ISSN: 2754-4990

Journal of Ophthalmology Research Reviews & Reports

SCIENTIFIC Research and Community

Research Article

Open Access

Evaluation of the Safety and Efficacy of Foldable One-Piece Intraocular Lens A1-UV for the Treatment of Cataracts: Summary of Two Clinical Trials

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ABSTRACT

Objective: Through the combined analysis of data from two clinical trials, the clinical safety and efficacy of aspheric intraocular lens A1-UV implantation in cataract patients was evaluated at 1 year after surgery.

Methods: A total of 239 subjects (239 eyes) were enrolled, including 117 subjects in the A1-UV group (study group), 61 subjects in the SN60WF group (control group 1) and AQBHL group (control group 2), respectively. Follow-up time points included: preoperative, intraoperative and postoperative 1~2days, 1 week, 1 month, 3 months, 6 months and 1 year. The evaluation indexes included: visual acuity, refraction, contrast sensitivity, intraocular pressure and complications. Statistical methods mainly include Wilcoxon rank-sum test, independent samples t-test, chi-square test or Fisher exact probability test.

Results: The uncorrected distance visual acuity of the A1-UV group increased from logMAR 0.77±0.33 preoperatively to 0.15±0.22 at 1 year after surgery, from 0.74±0.33 in the SN60WF group to 0.18±0.23 at 1 year after surgery, and from 0.78±0.34 in the AQBHL group to 0.21±0.24 at 1 year after surgery. For best-corrected distance visual acuity, the A1-UV group increased from logMAR 0.60±0.36 preoperatively to 0.05±0.10 at 1 year after surgery, the SN60WF group increased from 0.59±0.36 preoperatively to 0.07±0.15 at 1 year after surgery, and the AQBHL group increased from 0.59±0.35 preoperatively to 0.08±0.11 at 1 year after operation. There was no significant difference between the A1-UV group and the other two groups (all $P>0.05$). At different follow-up times after surgery, the residual diopters was significantly lower than that before operation (all $P<0.05$), and the refractive error before operation was effectively corrected. The contrast sensitivity was high, and the visual function was better. The mean intraocular pressure of the subjects implanted with A1-UV was within the normal range during each follow-up period after surgery. None of the patients had serious adverse events related to intraocular lens.

Conclusion: The efficacy and safety of A1-UV foldable one-piece intraocular lens in cataract treatment are good.

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Received: September 27, 2024; **Accepted:** September 30, 2024; **Published:** October 10, 2024

Keywords: Aspheric Intraocular Lens, Efficacy, Safety

Introduction

Cataract is a common senile disease, and it is the leading cause of blindness worldwide. The majority of patients with this disease are middle-aged and elderly people. The clinical manifestations of cataract patients are impaired vision, diopter change, intermittent or continuous increase in intraocular pressure, etc. When the condition is serious, they can cause blindness, which seriously affects the quality of life of the patients. Information shows that nearly 4 million cataract surgeries are performed in the United States each year and more than 4 million cataract surgeries are performed in the European Union. It is estimated that there are about 280 million people with cataracts worldwide, accounting for 33% of the global visual impairment, and the blindness rate of cataract patients is 51% [1-3]. Cataract phacoemulsification combined with intraocular lens (IOL) implantation is currently recognized as the safest, most effective, and fastest method of restoration, with small incisions, small damage, short time, fast healing, small astigmatism, and vision recovery after implantation fast, light inflammation and low incidence of infection [4-8].

The A1-UV posterior chamber monofocal IOL was approved by NMPA to launch in Chinese Mainland in 2014, which realized the dual breakthrough of domestic IOL in hydrophobic acrylate material and aspheric optical design. In the pre-market clinical trial of A1-UV, AcrySof IQ (model: SN60WF) was used as the positive control product. After A1-UV was launched, it participated as a positive control product in the clinical trial of another posterior chamber monofocal IOL AQBHL. Both of these pre-market clinical trials included A1-UV IOL. Merge the data from two clinical trials to form a new dataset, with A1-UV as the study group and SN60WF and AQBHL as the control groups. Based on the new dataset, a new statistical analysis was conducted to obtain the conclusion of this article.

Data and Methods

Object

Study 1: From 2012 to 2014, 119 patients participated in the pre-market clinical trial of A1-UV IOL at 4 hospitals [9]

1. Ophthalmic Center, Beijing Tongren Hospital, Capital Medical University, Beijing Institute of Ophthalmology, Beijing Ophthalmology & Visual Sciences Key Lab;
2. Peking University Third Hospital;
3. Tianjin Medical University Eye Hospital;
4. Army Medical University, Army Medical Center of PLA (Daping Hospital).

Among them, there were 58 patients in the A1-UV group and 61 patients in the SN60WF group.

Study 2: From 2014 to 2017, there were 120 patients who participated in the pre-market clinical trial of AQBHL IOL at 9 hospitals [10]

1. Ophthalmic Center, Beijing Tongren Hospital, Capital Medical University, Beijing Institute of Ophthalmology, Beijing Ophthalmology & Visual Sciences Key Lab;
2. Tianjin Medical University Eye Hospital;
3. Army Medical Center of PLA, Army characteristic medical center;
4. Eye&ENT Hospital of Fudan University;
5. First Affiliated Hospital, College of Medicine, Zhejiang University;
6. Affiliated Hospital of Nantong University;
7. Beijing Hospital;
8. Xi'an fourth Hospital, Shaanxi Eye Hospital;
9. Tianjin Medical University General Hospital.

Among them, there were 61 patients in AQBHL group and 59 in A1-UV group.

The inclusion and exclusion criteria for the two studies are the same. The following inclusion criteria shall be considered:

a) adult, no gender limit;
b) cataract;
c) calculated IOL power is within the range of the investigational IOL;
d) signed informed consent form;
e) clear intraocular media other than cataract.

The following exclusion criteria shall exclude patients prior to surgery:

a) previous intraocular or corneal surgery;
b) traumatic cataract;
c) pregnancy or lactation;
d) concurrent participation in another drug or device investigation;
e) instability of keratometry or biometry measurements;
f) history of intraocular inflammation;
g) Subjects who may be reasonably expected to require a secondary surgical intervention at any time during the investigation (other than YAG capsulotomy);
h) gonioscopic abnormalities;
i) irregular astigmatism.

The three IOLs (A1-UV, SN60WF, AQBHL) involved in the study have the same structure, materials, and optical design. They are all one-piece structures implanted in the posterior chamber and made of hydrophobic acrylic materials with added UV absorbers. They are all monofocal aspherical optical designs. The manufacturer of A1-UV and AQBHL is Eyebright Medical Technology (Beijing) Co., Ltd. and the manufacturer of SN60WF is Alcon Laboratories, Inc.

As this report is only a secondary analysis of past data and does not change the patient's original diagnosis and treatment plan or collect new data, it does not involve ethical review.

Method

Operative Method

All surgeries in each hospital were performed by the same experienced physician, and the surgical methods for the study and control groups were consistent. Preoperative dilated pupils and ocular surface anesthesia. 2.8 mm/3.0mm transparent corneal incision, injection of viscoelastic agent into the anterior chamber, 5.0-6.0 mm continuous circular capsulotomy, water separation, phacoemulsification of the lens nucleus, removal of cortex, and polishing of the posterior capsule. Inject viscoelastic agent into the capsule, place the IOL into the capsular bag and fully unfold it, and gently press the optical part of IOL to adhere to the capsule. Remove the viscoelastic agent from the anterior chamber, create a watertight incision, and complete the surgery. All patients underwent surgery successfully without any complications such as posterior capsule rupture during the operation.

Observation Method

The overall design of both clinical trials is prospective, multicenter, randomized, open, positive product parallel control, and both are single eye enrolled. The follow-up period is 1 year, and the follow-up time points include preoperative, intraoperative, and postoperative(1-2 days, 1 week, 1 month, 3 months, 6 months, and 1 year).

The effectiveness evaluation indicators all include visual acuity (best-corrected distance visual acuity, best-corrected near visual acuity, uncorrected distance visual acuity, uncorrected near visual acuity), refraction, and contrast sensitivity; The safety evaluation indicators all include the occurrence of complications such as corneal edema, anterior chamber reaction, conjunctival congestion/edema, iritis, endophthalmitis, pupillary block, capsule hyperplasia, posterior capsule opacity (PCO), abnormal IOL (such as discoloration, opacity, glistening, calcification, etc.) or abnormal position of the IOL, as well as the rate of secondary surgery.

Use the standard LogMAR visual acuity chart to check vision; Using manifest (subjective) refraction and the computer automatic optometry instrument to measure the spherical and cylindrical power, and calculate the diopter (spherical equivalent), the calculation formula is: Diopter =Spherical power+1/2 Cylindrical power; The contrast sensitivity test is required to be performed under the best-corrected distance visual acuity. The instrument provides two types of background light: photopic (85 cd/m^2) and mesopic (3 cd/m^2); There are a total of 5 spatial frequencies: 1.5 c/d, 3.0 c/d, 6.0 c/d, 12.0 c/d and 18.0 c/d. Perform two checks under each lighting background, and take the average of the two checks as the final statistical indicator. Measure intraocular pressure using a non-contact tonometer; Using a slit lamp microscope to examine complications such as corneal edema and anterior chamber reactions, and grading them according to recognized grading standards [11,12].

Statistics

Statistical analysis was conducted using SPSS 22.0 software. All statistical tests are conducted using a two-sided test, and a P-value less than 0.05 is considered statistically significant for the difference being tested. Mean and standard deviation were used to describe quantitative indicators, and counts and percentages were used to describe categorical indicators. For quantitative metrics, if the data follows a normal distribution, it is analyzed

using a t-test; If a normal distribution is not followed, the Wilcoxon rank-sum test is employed. For categorical data, chi-square test or Fisher's exact probability is used. Compare the SN60WF group or AQBHL group with the A1-UV group for inter group comparison.

Result

Basic Information

Two clinical trials enrolled a total of 239 subjects (239 eyes). The average age of the 117 subjects in the A1-UV group was 65.58 years old, with 43 males (36.75%) and 74 females (63.25%). The average age of the SN60WF group is 62.97 years old (61 cases), and the average age of the AQBHL group is 69.07 years old (61 cases). There were no statistically significant differences in age, gender distribution, axial length, anterior chamber depth, corneal curvature, and natural lens nucleus hardness between the three groups (all P>0.05). The three groups of subjects were balanced and comparable, as shown in Table 1.

Table 1: Basic Information

Group	Cases/ Eyes	Age[years old, x̄±s]	Gender(n)		Axial length(mm)	Anterior chamber depth (mm)	Corneal curvature (D)	Natural lens nucleus hardness			
			Male	Female				Grade 1	Grade 2	Grade 3	Grade 4
A1-UV	117	65.58±8.92	43	74	23.59±1.13	3.08±0.45	44.22±1.57	0	28	87	2
SN60WF	61	62.97±9.64	20	41	23.58±1.05	2.91±0.46	43.96±1.11	0	19	41	1
AQBHL	61	69.07±10.25	25	36	23.22±1.00	2.93±0.45	44.40±1.73	1	15	45	0
Test statistic 1	/	-1.292	0.276		-0.116	0.005	4.846	1.077			
P1	/	0.196	0.600		0.907	0.943	0.029	0.584			
Test statistic 2	/	1.291	0.304		-2.291	0.050	0.504	2.970			
P2	/	0.257	0.581		0.022	0.824	0.479	0.396			

Note: The P1 value is the comparison between the groups of "A1-UV" and "SN60WF", and the P2 value is the comparison of "A1-UV" and "AQBHL".

Effectiveness Evaluation Indicators

Visual Acuity

There was no significant difference in visual acuity between groups at preoperative and different postoperative follow-up times (both P>0.05). The visual acuity of the subjects in both groups was significantly improved compared with the preoperative at each follow-up time point after surgery (all P<0.01), and the refractive error before surgery was effectively corrected. The visual acuity of the subjects in both groups reached a stable state at 1 month after surgery, and there was no significant change in visual acuity at 3 months, 6 months and 1 year after surgery compared with 1 month after surgery (all P>0.05), which means that the correction effect was relatively stable. See Table 2.

Table 2: Comparison of logMAR Visual Acuity at Preoperative and Different Postoperative Follow-up Times(x̄±s)

Group	Uncorrected Distance Visual Acuity					
	Pre-OP	1 Week	1 Month	3 Months	6 Months	1 Year
A1-UV	0.77±0.33	0.19±0.21	0.18±0.20	0.17±0.18	0.17±0.19	0.15±0.22
SN60WF	0.74±0.33	0.19±0.17	0.18±0.16	0.17±0.19	0.17±0.18	0.18±0.23
AQBHL	0.78±0.34	0.22±0.18	0.20±0.17	0.22±0.22	0.20±0.19	0.21±0.24
Test statistic 1	-0.604	-0.376	-0.067	-0.196	-0.341	-0.499
P1	0.546	0.707	0.947	0.845	0.733	0.618
Test statistic 2	-0.039	-1.508	-1.052	-1.836	-1.393	-1.881
P2	0.969	0.132	0.293	0.066	0.164	0.060
Group	**Uncorrected Near Visual Acuity**					
	Pre-OP	**1 Week**	**1 Month**	**3 Months**	**6 Months**	**1 Year**
A1-UV	0.77±0.30	0.47±0.22	0.45±0.22	0.44±0.20	0.47±0.21	0.42±0.23
SN60WF	0.76±0.31	0.39±0.21	0.37±0.19	0.35±0.20	0.37±0.16	0.41±0.21
AQBHL	0.68±0.26	0.55±0.24	0.55±0.25	0.55±0.24	0.55±0.23	0.51±0.24
Test statistic 1	0.145	-2.353	-2.804	-2.478	-3.318	-0.249
P1	0.704	0.019	0.005	0.013	0.001	0.803
Test statistic 2	-1.541	-1.956	-2.529	-2.809	-1.939	-2.156
P2	0.123	0.050	0.011	0.005	0.053	0.031

Group	Best-corrected Distance Visual Acuity					
	Pre-OP	1 Week	1 Month	3 Months	6 Months	1 Year
A1-UV	0.60±0.36	0.07±0.14	0.08±0.13	0.07±0.11	0.06±0.14	0.05±0.10
SN60WF	0.59±0.36	0.09±0.15	0.07±0.12	0.07±0.12	0.06±0.13	0.07±0.15
AQBHL	0.59±0.35	0.10±0.13	0.10±0.13	0.09±0.12	0.09±0.11	0.08±0.11
Test statistic 1	-0.340	-0.812	-0.018	-0.428	-0.042	-0.973
P1	0.734	0.417	0.986	0.669	0.966	0.330
Test statistic 2	-0.361	-1.536	-1.150	-1.532	-1.644	-1.732
P2	0.718	0.124	0.250	0.125	0.100	0.083
Group	**Best-corrected Near Visual Acuity**					
	Pre-OP	**1 Week**	**1 Month**	**3 Months**	**6 Months**	**1 Year**
A1-UV	0.63±0.34	0.19±0.19	0.18±0.18	0.15±0.16	0.16±0.17	0.13±0.17
SN60WF	0.60±0.35	0.14±0.17	0.13±0.15	0.11±0.18	0.11±0.19	0.15±0.20
AQBHL	0.55±0.28	0.20±0.14	0.20±0.14	0.18±0.13	0.17±0.11	0.21±0.18
Test statistic 1	-0.510	-1.770	-1.645	-1.712	-1.824	-0.227
P1	0.610	0.077	0.100	0.087	0.068	0.820
Test statistic 2	-1.148	-1.055	-1.153	-1.747	-1.165	-2.741
P2	0.251	0.291	0.249	0.081	0.244	0.006

At 6 months and 1 year after surgery, the proportion of best-corrected distance visual acuity reaching 0.0LogMAR was 68 cases (59.13%) and 61 cases (65.59%) in the A1-UV group, 32 cases (54.24%) and 25 cases (49.02%) in the SN60WF group, 28 cases (47.46%) and 24 cases (50.00%) in the AQBHL group, respectively and there was no significant difference between the groups (all P>0.05).

At 6 months and 1 year after surgery, the proportion of best-corrected distance visual acuity reaching 0.2LogMAR was 105 cases (91.30%) and 88 cases (94.62%) in the A1-UV group, 56 cases (94.92%) and 45 cases (88.24%) in the SN60WF group, 51 cases (86.44%) and 45 cases (93.75%) in the AQBHL group, respectively and there was no significant difference between the groups (all P>0.05).

At 6 months and 1 year after surgery, the proportion of best-corrected distance visual acuity reaching 0.3LogMAR was 114 cases (99.13%) and 93 cases (100.00%) in the A1-UV group, 58 cases (98.31%) and 50 cases (98.04%) in the SN60WF group, 59 cases (100.00%) and 47 cases (97.92%) in the AQBHL group, respectively and there was no significant difference between the groups (all P>0.05).

At 6 months and 1 year after surgery, the proportion of uncorrected distance visual acuity reaching 0.0 LogMAR was 28 cases (24.35%) and 35 cases (36.84%) in the A1-UV group, 17 cases (28.81%) and 22 cases (43.14%) in the SN60WF group, 12 cases (20.34%) and 12 cases (25.00%) in the AQBHL group, respectively and there was no significant difference between the groups (all P>0.05).

At 6 months and 1 year after surgery, the proportion of uncorrected distance visual acuity reaching 0.2 LogMAR was 89 cases (77.39%) and 80 cases (84.21%) in the A1-UV group, 41 cases (69.49%) and 35 cases (68.63%) in the SN60WF group, 39 cases (66.10%) and 31 cases (64.58%) in the AQBHL group, respectively and there was no significant difference between the groups (all P>0.05).

At 6 months and 1 year after surgery, the proportion of uncorrected distance visual acuity reaching 0.3LogMAR was 104 cases (90.43%) and 84 cases (88.42%) in the A1-UV group, 49 cases (83.05%) and 38 cases (74.51%) in the SN60WF group, 50 cases (84.75%) and 40 cases (83.33%) in the AQBHL group respectively. Except that the A1-UV group was significantly better than the SN60WF group at 1 year after surgery, there was no significant difference between the other groups (all P>0.05).

Refraction

Except for the statistically significant difference between the A1-UV group and the SN60WF group at 1 year after surgery (P<0.05), there was no significant difference between the other groups at the follow-up time points (all P>0.05). One year after surgery, the residual refraction (0.13D) of the subjects implanted with A1-UV was slightly greater than that of SN60WF (0.02D), but all of them were close to emmetropia. At different follow-up times after surgery, the residual refractive power was significantly lower than that before operation (all P<0.05), which means that the refractive error before operation was effectively corrected. See Table 3.

Table 3: Comparison of Refractive Power at different Follow-up Times before and after Surgery(D)($\bar{x}\pm s$)

Group	Pre-OP	1 Week	1 Month	3 Months	6 Months	1 Year
A1-UV	-0.60±3.95	-0.01±0.95	0.00±0.84	-0.03±0.79	-0.01±0.80	0.13±0.88
SN60WF	-0.91±3.28	-0.16±0.92	-0.10±0.91	-0.11±0.78	-0.17±0.79	0.02±0.87
AQBHL	-1.27±3.49	-0.10±1.12	-0.26±1.07	-0.20±1.20	-0.24±1.09	-0.08±1.01
Test statistic 1	-0.602	-1.485	-1.209	-0.779	-1.606	-2.241
*P*1	0.547	0.138	0.227	0.436	0.108	0.025
Test statistic 2	-0.812	-0.278	-1.239	-1.055	-0.800	-0.712
*P*2	0.417	0.781	0.215	0.291	0.424	0.476

Contrast Sensitivity

At 3 months and 6 months after surgery, there was no significant difference in the contrast sensitivity of the subjects implanted with A1-UV and the other two types of lenses, and the contrast sensitivity was higher and the visual function was better. See Table 4 for details.

Table 4: Contrast Sensitivity at 3 and 6 Months Postoperatively($\bar{x}\pm s$)

Group	cases	3 months									
		Photopic					Mesopic				
		1.5 c/d	3c/d	6c/d	12c/d	18c/d	1.5 c/d	3c/d	6c/d	12c/d	18c/d
A1-UV	117	1.46±0.40	1.58±0.36	1.62±0.44	1.23±0.43	0.73±0.48	1.39±0.42	1.46±0.40	1.39±0.47	0.95±0.51	0.44±0.44
SN60WF	59	1.29±0.45	1.55±0.31	1.59±0.43	1.15±0.40	0.65±0.44	1.22±0.47	1.40±0.40	1.37±0.47	0.99±0.42	0.49±0.38
AQBHL	59	1.50±0.26	1.57±0.36	1.57±0.33	1.06±0.46	0.64±0.43	1.37±0.36	1.39±0.40	1.31±0.47	0.80±0.52	0.34±0.41
Test statistic 1	/	-2.028	-1.255	-0.709	-1.462	-0.916	-1.766	-0.929	-0.391	-0.259	-1.353
*P*1	/	0.043	0.210	0.478	0.144	0.360	0.077	0.353	0.696	0.796	0.176
Test statistic 2	/	-0.231	-0.278	-1.854	-2.500	-1.429	-0.400	-0.979	-1.307	-1.553	-1.781
*P*2	/	0.817	0.781	0.064	0.012	0.153	0.689	0.328	0.191	0.120	0.075
Group	**cases**	**6 months**									
		Photopic					Mesopic				
		1.5 c/d	3c/d	6c/d	12c/d	18c/d	1.5 c/d	3c/d	6c/d	12c/d	18c/d
A1-UV	115	1.44±0.39	1.59±0.34	1.62±0.41	1.22±0.43	0.74±0.43	1.38±0.39	1.47±0.40	1.41±0.52	0.92±0.51	0.44±0.44
SN60WF	59	1.32±0.46	1.57±0.30	1.63±0.41	1.25±0.39	0.75±0.44	1.27±0.47	1.46±0.37	1.42±0.43	1.00±0.43	0.55±0.40
AQBHL	59	1.55±0.25	1.62±0.27	1.60±0.30	1.06±0.49	0.66±0.43	1.42±0.26	1.43±0.33	1.33±0.41	0.76±0.54	0.36±0.41
Test statistic 1	/	-1.122	-0.870	-0.776	-0.511	-0.016	-1.049	-0.328	-0.145	-0.660	-1.888
P1	/	0.262	0.384	0.438	0.609	0.987	0.294	0.743	0.885	0.509	0.059
Test statistic 2	/	-1.062	-0.124	-0.861	-1.705	-1.031	-0.008	-1.013	-1.793	-1.850	-1.306
P2	/	0.288	0.901	0.389	0.088	0.302	0.993	0.311	0.073	0.064	0.192

Safety Evaluation Indicator

Intraocular Pressure

There was no significant difference between groups at any follow-up time point (all P>0.05). One year after surgery, the mean intraocular pressure of the subjects implanted with A1-UV was 13.52 mmHg, and the mean difference from baseline was -0.47 mmHg. The mean intraocular pressure of the subjects implanted with A1-UV was within the normal range during each follow-up period after surgery, indicating that A1-UV did not cause adverse effects on intraocular pressure, as shown in Table 5.

Table 5: Intraocular Pressure Examination at Preoperative and Different Postoperative Follow-up Times(mmHg)

Group	Pre-op	1 week	1 month	3 months	6 months	1 year
A1-UV	14.17±3.23	12.34±2.92	12.39±3.28	11.98±2.78	12.36±2.71	13.52±3.02
SN60WF	13.60±3.14	12.88±4.36	12.91±4.99	12.24±2.59	12.40±2.66	12.95±3.00
AQBHL	13.38±3.21	12.77±3.68	12.11±3.36	11.57±2.96	11.77±2.86	13.05±2.55
Test statistic 1	-0.750	-0.239	-0.090	0.641	-0.028	0.310
*P*1	0.453	0.811	0.928	0.424	0.977	0.579
Test statistic 2	-1.177	-0.972	-0.102	1.157	-1.326	0.595
*P*2	0.239	0.331	0.919	0.284	0.185	0.442

Complications and Adverse Events

Most of the complications and inflammatory reactions of slit lamp examination were concentrated in 1~2 days after surgery, the degree was mild, the duration was short, and they basically subsided 1 week after surgery, and did not cause serious adverse effects on the eye.

Compared to the threshold rate of ISO 11979-7:2024 Annex E, the incidence of adverse events was lower in A1-UV group, including endophthalmitis (1 eye), abnormal IOL position due to suspensory ligament rupture (1 eye), persistent corneal edema (2 eyes), iritis (1 eye), and raised IOP requiring treatment (1 eye), which did not result in serious adverse events and none of them were judged by physicians to be related to IOLs. There were no IOL abnormalities such as IOL discoloration, opacity, glistening, calcification, etc., no secondary surgery, and no PCO requiring Nd:YAG treatment.

Discussion

The materials, optical designs, and structures of the three IOLs in this study are the same, all of which are made of hydrophobic acrylates, with the addition of ultraviolet absorbers, all of which are monofocal aspheric optical designs, and the implantation sites are all in the posterior chamber capsular pocket, and all of them are single-piece structures. Hydrophobic acrylate is currently the mainstream material used in IOLs worldwide and has a long history of safe use in the clinic practice. In addition, basically all of the IOL materials need to add ultraviolet absorbers of benzophenones or benzotriazoles to block the absorption of ultraviolet light in natural light by mimicking the natural lens of the human eye. Monofocal aspherical IOL is the starting and basic model of premium refractive IOL. Compared with spherical IOL, aspheric IOL can offset the positive spherical aberration (SA) of part of the cornea, reduce the postoperative SA of the whole eye, and generate high-quality clear images on the retina, improves the patient's postoperative contrast sensitivity, and can better meet people's requirements for high visual quality after cataract surgery. Posterior chamber capsular bag fixed IOL is considered to be the best position for conventional implantation because of its excellent stability, little tissue friction and effective reduction of inflammation, which is implanted into the natural lens capsular bag of the human eye. The deformation rate of the single-piece IOL optical zone in the capsular bag is smaller than that of the three-piece IOL, reducing the probability of capsular wrinkle.

In this study, the data from two clinical trials were pooled and analyzed to form clinical evidence with a larger sample size and higher quality. The results showed that the mean value of uncorrected distance visual acuity in the SN60WF group was 0.18±0.23 at 1 year after surgery, which was close to 0.15±0.16 reported in previous studies [13]. The mean value of uncorrected distance visual acuity in the A1-UV group was 0.15±0.22, which was not statistically significant compared with the SN60WF group (P>0.05), indicating that the efficacy of the two IOLs was consistent. The difference between uncorrected distance visual acuity and best-corrected distance visual acuity after surgery is often due to postoperative residual refractive power, and the causes of postoperative refractive error include: The patient's eye condition is complex, the preoperative bio measurement error, the optimization of the A constant and the selection of the IOL refractive power calculation formula, the surgical astigmatism caused by the surgical operation or the position of the IOL deviates from the preset position [14]. Best-corrected distance visual acuity is the result of an examination after the effects of refractive error have been ruled out, and it is more reflective of the role of the IOL. The results of best-corrected distance vision are generally better than uncorrected distance vision. In this study, the best-corrected distance visual acuity in the three groups was close to 0 (decimal visual acuity 1.0), indicating that all three IOLs had good optical properties. The monofocal IOL can only form a focal point on the retina through optical action, and although patients can achieve good distance vision after surgery, they still need to wear glasses while near vision because the IOL itself does not have the ability to adjust optically. The reason for the slight improvement in uncorrected near visual acuity and best-corrected near visual acuity after surgery in this study is that after the removal of the cloudy lens, the light pathway is smoother and the retinal imaging is clearer.

Visual acuity (visual acuity surface) is currently the most common index to evaluate the quality of human eye function, and the examination of this index has the advantages of low cost and time-saving. In fact, visual acuity does not fully and accurately reflect the ability of the human eye to distinguish in real life. The visual target of the eye chart is the visual target with a contrast of 100% (i.e., the black visual target on a white background), so that high-contrast objects are almost non-existent in everyday life. The eye chart can only reflect the macular ability to distinguish small targets with high contrast (i.e., the contrast of the graph is obvious), but not the ability of the macula to distinguish between low-contrast (i.e., small contrast of the graph). The most important function of the visual system is forming sense, that is, not only to sense the light emitted or reflected by objects, but also to distinguish objects and recognize the shape of objects. Contrast sensitivity, in layman's terms, is the ability of the human eye to see large, blurred objects. The advantage of contrast sensitivity test is that it can reflect the human eye's ability to distinguish between different contrast patterns, and can more comprehensively evaluate the morphological function characteristics of the visual system. In everyday life, contrast sensitivity is more important than visual acuity. In this study, the three IOLs showed high contrast sensitivity values under different conditions, and their visual function was good.

In summary, the implantation of A1-UV IOL can significantly improve the subject's best-corrected distance visual acuity, best-corrected near visual acuity, uncorrected distance visual acuity, and uncorrected near visual acuity, and maintain a high level at 1 year after surgery. Implantation of an A1-UV IOL can significantly improve the subject's refraction and allow it to approach the emmetropic eye at 1 year after surgery. At the same time, the contrast sensitivity is higher, and the visual function is better.

In addition, the inflammatory response observed by slit lamp mainly occurred in the early postoperative period and the symptoms were mild. No serious adverse events related to the IOL occurred, indicating that A1-UV was relatively safe.

It can be seen that the efficacy and safety of A1-UV foldable one-piece IOL for cataract treatment have been verified.

References

1. Pascolini D, Mariotti SP (2012) Global estimates of visual impairment: 2010. British Journal of Ophthalmology 96: 614-618.
2. Flaxman SR, Bourne RR, Resnikoff S (2017) Global causes of blindness and distance vision impairment 1990-2020: A systematic review and meta-analysis. Lancet Glob Health 5: e1221-e1234.
3. Wang SY, Stem MS, Oren G, Shtein R, Lichter PR (2017) Patient-centered and visual quality outcomes of premium

cataract surgery: a systematic review. European Journal of Ophthalmology 27: 387-401.

4. Kohnen T (2008) Multifocal IOL technology: a successful step on the journey toward presbyopia treatment. Journal of Cataract & Refractive Surgery 34: 2005.
5. Keates RH, Sall KN, Kreter JK (1987) Effect of the Nd:YAG laser on polymethylmethacrylate, HEMA copolymer, and silicone intraocular materials. Journal of Cataract & Refractive Surgery 13: 401-409.
6. Cetinel S, Montemagno C (2015) Nanotechnology for the Prevention and Treatment of Cataract. Asia-Pacific Journal of Ophthalmology (Phila) 4: 381-387.
7. Lian RR, Afshari NA (2020) The quest for homeopathic and nonsurgical cataract treatment. Current Opinion in Ophthalmology 31: 61-66.
8. Yao K, Wang W (2020) A summary of 70 years of cataract diagnosis and treatment in China. Zhonghua Yan Ke Za Zhi 56: 321-324.
9. Song Xudong, Hao Yansheng, Li Xiaorong (2016) Evaluation of the safety and visual quality after implantation of the domestic made aspheric intraocular lens. Zhonghua Yan Ke Za Zhi 52: 99-103.
10. Song Xudong, Wang Ningli, Zhang Hong (2020) Multi-center study on safety and efficacy of Chinese preloaded intraocular lens system. Rec Adv Ophthalmology 40: 251-256.
11. Zhao JL, Li XX, Dong DS, Chen YX, Zou YH, et al. (2000) Clinical assessment of Pranoprofen eyedrops on postoperative inflammation of cataract extraction and non-infection inflammation of the anterior segments of the eye. Chinese Ophthalmology Res 18: 560-564.
12. Xie LX, Yao Z, Huang YS, Ying L (2004) Corneal endothelial damage and its repair after phacoemulsification. Chinese Journal Opthalmology 40: 21-24.
13. Yadav S, Sahay P, Maharana PK, Titiyal JS, Vajpayee RB, et al. (2017) Comparison of visual performance and after cataract formation between two monofocal aspheric intraocular lenses following phacoemulsification for senile cataract: A randomized controlled study. Indian Journal Ophthalmology 65: 1445-1449.
14. Li Yang, Chang Jun Lan, Xuan Liao (2022) Reasons and corrections of refractive error after cataract surgery. Int Eye Sci 22: 429-433.