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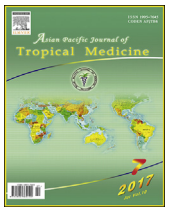

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Clinical study inpatient-reported outcomes after binocular implantation of aspheric intraocular lens of different negative spherical aberrations

Ze-Quan Xu[1,#], Xu-Hua Song[2,#], Wen-Zhe Li[3], Yan Dou[4], Qiang Wu[1✉]

[1]*Department of Ophthalmology, Shanghai Jiao Tong University Affiliated Sixth People's Hospital, No. 600, Yishan Road, Xuhui District, Shanghai, 200233, China*

[2]*Department of Ophthalmology, The First Affiliated Hospital of Hainan Medical College, No. 33, Longhua Road, Longhua District, Haikou 570102, China*

[3]*Clinical Medical College, Tianjin Medical University, No. 176, Xueyuan Road, Dagang District, Tianjin 100270, China*

[4]*Department of Foreign Languages, Hainan Medical University, No. 3, College Road, Longhua District, Haikou 571100, China*

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ABSTRACT

Objective: To compare patient-reported outcomes after implantation of the ZA9003 intraocular lens (IOLs), or the MCX11 ASP IOLs or the spherical IOLs (HQ-201HEP).
Methods: Prospective nonrandomized controlled trial was used. A total of 105 patients (210 eyes) were divided into three groups according to the type of IOLs: ZA9003 (35 patients, 70 eyes), MCX11 ASP (35 patients, 70 eyes) or HQ-201HEP (35 patients, 70 eyes). The main outcome was scores of Catquest nine-item short-form questionnaire. Additional outcome was best corrected visual acuities, spherical aberration (SA) and total higher-order aberrations (HOAs).
Results: The global score was significantly lower in the spherical IOL group than the aspherical IOL group of −020 μm SA ($P < 0.05$) and the aspherical IOL group of −027 μm SA ($P < 0.05$), and no significant difference was found in the global score between the aspherical IOL group of −020 μm SA than the aspherical IOL group of −027 μm SA ($P > 0.05$). Significant differences were also found in question 2, question 5, question 6 and question 8 between the spherical IOLs and the aspherical IOLs.
Conclusion: Implantation of an aspherical IOL could improve vision-related quality of life compared with a spherical IOL. However, there were no statistically significant differences in vision-related quality of life between aspheric IOLs with different negative spherical aberrations.

1. Introduction

Over the years, the incidence of cataract cases and the demand of a better quality of life are both increasing. Thus, the cataract surgeries techniques are evolving, as a results, better designs of intraocular lens (IOLs) used to substitute for the human lens are now available. The human cornea generally has a positive spherical aberration (SA) with a mean of (0.280 ± 0.086) μm [1]. Conventional spherical IOL could increase the positive SA after IOL implantation, to reduce the retinal image quality, whereas the advanced aspherical IOL is designed to neutralize the SA. Up to date, several aspheric IOLs are available, including the Tecnis Z9003 (SA = −0.27), MCX11 ASP (SA = −0.20). Previous studies already confirmed that a aspherical IOL neutralizes ocular SA and decreases total higher-order aberrations (HOAs) while enhancing contrast sensitivity compared with a spherical IOL [2–4]. However, what still remains controversial is the amount of residual SA: whether correcting all residual SA or remaining

First author: Ze-Quan Xu, Department of Ophthalmology, Shanghai Jiao Tong University Affiliated Sixth People's Hospital, No. 600, Yishan Road, Xuhui District, Shanghai, 200233, China.
✉Corresponding author. Qiang Wu, Department of Ophthalmology, Shanghai Jiao Tong University Affiliated Sixth People's Hospital, No. 600, Yishan Road, Xuhui District, Shanghai, 200233, China.
E-mail: qiang.Wu@shsmu.edu.cn
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# These authors contributed equally to this work.

partial SA (0.1) could provide the best postoperative visual quality. Some researchers suggested a target of 0 μm, which is the aim of Tecnis Z9003 IOL [5]. On the contrary, some researchers suggested target of 0.1 μm, which is the aim of the MCX11 ASP IOL [6], because they believed that residual SA could improve depth of focus [7]. Because the function of SA is still not completely clear and it has complex interaction with other aberrations [8], the relationship between residual SA and better visual-related quality of life is still ill-defined.

To the best of our knowledge, studies on aspherical IOLs mainly focused on conventional clinical measurements of visual function (visual acuity and contrast sensitivity). However, few studies concerned subjective visual-related quality of life. Patient-reported outcomes (PROs), the foremost representative of which is reliable and validated multi-item questionnaires [9], could directly and effectively reflect the visual-related quality of life. And Catquest nine-item short-form (Catquest-9SF) is a reliable and valid questionnaire which specifically measures the visual-related quality of life of cataract patients [10,11].

We conducted this prospective study to compare the vision-related quality of life of patients who were respectively implanted with Tecnis Z9003 IOLs, MCX11 ASP IOLs or HQ-201HEP IOLs, by using the Catquest-9SF questionnaire.

2. Subjects and methods

2.1. Patients

This prospective nonrandomized study included patients undergoing bilateral implantation of HQ-201HEP IOLs (group 1), MCX11 ASP IOLs (group 2) or ZA9003 IOLs (group 3) from September 2014 to March 2016. HQ-201HEP (HexaVision, Inc.) is a conventional spheric IOL with a positive SA, MCX11 ASP (HumanOptics Inc.) is an aspheric IOL with a negative SA (Z[4,0] = −0.20 μm) while TecnisZA9003 (AMO Inc.) is an aspheric IOL with a negative SA (Z[4,0] = −0.27 μm).

We included patients as follows: The presence of bilateral cataract, age between 60 and 80 years, corneal astigmatism <1.5 diopters. We excluded patients as follows: ocular co-pathology that may influence vision; complicated cataract (included congenital cataract); amblyopia; tremor or mobility problems causing inconvenience during slit-lamp examination; previous corneal surgery or intraocular or laser therapy. Patients who had intraoperative or postoperative complications which have influence on visual result were also excluded.

The written informed consent which was approved by the Office of Research Ethical Committee of the Shanghai Jiao Tong University Affiliated Sixth People's Hospital was obtained from all subjects. The Declaration of Helsinki was strictly followed in every step.

A total of 105 patients were recruited in this study. There were slightly more females (59%). The median age was 67 (60–87) years. Gender and age did not differ among the three groups ($P > 0.05$).

2.2. Methods

All patients had a complete ocular examination 3 d before surgery. The examination included best corrected visual acuities (BCVAs), auto-refraction (KR-1W, Topcon) and Wavefront analysis (KR-1W, Topcon) included SA and total higher-order aberrations (HOAs), intraocular pressure, fundus evaluation and PROs measured by Catquest-9SF. Post-operation assessments were performed 6 months after surgery in the second eye.

BCVAs were analyzed using logMAR. Shack-Hartmann aberrometry (KR-1W, Topcon) was used to obtain mean root mean square scores for total HOAs and SA under a 4.0 mm pupil. Data of auto-refraction under a 4.0 mm pupil were also obtained from KR-1W. Vision-related quality of life was evaluated by PROs measured with Catquest-9SF. Through explanations of the questions were given by our team member to assist the patients to complete the Catquest-9SF if the patient requested.

All operations were performed by the same surgeon using an identical technique with an interval of 1–4 weeks between the two eyes.

2.3. Statistical analysis

All data are recorded as mean ± SD, and statistical analysis was performed with SPSS 22.0 (SPSS Inc., Chicago, Illinois). The data fitted the normal distribution after the Kolmogorov–Smirnov test. ANOVA was used to evaluate differences between the three groups, and $P < 0.05$ was considered statistically significant.

3. Results

3.1. Results of BCVA, SA and HOAs

Table 1 summarizes the mean preoperative and postoperative BCVA, SA and HOAs. There were no significant differences between groups in BCVA. However, SA was significantly higher in the spherical IOL group than the aspherical IOL group of −020 μm SA ($P < 0.05$) and the aspherical IOL group of −027 μm SA ($P < 0.05$), respectively. Meanwhile, SA was significantly higher in the aspherical IOL group of −020 μm SA than the aspherical IOL group of −027 μm SA ($P < 0.05$).

HOAs were significantly higher in the spherical IOL group than the aspherical IOL group of −020 μm SA ($P < 0.05$) and the aspherical IOL group of −027 μm SA ($P < 0.05$), respectively. However, no significant difference was found in HOAs between the aspherical IOL group of −020 μm SA and the aspherical IOL group of −027 μm SA ($P > 0.05$).

3.2. Results of Catquest-9SF scores

Table 2 summarizes the mean preoperative and postoperative Catquest-9SF scores: no significant difference was found in global scores and scores of each item among the three groups.

Table 2 also summarizes the mean postoperative Catquest-9SF scores. Global score was significantly lower in the spherical IOL group than the aspherical IOL group of −020 μm SA ($P < 0.05$) and the aspherical IOL group of −027 μm SA ($P < 0.05$), and no significant difference was found in the global score between the aspherical IOL group of −020 μm SA than the aspherical IOL group of −027 μm SA ($P > 0.05$).

Significant differences were also found in question 2, question 5, question 6 and question 8 between the spherical IOL group and the aspherical IOL group.

Table 1
Summary of preoperative and postoperative BCVA, SA and HOAs.

Group	BCVA (logMAR)		SA (μm)		HOAs (μm)	
	Preoperative	Postoperative	Preoperative	Postoperative	Preoperative	Postoperative
Group 1	0.716 ± 0.162	0.021 ± 0.070	0.174 ± 0.064	0.259 ± 0.011[a]	0.220 ± 0.021	0.478 ± 0.172[a]
Group 2	0.707 ± 0.170	0.019 ± 0.087	0.184 ± 0.035	0.068 ± 0.034[b]	0.222 ± 0.018	0.183 ± 0.073[b]
Group 3	0.712 ± 0.167	0.016 ± 0.068	0.157 ± 0.044	0.020 ± 0.037[c]	0.213 ± 0.023	0.153 ± 0.079[b]

Group 1: HQ-201HEP IOL; Group 2: MCX11 ASP IOL; Group 3: Tecnis Z9003 IOL; BCVA: best corrected visual acuities (logMAR); SA: spherical aberration; HOAs: higher-order aberrations. Within the same column, different letters mean significant difference ($P < 0.05$) between groups, while the same letters mean no significant difference.

Table 2
Mean preoperative Catquest-9SF scores.

Score	Group	Preoperative	Postoperative
Global score	Group 1	17.54 ± 3.06	25.23 ± 3.48[a]
	Group 2	16.46 ± 2.90	27.49 ± 3.74[b]
	Group 3	17.49 ± 2.15	27.57 ± 4.59[b]
Score of Q1	Group 1	1.97 ± 0.89	2.71 ± 0.89
	Group 2	1.77 ± 0.84	2.83 ± 0.89
	Group 3	2.06 ± 0.72	2.91 ± 0.82
Score of Q2	Group 1	1.17 ± 0.38	2.43 ± 0.50[a]
	Group 2	1.17 ± 0.38	2.94 ± 0.48[b]
	Group 3	1.20 ± 0.41	2.91 ± 0.51[b]
Score of Q3	Group 1	2.06 ± 0.91	3.14 ± 0.77
	Group 2	1.86 ± 0.84	3.26 ± 0.74
	Group 3	2.09 ± 0.70	3.37 ± 0.69
Score of Q4	Group 1	2.06 ± 0.42	2.89 ± 0.47
	Group 2	2.11 ± 0.40	2.97 ± 0.78
	Group 3	2.09 ± 0.44	3.00 ± 0.80
Score of Q5	Group 1	1.57 ± 0.65	2.43 ± 0.50[a]
	Group 2	1.60 ± 0.65	2.83 ± 0.38[b]
	Group 3	1.49 ± 0.62	2.83 ± 0.51[b]
Score of Q6	Group 1	2.49 ± 0.78	2.83 ± 0.86[a]
	Group 2	2.20 ± 0.83	3.37 ± 0.60[bc]
	Group 3	2.40 ± 0.85	3.23 ± 0.55[ac]
Score of Q7	Group 1	1.74 ± 0.70	2.91 ± 0.89
	Group 2	1.54 ± 0.70	2.89 ± 0.87
	Group 3	1.71 ± 0.71	2.83 ± 0.89
Score of Q8	Group 1	2.03 ± 0.71	2.80 ± 0.53[a]
	Group 2	1.86 ± 0.81	3.29 ± 0.46[b]
	Group 3	2.03 ± 0.86	3.34 ± 0.59[b]
Score of Q9	Group 1	2.46 ± 0.70	3.09 ± 0.66
	Group 2	2.34 ± 0.68	3.11 ± 0.67
	Group 3	2.43 ± 0.65	3.14 ± 0.69

Group 1: HQ-201HEP IOL; Group 2: MCX11 ASP IOL; Group 3: Tecnis Z9003 IOL; Q1: vision difficulty in daily life; Q2: general vision satisfaction; Q3: read newspaper; Q4: recognize the faces of people; Q5: see prices when shopping; Q6: see to walk on uneven ground; Q7: see to do delicate work; Q8: read text on TV; Q9: see to carry on a hobby. Within the same column, different letters mean significant difference ($P < 0.05$) between groups, while the same letters mean no significant difference.

4. Discussion

The aspherical IOLs can significantly neutralize SA and largely decrease total HOAs while enhancing contrast sensitivity as previous studies already confirmed [2–4,12]. However, it is not yet conclusive on which type of aspherical IOL could bring better visual quality, among different aspherical IOL with different SA. Only a few studies measured vision-related quality of life of pseudophakic patients who were implanted aspherical IOLs, fewer studies compared vision-related quality of life using validated multi-item questionnaires.

The questionnaire we used in this study was Catquest-9SF, which has been adopted by the International Consortium for Health Outcomes Measurement (ICHOM) to specifically measure the risk factors and outcomes of cataract. Originally, Catquest-9SF was available in Swedish. Currently, Catquest-9SF was translated and culture adapted, as well as validated, in many countries [13]. Recently, it has been assessed using Rasch analysis in Chinese populations [14]. In previous studies, other questionnaires such as VF-14, NEI VFQ-25, and NEI VFQ-39 were used to evaluate visual function of aspherical IOLs. However, data on this area were rare and partly contradictory. Thus, studies utilizing an improved questionnaire instrument which is sensitive enough are needed, which was the reason we chose Catquest-9SF [15].

Preoperatively, there were no statistically significant differences between the three groups in scores of Catquest-9SF both in global scores and scores of each question. Postoperatively, global scores were significantly better in aspherical IOLs than spherical IOLs and lower SA and total HOAs in aspherical IOLs could explain for this. And aspherical IOLs can significantly reduce SA while spherical IOLs significantly induce SA, which is also consistent with the results of previous studies [2–4,12]. Similar results were also found in question 2 (general vision satisfaction), question 5 (see prices when shopping), question 6 (see to walk on uneven ground) and question 8 (read text on TV). We can safely conclude that aspherical IOLs could improve the vision-related quality of life than spherical IOLs.

Although lower SA was found in aspherical IOLs of –027 μm SA than aspherical IOLs of –020 μm SA, no significant differences were found between them in total HOAs and Catquest-9SF score. The reason behind this may be that the implantation of aspheric IOLs only changes the SA, but other aberrations (such as coma or trefoil or secondary astigmatism) are not changed, which are also important contributors to the total HOAs [4].

Some researcher insisted that total correction of SA may be harmful for near vision such as reading ability [16]; the results, however, did not repeat in other studies [17,18]. In our studies, we did not find significant differences between the two kinds of aspherical IOLs in patients' vision-related quality of life.

There were no statistically significant differences between the three groups both in preoperative and also postoperative (6th month) BCVA, which means the enhancement in visual acuity was similar in the three groups. The results are consistent with previous studies [2–4,12]. However, visual acuity alone could not fully represent the vision quality as the majority have already reached a consensus, visual acuity could only reflect a small part of vision quality [19].

Nevertheless, there are a few limitations of our study. Firstly, we didn't include another type of aspherical IOL-the design of 0 μm ZA [20] in our comparative study. Secondly, items in questionnaires that are specific to glare-related and halo-related

symptoms may be needed to detect the full benefits of subjective vision in eyes with aspherical IOLs since glare and halo are important side effects of the cataract operation [21].

In conclusive, the design of reduction of the SA itself is proved to be more significant than the actual amount of SA reduction because technically there were no significant differences between the different types of aspheric IOLs but there were significant differences between aspheric IOLs and spheric IOLs in PROs measured by Catquest-9SF.

Conflict of interest statement

All the authors have no conflict of interest.

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