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*Original Article*

# Visual quality assessment after SV25T0 intraocular lens implantation

Zi Ye, Zhao-Hui Li, Shou-Zhi He, Bing Chen, Chun-Yan Ren, Xiao-Jun Xing

*Department of Ophthalmology, The PLA General Hospital, Beijing 100853, China*

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**Abstract:** This study aimed to evaluate the visual quality after implantation of the SV25T0 intraocular lens in the cataract patients. A retrospective study was performed in Chinese PLA General Hospital during 2014. Three groups of patients were classified based on the different types of intraocular lens (SV25T0, SN60WF and SN6AD1). The uncorrected near visual acuity (UCNVA) at 40 cm was measured at three months after operation; the objective and subjective visual quality were also evaluated by the OQAS II analysis system and visual function index scale (VF-14). Totally 30 patients with 60 eyes were recruited. The mean of UCNVA at 40 cm with SN60WF was better than that with SV25T0 ($P<0.001$), both of which were better than that with SN6AD1 ($P=0.006$) at three months after operation. No significant changes were found among the three groups for the outcomes of MTF, SR, VA100, VA20, VA9 and OSI (all $P>0.05$). The changes on the LogMAR preoperative best corrected visual acuity in the SV25T0 group was greater than those in the other two groups ($P=0.016$). SV25T0 allowed the patients to obtain better postperative best corrected visual acuity and visual quality, which may be recommended to use in the cataract patients.

**Keywords:** Visual quality, SV25T0, uncorrected near visual acuity, OQAS II analysis system

## Introduction

The clinical application of multifocal intraocular lenses has become a hot research field since the multifocal intraocular lens was first clinically used in 1987 [1]. Many previous studies have confirmed the positive effect of multifocal intraocular lenses. However in some cases, the patient could not adapt to the intraocular lens owing to many postoperative side effects, leading to the removal of the intraocular lens [2-4]. Multifocal intraocular lenses can be divided into three types: refraction, diffraction and refraction-diffraction hybrid, among which the hybrid type is the best one [5]. Currently, it was believed that the hybrid intraocular lens of AcrySof ReSTOR SN6AD1 was able to improve near vision [6, 7], while may decrease the visual quality in a degrees [8] and generate significant postoperative side effects [9]. AcrySof ReSTOR SV25T0 is one type of bifocal intraocular lenses based on SN6AD1 that was launched in 2012. To our knowledge, only a few studies on the clinical applications of SV25T0 have been reported, and they are all in vitro studies [10, 11]. Issues such as how the lens affects visual quality after implantation and whether the lens meets the requirements of the postoperative recovery of full visual acuity in patients remain unknown and urgently need further study.

The purpose of the current study was to evaluate the visual quality of the affected eyes after SV25T0 implantation in the cataract patients compared to that after SN6AD1 and SN60WF implantation, thereby providing clinical guidance of the application of SV25T0.

## Materials and methods

### *Cases collection*

A retrospective study was performed in the Chinese PLA General Hospital from May 2014 to August 2014. Three groups of patients who met the criteria were collected based on the implantation of intraocular lens types (SV25T0, SN60WF and SN6AD1) for the affected eye. Our experimental procedure was approved by the ethics committee of the hospital and all participants provided written informed consent. Our study followed the Declaration of Helsinki.

**Table 1.** Item content for the translated Chinese VF-14 instruments

| Item | Translated Chinese Version |
|---|---|
| 1 | Reading small print, such as labels on medicine bottles, a telephone book, price list, watch |
| 2 | Reading a newspaper or a book |
| 3 | Reading large font, such as a large-print book or newspaper, numbers on a telephone or mobile phone, wall clock |
| 4 | Recognizing familiar people when they are close to you |
| 5 | Seeing steps, stairs, or curbs |
| 6 | Reading signs, such as traffic signs, street signs, store signs, advertising board, or plate number |
| 7 | Doing fine handwork, such as threading a needle, sewing, knitting, crocheting |
| 8 | Signing your name or filling out forms |
| 9 | Playing games, such as card games, mahjong, chess |
| 10 | Taking part in sports, such as playing Ping-Pong or badminton, strolling, doing exercise, shadowboxing |
| 11 | Cooking |
| 12 | Watching television |
| 13 | Day driving such as automobile, motorcycle, or nonmotorized vehicle |
| 14 | Night driving such as automobile, motorcycle, or nonmotorized vehicle |

The inclusion criteria of cases were as follows: a cataract patient with a relatively healthy eye; a cataract patient with a cataract diagnosed by an experienced doctor with slit-lamp examination; preoperative corneal astigmatism <1.0D [12]; a preoperative pupil diameter of approximately 2.5-4.0 mm; no history of refractive surgery; no history of intraocular surgery; underwent phacoemulsification and implantation of intraocular lens in the capsular bag. The exclusion criteria of cases were as follows: obvious retinopathy observed by the preoperative ultrasound B; the presence of other eye diseases, such as glaucoma, uveitis, and ocular trauma; ocular congenital anomalies; a follow-up period of <3 months; a preoperatively detected pupil diameter that was too small (<1 mm) or too large (>6 mm); diabetes or hypertension that caused retinopathy; special populations, such as those have too high expectations or are overly sensitive. According to the type of intraocular lens implemented (all were from Alcon Laboratories, Inc., Fort Worth, TX, USA) in the affected eye, the collected cases were divided into three groups, including the SV25T0, SN60WF and SN6AD1 groups.

*Surgery*

The surgeries for all of the cases were performed by the same experienced physician with the same procedure. After topical anesthesia, a 2.2-mm coaxial micro incision was created. This was followed by continuous centered curvilinear capsulorhexis. Phacoemulsification and intraocular lens implantation were conducted using the phacoemulsification system from Infinity (Alcon Inc., Irvine, CA, USA) and Signature (Abbott Medical Optics Inc., Andrew Place Santa Ana, CA, USA).

*Data measurement and recording*

All data measurements were completed by the same trained technicians to obtain an average of three repeated measurements. The data were entered by two physicians. The lens nucleus hardness was graded according to the Emery hardness grading standard. The refractive data were quantified via the axial length (AL), astigmatism and mean keratometry (Km) by the IOLMaster biometer (Meditec AG, Zeiss, Germany) and the lens power was calculated using the SRK-T formula. The preoperative best corrected visual acuity (BCVA) was measured before operation and at three months after operation and uncorrected near visual acuity (UCNVA) at 40 cm was measured only at three months after operation which was analyzed by the LogMAR method.

For the objective assessment of visual quality, the parameters were measured with the OQAS II visual quality analysis system (Visiometrics Company, Spain) before operation and at three months after the surgery, which included the modulation transfer function (MTF), Strehl ratio (SR), visual acuity (VA) with contrasts of 100%, 20% and 9%, and objective scattering index (OSI). The subjective visual quality was evaluated by the visual function index scale (VF-14) (**Table 1**).

*Data analysis*

Descriptive statistics were calculated for all variables; continuous variables were summa-

**Table 2.** The basic characteristics of the patients in the three groups

| Characteristics | SV25T0 (G1) | SN60WF (G2) | SN6AD1 (G3) | *P* value* | | | |
|---|---|---|---|---|---|---|---|
| | | | | All | G1 *vs.* G2 | G1 *vs.* G3 | G2 *vs.* G3 |
| Age, year, mean ± SD | 65.30±10.17 | 70.90±6.35 | 69.30±11.71 | 0.423 | 0.411 | 0.630 | 0..928 |
| Sex, female, % | 5 (50) | 10 (100) | 9 (90.0) | 0.027 | 0.033 | 0.141 | 1.000 |
| Lens nucleus hardness | 2.85±0.59 | 2.95±0.22 | 3.10±0.64 | 0.711 | 0.815 | 0.287 | 0.633 |
| Axial lengths (mm) | 23.31±0.51 | 23.36±0.67 | 23.04±0.83 | 0.278 | 0.969 | 0.420 | 0.295 |
| Astigmatism (diopter) | 0.47±0.20 | 0.54±0.24 | 0.64±0.28 | 0.111 | 0.623 | 0.092 | 0.457 |
| Mean keratometry (diopter) | 43.35±1.25 | 43.52±1.69 | 44.08±0.95 | 0.205 | 0.920 | 0.206 | 0.384 |
| BCVA before operation | 0.23±0.19 | 0.35±0.13 | 0.29±0.15 | 0.083 | 0.067 | 0.464 | 0.525 |
| MTF before operation | 5.40±3.73 | 7.71±3.63 | 6.76±4.28 | 0.1774 | 0.154 | 0.513 | 0.723 |
| VA100 before operation | 0.18±0.12 | 0.26±0.12 | 0.21±0.13 | 0.163 | 0.140 | 0.699 | 0.506 |
| VA20 before operation | 0.18±0.11 | 0.24±0.11 | 0.27±0.27 | 0.256 | 0.461 | 0.250 | 0.909 |
| VA9 before operation | 0.19±0.11 | 0.26±0.11 | 0.27±0.21 | 0.185 | 0.296 | 0.212 | 0.978 |
| OSI before operation | 8.53±3.40 | 6.20±2.67 | 7.56±2.93 | 0.056 | 0.045 | 0.569 | 0.332 |
| Score of VF-14 scale | 3.30e of | 13.40±2.17 | 3.900±2.1 | <0.001 | <0.001 | 0.778 | <0.001 |

*The ANOVA model was used to compare the differences among the three groups. It was statistically significant if *P* value was less than 0.017 when comparing for any of two groups.

rized as means and standard deviations (SD) or as medians and interquartile ranges, and categorical variables were summarized as frequencies and proportions. Analysis of variance (ANOVA) was also used to compare the related variables among the three groups.

Hierarchical linear models (HLMs) were used for multivariate analysis, which was help to handle multiple measurements, intra-individual correlation in observations over time, and the nested structure of the data. For the analyses, each available measurement of each participant was treated as one single observation, i.e. there were up to two observations per participant. Separate models were computed for each outcome (all fixed effects, time-invariant), and accounting for intra-individual correlation over time (first-order autoregressive covariance structure). To allow for non-linear development of outcomes, time was treated as a categorical variable with each measurement representing one category, and was included as time-varying fixed effect. To test for between-group differences in within-group changes over time, a time-by-group interaction term was added as time-varying fixed effect. Estimates for within-group changes over time and *P*-values of between-group differences in within-group changes over time were reported for each outcome.

A two-sided *P* value of <0.05 was considered to be statistically significant. All analyses were performed using SAS software, version 9.3 (SAS Institute Inc., Cary, NC, USA).

## Results

Totally 30 patients with 60 eyes were recruited in this study, who were equally divided into three groups according to the different type of intraocular lens implanted in the affected eyes: the SV25T0 group, the SN6AD1 group and the SN60WF group. The basic characteristics of the patients in the three groups were presented in **Table 2**. No significant differences were found on the variables of age, lens nucleus hardness, axial lengths, astigmatism and mean keratometry among the three groups (all P>0.05) except for the sex (P=0.027). The evaluated parameters of the preoperative visual quality also exhibited no significant difference among the three groups.

HLMs were used to analyze the changes within group over time and between groupsbased on the evaluation parameters of the preoperative visual quality (**Table 3**). The within-group changes for all the variables were statistically significant in the three groups, respectively (all P<0.001). However, no significant changes were found among the three groups for the outcomes of MTF, SR, VA100, VA20, VA9 and OSI (all P>0.05). The change on LogMAR BCVA in the SV25T0 group was greater than those in the other two groups (P=0.016).

**Table 3.** Within group changes in the outcomes over time and between-group differences by HLMs

| Outcome | SV25T0 (G1) | | SN60WF (G2) | | SN6AD1 (G3) | | P of Between-group changes (time by group) | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | WGC | P | WGC | P | WGC | P | All | G1 *vs.* G2 | G1 *vs.* G3 | G2 *vs.* G3 |
| LogMAR BCVA | 0.796 | <0.001 | 0.643 | <0.001 | 0.627 | <0.001 | 0.016 | 0.262 | 0.009 | 0.799 |
| MTF | 21.764 | <0.001 | 18.567 | <0.001 | 16..394 | <0.001 | 0.195 | 0.282 | 0.074 | 0.464 |
| SR | 0.092 | <0.001 | 0.108 | <0.001 | 0.071 | <0.001 | 0.144 | 0.386 | 0.265 | 0.050 |
| VA100 | 0.684 | <0.001 | 0.651 | <0.001 | 0.542 | <0.001 | 0.348 | 0.746 | 0.167 | 0.287 |
| VA20 | 0.658 | <0.001 | 0.674 | <0.001 | 0.425 | <0.001 | 0.052 | 0.887 | 0.042 | 0.030 |
| VA9 | 0.627 | <0.001 | 0.711 | <0.001 | 0.420 | <0.001 | 0.060 | 0.498 | 0.099 | 0.022 |
| OSI | -7.234 | <0.001 | -4.821 | <0.001 | -5.782 | <0.001 | 0.059 | 0.019 | 0.150 | 0.338 |

WGC, within-group changes over time; BCVA, best corrected visual acuity; MTF, modulation transfer function; SR, Strehl ratio; VA, visual acuity; OSI, objective scattering index.

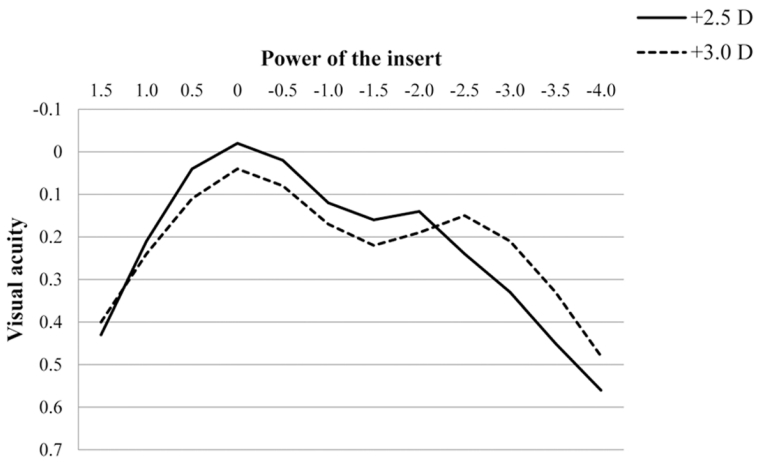


**Figure 1.** The defocus curve of the SN60WF and SN6AD1 groups within the range of -4.0D to +1.5D.

The mean LogMAR UCNVA at 40 cm with SN60WF was worse than that with SV25T0 (0.66 *vs.* 0.24, P<0.001), which was similar to that with SN6AD1 (0.24 vs. 0.15, P=0. 070).

The defocus curve of the SV25T0 and SN6AD1 groups within the range of -4.0D to +1.5D (in 0.5D increments) was shown in **Figure 1**. The best near visual acuity of the SN6AD1 group appeared at approximately -2.5D, whereas it was at approximately -2.0D in the SV25T0 group (**Table 4**).

The subjective visual quality after operation was assessed by the VF-14 Scale and the results were shown in **Table 2**. The scores (means ± SDs) of VF-14 were 3.30±1.95, 13.40±2.17 and 3.90±1.79 in the SV25T0, SN60WF and SN6AD1 groups, respectively (P<0.001), which demonstrated the lowest score in the SV25T0 group.

## Discussion

Previous studies demonstrated that implantation of SV25T0 improved the distance vision and near visual acuity after surgery as well as visual quality. Madrid-Costa [11] found the better distance visual quality in the implantation of SV25T0 and the better near distance at 40 cm in the implantation of SN6AD1 in vitro visual quality. Compared with an intraocular lens with high addition power (+4.0D add) in vivo, one with low addition power (+3.0D add) provided better intermediate distance vision [13], with a lower incidence of postoperative halos [14], but with the poor near distance vision [15, 16]. This study found the SV25T0 had the similar UCNVA at 40 cm with SN6AD1. As indicated by the defocus curve, the focus that corresponded to the peak of near visual acuity for SV25T0 was at -2.0D. Thus, the optimal reading distance was approximately 50 cm, with a range of approximately 40-67 cm. Compared with SN6AD1 (the focus was at -2.5D, at a distance of approximately 40 cm, with a range of approximately 33-50 cm), its optimal reading distance was a little longer, which was consistent with the in vitro findings [10]. The SV25T0 lens is recommended when eyes are commonly used at intermediate distances, such as when driving (especially driving at night) or browsing the Internet. In contrast, when the eye use is typically at near distances, such as reading or doing needlework, the SN6AD1 lens may be a better choice.

**Table 4.** The characteristics of the three types of intraocular lenses

| Type of intraocular lens | SN60WF | SN6AD1 | SV25T0 |
|---|---|---|---|
| Material | Hydrophobic acrylate | | |
| Style | Aspherical lens with two loops in a piece | | |
| Function | Yellow lens with blue-ray filtration | | |
| Number of focus | Single focus | Bi-focus | Bi-focus |
| Light energy distribution | - | 84.5% | 87.4% |
| Addition power (lens plane) | - | +3.0D | +2.5D |
| Addition power (glasses plane) | - | +2.5D | +2.0D |
| Number of ladders | - | 9 | 7 |
| Diameter of the Center ladder | - | 0.86 mm | 0.938 mm |
| Focused vision of the center ladder | - | Intermediate distance | Intermediate distance |
| Spherical aberration | -0.2 μm | -0.1 μm | -0.2 μm |
| Optical section | 6.0 mm | 6.0 mm | 6.0 mm |
| Diameter of the diffraction zone | - | 3.6 mm | 3.4 mm |
| Diameter of the refraction zone | - | 2.4 mm | 2.6 mm |
| A constant | 118.7 | 118.9 | 119.1 |

The improvement in visual acuity after the implantation of the SV25T0 bifocal intraocular lens was not at the expense of visual quality. Previous studies have demonstrated that multifocal intraocular lenses improved near visual acuity. However, the visual quality was affected because of spectral effects [17]. The objective visual quality of SV25T0 was similar to that of SN60WF and SN6AD1. With sufficient light, SV25T0 can obtain the same visual quality as SN60WF. However, when the light is dim, SV25T0 become worse than SN60WF. Regardless of the lighting conditions, SV25T0 is better than SN6AD1. This difference may be related to the characteristics of the intraocular lens. Compared with SN6AD1, SV25T0 has a smaller number of ladders and a smaller-diameter diffraction zone, with a wider distribution of light energy. In this study, the degree of postoperative intraocular scattering, halos and glare were quantitatively analyzed. The extent of postoperative intraocular scattering in all three groups significantly decreased, especially for SV25T0. The SV25T0 minimized postoperative halos and glare, which showed no statistically significant difference to other groups.

The subjective visual quality rating scales used in previous studies were designed for native English speakers. The Chinese version of the VF-14 scale has been approved by the standard reliability and validity tests [18]. The subjective visual quality of SV25T0 was the better than that of SN6AD1 and SN60WF, as well as fewer adverse reactions. In other words, the patients get more comfortable feeling with the implantation of SV25T0 and further improve the quality of life compared to other two types. From this point, the SV25T0 is woth a recommendation.

Like SN6AD1 and SV25T0, SN60WF is a one-piece intraocular lens with the blue-ray filtration function. Except for a single focus, all other biological characteristics are similar to the bifocal intraocular lens. The blue-ray filtration function can reduce glare [19]. When choosing SN60WF as a control group, the impact of this feature could be controled. The basic characteristics of patients and eyes before operation were comparable, which made the results more reliable.

This study was only a preliminary exploration of the postoperative visual quality for SV25T0 with some limitations. As a single-center trial, selected bias should be considered due to the small sample size. Multi-center randomized controlled trials with large sample sizes need to be performed in the future.

In summary, our *in vivo* study found that SV25T0 allowed the patients to obtain better postperative best corrected visual acuity and visual quality, which may be recommended to use in the cataract patients.

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Regarding this report, the authors do not have any commercial or other association that would be considered a conflict of interest.

## Disclosure of conflict of interest

None.

**Address correspondence to:** Dr. Zhao-Hui Li, Department of Ophthalmology, The PLA General Hospital, No. 28 Fuxing Road, Haidian District, Beijing 100853, China. E-mail: yezi3012015@126.com

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