· Clinical Research ·

Comparison of visual quality after implantation of A1-UV and SN60WF aspheric intraocular lens

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Abstract
● **AIM:** To compare the visual performance of pseudophakic eyes implanted with A1-UV and SN60WF aspheric intraocular lens (IOL), and to investigate the correlations between visual quality parameters and pupil size.

● **METHODS:** This prospective comparative study included 105 eyes of 90 patients with age-related cataract who underwent uneventful phacoemulsification. The subjects were divided into two groups according to the implanted IOL type. Three months postoperatively, visual acuity and contrast sensitivity were measured, wave-front aberrations were assessed using a KR-1W aberrometer (Topcon), and objective optical quality parameters were performed using an optical quality analysis system-OQAS II (Visiometrics). Independent sample *t*-test and Spearman correlation analysis were used for data analysis.

● **RESULTS:** There were no significant differences found in visual acuity, contrast sensitivity and visual quality parameters between the two groups ($P>0.05$). The measured intraocular spherical aberration (SA) in A1-UV IOL eyes of -0.19±0.05 μm was close to the designed SA value of -0.20 μm. The modulation transfer function cutoff, Strehl ratio and OQAS values were negatively correlated with pupil size in both groups ($P<0.01$).

● **CONCLUSION:** The subjective and objective visual quality in pseudophakic eyes with A1-UV and SN60WF IOLs are comparable. For aspheric IOL eyes, visual quality decreases with increasing pupil size.

● **KEYWORDS:** cataract; aspheric; intraocular lens; visual quality; pupil size
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INTRODUCTION
Generally, corneal spherical aberration (SA) is positive and relatively stable, whereas the lenticular SA gradually changes from negative to positive with age. This change disrupts the ideal state of mutual compensation between the two optical systems, which leads to a total ocular SA increase and a visual quality degradation. Aspheric intraocular lens (IOL) is designed to reduce ocular SA and improve functional vision, by compensating for positive corneal SA[1]. Accordingly, the SA values of two aspheric IOL-A1-UV (Eyebright, China) and SN60WF (Alcon, USA) were designed as -0.20 μm, aiming to achieve optimized visual quality and focal depth with the ocular SA value of +0.10 μm after IOL implantation. Furthermore, a comparison between the A1-UV IOL and SN60WF IOL can minimize the potential impact of material due to their same hydrophobic acrylic materials and similar profiles. The latter is one of the most commonly implanted monofocal aspheric IOLs. In the present study, we comprehensively compared the subjective and objective visual quality of pseudophakic eyes with A1-UV and SN60WF IOLs, as well as explored the correlations between visual quality parameters and pupil size, using the wave-front aberrometer, double-pass instrument and contrast sensitivity chart in combination. This study aimed to provide a basis for the clinical application of the A1-UV IOL.

SUBJECTS AND METHODS
Ethical Approval This prospective, comparative study was approved by the Institutional Review Board of Affiliated Hospital of North Sichuan Medical College, China [2018ER(A)019]. All procedures adhered to the tenets of Helsinki Declaration and were conducted on the basis of the approved research protocol. Written informed consents were obtained from all subjects following an explanation of the nature and possible consequences of the study.

Table 1 Clinical characteristics of both groups

Groups	Eyes (n)	Sex (female, %)	Eye (right, %)	Age (mean±SD, y)	IOL (mean±SD, D)
A1-UV	47	47.50	46.81	68.95±5.61	20.80±1.46
SN60WF	49	45.24	53.06	71.07±5.59	21.12±1.67
Test	-	χ^2=0.42	χ^2=0.38	t=1.68	t=0.91
P	-	0.84	0.54	0.10	0.37

Study Design and Subjects All subjects underwent standardized phacoemulsification and IOL implantation procedures as described elsewhere. All subjects were recruited at the Affiliated Hospital of North Sichuan Medical College between September 2017 and October 2018. Patients with age-related cataract and undergoing phacoemulsification, with normal cognitive abilities and tear film function were eligible for inclusion. Exclusion criteria included corneal cylinder greater than 1 diopter, corneal SA at 6 mm pupil diameter less than +0.20 μm, corneal pathology, advanced glaucoma, or uveitis, and retinal or optic neuropathy. Patients with intraoperative and postoperative complications, or a history of intraocular and corneal surgery also were excluded. Grouping was based on the type of IOL. For all participants, the IOL type implanted was based on the patient's choice and economic affordability, and the IOL power presupposed was aimed to emmetropia.

Main Examinations and Outcomes Preoperative routine examinations included visual acuity, slit-lamp, fundus, ultrasound, endothelial cell count and intraocular pressure. Visual acuity was measured using the Logarithmic Visual Acuity Chart (PrecisionVision, IL, USA) at a distance of 4 m and luminance of 85 cd/m^2. Ocular biological parameters were measured by an optical biometry device (IOLMaster 500; Carl Zeiss Meditec., Jena, Germany), and corneal SA (Zernike coefficient, Z_4^0) were measured by a Hartmann-Shack aberrometer-KR-1W (Topcon, Tokyo, Japan). Pupils were dilated using a mixture of 0.5% tropicamide and 0.5% phenylephrine, namely Mydrin P (Santen Pharmaceutical, Osaka, Japan). Each parameter was measured at least three times by a single well-trained examiner who was not included in the study.

Postoperative examination was conducted at 3mo after surgery, and the protocol was the same as that preoperatively. In addition, other higher-order aberrations (HOA) including coma (Z_3^{-1}, Z_3^1), trefoil (Z_3^{-3}, Z_3^3), and total HOA (tHOA) were measured at pupil diameters of 4.0 mm and 6.0 mm. The Optical Quality Analysis System (OQAS) II (Visiometrics SL, Terrassa, Spain) was used to measure optical quality parameters, including objective scatter index (OSI), modulation transfer function cutoff (MTF cutoff), Strehl ratio (SR), and OQAS values (OV100%, 20%, and 9%) at 2.0 mm, 4.0 mm, and 6.0 mm aperture. CSV-1000 chart (Vector Vision, Ohio, USA) was utilized to measure contrast sensitivity (CS) under a luminance of 3 cd/m^2. The decentration and tilt of IOLs were tested using a Scheimpflug imaging system (Pentacam Oculus, Wetzlar, Germany).

Statistical Analysis Statistical analyses were performed using SPSS 21.0 software (SPSS Inc., IL, USA). Continuous variables were expressed as mean±standard deviation (SD); nominal variables were expressed as absolute frequency (n) and relative frequency (%). Chi-square test was used to compare the proportions between the two groups, such as gender and eye laterality. Independent sample t-test was performed to compare the continuous variables between the two groups. Spearman correlation analysis was used to detect the correlations between OQAS parameters and pupil size. A P value less than 0.05 was considered statistically significant.

RESULTS

Subject Characteristics A total of 90 cataract patients (105 eyes) aged 50 to 80y undergoing uneventful phacoemulsification were included in this study, of whom 42 patients (49 eyes) were implanted with A1-UV IOLs and 48 patients (56 eyes) were implanted with SN60WF IOLs. No surgical complications occurred. There were 8 cases (9 eyes) lost to follow-up. Thus, 82 patients (96 eyes) were included in the study, including 40 patients (47 eyes) in A1-UV group and 42 patients (49 eyes) in SN60WF group.

The demographics and general characteristics between the two groups were similar. No statistically significant difference was found in gender (P=0.84), eye laterality (P=0.54), age (P=0.10) and IOL power (P=0.37) between the two groups (Table 1). In A1-UV group, the corneal SA were 0.28±0.08 μm preoperatively and 0.29±0.09 μm postoperatively (P=0.88); in SN60WF group, the counterparts were 0.30±0.06 μm and 0.31±0.07 μm respectively (P=0.85).

Visual Acuity and Contrast Sensitivity Visual acuity was expressed as logMAR scale for statistical purposes following Bailey's recommendation[2]. There were no statistically significant differences between the two groups in uncorrected distance visual acuity (UCVA; P=0.75) and best corrected distance visual acuity (BCVA; P=0.35) postoperatively. No significant differences were found in CS at any of the four spatial frequencies (P>0.05), as shown in Table 2.

Higher-order Aberrations In comparisons between the two groups, there were no significant differences found in corneal,

Table 2 Postoperative values of visual acuity and contrast sensitivity mean±SD

Parameters	A1-UV	SN60WF	*t*	*P*
VA (logMAR)				
UCVA	0.12±0.10	0.12±0.11	0.32	0.75
BCVA	0.02±0.05	0.03±0.05	0.93	0.35
CS (cpd)				
3	1.67±0.17	1.67±0.19	-0.19	0.85
6	1.87±0.18	1.88±0.19	0.03	0.97
12	1.49±0.17	1.48±0.32	-0.14	0.89
18	0.97±0.29	0.91±0.36	-0.80	0.43

intraocular and ocular higher-order aberrations, including SA, coma, trefoil and tHOA at both 4.0 and 6.0 mm pupil (*P*>0.05). At the pupil diameter of 6 mm, the intraocular SAs were -0.19±0.05 μm in A1-UV group and -0.21±0.05 μm in SN60WF group (*P*=0.13), and the ocular SA of A1-UV and SN60WF were 0.10±0.08 μm and 0.11±0.11 μm respectively (*P*=0.63). The outcomes of postoperative HOA were presented in Table 3.

Objective Optical Quality Parameters No statistically significant differences were detected in postoperative OSI between A1-UV group and SN60WF group (1.46±0.59 and 1.45±0.61, respectively; *P*=0.93) at 4 mm aperture. At different sizes of apertures (2, 4, and 6 mm), there were no statistical differences in MTF cutoff, SR, OV100%, OV20% and OV9% between the two groups (*P*>0.05). Table 4 shows the postoperative mean values of OQAS parameters.

For MTF cutoff, the correlation coefficients were -0.62 (*P*<0.01) in A1-UV group and -0.44 (*P*<0.01) in SN60WF group; For SR, the correlation coefficients of the two groups were -0.53 (*P*<0.01) and -0.42 (*P*<0.01) respectively. For OV100%, 20% and 9%, the correlation coefficients were -0.60, -0.55, and -0.50 (*P*<0.01) respectively in the A1-UV group, and -0.65, -0.45, and -0.48 (*P*<0.01) respectively in the SN60WF group (Figure 1).

DISCUSSION

SA is the only HOA with rotational symmetry, aspheric IOL with the same properties can be used to neutralize corneal SA. Aspheric IOL is the most commonly used functional IOL in clinical practice, and the safety and efficacy of aspheric A1-UV IOL and SN60WF IOL have been confirmed[3]. To the best of our knowledge, the comprehensive evaluation and comparison of subjective and objective visual quality based on these two aspheric IOL have not been reported in peer-reviewed literature, and this prospective study provides detailed information on these aspects.

In the present study, there were no statistical differences in postoperative visual activity (UCVA and BCVA) and CS (at spatial frequencies 3, 6, 12 and 18 cpd) between the two

Table 3 Postoperative values of wave-front aberrations mean±SD

Aberrations	A1-UV	SN60WF	*t*	*P*
Corneal aberrations (μm)				
4 mm				
tHOA	0.22±0.07	0.26±0.14	1.58	0.12
Trefoil	0.19±0.07	0.19±0.14	0.17	0.87
Coma	0.10±0.04	0.12±0.09	0.93	0.36
SA	0.06±0.03	0.06±0.03	0.40	0.69
6 mm				
tHOA	0.55±0.14	0.59±0.12	1.44	0.15
Trefoil	0.41±0.16	0.40±0.27	-0.29	0.77
Coma	0.28±0.12	0.28±0.16	0.08	0.94
SA	0.29±0.09	0.31±0.07	1.52	0.13
Intraocular aberrations (μm)				
4 mm				
tHOA	0.19±0.08	0.15±0.08	-1.85	0.07
Trefoil	0.09±0.06	0.10±0.07	0.68	0.50
Coma	0.07±0.03	0.08±0.06	1.18	0.24
SA	-0.04±0.03	-0.04±0.02	-1.14	0.26
6 mm				
tHOA	0.39±0.10	0.44±0.18	1.63	0.11
Trefoil	0.18±0.08	0.19±0.11	0.67	0.50
Coma	0.19±0.09	0.20±0.17	0.23	0.82
SA	-0.19±0.05	-0.21±0.05	-1.54	0.13
Ocular aberrations (μm)				
4 mm				
tHOA	0.23±0.06	0.20±0.11	-1.35	0.18
Trefoil	0.15±0.06	0.13±0.11	-1.14	0.26
Coma	0.12±0.12	0.11±0.06	-0.06	0.95
SA	0.02±0.03	0.02±0.02	-0.56	0.58
6 mm				
tHOA	0.66±0.17	0.69±0.32	0.37	0.71
Trefoil	0.41±0.18	0.37±0.28	-0.60	0.55
Coma	0.36±0.16	0.38±0.19	0.43	0.67
SA	0.10±0.08	0.11±0.11	0.48	0.63

groups postoperatively. The result was comparable to previous study[3]. Lasta *et al*[4] suggested that the closer the ocular SA was to zero, the better the retinal image quality was, whereas the focal depth would be reduced. Vázquez-Villa *et al*[5] suggested that the best focal depth and CS could be obtained with a target ocular SA value of 0.10 μm in pseudophakic eye. Our previous studies have also shown that leaving a modest amount of positive ocular SA may be beneficial to improve the visual quality[6]. Given the above, we recruited cataract patients whose preoperative corneal SAs were all greater than +0.20 μm, so as to avoid the undesirable negative residual ocular SA that might affect the visual quality after surgery.

Preoperatively, we measured the corneal SA of A1-UV and SN60WF groups at 6 mm pupil diameter in consideration of its variability in the general population[7] and its dependence on pupil size[8]. The result showed that there was no significant difference in corneal SA between the two groups, indicating

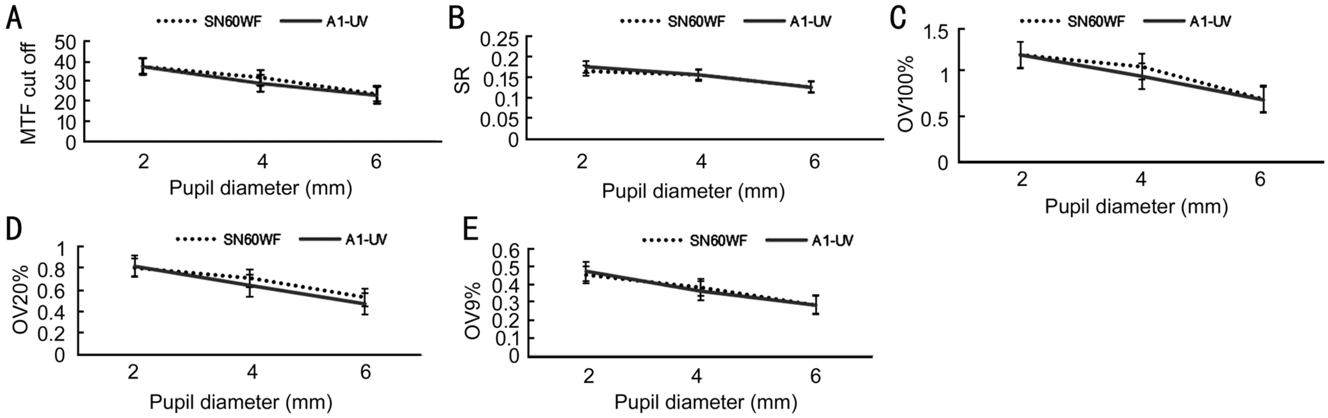

Figure 1 Correlations between OQAS parameters and pupil size A: MTF cutoff; B: SR; C: OV100%; D: OV20%; E: OV9%.

Table 4 Postoperative values of optical quality parameters mean±SD

Groups	MTF cutoff (c/deg)	SR	OV		
			100%	20%	9%
2 mm					
A1-UV	37.43±9.21	0.18±0.04	1.20±0.33	0.83±0.30	0.48±0.16
SN60WF	37.77±9.08	0.17±0.04	1.20±0.31	0.82±0.28	0.46±0.18
t	0.15	-0.81	0.42	-0.27	-0.55
P	0.88	0.42	0.68	0.79	0.58
4 mm					
A1-UV	29.23±7.36	0.16±0.03	0.96±0.26	0.65±0.19	0.37±0.11
SN60WF	32.08±8.98	0.16±0.03	1.07±0.30	0.72±0.24	0.39±0.13
t	1.40	0.03	1.61	1.15	0.64
P	0.17	0.97	0.11	0.26	0.53
6 mm					
A1-UV	22.88±6.74	0.13±0.03	0.70±0.21	0.48±0.15	0.29±0.10
SN60WF	24.02±8.94	0.13±0.04	0.71±0.31	0.54±0.23	0.29±0.13
t	0.06	0.11	0.37	1.39	0.12
P	0.56	0.92	0.72	0.17	0.91

consistent baseline data in this regard. We also compared corneal SA of each group pre- and post-surgery, and no significant pre- and post-surgical differences were found in either group, suggesting that the operation had minimal impact on corneal SA.

Moreover, there were no statistically significant differences in corneal, intraocular, and ocular tHOA, SA, coma, and trefoil between the two groups. With increasing pupil size, however, the corneal, intraocular, and ocular aberrations all tended to increase. At 6 mm pupil, the measured intraocular SAs (-0.19±0.05 and -0.21±0.05 μm respectively) in eyes with A1-UV IOLs and SN60WF IOLs were close to their designed SA value of -0.20 μm, and the ocular SAs (0.10±0.08 and 0.11±0.11 μm respectively) were also in line with the targeted postoperative residual SA value of +0.10 μm.

Recently, a double-pass based technology-OQAS system has been successfully applied in laboratorial and clinical studies on the optical quality evaluation, especially before and after cataract surgery[6,9-12]. Also, the previous studies have demonstrated its excellent repeatability and reproducibility[13-14]. It is capable of acquiring the complete and objective information about ocular optical quality by means of medium refraction and retinal reflection. Hwang *et al*[15] showed that these objective optical quality parameters, including OSI, MTF cutoff, SR, OV (100%, 20%, 10%), were useful for preoperative decision-making, of which OSI has the highest specificity and sensitivity. The OSI is the ratio of the light intensity of the acquired double-pass images between the peripheral ring (12-20 arc minutes) and the central circle (1 arc minute). With the rise of OSI value, the intraocular forward scattering increases and the optical quality decreases. Our results showed that the OSI values were all less than 2 (1.45±0.61 and 1.46±0.59, respectively in A1-UV and SN60WF group) 3mo postoperatively, suggesting that the visual performance of these two aspheric IOLs was excellent.

The MTF is used to describe the contrast between the retinal image and the actual image; MTF cutoff is set as the highest spatial frequency at which the MTF reaches the lowest contrast of 1%. The SR, namely Strehl 2D ratio, is calculated as the ratio of the area under the MTF curve of the measured eye to that of the ideal aberration-free eye. In optical systems, higher values of MTF cutoff and SR generally mean better visual quality. We compared the MTF cutoff and SR values after the implantation of A1-UV IOL and SN60WF IOL, and the results showed no difference between the two groups, with the mean values reaching the normal level in same age group[16].

Visual acuity measurement is usually carried out under the luminance and high-contrast condition, while the contrast in the actual environment varies greatly[17]. On this basis, OVs (100%, 20%, and 9%) respectively represent the simulated contrast visual acuity of photopic, mesopic and scotopic vision, namely daytime, dusk and night. The OVs were derived from the same MTF curve at different spatial frequencies and showed a similar evolution to the MTF cutoff. In this study, no significant difference was detected in OV (100%, 20% and 9%) between A1-UV and SN60WF at 4 mm pupil. The values of OV100% and OV20% were higher, while the OV9% was relatively lower. Martínez-Roda *et al*[18] stratified the effect of age on the visual quality of healthy volunteers, and found that aging has a significant influence on low-contrast parameters; their OV9% values were in concordance with that in our study (0.37±0.11 in A1-UV and 0.39±0.13 in SN60WF). A previous study also showed that OV decreased significantly with decreased environmental contrast regardless of age, ocular condition, or IOL type[19]. Since the environmental illumination is mainly close to that of daytime and dusk, two aspheric implants, A1-UV and SN60WF, can completely meet the daily needs of people.

Theoretically, pupil size is an extremely important factor for retinal image and visual quality. According to previous studies, the HOA of normal human eyes increased[20] while the MTF[21] and SR[22] decreased with a dilated pupil. The corneal, intraocular and ocular HOAs in pseudophakic eyes also increased with pupil expansion, indicating that the visual quality decreased[10]. OQAS II can measure the OSI, MTF cutoff, SR, OV (100%, 20%, 9%) and other parameters, and thus form the objective and systematic evaluation of visual quality. To date, only one report using OQAS to evaluate astigmatic eyes has been carried out at different pupil sizes[23]. In order to obtain more information and more comprehensively evaluate the visual quality after A1-UV IOL and SN60WF IOL implantation, this study compared MTF cutoff, SR, OV (100%, 20%, 9%) and for the first time analyzed the correlations between these parameters and pupil size. At the pupil diameters of 2, 4, and 6 mm, there were no significant differences found in these parameters between the two IOLs; the MTF cutoff, SR and OV (100%, 20%, 9%) of both IOLs were negatively correlated with pupil diameter, which also indicated that image quality decreased with dilated pupil.

Our study may be limited to 1) given that the differences detected in visual parameters were minimal between eyes implanted with the two IOLs, a larger sample size may be required to detect the true differences. However, our results may provide pilot data for future research, and multicenter clinical trials with larger sample size are warranted; 2) a small number of subjects were included bilaterally, in which the interocular correlation may bias our results; 3) a questionnaire of visual satisfaction may provide a more complete visual assessment for the participants.

To sum up, the present study evaluated the subjective and objective visual quality of A1-UV and SN60WF aspherical IOL after implantation, and suggested that they were comparable and satisfactory. The A1-UV IOL provides a more cost-efficient option for the cataract patients. At the same time, we innovatively explored the correlations between OQAS parameters and the pupil diameter, and found that all of them decreased with pupil dilation. With OQAS parameters, it is proven that visual quality is negatively correlated with pupil diameter.

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