

Clinical Study of Customized Selected Aspherical Intraocular Lens Implants

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Abstract

Aims: To compare if there is an improvement in visual functions with age-related cataracts between patients receiving customized selected aspherical intraocular lens (IOL) implants and patients randomly assigned lenses.

Methods: Ninety-four patients (94 eyes) with age-related cataracts were placed in experimental group or a group receiving randomly assigned (RA) lenses. All patients were undergone Pentacam corneal spherical aberration measurement before surgery; The targeted range for residual total spherical aberration after surgery was set to 0-0.3 μm in experimental group. Patients with a corneal spherical aberration $\leq 0.3 \mu\text{m}$ were implanted with a zero-spherical aberration advanced optics (AO) aspherical intraocular lens and patients with an aberration $0.3 \mu\text{m}$ received a Tecnis ZA9003 aspherical lens. RA patients were randomly implanted with an AO lens or a Tecnis ZA9003 lens. Three months after surgery total spherical aberration, photopic/mesopic contrast sensitivities, photopic/mesopic with glare contrast sensitivities, and LogMAR vision were measured.

Results: Statistical analysis on LogMAR vision showed no significant difference between two groups ($P = 0.308$). The post-surgical total spherical aberration was $0.120 \pm 0.097 \mu\text{m}$ and $0.158 \pm 0.152 \mu\text{m}$ in the experimental and RA groups, respectively ($P = 0.08$). The mesopic contrast sensitivities at spatial frequencies of 6, 12 and 18 c/d in the experimental group were significantly higher than of the RA group ($P = 0.00$; $P = 0.04$; $P = 0.01$). The mesopic with glare contrast sensitivity in the RA group at a spatial frequency of 18 c/d was also significantly higher vs. the RA group ($P = 0.02$).

Conclusion: Pre-surgical corneal spherical aberration measurement in cataract patients followed by customized selection of aspherical intraocular lens implants improved mesopic contrast sensitivities and mesopic with glare contrast sensitivities at high spatial frequencies, and thus is a superior strategy compared to the random selection of aspherical intraocular lens implants.

Keywords: Intraocular lens; Cataract extraction; Corneal wavefront aberration; Mesopic vision; Night vision

Introduction

Cataract phacoemulsification and intraocular lens implantation are common techniques for treating cataracts. Ophthalmologists often seek to decrease the post-operative aberration of the whole eye and improve the quality of the patient's vision. Aspherical intraocular lenses are widely used in intraocular lens implantation. Here, the goal is to cancel the aberration in the human cornea, thus reducing the total aberration of the whole eye after surgery and improving visual acuity. Recent clinical studies have shown that aspherical intraocular lenses significantly improve post-operative vision in cataract patients compared with traditional intraocular lenses [1,2]. A wide range of aspherical intraocular lenses are currently available for clinical application, although the value added from the asphericity differs between them. Two questions emerge: (1) Can a random choice of different types of aspherical intraocular lenses used for implantation benefit all cataract patients, and (2) can customized implantation of corresponding aspherical intraocular lenses, which have a negative spherical aberration based on the pre-surgical corneal spherical aberration, improve visual quality. We report the results of a prospective, controlled study conducted to address these questions.

Materials and Methods

Subjects

Ninety-four patients (94 eyes) with age-related cataracts were included in this study (44 males and 50 females, aged 51-84 (mean 67 ± 9) years). The selection criteria were as follows: ≥ 50 and ≤ 85 years

old and diagnosed with only age-related cataracts; pre-surgical axial range: 22-26 mm; normal cognition; normal tear film; the ability to attend follow-ups as scheduled. The exclusion criteria were as follows: previous history of impaired visual recovery after surgery, including pre-surgical eye trauma, retinal diseases, glaucoma and corneal disease; history of corneal refractive surgery; post-surgical complications, including increased intraocular pressure and endophthalmitis. Informed and written consent was obtained from all individuals, and the study was approved by the local ethical review boards in accordance with the Declaration of Helsinki.

Clinical observations

Slit lamp microscopy: Before and 1 day, 1 week, and 3 months after surgery, the degree of corneal edema, wound healing status, and anterior chamber reactions were examined and recorded. 2) Patients were measured before and 3 months after surgery, using the Pentacam HR anterior segment measurement and analysis system (Oculus, Germany). Measurements were performed by the same person, and the

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test results, which were repeatable and with complete tear film, were averaged and recorded. 3) Five meter distance vision was measured according to the international standard vision chart and the LogMAR vision was recorded. Using an Allegretto Wave Analyzer total spherical aberration meter (Wavelight AG, Germany), the aberration of the whole eye was measured with the 6 mm pupil diameter. In each case, the highest-quality images were used to establish the parameters and calculate the average. Contrast and glare sensitivities were determined using contrast sensitivity examination equipment (OPTEC-6500, Stereo Optical, and U.S.A). At the three-month follow-up, the best corrected distance visual acuity, whole-eye aberration, and the contrast sensitivities measured under the following conditions, photopic (light intensity: 85 cd/m²), photopic with glare (glare intensity: 135 Lux), mesopic (light intensity: 3 cd/m²), and mesopic with glare (glare intensity: 28 Lux). The recorded contrast sensitivity values were transformed into log values.

Criteria for receiving a customized selected aspherical intraocular lens implant and patient grouping

Wang et al. [3] provided a detailed review of whole-eye aberration values. With a defocus of 0.00 or -0.50 D, most eyes achieved the best image quality at an ocular SA of -0.10 to 0.00 μm and 0.15 to 0.30 μm, respectively. Therefore, the post-surgical whole-eye refractive status was maintained between 0 and -0.5 D. The refraction of the intraocular lens was calculated according to an IOL Master Measurement. The goal of a customized selected aspherical intraocular lens implant is to achieve a targeted total spherical aberration between 0 and 0.3 μm after surgery. The patients were divided into two groups based on the sequence of admission. An experimental group included patients receiving aspherical intraocular lenses based on their pre-surgical corneal spherical aberration. The selection method was as follows: When the corneal spherical aberration was < 0.3 μm, the patient received an Akreos AO intraocular lens implant (Bausch & Lomb, Inc, San Dimas, California, USA); when the corneal spherical aberration was ≥ 0.3 μm, the patient received a Tecnis Z9003 intraocular lens implant (Advanced Medical Optics, Inc, Santa Anna, California, USA). In the random assignment group (RA), patients received an Akreos AO or Tecnis Z9003 intraocular lens implant based on the result of a coin toss. Because the Acrysof IQ blue-blocking intraocular lens with a -0.2 μm aberration might affect contrast sensitivity, it was not included in the study. This study applied the triple-blind methodology. The surgeons, post-surgical examination physicians and patients were not aware of the patient's group status.

Surgical methods

Surgery was performed following ocular anesthesia and employed a transparent corneal incision. The main incision was made at the 10 O'clock position with a 3.0 mm disposable microkeratome, and an auxiliary incision was made on the corneal edge at the 2 O'clock position

using a 15° corneal puncture knife. After injection of a viscoelastic agent into the anterior chamber, a continuous 5.5 mm diameter circular capsulorhexis was performed. Ultrasonic emulsification was applied to the lens and the residual cortex aspirated, after which the intraocular lens was implanted in the lens capsule and the viscoelastic agent removed.

Statistics

The data was analyzed using SPSS17.0 statistical software (SPSS Inc.); all data is expressed as the mean and standard deviation. The data were tested with the Shapiro-Wilk test to determine if it was normally distributed, and if this test failed then non-parametric statistical tests were used. Statistical analyses were performed using Mann-Whitney U test and Spearman's correlation test, and the χ²-test. P values ≤ 0.05 were considered to indicate a statistically significant difference.

Results

General conditions

There was no statistical significance (P > 0.05) between the number of eyes in the experimental and RA groups, the gender or age of the patients, the axial length, or the refraction of the implanted intraocular lens (Table 1). The intraocular lenses in all of the patients were positioned normally at follow-up. No significant opacity was observed in the posterior capsule of the lens, and post-operative complications were not found.

Pre-surgical and post-surgical corneal spherical aberration and post-surgical total spherical aberration

Before surgery, there was no statistically significant difference (P = 0.569) in the total corneal spherical aberration (including anterior and posterior corneal surfaces, SA) of the experimental (0.300 ± 0.151 μm) vs. the RA group (0.316 ± 0.117 μm), nor was there a significant post-operative difference at three months (0.277 ± 0.126 μm vs. 0.299 ± 0.110 μm, respectively; P = 0.362). In addition, the 6 mm pupil diameter of total spherical aberration measured three months after surgery was also not shown significantly different between the experimental and RA patients (0.120 ± 0.097 μm vs. 0.158 ± 0.152 μm, respectively; P = 0.08). The total spherical aberration in the targeted 0-0.3 μm range was achieved in 85.1% of the experimental patients (40/47), but only 59.5% of the RA patients (28/47) (Figure 1).

Post-surgical LogMAR vision

Three months after surgery, the corrected distance vision was 0.033 ± 0.059 in the experimental group and 0.036 ± 0.056 in the RA group, which was not statistically significant (P = 0.308).

Contrast and glare sensitivities three months after surgery

Three months after surgery, comparison between the two groups

Group	Total number of eyes (n)	Gender		Age (x ± sd)	Axial length (mm, x ± sd)	Intraocular lens (D, x ± sd)	AO [†] (n)	Tecnis [‡] (n)
		Male	Female					
Experimental	47	22	25	68 ± 10.25	23.60 ± 0.93	20.66 ± 1.86	21	26
Random	47	22	25	66 ± 8.77	23.81 ± 1.43	20.35 ± 2.54	27	20
t		0.475 ^a		0.804	-1.117	0.876	1.533 ^a	
P		0.491		0.425	0.266	0.382	0.216	

Note: ^a the χ² value

[†]Akreos AO intraocular lens implant (Bausch & Lomb, Inc.)

[‡] Tecnis Z9003 intraocular lens implant (Advanced Medical Optics, Inc.)

Table 1: Cataract patients in the control and experimental groups.

showed similar enhancement of contrast sensitivities under photopic and photopic with glare conditions (Table 2). However, in the experimental group the mesopic contrast sensitivities were 1.887 ± 0.199 , 1.140 ± 0.205 and 0.735 ± 0.202 , when tested at the respective spatial frequencies of 6, 12 and 18 c/d. These values were significantly higher than the values seen in the RA group under the same conditions (1.681 ± 0.150 ; 1.046 ± 0.178 ; 0.625 ± 0.250) (Figure 2A). The mesopic with glare contrast sensitivity in the experimental group was 0.6638 ± 0.240 at a spatial frequency of 18 c/d, and was significantly higher compared with that of the RA group (0.556 ± 0.275) (Figure 2B).

Correlation of the predicted and measured values of post-surgical aberration

The total spherical aberration was predicted according to the simplified formula $SA_{eye} = SA_{individual\ cornea} + SA_{lens}$ [4]. The $SA_{individual\ cornea}$ was the 6 mm pupil diameter corneal aberration measured 1 day before the surgery. The SA_{lens} of the Akreos AO intraocular lens was $0\ \mu\text{m}$, and that of the Tecnis Z9003 intraocular lens was $-0.27\ \mu\text{m}$. The predicted values of the total spherical aberration were positively correlated with the values measured after the surgery ($r = 0.846$, $P < 0.01$; Figure 3). The difference between the predicted and measured postoperative SA for the entire investigated population showed that the mean absolute error was $0.046 \pm 0.079\ \mu\text{m}$.

Discussion

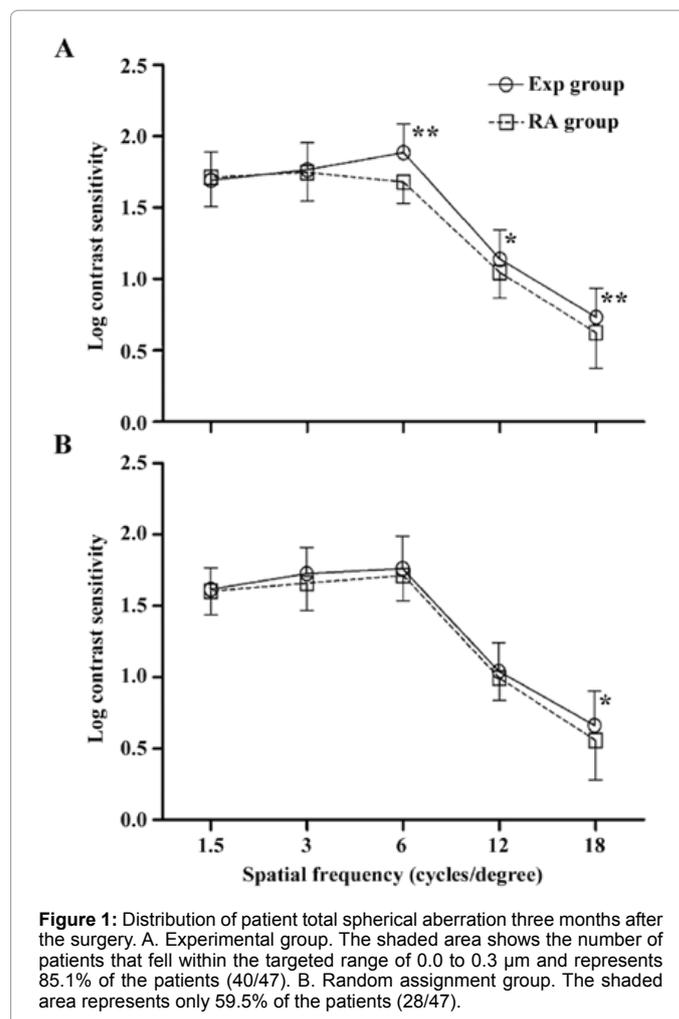
The variation in spherical aberration of the human cornea is relatively large. Wang et al. [5] observed the distribution of high-level imaging from the anterior corneal surface in a given population (134 cases, 228 eyes; aged 20-79 years). Their results showed that the spherical aberration from the anterior corneal surface varied between

Cycles per degree	Experimental	RA	P value
Photopic contrast			
1.5	1.76 ± 0.19	1.78 ± 0.15	0.62
3	1.90 ± 0.32	1.90 ± 0.30	0.99
6	1.90 ± 0.21	1.87 ± 0.18	0.40
12	1.23 ± 0.22	1.21 ± 0.22	0.60
18	0.95 ± 0.66	$0.79 \pm .33$	0.11
Photopic contrast with glare			
1.5	1.70 ± 0.20	1.73 ± 0.19	0.61
3	1.76 ± 0.23	1.75 ± 0.20	0.88
6	1.86 ± 0.21	1.82 ± 0.16	0.22
12	1.16 ± 0.22	1.10 ± 0.19	0.15
18	0.83 ± 0.25	0.77 ± 0.25	0.08
Mesopic contrast			
1.5	1.69 ± 0.20	1.71 ± 0.21	0.60
3	1.77 ± 0.19	1.75 ± 0.20	0.64
6	1.89 ± 0.20	1.68 ± 0.15	0.00**
12	1.14 ± 0.20	1.04 ± 0.18	0.04*
18	0.74 ± 0.20	0.62 ± 0.25	0.01**
Mesopic contrast with glare			
1.5	1.62 ± 0.15	1.60 ± 0.16	0.64
3	1.73 ± 0.18	1.66 ± 0.19	0.06
6	1.76 ± 0.22	1.71 ± 0.18	0.08
12	1.04 ± 0.2	1.00 ± 0.16	0.23
18	0.66 ± 0.24	0.56 ± 0.27	0.02*

*significantly different at 0.05 level

**significantly different at 0.01 level

Table 2: Contrast sensitivity (log values) under photopic, photopic with glare, mesopic, and mesopic with glare conditions.



individuals, and that the values were all positive and averaged $0.280 \pm 0.086\ \mu\text{m}$. He et al. [6] studied the anterior corneal surface aberration of both eyes in 45 young people and found that the average spherical aberration coefficient was $0.30 \pm 0.08\ \mu\text{m}$. Tong et al. [7] measured the 6 mm anterior corneal spherical aberration in 144 cases (188 eyes) of age-related cataract patients and reported a mean of $0.231 \pm 0.092\ \mu\text{m}$ (range: -0.096 to $0.469\ \mu\text{m}$). In agreement with the precious finding, we found the total corneal spherical aberrations (including anterior and posterior corneal SA) before surgery of the experimental and RA groups were $0.300 \pm 0.151\ \mu\text{m}$ and $0.316 \pm 0.117\ \mu\text{m}$ respectively (total range for all patients: 0.03 to $0.639\ \mu\text{m}$). Thus, if corneal spherical aberration is not measured before intraocular lens implantation and the aspherical intraocular lens is selected randomly, the optimum expected post-surgical total spherical aberration might not be achieved for all patients.

The purpose of customized selected aspherical intraocular lens implantation based on corneal aberration is to reduce a patient's aberration and keep this within a target range. We set the targeted residual total spherical aberration after surgery between $0-0.3\ \mu\text{m}$ and achieved a post-surgical total spherical aberration of $0.120 \pm 0.097\ \mu\text{m}$ in the experimental group. Although the total spherical aberration was not significantly different between the experimental and RA patients three months after surgery, a higher proportion of experimental patients fell within the targeted range compared to RA

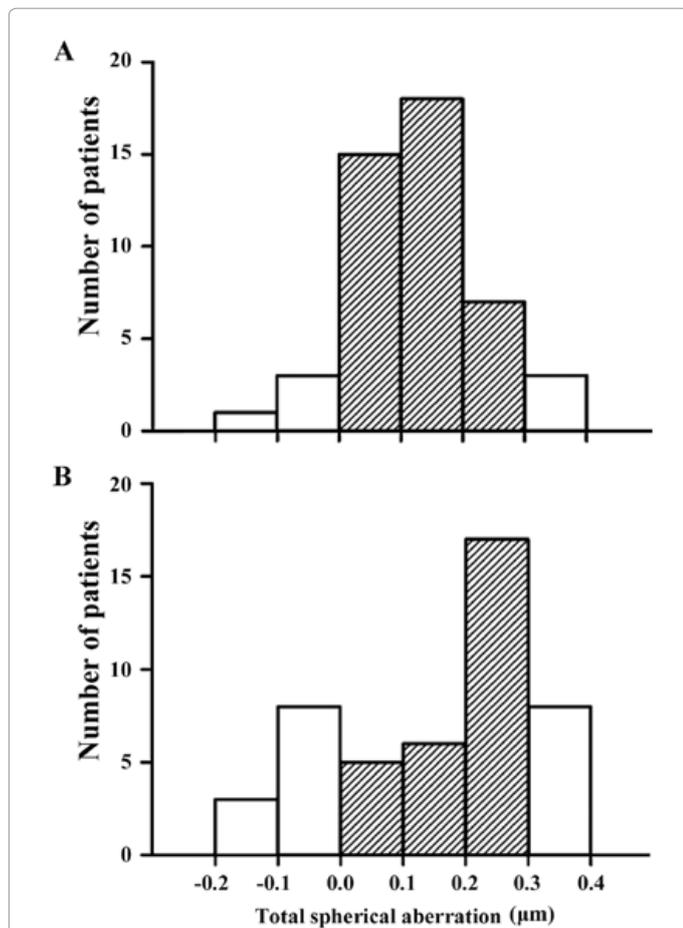


Figure 2: Contrast sensitivities at different spatial frequencies for the experimental (Exp) and randomly assigned (RA) groups three months after surgery. A. Mesopic conditions. B. Comparison of mesopic with glare. Significant comparisons between Exp vs. RA are indicated (* $p \leq 0.05$, ** $p \leq 0.01$).

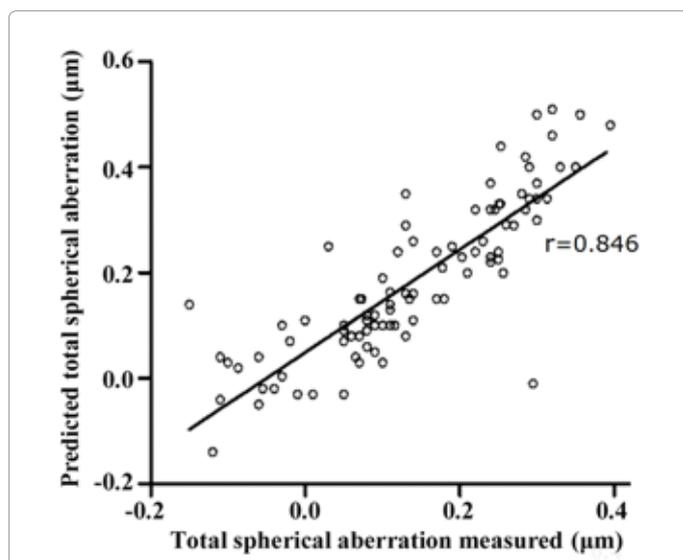


Figure 3: Correlation between predicted and measured values of the total ocular aberration three months after the surgery.

patients. Nochez et al. [8] performed a customized selected aspherical intraocular lens implantation in order to produce a residual ocular SA close to $+0.10 \mu\text{m}$ and achieved a final ocular SA of $0.085 \pm 0.084 \mu\text{m}$ after surgery. Packer et al. [9] selected an aspheric IOL for implantation based on preoperative corneal spherical aberration and the labeled IOL (AO, AcrySof IQ and Tecnis Z9002) spherical aberration, such that the arithmetic sum of these two values was closest to zero. The result showed that total postoperative ocular spherical aberration for the entire population measured $-0.013 \pm 0.072 \mu\text{m}$. However, this study [9] lacked a random implant group for evaluation of visual function. Although they suggested that customized selected aspherical intraocular lens implants improved the post-surgical total spherical aberration to close to zero, no evidence was provided as to whether visual quality was further improved.

The ultimate goal in reducing a patient's aberration to the targeted range is to provide a better visual outcome after the surgery. Customized selected aspherical intraocular lens implantation would be meaningless if it only achieved the targeted aberration without improving visual function. Therefore, contrast sensitivity was examined after the surgery in both groups. The results showed that contrast sensitivity in the mesopic and mesopic with glare conditions at middle and high spatial frequencies was better in the experimental vs. the RA group. This finding is in agreement with a similar recent study by Nochez et al. [8] in which patients were implanted with zero-aberration Acri.Smart 46LC lenses (the reference group) or Acri.Smart36A lenses (experimental group) based on pre-surgical corneal spherical aberration. These authors showed that under mesopic conditions at high spatial frequencies, the contrast sensitivity was significantly better in the experimental group. Beiko [10] performed a similar clinical trial, in which patients were divided into two groups, one with a corneal spherical aberration greater than $+0.33 \mu\text{m}$, and a group for which corneal spherical aberration was not measured. Patients in both groups received a Tecnis intraocular lens (aberration: $-0.27 \mu\text{m}$) implant. The results indicated that the visual contrast sensitivity in the customized implant group (i.e. those based on pre-surgical measurements) was higher than that of the control group. These results underscore the necessity of customizing aspherical intraocular lens implantation, especially for patients with a higher requirement for mesopic or night vision (e.g. taxi drivers).

Our study showed that the pre-operative predicted values of the total spherical aberration were positively correlated with the values measured after the surgery ($r = 0.846$, $P < 0.01$). However, we found a mean absolute predictive error of $0.046 \pm 0.079 \mu\text{m}$ for postoperative SA in agreement with Nochez et al. [8] ($0.040 \pm 0.047 \mu\text{m}$) and very similar to that of Packer et al. [9] ($0.058 \pm 0.056 \mu\text{m}$) who tested three different IOLs (AO, AcrySofIQ and Tecnis). Minor variations in predictive value were explained as a result of the postoperative aperture size being limited by the capsulorhexis and by variations in pupil dilatation [9]. In our study, one should be aware that there were minor variations in the corneal spherical aberration before and after surgery between the two groups (pre: $0.300 \pm 0.151 \mu\text{m}$ and $0.316 \pm 0.117 \mu\text{m}$, post: $0.277 \pm 0.126 \mu\text{m}$ and $0.299 \pm 0.110 \mu\text{m}$). These variations of corneal spherical aberration maybe one of the reasons for the predictive error of postoperative SA.

Further clinical studies are needed on the selective implantation of aspherical intraocular lens based on corneal aberrations. There are relatively few types of aspherical intraocular lens to choose from and the aspherical parameters are not comprehensive, but this might still be a future trend. Following the development of corneal refractive surgery in recent decades, myopic refractive surgery might increase

corneal positive spherical aberration [11], while hyperopic refractive surgery might reduce it [12], even to negative values. For this reason, in addition to accurate calculation of intraocular lens refraction, cataract patients with previous refractive surgery should receive corresponding aspherical intraocular lens based on their corneal spherical aberration.

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Patient consent Obtained.

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