

Comparison of posterior capsule folds following intracapsular implantation of three types of intraocular lenses with different haptic design

Ling-Lin Zhang, Jing Yuan, Xiao-Jun Cai

Department of Ophthalmology, Zhongnan Hospital, Wuhan University, Wuhan 430071, Hubei Province, China

Correspondence to: Xiao - Jun Cai. Department of Ophthalmology, Zhongnan Hospital, Wuhan University, Wuhan 430071, Hubei Province, China. xiaojunca168@163.com

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三种襻型人工晶状体囊袋内植入后囊膜皱褶发生率比较

张玲琳,袁景,蔡小军

(作者单位:430071 湖北省武汉市武汉大学中南医院眼科)

作者简介:张玲琳,毕业于武汉大学,硕士研究生,研究方向:白内障

通讯作者:蔡小军,毕业于武汉大学,博士研究生,主任医师,眼科主任,教授,研究方向:白内障及青光眼方向. xiaojunca168@163.com

摘要

目的:比较植入不同襻型人工晶状体(IOL)后囊膜皱褶的发生率,以确定后囊膜皱褶发生的相关风险因素。

方法:回顾性研究。收集行超声乳化白内障吸除+囊袋内IOL植入术的患者,所植入人工晶状体为两襻三片式IOL(HOYA PY60AD)、四襻一片式IOL(Bausch & Lomb AO)、两襻一片式IOL(AMO Tecnis ZCB00)中任意一种。收集纳入该研究的患者的年龄、性别、眼轴、眼压、人工晶状体类型。术后2d在裂隙灯下评估后囊膜皱褶形成情况。采用logistic回归分析确定后囊膜皱褶发生的风险指标。

结果:一共收集187例242眼,其中80眼植入HOYA PY60AD IOL,81眼植入Bausch & Lomb AO IOL,81眼植入AMO Tecnis ZCB00 IOL。植入HOYA PY60AD IOL的患眼后囊膜皱褶发生率显著高于植入AMO Tecnis ZCB00 IOL者(56.3% vs 38.3%, $P=0.027$)。植入Bausch & Lomb AO IOL的患眼后囊膜发生率显著低于植入AMO Tecnis ZCB00 IOL(14.8% vs 38.3%, $P=0.001$)。多因素logistics回归分析显示人工晶状体类型和眼轴长度是影响皱褶发生的独立风险因素。相较于AMO Tecnis ZCB00 IOL,使用HOYA PY60AD IOL提高后囊膜皱褶发生风险 [$P=0.020$, $OR(95\% CI)=2.145(1.129,4.073)$],使用Bausch & Lomb AO IOL降低后囊膜皱褶发生风险 [$P=0.001$, $OR(95\% CI)=0.274(0.127,0.591)$];眼轴越短,后囊膜皱褶发生风险越大 [$P=0.012$, $OR(95\% CI)=0.669(0.489,0.915)$]。

结论:在人工晶状体设计中,晶状体襻是重要考虑因素。相比于AMO Tecnis ZCB00 IOL,HOYA PY60AD IOL更容易出现后囊膜皱褶,Bausch & Lomb AO IOL不容易出现后囊膜皱褶;眼轴较短的患眼更容易出现后囊膜皱褶。

关键词:后囊膜皱褶;人工晶状体;人工晶状体襻;眼轴

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Abstract

• AIM: To compare the incidence of posterior capsule folds among different types of intraocular lens (IOL) to determine risk factors of posterior capsule folds.

• METHODS: It was a retrospective study. We collected the cases in which the patients underwent phacoemulsification (PHACO) and IOL implantation and at least one of the three types of IOL was implanted, including 2-haptic 3-piece IOLs (HOYA PY60AD), 4-haptic 1-piece IOLs (Bausch & Lomb AO), 2-haptic 1-piece IOLs (AMO Tecnis ZCB00). The posterior capsule folds were measured using slit lamp microscope 2d after the surgery. Information of patient's age, gender, length of ocular axis, intraocular pressure, types of IOL were recorded. Posterior capsule fold risk indicators were identified by using logistic regression analysis.

• RESULTS: One hundred eighty-seven patients (242 eyes) had been collected, including 80 eyes implanted with HOYA PY60AD IOLs, 81 eyes implanted with Bausch & Lomb AO IOLs, 81 eyes implanted with AMO Tecnis ZCB00 IOLs. The incidence of posterior capsule folds of patients implanted with HOYA PY60AD IOLs was significantly higher than those of patients implanted with AMO Tecnis ZCB00 IOLs (56.3% vs 38.3%, $P=0.027$). While the incidence of patients implanted with Bausch & Lomb AO IOLs was significantly lower than those of patients implanted with AMO Tecnis ZCB00 IOLs (14.8% vs 38.3%, $P=0.001$). Multi-factor logistics regression analysis demonstrated that independent risk factors were type of IOLs and length of ocular axis. Compared with AMO Tecnis ZCB00 IOLs, using HOYA PY60AD IOLs increased the risk of posterior capsule folds [$P=0.020$, $OR(95\% CI)=2.145(1.129,4.073)$], while using Bausch & Lomb AO IOLs reduced the risk [$P=0.001$, $OR(95\% CI)=0.274(0.127,0.591)$]. Shorter ocular axis might increase the risk of posterior capsule folds [$P=0.012$, $OR(95\% CI)=0.669(0.489,0.915)$].

• **CONCLUSION:** Haptic design should be an important consideration in IOL design. Compared with AMO Tecnis ZCB00 IOLs, using HOYA PY60AD IOLs is more likely to lead to posterior capsule folds formation, while using Bausch & Lomb AO IOLs is less likely to lead the formation. The posterior capsule folds are more engendered in eyes with shorter ocular axis.

• **KEYWORDS:** posterior capsule folds; intraocular lens; haptic design; ocular axis

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INTRODUCTION

Currently, phacoemulsification with intraocular lens (IOL) implantation is the mainstream treatment of cataract, one characteristic of which is to retain the posterior capsule^[1]. Over the past decades, continuous evolution and refined accuracy in cataract surgery has led to increased expectations of patients^[2]. In long-term clinical work, we found a phenomenon frequently that folds formed on the posterior capsule membrane in cataract patients postoperatively. The posterior capsule folds usually pass through the central area of the pupil, which formed as a single or several straight line and led to unevenness on posterior capsule. Previously studies have found Nd:YAG laser release incision of posterior capsular folds can significantly improve the visual acuity^[3-4], indicating that posterior capsular folds have direct impact on postoperative visual acuity in cataract patients. Furthermore, posterior capsular folds may have connection with the occurrence of the posterior capsular opacification^[5]. Posterior capsular folds are of great significance for the refinement of cataract surgery. However, the mechanisms of posterior capsular folds formation are still unclear.

The main focus of our study was to investigate how the different IOL loops types affect posterior capsule folds formation. In this study, three different types of IOLs were chosen: HOYA PY60AD, Bausch & Lomb AO and AMO Tecnis ZCB00, which share similar design of optical part, but differ in haptic design. We compared the incidence of posterior capsule folds among three types of IOLs. Then multivariate logistics regression analysis was conducted to determine risk factors of posterior capsule folds.

SUBJECTS AND METHODS

Patients Our retrospective study was performed at the Department of Ophthalmology, Zhongnan Hospital of Wuhan University, and was approved by the Institute Research Medical Ethics Committee of Zhongnan Hospital, Wuhan University. From August 2016 to April 2017, we collected the data of patients who had undergone phacoemulsification (PHACO) combined with IOL implantation surgery. By reviewing the medical files, records were analyzed on preoperative axial length, types of IOLs and postoperative

intraocular pressure (IOP). Inclusion criteria were the patients implanted one or two of the three types of IOLs: HOYA PY60AD (Hoya Corporation, Japan), Bausch & Lomb AO (Bausch & Lomb Incorporated, America) and AMO Tecnis ZCB00 (Abbott Medical Optics Incorporated, America). Exclusion criteria were dislocation of lens, incomplete posterior capsule (i. e. posterior capsule has coloboma or get impaired for any reason), age younger than 40y, a history of ocular disease, intraocular surgery, laser treatment, diabetes requiring medical control, glaucoma, uveitis, pseudoexfoliation and posterior segment pathology, dilated pupil diameter less than 5 mm.

Materials We chose three types of IOLs for research: HOYA PY60AD, Bausch & Lomb AO and AMO Tecnis ZCB00. The three types of IOLs have different haptic designs and other design factors are consistent, such as aspheric surface, negative spherical aberration (SA), square edge, and optic diameter of 6.0 mm. HOYA PY60AD IOL has two haptics, which are made of polymethacrylates (PMMA). Bausch & Lomb AO IOL has four haptics, which are made of acrylic. AMO Tecnis ZCB00 IOL has 2 haptics, which are made of acrylic (Table 1).

Surgical Methods All patients had standard cataract surgery performed by a single experienced surgeon (Cai XJ) using peribulbar anesthesia. A 3 mm limbus tunnel incision was made, and the anterior chamber was reformed with sodium hyaluronate 1%. A capsulorhexis was created, aiming for good centration and a 5.0 mm diameter. The nucleus was removed by PHACO-chop technique under Alcon ultrasonic emulsification system (Alcon Laboratories Incorporated, America) and lens cortex was removed by irrigation/aspiration (I/A) with balanced salt solution (BSS). Lens epithelial cells (LECs) were cleared by polishing posterior capsule and no attempt was made to remove LECs by polishing the anterior capsule. The bag was reformed with viscoelastic agent and the section enlarged, then IOL was implanted in the bag. The viscoelastic agent was removed by I/A with BSS. Surgical complications such as posterior capsular rupture led to patient exclusion.

Assesment of Posterior Capsule Folds Postoperatively, all patients used pranoprofen drops and tobramycin and dexamethasone drops 4 times a day. Patients were examined 2d after surgery. We used tropicamide - phenylephrine ophthalmic solution for dilating pupils, then observed posterior capsule under the slit-lamp microscope when pupil diameter was between 5-6 mm. The criterion of posterior capsule folds is observable linear fold on the central 5 mm zone of posterior capsule. The observations and records were done by a single researcher (Zhang LL).

Data Analysis In our study, *P* values below 0.05 were considered statistically significant. We performed the statistical analysis using the SPSS (version 21.0).

RESULTS

The Basic Characteristics of Patients We observed 242 eyes (187 patients) that matched inclusion and exclusion criteria. There were no complications during and after the

Table 1 Brief introduction of the three intraocular lens

Parameters	HOYA PY60AD	Bausch & Lomb AO	AMO Tecnis ZCB00
Optical characteristics	Aspheric surface/negative SA	Aspheric surface/negative SA	Aspheric surface/negative SA
Optic diameter	6 mm	6 mm	6 mm
Edge design	360°polish square edge	360°polish square edge	360°polish square edge
IOLs length	12.5 mm	10.5–11.0 mm	13 mm
Angle between optic and haptics	5°	0°	5°
IOLs material	Hydrophobic acrylic	Hydrophilic acrylic	Hydrophobic acrylic
Number of haptic	2	4	2
Material of haptic	Polymethyl methacrylate	Acrylic	Acrylic

IOL: Intraocular lens.

Table 2 The basic characteristics of patients implanted with different IOLs

Parameters	HOYA PY60AD	Bausch & Lomb AO	AMOTecnis ZCB00	χ^2	<i>P</i>
Age (y)					
≤70	32	38	31	1.392	0.59
>70	48	43	50		
Sex					
M	35	36	30	1.11	0.57
F	45	45	51		
IOP(mm, $\bar{x} \pm s$)	13.26±0.39	13.48±0.36	13.47±0.34	0.58	0.94
Axial length (mm, $\bar{x} \pm s$)	23.68±0.11	23.69±0.10	23.66±0.10	0.016	0.98
Total	80	81	81	-	-

IOL: Intraocular lens; IOP: Intraocular pressure.

Table 3 Comparison of posterior capsule folds incidences

IOLs	<i>n</i>	Posterior capsule folds		χ^2	<i>P</i>
		Positive (%)	Negative (%)		
HOYA PY60AD	80	45 (56.3)	35 (43.8)	5.220 ^a	0.027
Bausch & Lomb AO	81	12 (14.8)	69 (85.2)	11.429 ^a	0.001
AMO Tecnis ZCB00	81	31 (38.3)	50 (61.7)	-	-

IOL: Intraocular lens; ^aCompared with the incidence of posterior capsule folds in patients with AMO Tecnis ZCB00.

cataract surgery. Among 242 eyes underwent PHACO and implanted with IOLs, 80 eyes of 59 patients implanted with HOYA PY60AD IOLs, 81 eyes of 59 patients implanted with Bausch & Lomb AO IOLs, 81 eyes of 69 patients implanted with AMO Tecnis ZCB00 IOLs. The basic characteristics of patients are summarized in Table 2. Clinical factors were analysed through Chi-square test and one-way ANOVA. There was no statistical significance among the patients who implanted different IOLs ($P>0.05$).

Comparison of Posterior Capsule Folds Incidences The measurement of posterior capsule folds was obtained at 2d postoperatively. Observed formation of posterior capsule folds was considered positive. Among the patients implanted HOYA PY60AD IOLs, 45 eyes out of 80 eyes (56.3%) formed posterior capsule folds. The positive rate of the patients implanted Bausch & Lomb AO IOLs is 14.8% (12 out of 81). The positive rate of the patients implanted AMO Tecnis ZCB00 IOLs is 38.3% (31 out of 81). Chi-square test analysis showed the difference between positive rate of patients implanted AMO Tecnis ZCB00 IOLs and that of patients implanted HOYA PY60AD IOLs was statistically significant, also, the difference between positive rate of patients implanted AMO Tecnis ZCB00 IOLs and that of patients implanted Bausch & Lomb AO IOLs was statistically significant.

Table 4 Multivariate logistics regression analysis

Factors	Logistics analysis	
	<i>P</i>	OR(95% CI)
Sex	0.941	-
Age	0.160	-
Axial length	0.012	0.669(0.489,0.915)
IOP	0.818	-
HOYA PY60ADIOL	0.020	2.145(1.129,4.073)
Bausch & Lomb AOIOL	0.001	0.274(0.127,0.591)

IOP: Intraocular pressure; IOL: Intraocular lens.

Multivariate Logistics Regression Analysis Furthermore, multivariate logistics regression analysis was conducted to determine risk factors of capsule folds. We compared all the positive cases and negative cases from the factors including age, sex, axial length, IOP and IOLs types. The results demonstrated that IOLs types and axial length were independent risk factors. Compared with AMO Tecnis ZCB00 IOLs, using HOYA PY60AD IOLs increases the risk of posterior capsule folds [$P=0.020$, OR (95% CI) = 2.145 (1.129, 4.073)], while using Bausch & Lomb AO IOLs reduces the risk [$P=0.001$, OR (95% CI) = 0.274 (0.127, 0.591)]. Shorter ocular axis may increase the risk of

posterior capsule folds [$P = 0.012$, $OR (95\% CI) = 0.669 (0.489, 0.915)$].

DISCUSSION

Posterior capsule fold is a common phenomenon after PHACO combined with IOLs implantation^[6]. Accumulated evidences have indicated posterior capsule folds have impact on postoperative visual acuity of cataract patients. It impedes the perfection process of cataract surgery and Nd: YAG laser release incision of posterior capsular folds causes additional financial burden for patients. However, the mechanism of posterior capsular folds formation remains largely unclear.

In this study we explored the connection between posterior capsule folds and IOLs haptic design. The positive rate of patients implanted with HOYA PY60AD IOLs (56.3%) is significantly higher than that of patients implanted with AMO Tecnis ZCB00 IOLs (38.3%). HOYA PY60AD IOL and AMO Tecnis ZCB00 IOL both have two lens haptics. This result may be explained by the different material of the two types of IOL haptics. HOYA PY60AD IOL haptics are made of PMMA and AMO Tecnis ZCB00 IOL haptics are made of acrylic acid. Compressive resistance of PMMA is close to 7 times than that of acrylic acid^[7-8]. More compressive resistive IOL haptics lead have higher pressure on the contact point between IOL and the lens capsule^[5], thus leading to greater tension on posterior capsule between the two contact points. Insufficient pressure of contact between haptics and capsular bag leads to unstable fixation^[9] while high pressure on the contact point stretching of the capsular bag leading to the formation of posterior capsule folds^[10]. This result of our study is consistent with previously study, which showed using MA60BM IOLs (haptics made of PMMP) increases the incidence of posterior capsular folds compared with SA30AL IOLs (haptics made of acrylic acid)^[11]. Our study had a larger sample and provided a stronger evidence for the connection between posterior capsular fold and haptic material. What's more, the IOLs explored in this study are frequently used currently and provide suggestion for surgeons in the selection of intraocular lenses.

Among the patients implanted Bausch & Lomb AO IOLs, 12 eyes out of 81 eyes (14.8%) formed posterior capsule folds, incidence of which is significantly lower than that of AMO Tecnis ZCB00 IOL. Both of the two types of IOLs have haptic made of acrylic acid. However, AMO Tecnis ZCB00 IOL has two haptics while Bausch & Lomb AO IOL has four haptics. Compared with two-haptics IOL, four-haptics IOL leads to the pressure on the capsule bag being dispersed. For this reason, it is more difficult to form posterior capsule folds. Similar result has been achieved by previous study^[12], which found incidence of posterior capsule folds of patients with four-haptics IOLs is lower than that of patients with two-haptics IOLs. In this study, among patients with four-haptics IOLs, none of the patients formed posterior capsule folds one day postoperatively. In our research, patients with Bausch & Lomb AO IOLs have the lowest incidence, but posterior capsule folds still formed in 14.8% of the patients. The

reason for the discrepancy may be derived from the differences of case screening criteria and posterior capsule folds assessment. In our study, we have a stricter inclusion criteria and exclusion criteria. The observer who evaluated the capsule folds cannot be completely blinded off the information of implanted IOLs. So this limitation should be also taken into consideration.

Furthermore, though multivariate logistics regression analysis, IOLs types and axial length were identified as independent risk factors. Using HOYA PY60AD IOL and shorter ocular axis increase the risk of posterior capsule folds. The ocular axis can indirectly reflect the size of the lens capsule; the shorter the ocular axis, the smaller the capsular bag^[13]. For patients with smaller capsular bag, the IOL haptics are relatively larger, thus generate greater force on the bag, which may cause the posterior capsular folds. Therefore, even if implanted with the same types of IOL, patients with shorter ocular axis more likely to form posterior capsular folds.

Posterior capsular folds may have bad impact on cataract surgery effect and reduce patient satisfaction postoperatively. First, it interferes with the normal ocular refractive system. Light travelling through eye depends a complex optical system. Homogeneity of light refraction of the optical system is related with the distances between components and the overall focal length of an optical system^[14]. The existence of posterior capsular folds increases unevenly the distance between the posterior capsule membrane and IOL, thus result in an abnormal light refraction in optical system of the eye^[15]. The presence of scattered light in the field of vision leads to disability glare^[16]. Visual quality questionnaire survey showed disability glare is the chief and most annoying postoperative complaint of patients^[17]. Second, previous study indicated that posterior capsular opacification (PCO) is related with posterior capsular folds. Six months after implantation of Hydroview H60M IOLs, 46% patients formed posterior capsular folds, the direction of which is consistent with the emergence of the LECs proliferation^[8]. A recent study shows that existence of multiple striae persisting in patients beyond 6mo after operation is a contributing factor leading to the PCO development^[18]. In this study, the rate of posterior capsule folds is lower in Bausch & Lomb AO IOL, which is hydrophilic acrylic IOL, than HOYA PY60AD IOL and AMO Tecnis ZCB00 IOL, which are hydrophobic acrylic IOLs. Accumulated evidences have proved that the rate of PCO is higher in hydrophilic IOLs than in hydrophobic acrylic IOLs^[19-20]. It is reasonable to speculate that the difference may result partly from less posterior capsule folds occurrence in hydrophobic acrylic IOLs. The process of PCO starts from proliferation and migration of LECs^[21]. Currently, the square angle design make the capsular membrane tightly wrap around the rim of the intraocular lens, thus forming a discontinuous sharp bend on capsular membrane and blocking the migration of epithelial cells^[22-23]. However, the existence of posterior capsular folds leaves a space between capsular membrane and IOL. This space provides channel for proliferation and

migration of lens epithelial cell, which finally develop into PCO. Therefore, posterior capsular folds will have bad influence on cataract surgery outcome. Haptic design should be an important consideration in IOL design and the research about the mechanism of its formation are urgently needed.

Our study introduced a new direction for further research of cataract surgery and provided evidences for selection of IOLs. Compared with AMO Tecnis ZCB00 IOLs, using HOYA PY60AD IOLs is more likely to lead to posterior capsule folds formation, while using Bausch & Lomb AO IOLs is less likely to lead the formation. The posterior capsule folds were less engendered in eyes with longer ocular axis. The stabilities of the three types of IOLs have no statistical difference^[8,24]. In order to minimize the risk of posterior capsule folds occurrence, Bausch & Lomb AO IOL is a better choice than HOYA PY60AD IOL and AMO Tecnis ZCB00 IOL.

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