Stability and Clinical Outcomes of A New One Piece Toric Intraocular Lens with Anchor-wing Haptics

Iichiro Sugita (iichiro@sugita.or.jp)
MedStar Harbor Hospital https://orcid.org/0000-0002-2311-2203
Tomoichiro Ogawa
Miyamaedaira Ogawa Eye Clinic
Kazuo Ichikawa
Chukyo Eye Clinic
Takahide Okita
Sugita Eye Hospital
Kazuno Negishi
Keio University School of Medicine
Tadashi Nakano
The Jikei University School of Medicine
Hiroshi Tsuneoka
The Jikei University School of Medicine

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Abstract

Background: To evaluate the safety and efficacy of a new toric intraocular lens (IOL) with anchor-wing haptics.

Methods: The new toric IOL with anchor-wing haptics (NS60YT, NIDEK Co., Ltd.) was implanted in eligible patients with age-related cataracts with preoperative corneal astigmatism of 1.0 D or greater at one university hospital and two private hospitals in Japan. Four cylinder powers of the IOL were evaluated as follows: 1.50 D (NS60YT3), 2.25 D (NS60YT4), 3.00 D (NS60YT5) and 4.50 D (NS60YT7). All patients were assessed out to 12 months postoperatively. The primary endpoint was uncorrected visual acuity (UCVA) with spherical addition 6 months postoperatively, and the primary analysis calculated the proportion of UCVA with spherical addition of 0.8 or better. The magnitude of rotation was compared to the intended axis of IOL implantation at each postoperative examination. Adverse events were evaluated for the safety analysis.

Results: The study enrolled 64 eyes of 53 patients. At 6 months postoperatively, for all models, mean UCVA with spherical addition of 0.8 or better was achieved in 90% [95% confidence interval (CI): 80-96] of eyes. The mean IOL rotation was 5.3±4.3° 12 months after surgery. Between each postoperative examination from 1 day to 12 months, the mean magnitude of rotation ranged between 1.9° to 2.5°.There were no vision threatening intraoperative or postoperative complications for the duration of the study.

Conclusions: The NS60YT IOL remained stable after implantation and was efficacious for treating 1.00 D or greater astigmatism in patients with senile cataracts.

Trial registration: This study was registered at ClinicalTrials.gov (NCT03242486) on August 8, 2017 - Retrospectively registered. (https://clinicaltrials.gov/ct2/show/NCT03242486)

Background

Reduction of astigmatism during cataract surgery is an important factor in visual function and patient satisfaction. Approximately 35% of cataract patients have preoperative corneal astigmatism of 1.0 D or greater and approximately 20% have 1.5 D or greater astigmatism [1–4]. Residual astigmatism after phacoemulsification and intraocular lens (IOL) implantation is a significant cause of suboptimal vision, increased spectacle dependence or patient dissatisfaction [5, 6]. Generally there are two methods currently used for treating cataracts with corneal astigmatism – simultaneous phacoemulsification with toric IOL implantation or a two-step surgery to correct astigmatism with limbal relaxing incisions after IOL implantation. The advantages of toric IOL implantation include a wider range of correction and the use of one procedure to simultaneously correct the refractive error, reducing the burden on the patient and the surgeon [7].

The Aktis toric (Model NS60YT; Nidek Co., Ltd.) is a newly developed IOL that is based on the existing monofocal Nex-Acri® AA 1P IOL platform (Nidek Co., Ltd.). Rotational stability is maintained by anchor-wing haptics. In this prospective, multicenter study, we present the stability and clinical outcomes of NS60YT implantation for the correction of moderate to high astigmatism.

Methods

This single-arm, open-label, multicenter, prospective clinical study evaluated implantation of the NS60YT in patients with age-related cataracts at one university hospital and two private hospitals in Japan. This study was approved by the Jikei University Hospital Institutional Review Board for Medical Devices, the Sugita Eye Hospital Institutional Review Board, and the Joint Institutional Review Board of the hospitals. The study adhered to the Declaration of Helsinki and the Japanese Ministerial Ordinance on Good Clinical Practice for Medical Devices (GCP). The manuscript reporting adheres to the CONSORT guidelines. The study protocol is available in https://clinicaltrials.gov. Written informed consent was obtained from all patients before participation. The study period was from December 2014 to November 2017. The duration of follow up was 12 months postoperatively.

Intraocular lens

The NS60YT is a single-piece toric IOL based on the Nex-Acri® series (Nidek Co., Ltd.) (Fig. 1). The optical diameter is 6.0 mm, the overall diameter is 13.0 mm including the anchor-wing haptics. The lens is a biconvex lens and the rear surface is aspheric. The cylindrical power is placed on the front of the lens for the correction of corneal astigmatism. The IOL consists of hydrophobic soft acrylic resin with an ultraviolet absorber and proprietary material to enhance compatibility with the injector. The lens has two dots on either side of the optic periphery, indicating the flattest meridian to mark the cylinder axis. This study evaluated 4 different toric IOL powers as follows: 1.50 D, 2.25 D, 3.00 D and 4.50 D (Table 1).

Patients

Patients were included if they were over 40 years old with age-related cataracts in one or both eyes with a pupil diameter of 5.0 mm or more at mydriasis and had 1.0 D or greater preoperative corneal astigmatism. Other inclusion criteria were, a predicted postoperative astigmatism less than 0.5 D, and the predicted postoperative uncorrected visual acuity (UCVA) with spherical addition of 0.8 or better. “UCVA with spherical addition” is visual acuity measured under conditions where a spherical trial lens is added to correct the postoperative spherical refractive error determined before surgery for each patient. For example, when the target spherical refractive error is -1.5 D preoperatively, the visual acuity value measured with a -1.5 D spherical trial lens added postoperatively is considered the “UCVA with spherical addition”.

Patients were excluded if they had irregular corneal astigmatism, long axial length (28 mm or longer), and other diseases or complications that might affect the efficacy and safety of IOL implantation.

Preoperative examination

Within 60 days prior to surgery, the patient underwent a thorough ophthalmic examination including, slit lamp microscopy, corneal topography (OPD-Scan® III; Nidek Co., Ltd.), measurement of pupil diameter, tonometry, fundus examination, and axial length measurement (IOLMaster®; Carl Zeiss Meditec AG).

Calculation of intraocular lens power using a toric calculator

The IOL spherical power was selected by the surgeon based on the desired postoperative refractive error for each patient using the biometry values. The SRK/T formula was used for all eyes. The A-constants (119.7) were adjusted for each clinical site based on the constant for the Nex-Acri® AA 1P that is the same shape as NS60YT. The Nidek Toric Calculator For Clinical Trials was used to select cylinder power and to calculate the angle of implantation. Data entry of the preoperative corneal astigmatism, the surgically induced astigmatism for each surgeon, and the incision position allows calculation of the predicted postoperative corneal astigmatism, the IOL implantation axis, and the predicted postoperative residual astigmatism for each model. Based on these variables, the surgeons selected the optimum IOL model that predicted the lowest postoperative astigmatism.

Surgery

All surgeries were performed with topical anesthesia using a sterile technique as follows: a 2.2 to 2.5 mm corneal, scleral or sclerocorneal incision was created and the cataractous lens was removed by phacoemulsification and aspiration, and an IOL was inserted into the lens capsule so that the toric marks on the IOL were aligned with the marks for axis alignment. An injector (Nex-IJ; Nidek Co., Ltd.) was used for IOL insertion. In patients scheduled for bilateral surgery, the fellow eye underwent surgery after the initial eye was evaluated at 1 week postoperatively and there were no complications.

Postoperative examination

Postoperative examinations were performed the day after surgery (1-2 days), 1 week after surgery (7-14 days), 1 month after surgery (30-60 days), 3 months after surgery (90-150 days), 6 months after surgery (180-240 days), and 12 months after surgery (360-420 days). Postoperative examinations included slit lamp microscopy, tonometry, fundus examination, measurements of corneal curvature, UCVA, UCVA with spherical addition, sphere-corrected visual acuity (VA), best corrected distance visual acuity (BCVA), axis of the IOL , and a patient questionnaire (only at 6 months postoperatively). Sphere-corrected VA is the visual acuity when only the sphere was corrected from the UCVA with spherical addition based on the postoperative spherical error.

The axis of the IOL was measured manually using slit lamp photography or from the image obtained with anterior segment imaging devices (KATS-1000; Konan medical Co., Ltd. and Casia; Tomey Corp.). The image was regarded as horizontal, and the angle was measured between the horizontal line and the toric mark. The patient questionnaire classified the patient’s current vision into five rankings of, “very satisfied”, “satisfied”, “neither satisfied nor dissatisfied”, “dissatisfied”, and “very dissatisfied”.

Data were collected on all postoperative adverse events irrespective of causality. The following adverse events that may occur after cataract surgery were summarized as anticipated adverse events at every postoperative examination: secondary cataract (requiring posterior capsulotomy), macular degeneration, macular edema, hypopyon, infectious and noninfectious endophthalmitis, pupil block, retinal detachment, corneal edema, iritis, increased intraocular pressure (IOP), and IOL dislocation. Increased IOP was defined as 23 mm Hg or higher and an increase of 5 mm Hg or higher compared to the preoperative IOP.

Statistical analysis

We used previous studies of toric IOLs that were targeting emmetropia as the historical control to determine the number of cases that achieved a postoperative UCVA of 0.8 or better [8-10]. The analysis indicated 47 eyes were required for NS60YT3, NS60YT4, NS60YT5 (significance level $\alpha = 0.05$, power $1-\beta = 0.80$), based on the threshold response rate ($\pi 0$) 0.5 and the expected response rate ($\pi 1$) 0.7. For high astigmatism (NS60YT7), data were collected on only 5 eyes due to the lack of appropriate patients.

The primary endpoint was the UCVA with spherical addition 6 months after surgery, and the primary analysis calculated the proportion of UCVA with spherical addition of 0.8 or better and a 95% confidence interval (CI). The Clopper-Pearson method was used to calculate 95% CIs. Secondary endpoints included UCVA, sphere-corrected VA, BCVA, refractive cylinder correction, and the magnitude of IOL rotation. Decimal visual acuity was converted to logMAR values for statistical analysis. The magnitude of IOL rotation was calculated as the absolute value of the error between the actual IOL axis and preoperative IOL insertion axis calculated with the Nidek Toric Calculator For Clinical Trials.

Safety endpoints included the presence, absence, and incidence rate of adverse events after IOL insertion, and the presence or absence of anticipated adverse events. SAS (Version 9.3, SAS Institute Inc.) was used for statistical analysis. $P < 0.05$ was considered statistically significant.

Results

The study sample was comprised of 64 eyes of 53 patients. Two eyes of one patient were excluded from all analyses due to non-compliance with GCP. One patient died after 6 months examination due to reasons unrelated to cataract surgery. Therefore, the full analysis set for efficacy, included 62 eyes of 52 patients at 6 months postoperatively and 61 eyes of 51 patients at 12 months postoperatively. Table 2 presents patient demographics, baseline examination data and IOL calculation data. The mean age at enrollment was 68.6 ± 9.5 years (Table 2). The mean targeted postoperative refraction was -1.1 ± 1.2 D (Table 2).

Primary endpoint - uncorrected visual acuity with spherical addition

Table 3 presents the postoperative UCVA with spherical addition of 0.8 or better and 95% CI. At 6 months, the primary endpoint was achieved in 90% (56/62 eyes) for all models, 100% (21/21 eyes), 80% (16/20 eyes), 93% (14/15 eyes), and 83% (5/6 eyes) for NS60YT3, NS60YT4, NS60YT5 and NS60YT7, respectively. At 12 months, 87% achieved the primary endpoint for all models.

Other efficacy parameters and safety parameters

Visual acuity

Table 4 presents the UCVA, UCVA with spherical addition, sphere-corrected VA, BCVA and subjective cylindrical power up to 12 months postoperatively. UCVA with spherical addition, sphere-corrected VA and BCVA remained stable until 12 months postoperatively after 1 month postoperatively (Table 4). The

proportion of subjective cylindrical power less than 0.50 D and less than 1.00 D at 12 months was 59% (36/61 eyes) and 89% (54/61 eyes) for all models combined, respectively.

Fig. 2 presents the double angle polar plots. There were no remarkable changes observed between the preoperative corneal astigmatism (Fig. 2a) and the 12 months postoperative corneal astigmatism (Fig. 2b). However, in eyes with subjective cylinder at 12 months postoperatively, the cylinder components tended towards against-the-rule (ATR) astigmatism (Fig. 2c).

Intraocular lens rotation (including additional analysis)

Fig. 3 presents the distribution of the rotation (absolute value) at 12 months compared to the axis of IOL insertion. A deviation less than 10° between the IOL axis relative to the insertion axis was noted in 89% (54/61 eyes) of all models. No cases required repositioning surgery due to postoperative IOL rotation.

Fig. 4 plots the postoperative changes in rotation relative to the insertion axis. The magnitude of rotation in all models was 5.5 ± 3.8° at 1 day, 5.6 ± 4.0° at 1 week, 5.1 ± 4.2° at 1 month, 5.4 ± 4.2° at 3 months, 5.0 ± 4.4° at 6 months, and 5.3 ± 4.3° at 12 months. Additional analysis indicated that the magnitude of rotation the day after surgery was 5.5°, and the mean rotation between each examination after day 1 was 2.5° or less (Table 5). A rotation of 5.0° or more occurred in 52% by day 1, however, a rotation of 5.0 ° or more after day 1 was approximately 10% for each period (Table 5). The direction of rotation after 12 months was clockwise in 61% (37/61) of eyes, counterclockwise in 31% (19/61) of eyes, and the IOL did not rotate in 8% (5/61) of eyes. There was no statistically significant association between the direction of rotation and the preoperative corneal cylinder axis (Fisher's exact test, $P = 0.781$).

Patient satisfaction

A questionnaire at 6 months queried patient satisfaction. For all models, the results were "very satisfied" 52% (32/62 eyes), "satisfied" 40% (25/62 eyes), "neither satisfied nor dissatisfied" 3% (2/62 eyes), "dissatisfied" 5% (3/62 eyes), and "very dissatisfied" 0% (0/62 eyes). Thus, "very satisfied" and "satisfied" accounted for 92% of eyes.

Safety

Postoperative adverse events where a causal relationship could not be ruled out included 4 eyes (6%) with mild posterior capsule opacification. Anticipated adverse events (defined separately at the beginning of the study) developed in 6 eyes of 5 patients. These included 2 eyes (3%) with secondary cataract (requiring posterior capsulotomy) and 4 eyes (6%) with increased IOP. One patient died during the course of the study due to multiple organ failure which was a non-ocular adverse event and with no causal relationship to cataract surgery or IOL implantation.

Discussion

This prospective evaluation of a new toric IOL (NS60YT) indicated the majority of eyes had excellent vision after cataract surgery. For example, BCVA at 12 months postoperatively was − 0.10 ± 0.06 logMAR (1.27). The

primary endpoint of the study was UCVA with spherical addition for this Japanese population. The UCVA with spherical addition is the visual acuity measured by correcting the predicted postoperative spherical refractive error determined for each patient before surgery. This index was used as the primary endpoint taking into consideration the tendency of lens selection in Japan. Japanese cataract patients tend to prefer some nearsightedness instead of emmetropia postoperatively. Using an UCVA with spherical addition as the primary endpoint enabled comparison with the published literature on toric IOLs targeting emmetropia despite targeting postoperative myopia (in the current study).

At 6 months postoperatively, 90% (56/62 eyes) of all eyes achieved UCVA with spherical addition of 0.8 or better. The lower limit (80%) of the 95% CI exceeded the expected response rate of 70%, which was the basis for determining the number of cases. This outcome indicates, that patients achieved equivalent or better postoperative visual acuity with the NS60YT in comparison with commercially available toric IOLs as the historical controls.

The UCVA with spherical addition is the visual acuity obtained by correcting the spherical refractive error that was agreed upon preoperatively (with subjective patient input), while the sphere-corrected VA is the visual acuity obtained by further correcting the postoperative spherical refractive error only. In addition, the BCVA is the best visual acuity obtained by further correcting the residual postoperative cylindrical power from the sphere-corrected VA. This means that the difference between the UCVA with spherical addition and the sphere-corrected VA is the spherical refractive error with respect to the target refractive power. Additionally, the difference between the sphere-corrected VA and the BCVA is the cylindrical refractive error. Twelve months after surgery, the outcomes of the current study indicate a sphere-corrected VA of less than 0.8 in only one eye (2%), and 0.8 or better in the other 60 eyes (98%). This outcome indicates excellent cylinder correction with the NS60YT.

Vector analysis indicated that the postoperative subjective cylinder had a distribution toward ATR astigmatism. This trend is similar to the outcomes of wavefront analysis reported by Ninomiya et al [11]. The primary cause of ATR astigmatism after surgery could be due to the effect of the posterior corneal astigmatism. The current study used only the anterior corneal surface to evaluate corneal astigmatism, and the Nidek Toric Calculator For Clinical Trials did not consider the posterior corneal astigmatism for lens selection. Koch et al [12] have reported that posterior corneal astigmatism causes overcorrection of with-the-rule (WTR) astigmatism and decreases the correction of ATR astigmatism when the lens is selected based on the anterior corneal astigmatism only. Hence, our outcomes are consistent with Koch et al's observations [13]. Savini et al have published nomograms for selecting the IOL power when only the anterior corneal astigmatism is used. For preoperative WTR astigmatism, residual astigmatism is calculated based on the result from subtracting 0.59 D to 0.70 D from the predicted postoperative corneal astigmatism [14]. For preoperative ATR astigmatism, residual astigmatism is calculated based on the result of adding 0.32 D to 0.70 D to the predicted postoperative corneal astigmatism [14]. Future versions of the Nidek Toric Calculator should be improved to compensate for the posterior surface power when only anterior corneal surface data are used.

Accurate cylinder axis marking and rotational stability in the eye are important because the astigmatism correction of an IOL decreases by 3.3% for an axial misalignment of 1°, and toric IOL implantation is

completely ineffective when the misalignment is 30° or greater [15]. The outcomes of the current study indicate the NS60YT has good rotational stability. For example, the mean IOL rotation at 6 months was 5.0 ± 4.4°for all models combined which is well within the range reported for other IOLs. Previous studies have reported single-piece toric IOLs rotation between the intended axis and the observed axis at 6 month postoperatively from 2 to 9°[9, 16–20]. Additionally, the magnitude of rotation ranged between 1.9° to 2.5° between each postoperative examination from 1 day to 12 months and the mean rotation was 3.1 ± 2.9°. The tendency to rotate early in the postoperative period and then stabilize was similar to the previous literature on existing single-piece toric IOLs [21–23].

Table 6 presents data for seven cases with a rotation of 10° or greater at 12 months postoperatively relative to the IOL insertion axis. Five cases (except Cases 3 and 4) rotated 10° or more at 1 day. In Case 4, a rotation of 10° or more was observed initially at 1 month. This case had an incomplete closed capsulorhexis with 2 tears. Perhaps postoperative healing and suboptimal capsular contraction due to the tears may have played a role in the rotation. Case 3 presented with a rotation of 10° or more initially at 12 months but did rotate 1° at 1 day. The subsequent rotations were as follows: -4° at 1 week; -2° at 1 month; -9° at 3 months; -9° at 6 months; and − 13° at 12 months. In addition to the possibility that the IOL was actually rotating, this may be due to the influence of head inclination during photography. The cause of rotation in this case is unknown, however, the patient was asymptomatic and there were no postoperative sequelae. In these cases, the UCVA with spherical addition was 0.8 or better with Cases 2 and 4 excluded, and the sphere corrected VA was 0.9 or better with Case 2 excluded. Patient satisfaction with their vision remained high in all cases with a rotation of 10° or more.

Table 6
Cases with rotation of 10° or greater.

	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6	Case 7
Amount of rotation (°)*	15	-16	-13	10	-18	18	-12
Expected IOL axis angle (°)	4	10	95	177	87	94	161
IOL axis angle (°)	19	174	82	7	69	112	149
When the rotation exceeded 10°	1 day	1 day	12 months	1 month	1 day	1 day	1 day
Model	NS60YT7	NS60YT3	NS60YT5	NS60YT3	NS60YT3	NS60YT3	NS60YT3
Spherical power (D)	17.0	19.0	21.5	20.0	21.5	18.0	20.0
AL (mm)	25.50	25.00	23.61	24.85	23.13	25.17	25.28
Age (y)	72	63	45	72	58	59	70
Anterior capsulotomy	CCC	CCC	CCC	CCC with 2-tear	CCC	CCC	CCC
UCVA with spherical addition	1.2	0.6	1.5	0.7	1.2	1.2	0.9
Sphere-corrected VA	1.2	0.6	1.5	0.9	1.2	1.5	1.0
BCVA	1.5	0.9	1.5	1.0	1.2	1.5	1.2
(Cylinder correction amount)	(-1.75 D)	(-1.00 D)	(-0.50 D)	(-0.25 D)	(-1.50 D)	(-0.25 D)	(-0.75 D)
Questionnaire results (at examination of 6 months)	Very satisfied	Satisfied	Satisfied	Very satisfied	Very satisfied	Satisfied	Satisfied

AL = axial length; BCVA = best corrected visual acuity; CCC = continuous curvilinear capsulorhexis; IOL = intraocular lens; UCVA = uncorrected visual acuity; VA = visual acuity

*Rotation amount: plus = counterclockwise, minus = clockwise

This study evaluated the difference of the IOL axis at each postoperative examination relative to the insertion axis. Therefore, the evaluation included fixed axis deviation of the IOL intraoperatively and the rotation from the early postoperative phase onwards. To verify the rotation from the insertion axis more accurately, the amount of rotation immediately after insertion of the IOL needs to be evaluated.

Conclusions

In summary, the outcomes of this study indicate that the new toric IOL with anchor-wing haptics is safe and effective for implantation during cataract surgery. Axis rotation was very low in the majority of cases and clinically insignificant and no cases warranted repositioning of the IOL. Implantation of this toric IOL provides satisfactory postoperative visual acuity and good patient satisfaction

Abbreviations

ATR
Against-the-rule
AL
Axial length
BCVA
Best corrected visual acuity
CCC
Continuous curvilinear capsulorhexis
CI
Confidence interval
D
Diopter
GCP
Good clinical practice
IOL
Intraocular lens
IOP
Intraocular pressure

Declarations

Ethics approval and consent to participate

This study adhered to the principles of the Declaration of Helsinki. This study was approved by the Jikei University Hospital Institutional Review Board for Medical Devices, the Sugita Eye Hospital Institutional Review Board, and the Joint Institutional Review Board of the hospitals. Written informed consent was obtained from all individual participants included in the study.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

Dr. Sugita, Ogawa, Ichikawa, Okita, Nakano, and Tsuneoka report grants and Dr Negishi report personal fees from NIDEK CO., LTD., during the conduct of the study;. Dr. Sugita reports grants and personal fees from Alcon Japan Ltd., personal fees and non-financial support from Santen Pharmaceutical Co., Ltd., non-financial support from HOYA Corporation, personal fees from Kowa Co., Ltd., grants and personal fees from Senjyu Pharmaceutical Co., Ltd., personal fees from Carl Zeiss Meditec AG, personal fees from Bayer AG, personal fees from Pfizer Inc., personal fees from Nikon Corporation, outside the submitted work; . Dr. Ichikawa reports grants and personal fees from Alcon, grants and personal fees from ZEISS, grants and personal fees from STAAR, personal fees from HOYA, personal fees from SANTEN, personal fees from KY CenterVue, personal fees from Igaku shoin, personal fees from Kowa, personal fees from JFC, personal fees from Novartis, outside the submitted work; . Dr. Negishi reports grants from Fuji Xerox Co, grants from Hitachi Automotive Systems, Ltd., grants from Universal View Co., Ltd., grants and personal fees from Alcon Japan Ltd. , grants and personal fees from Santen Pharmaceutical, grants and personal fees from HOYA Corporation, grants and personal fees from AMO Japan K.K., grants from Kowa Company, grants from Kowa Pharmaceutical Company Ltd. , grants from Tomey Corporation, personal fees from Senju Pharmaceutical , personal fees from Otsuka Pharmaceutical, personal fees from NIDEK Co., Ltd., personal fees from Carl Zeiss Meditec AG, outside the submitted work; Dr. Negishi has a patent (PCT/JP2015/65997, PCT/JP2016/085903) for potential products for myopia suppression pending to Tsubota Laboratory Inc.

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Authors’ contributions

KN and HT contributed to the study conception and design. Material preparation, data collection and analysis were performed by IS, TO, KI, TO, TN, and HT. The first draft of the manuscript was written by IS and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript, and agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

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Not applicable

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Tables

Table 1 Cylindrical power of each model of the NS60YT intraocular lens.

Model name	IOL surface power (D)	Power at the Corneal Plane (D)
NS60YT3	1.50	1.05
NS60YT4	2.25	1.57
NS60YT5	3.00	2.08
NS60YT7	4.50	3.11

Table 2 Demographics and preoperative data of patients scheduled to undergo cataract surgery with implantation of the NS60YT intraocular lens.

Parameter	All models	NS60YT3	NS60YT4	NS60YT5	NS60YT7
Number of eyes, n	62	21	20	15	6
Number of patients, n	52	20	20	13	6
Age					
Mean (years) ± SD	68.6 ± 9.5	69.1 ± 9.2	68.1 ± 10.2	66.7 ± 10.7	73.2 ± 4.6
Minimum value, maximum value	42, 84	54, 84	48, 84	42, 79	66, 79
Sex, n					
Male	27	8	8	9	2
Female	35	13	12	6	4
Mean pupil diameter (mm) ± SD	7.43 ± 0.82	7.57 ± 0.62	7.25 ± 0.71	7.32 ± 0.99	7.75 ± 1.25
Mean AL (mm) ± SD	24.21 ± 1.33	24.01 ± 1.35	23.99 ± 1.47	24.77 ± 1.21	24.24 ± 0.92
Mean preoperative corneal astigmatism (D) ± SD	1.73 ± 0.54	1.32 ± 0.18	1.63 ± 0.24	1.95 ± 0.30	2.99 ± 0.47
Preoperative corneal astigmatism angle, n (%)					
WTR astigmatism (0° to 29°, 150° to 180°)	29 (47)	7 (33)	9 (45)	10 (67)	3 (50)
OBL astigmatism (30° to 59°, 120° to 149°)	1 (2)	0 (0)	1 (5)	0 (0)	0 (0)
ATR astigmatism (60° to 119°)	32 (52)	14 (67)	10 (50)	5 (33)	3 (50)
Mean postoperative target power (D) ± SD	-1.1 ± 1.2	-0.8 ± 1.3	-0.9 ± 1.0	-1.6 ± 1.4	-1.3 ± 1.3

ATR = against-the-rule; AL = axial length; IOL = intraocular lens; OBL = oblique; SD = standard deviation; WTR = with-the-rule

Table 3 Uncorrected visual acuity with spherical addition of 20/25 or better, 6 and 12 months after cataract surgery with implantation of the NS60YT intraocular lens.

Postoperative		All models	NS60YT3	NS60YT4	NS60YT5	NS60YT7
6 months	Number of eyes, n	62	21	20	15	6
	UCVA with spherical addition of 0.8 or better, n (%)	56 (90)	21 (100)	16 (80)	14 (93)	5 (83)
	95% CI (%)	80, 96	84, 100	56, 94	68, 100	36, 100
12 months	Number of eyes, n	61	21	20	14	6
	UCVA with spherical addition of 0.8 or better, n (%)	53 (87)	18 (86)	18 (90)	12 (86)	5 (83)
	95% CI (%)	76, 94	64, 97	68, 99	57, 98	36, 100

CI = confidence interval; UCVA = uncorrected visual acuity

Table 4 Mean efficacy parameters for eyes that underwent cataract surgery with NS60YT intraocular lens implantation.

	1 day	1 week	1 month	3 months	6 months	12 months
UCVA (logMAR)	0.29 ± 0.38	0.28 ± 0.40	0.27 ± 0.42	0.28 ± 0.43	0.29 ± 0.45	0.28 ± 0.42
UCVA with spherical addition (logMAR)	0.08 ± 0.19	0.04 ± 0.17	0.03 ± 0.19	0.03 ± 0.16	0.02 ± 0.17	0.00 ± 0.11
Sphere-corrected VA (logMAR)	-0.01 ± 0.11	-0.04 ± 0.09	-0.05 ± 0.07	-0.05 ± 0.07	-0.05 ± 0.07	-0.05 ± 0.07
BCVA (logMAR)	-0.05 ± 0.09	-0.08 ± 0.07	-0.09 ± 0.05	-0.10 ± 0.05	-0.10 ± 0.06	-0.10 ± 0.06
Subjective cylindrical power (D)	0.54 ± 0.61	0.53 ± 0.56	0.55 ± 0.46	0.61 ± 0.45	0.58 ± 0.49	0.55 ± 0.47

BCVA = best corrected visual acuity; IOL = intraocular lens; logMAR = logarithm of the minimum angle of resolution; UCVA = uncorrected visual acuity; VA = visual acuity

Table 5 Rotational stability of the NS60YT intraocular lens.

Postoperative	Number of eyes, n	Rotation amount (absolute value) ± SD(°)	Lens rotation amount, n (%)		
			Less than 5.0°	5.0° or more and less than 10.0°	10.0° or more
1 day	61	5.5 ± 3.8	29 (48)	22 (36)	10 (16)
1 day to 1 week	61	2.5 ± 2.7	55 (90)	4 (7)	2 (3)
1 week to 1 month	61	2.2 ± 1.7	55 (90)	6 (10)	0 (0)
1 month to 3 months	61	2.0 ± 1.8	56 (92)	5 (8)	0 (0)
3 months to 6 months	61	2.1 ± 2.0	53 (87)	8 (13)	0 (0)
6 months to 12 months	61	1.9 ± 1.5	57 (93)	4 (7)	0 (0)
1 day to 12 months	61	3.1 ± 2.9	47 (77)	11 (18)	3 (5)

SD = standard deviation

Table 6 Cases with rotation of 10° or greater.

	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6	Case 7
Amount of rotation (°)*	15	-16	-13	10	-18	18	-12
Expected IOL axis angle (°)	4	10	95	177	87	94	161
IOL axis angle (°)	19	174	82	7	69	112	149
When the rotation exceeded 10°	1 day	1 day	12 months	1 month	1 day	1 day	1 day
Model	NS60YT7	NS60YT3	NS60YT5	NS60YT3	NS60YT3	NS60YT3	NS60YT3
Spherical power (D)	17.0	19.0	21.5	20.0	21.5	18.0	20.0
AL (mm)	25.50	25.00	23.61	24.85	23.13	25.17	25.28
Age (y)	72	63	45	72	58	59	70
Anterior capsulotomy	CCC	CCC	CCC	CCC with 2-tear	CCC	CCC	CCC
UCVA with spherical addition	1.2	0.6	1.5	0.7	1.2	1.2	0.9
Sphere-corrected VA	1.2	0.6	1.5	0.9	1.2	1.5	1.0
BCVA	1.5	0.9	1.5	1.0	1.2	1.5	1.2
(Cylinder correction amount)	(-1.75 D)	(-1.00 D)	(-0.50 D)	(-0.25 D)	(-1.50 D)	(-0.25 D)	(-0.75 D)
Questionnaire results (at examination of 6 months)	Very satisfied	Satisfied	Satisfied	Very satisfied	Very satisfied	Satisfied	Satisfied

AL = axial length; BCVA = best corrected visual acuity; CCC = continuous curvilinear capsulorhexis; IOL = intraocular lens; UCVA = uncorrected visual acuity; VA = visual acuity

*Rotation amount: plus = counterclockwise, minus = clockwise

Figures

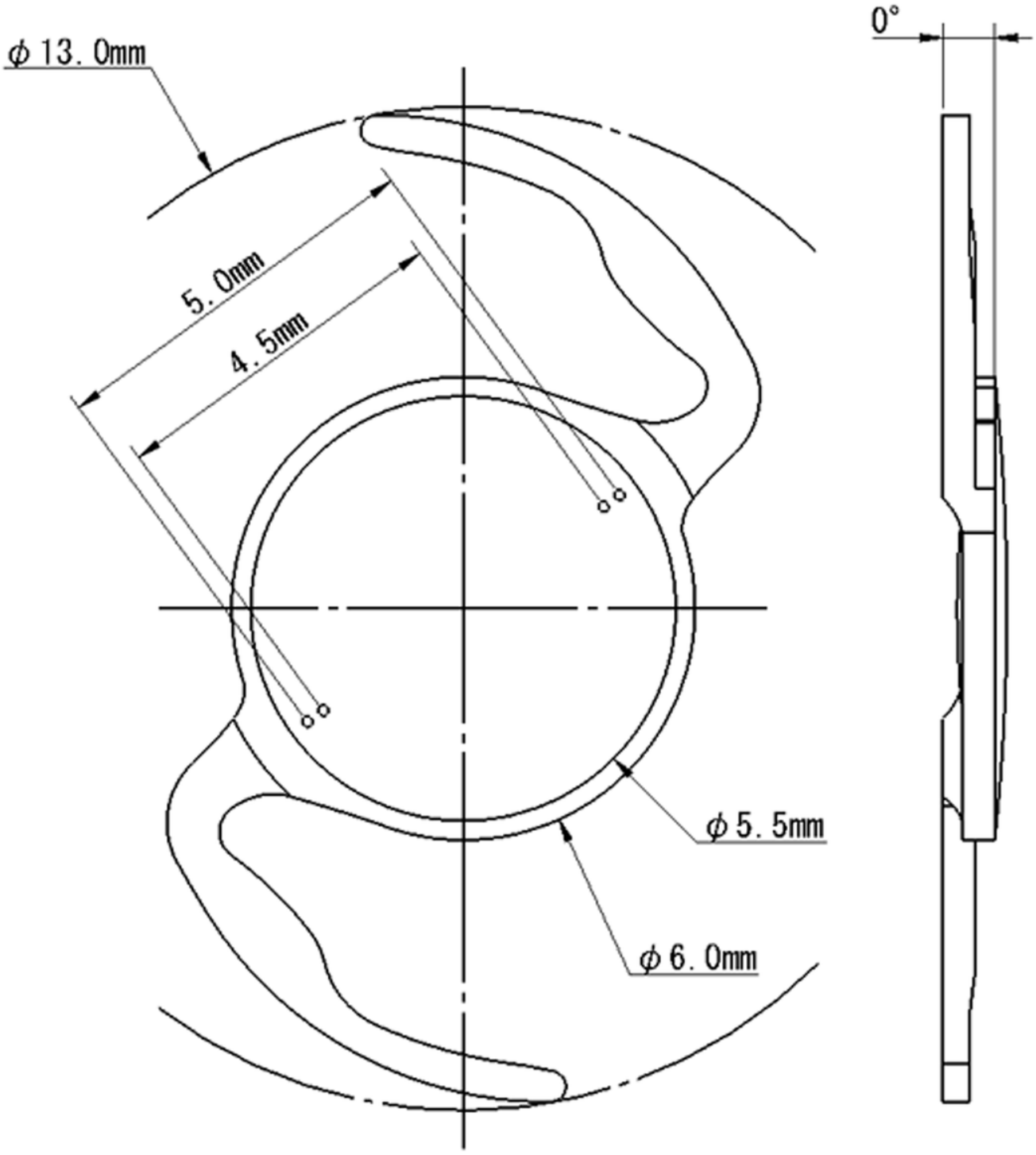

Figure 1

Design specifications of the NS60YT intraocular lens The shape of anchor-wing haptics contributes to intraocular lens stability because it is difficult to generate a force in the rotational direction by compression. Additionally, the contact area in the capsule is large which contributes to good fixational stability.

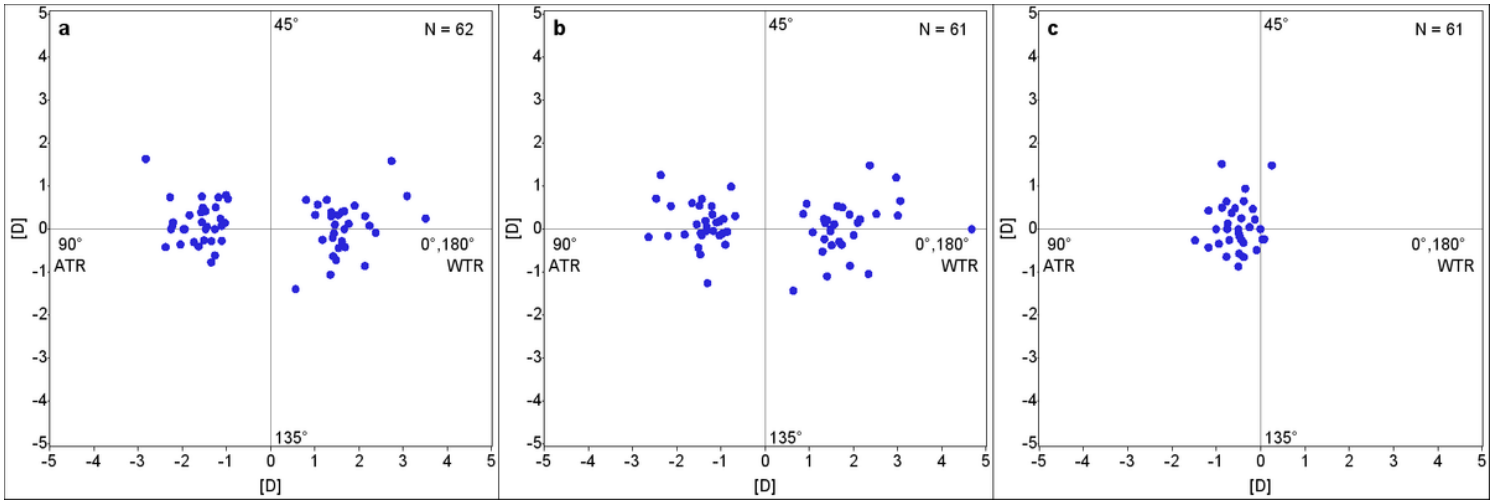

Figure 2

Corneal astigmatism and postoperative subjective cylinder components (ATR = against-the-rule; WTR = with-the-rule) (a) Preoperative corneal astigmatism (b) 12 months postoperative corneal astigmatism (c) 12 months postoperative subjective cylinder components

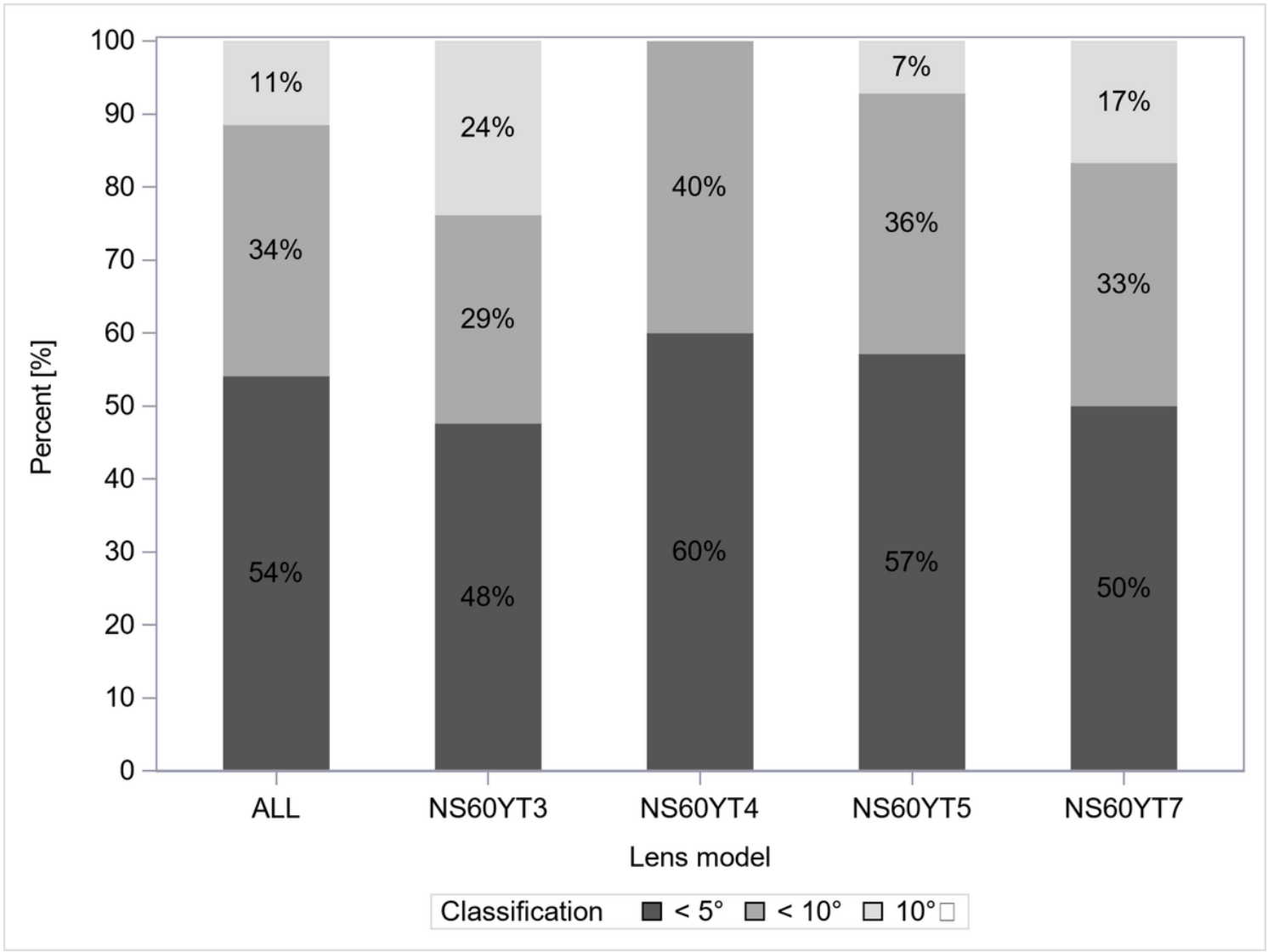

Figure 3

Distribution of intraocular lens rotation at 12 months after surgery

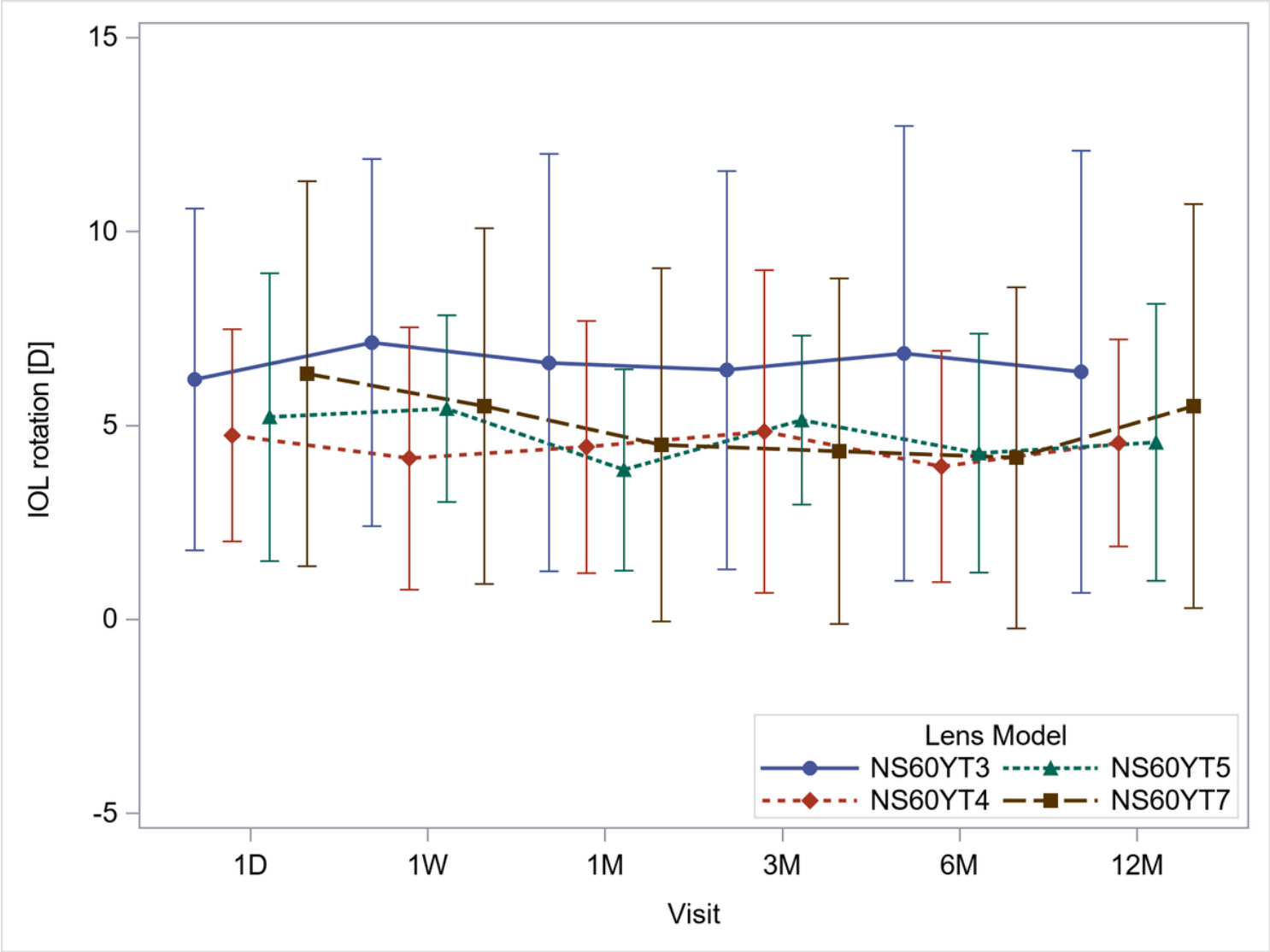

Figure 4

Rotation over time of the intraocular lens axis from the expected insertion axis

Supplementary Files

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- CONSORT2010Checklist.doc