the nonsurgical eye. The corneal limbus was marked at the 0-degree and 180-degree positions using a corneal marker with an air-bubble (AE-2791TBL Nuijts/Lane Preop Toric Reference Marker, American Surgical Instruments Corp.) to ensure accurate horizontal positioning of the marker on the limbus.

The same surgeon (A.R.V.) performed all surgeries using topical anesthesia, microcoaxial phacoemulsification, and a standardized technique. The incision size was determined based on the steep meridian of astigmatism. A temporal 2.2 mm clear corneal incision (CCI) was used in eyes with with-the-rule astigmatism and a 2.4 mm CCI in eyes with against-the-rule astigmatism. After bimanual irrigation/aspiration was performed, the capsular bag was filled with sodium hyaluronate 1.0% (Provisc). The axis of IOL placement was marked with a Villaseñor-Navarro degree gauge and a toric axis marker (AE-2740 Nuijts toric axis marker, American Surgical Instruments Corp.).

The IOL was implanted in the capsular bag using a Monarch II injector with a C-cartridge (Alcon Laboratories, Inc.). As a first step, the IOL was rotated into a position approximately 10 degrees short of the actual marked axis of placement. The residual ophthalmic viscosurgical device (OVD) was removed from behind the IOL and the anterior chamber. Finally, the IOL was rotated to align the peripheral dots on the IOL with the marked steep meridian on the cornea.

The anterior chamber was reformed, and stromal hydration of the main and paracentesis incisions was performed in footpedal position 1 (irrigation) before the irrigation probe was removed from the eye. Correct alignment of the IOL was verified at the end of surgery. All incisions were hydrated, and 500 µg/0.1 mL of moxifloxacin hydrochloride (Vigamox) was injected intracamerally.

Postoperatively, the patients were examined at 1 day, 1 week, and 1, 3, and 6 months.

Intraocular Lens Rotation Assessment

Digital retroillumination images were captured at baseline (within 24 hours of surgery) and 1 week, 1 month, and 3 and 6 months postoperatively using a Nikon digital zoom camera mounted on a Nikon photo slitlamp. The details have been described.¹³ The same observer (G.D.S.) captured and analyzed the images at all follow-up visits. The images were used to measure IOL rotation with the purpose-designed software.¹³ Briefly, in the baseline image, the geometric center of the IOL was determined using the software and an episcleral vessel was identified. Then, the exact position of the toric axis marks and episcleral vessels were measured in steps of 0.1 degree using the measuring axis of the grid in the baseline image. At subsequent follow-ups, before the location of the toric axis marks was determined, the episcleral vessel identified in the baseline image was used as a reference meridian; all the subsequent

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images were aligned so that the episcleral vessel was at the same angle as in the baseline image. The distance between the episcleral vessel and the geometric center of the IOL was also the same in all images. This minimized the influence of cyclorotation on the recording of the position of the toric axis marks. Next, the point locations of the toric axis marks were recorded in degrees on all subsequent images. The difference in the position of the toric axis marks at each follow-up was used to determine the rotation of the IOL in a chronological sequence. The axis of placement was divided into the following 3 categories: vertical ($90 \text{ degrees} \pm 30 \text{ [SD]}$), horizontal ($0, 180 \pm 30 \text{ degrees}$), and oblique ($45, 135 \pm 15 \text{ degrees}$).

Outcome Measures and Statistical Analysis

The primary outcome measures were the correlation of IOL rotation with the AL and orientation of the IOL in the bag. These observations were recorded at 6 months.

Statistical analysis was performed using the Pearson coefficient of correlation and analysis of variance (ANOVA). The rotational stability of the IOL was calculated as the total absolute rotation; that is, the total rotation measured from baseline to 6 months postoperatively. The mean absolute difference was defined as the difference between 2 time points.

RESULTS

The study enrolled 173 patients, 5 of whom were excluded from the analysis because they had no follow-up. The final study population comprised 168 eyes of 168 patients. The mean age of the 92 men (54.8%) and 76 women (45.2%) was 57 ± 12.94 years (range 37 to 73 years).

The mean total absolute rotation 6 months postoperatively was 1.6 ± 0.5 degrees (median 1.6 degrees). Table 1 shows the total absolute rotation at 6 months. Table 2 shows the mean, median, and range of absolute toric IOL rotation over time. Figure 1 shows the position of the toric IOL at baseline and 1 and 6 months postoperatively. Table 3 shows the distribution of eyes in which 0.1-degree IOL rotation was detected at every follow-up visit. The maximum rotation occurred between 1 week and 1 month.

The mean AL was 23.86 ± 1.63 mm (range 19.5 to 29.03 mm). The median AL was 23.6 mm. A strong correlation coefficient between the AL and total absolute rotation was observed at 6 months ($r = 0.93, P < .001$). A significant increase in total absolute rotation with unit increase in AL at 6 months was confirmed using regression analysis ($R^2 = .87, P = .00$) (Figures 2 and 3).

Table 1. Total mean absolute rotation at 6 months.

Rotation (Degree)	Eyes, n (%)
<0.5	1 (0.61)
0.6–1.0	29 (17.3)
1.1–2.0	112 (66.7)
>2.0	26 (15.9)

Table 2. Mean absolute toric IOL rotation over time.

Value	Rotation (Degrees)			
	Baseline–1 Wk	1 Wk–1 Mo	1 Mo–3 Mo	3 Mo–6 Mo
Mean	0.27 ± 0.08	0.99 ± 0.43	0.19 ± 0.07	0.12 ± 0.05
Median	0.30	1.00	0.20	0.10
Minimum	0.10	0.10	0.10	0.00
Maximum	0.50	2.10	0.40	0.30

The mean total absolute rotation of vertically aligned IOLs was 1.72 ± 0.5 degrees ($n = 54$ eyes). The mean total absolute rotation of horizontally aligned IOLs was 1.54 ± 0.4 degrees ($n = 57$ eyes). The mean total absolute rotation of obliquely aligned IOLs was 1.53 ± 0.5 degrees ($n = 52$ eyes). The mean absolute difference at 6 months was not significantly different between the 3 axis-placement categories (vertical, horizontal, oblique) when correlated with the rotation ($P = .102$, ANOVA).

Clockwise rotation occurred in 128 eyes (76.2%) and counterclockwise rotation in 40 eyes (23.8%). No IOL required repositioning.

DISCUSSION

The advent of toric IOL technology has given surgeons a safe, predictable way to manage patients with preexisting corneal astigmatism. Despite accurate toric IOL power calculation and intraoperative alignment, the patient may lose the benefits of astigmatic correction if the toric IOL rotates postoperatively. In the present study, we attempted to assess the efficacy of our software in evaluating the influence of AL and axis of toricity on IOL rotation under standardized settings. We detected significant IOL movement at each follow-up and a correlation between AL and rotational stability (ie, greater rotation in myopic eyes). The maximum rotation in myopic eyes was 3 degrees.

In a previous study,¹⁴ 3 of 263 IOLs rotated more than 15 degrees off axis and required surgical repositioning. The author suggests that the high degree of rotation in these 3 cases might be attributed to the high level of myopia in the eyes. In a consecutive series of 100 cases, the same author⁵ reported excellent rotational stability of the Acrysof toric IOL; the mean IOL rotation was 3.35 ± 3.41 degrees. He also suggested that significant postoperative rotation of the Acrysof toric IOL is rare. In the same study, 90% of IOLs were aligned within ± 5 degrees of the intended axis and 99% of IOLs within ± 10 degrees and no IOL required surgical repositioning.⁵

The findings in this current study agree with those previously reported in the literature. We found a correlation between a high AL and 3-degree rotation of toric

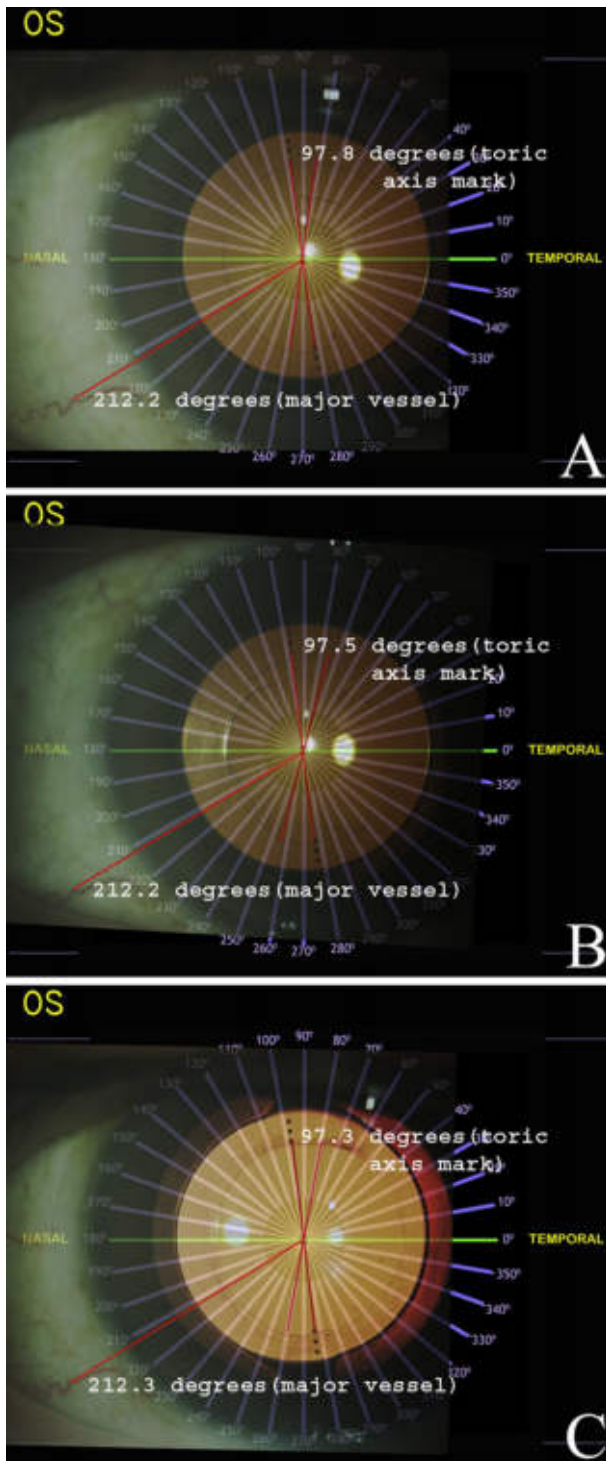


Figure 1. Postoperative toric IOL shows minimum rotation (0.5 degree) at the 6-month follow-up. A: Position of toric IOL at baseline. B: Position of toric IOL at 1 month. C: Position of toric IOL at 6 months.

IOLs. However it is uncertain whether the 1 to 3 degrees of postoperative rotation is clinically significant. We believe other factors, such as slight tilting of the

Table 3. Distribution of eyes with rotation of 0.1 degree over time.

Follow-up	Eyes with 0.1 Degree Rotation, n (%)
Baseline to 1 wk	4 (2.4)
1 wk to 1 mo	6 (3.6)
1 mo to 3 mo	5 (3)
3 mo to 6 mo	10 (6)

head and errors in measuring keratometry or topography, may contribute to imprecise alignment. Ruhswurm et al.¹ evaluated the rotational stability of 1-piece plate-haptic silicone toric IOLs. They measured IOL rotation in 5-degree steps and found that an increase in AL was associated with greater IOL rotation. In his preliminary experience with shorter toric IOLs, Chang² found significant misalignment within the first 24 hours postoperatively in 6 consecutive myopic patients. We believe that the relative accuracy of the conventional method of evaluating postoperative IOL orientation through a dilated slitlamp examination is subject to the observer's experience and bias and has inherent precision limits.

It has been suggested that large-diameter capsular bags might be associated with a reduction in the equatorial friction for a given IOL and therefore a decrease in IOL stability.² Studies show that capsular bag diameter tends to correlate with an increase in AL.¹⁵⁻¹⁷ Thus, early rotation is more likely to occur in highly myopic eyes. Patel et al.⁶ used serial digital photography to compare rotation between plate-haptic IOLs and loop-haptic IOLs. They found a significant correlation between an increase in AL and IOL rotation with the plate-haptic IOLs but not with the loop-haptic IOLs. This difference was because they used a 3-piece silicone loop-haptic IOL with a haptic diameter of 13.5 mm. The dynamics of rotation of this IOL

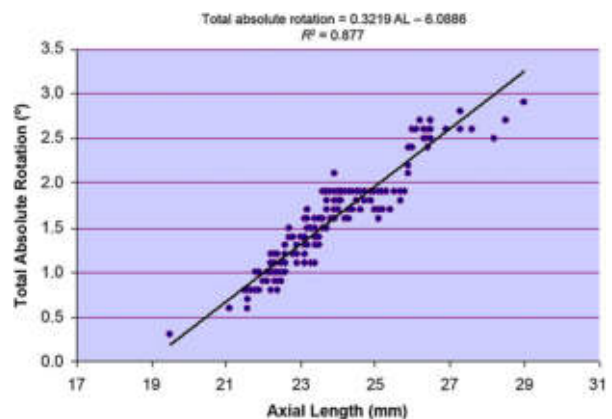


Figure 2. Relationship between AL and total absolute rotation at 6 months.

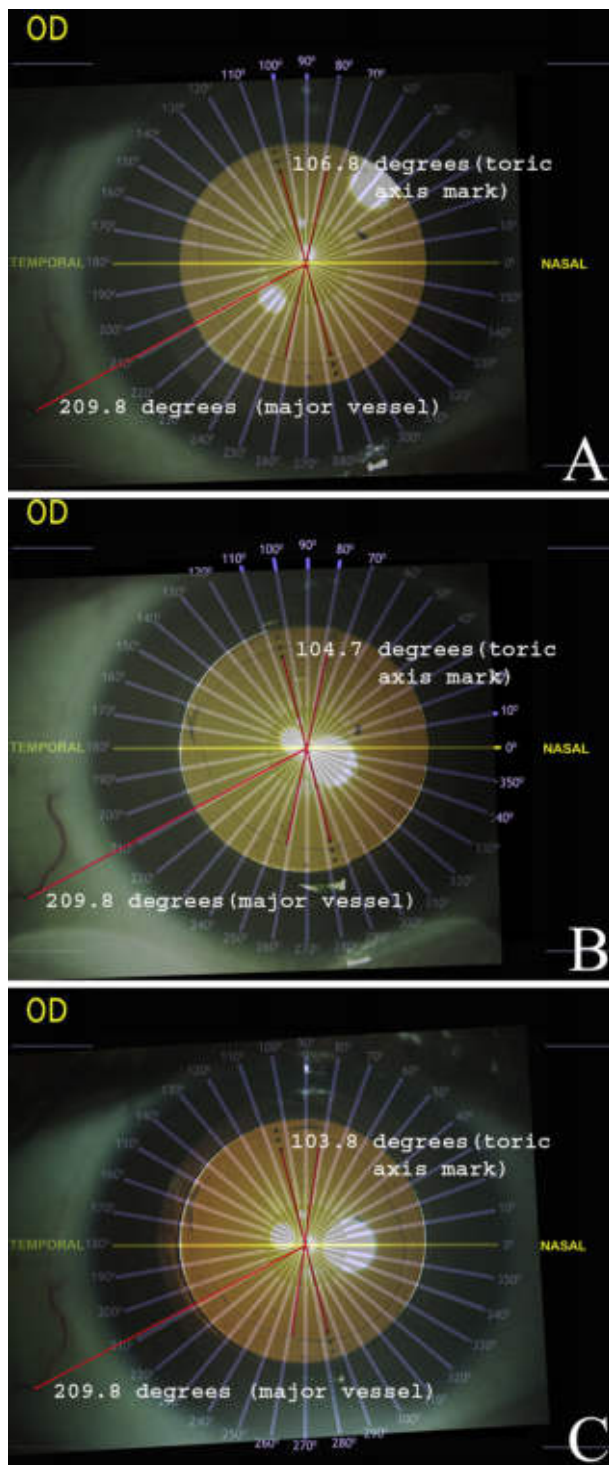


Figure 3. Postoperative toric IOL shows maximum rotation at the 6-month follow-up. A: Position of toric IOL at baseline. B: Position of toric IOL at 1 month. C: Position of toric IOL at 6 months.

would be different from the 1-piece design used in our study. However, Saldanha et al.¹⁸ used sequential digital images and found no statistically significant correlation between IOL rotation and increasing AL.

This can be attributed to the use of a 3-piece loop-haptic acrylic IOL with a longer haptic diameter (13.5 mm). Furthermore, the authors did not specify the range of AL in the eyes in their study; this is a crucial, albeit indirect, factor for determining capsular bag size in these cases.

It has been reported that the axis of implantation is another factor affecting toric IOL rotation.¹ In our study, using our software we did not detect a statistically significant difference in postoperative rotation between 3 groups with different axis placements. Sun et al.¹⁹ report results similar to ours. They implanted AA4203TF toric IOLs (Staar) and used the anterior surface-alignment engravings on the IOL to confirm rotation. The Mendez gauge was reapplied to verify final alignment. They found no statistically significant linear or nonlinear regression correlation between intraoperative axis alignment and postoperative rotation at 3 months. Mendicutte et al.²⁰ measured IOL rotation in 1-degree steps but found no correlation between the planned intraoperative axis alignment and the postoperative rotation of the IOL. Ruhswurm et al.¹ measured IOL rotation in 5-degree steps using the eyepiece of a slitlamp and found significantly greater IOL rotation with the vertical axis, while Till et al.²¹ observed that the oblique axis was the most unstable (rotation measurement technique not specified). However, the difference between the 3 axis groups of placement was not statistically significant in either study.

There are reports of counterclockwise rotation of plate-haptic toric IOLs.⁷ In a comparative study of plate-haptic IOLs and loop-haptic IOLs, Patel et al.⁶ found counterclockwise rotation. However, in the present study, more than 75% of eyes had clockwise rotation. In the previous study,⁶ the authors suggest that counterclockwise rotation of the IOL occurs in the direction of least resistance in the areas of the open capsular bag. They further suggest that expansion of the capsular bag also produces counterclockwise rotation. In the same study, compression of the haptics resulting in separation of the fused capsule was the mechanism of the clockwise rotation. A few authors also speculate that haptic compression or expansion might induce torque on the optic, causing it to rotate independently of the haptic.²²

In the present study, we do not report the uncorrected and corrected visual acuity with different ALs and with different degrees of IOL movement. Although this was not the original aim of the present study, we believe it would be interesting to correlate our observations of the rotational stability of the toric IOL. In this prospective study, we were aware of the importance of implementing standardized surgical techniques. Thus, we ensured that the same surgeon

performed all in-the-bag IOL implantations and that the same observer analyzed the rotational stability of toric IOLs at every follow-up using the software. This standardization helped us objectively evaluate the efficiency of the software. We could accurately assess whether the software can detect the level of influence of the risk factors for poor rotational stability of toric IOLs. Our software can provide 0.1 degree of accuracy and thus played a crucial role in helping us evaluate the risk factors and arrive at conclusive results.

One benefit of using our software is that we could counsel patients regarding positive postoperative outcomes. This is because rotational stability plays a key role in the success of toric IOL implantation, and the IOLs were stable without rotation 1 month after surgery. Hence, it would be safe to predict positive postoperative outcomes with the use of our software. Moreover, in patients with high myopia, the surgeon must exercise caution when calculating IOL power, marking the IOL, and implanting it because of the large capsule size.

In conclusion, our software was accurate and easy to use, providing precise IOL rotation measurements. Moreover, the method was reproducible. Rotation was not influenced by IOL alignment in the capsular bag postoperatively. Greater rotation was observed in eyes with longer ALs, although its clinical significance remains uncertain.

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