Visual Acuity in Patients Having Foldable and Non-foldable Intra-ocular Lens for Cataract Surgery

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Background: *Intra-ocular lens (IOLs) is the most commonly use organ substitute worldwide. Question of different type of IOLs which would offer different post operative visual acuity (VA) has been asked.*
Objectives: *To compare the pre-operative and post operative visual acuity (VA) of cataract patients operated-patient and the use of non foldable and foldable IOLs in different age groups.*
Method: *Retrospective study of post operative VA of cataract patients-operated from Priest, Lerdsin Hospital in Bangkok and Lampang Hospital in northern part of Thailand. Methods to operate and type of IOLs implantation were recorded. The cases with pre-operative and intra-operative complications were excluded.*
Results: *Post operative VA of cataract patients was better than pre-operation VA with statistically significant at p-value less than 0.05 and the results persisted for every age group. With phacoemulsification (PE) techniques, non-foldable IOLs offered better post operative VA than foldable IOLs in every age group except in age group of less than 40 and age group over 59 that showed statistically significant different at p-value less than 0.05 .*
Conclusion: *Due to the nature of retrospective study, the cause of poor post operative VA was due to astigmatism which the pre-operative astigmatism were not recorded to fulfill complete analysis.*

Keywords : *Intra-ocular lens(IOL), Foldable IOLs, Non-foldable IOLs, Decimal visual acuity, LogMar visual acuity*

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Cataract accounts for 50% of blindness globally and remain the leading cause of visual impairment in all regions of the world. This number is expected to rise due to an aging population and increase in life expectancy[1].According to the National Survey of Blindness in Thailand conducted in 1984, 1987 and 1994[2], cataract was also major cause of blindness in Thailand. Despite improvements in surgical outcome led to increase surgical volume, its prevalence was less but still present high number of cataract backlog[3]. Ministry of Public Health (MOPH) and National Health Security Office (NHSO) conducted regular services and launched the intervention program continuously with complete coverage and good quality of care as international standard. Although cataracts are not preventable, their surgical treatment is one of the most cost-effective interventions in healthcare. For cataract extraction, conventional aphakic spectacles were replaced by IOLs. From New Zealand survey in 2000 and 2003[4] revealed that 65 % of IOLs used were one

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piece foldable type. IOLs were compulsory in Thailand since 1989[5] and provided without charge to the patients with the health card (universal coverage-UC), the social security patients (Ministry of Labor) and government personnel and their parent (Comptroller General Department of Ministry of Finance). The normal rigid IOLs cost less than 3,000 Baht ($85) and the foldable IOLs cost 4,000-8,000 Baht ($114-228). Therefore, it has been questioned whether the different type of IOL would affect the post operative VA. Previous study[6,7] about quality of life (QOL) and quality of vision of cataract patients receiving different price IOLs were done. In Thailand, the study revealed some difference in quality of vision[8]. Higher price IOLs did not offer better QOL.

The International Health Policy Program (IHPP) is responsible for providing health economic information to policy makers in MOPH and NHSO to allocate limited resources most cost effectively.

Objective

IHPP worked with the Committee of Eye Health Promotion of MOPH to conduct a study to comparing the post operative VA of cataract patients operated with IOLs implantation; rigid non-foldable IOLs were compared with foldable IOLs.

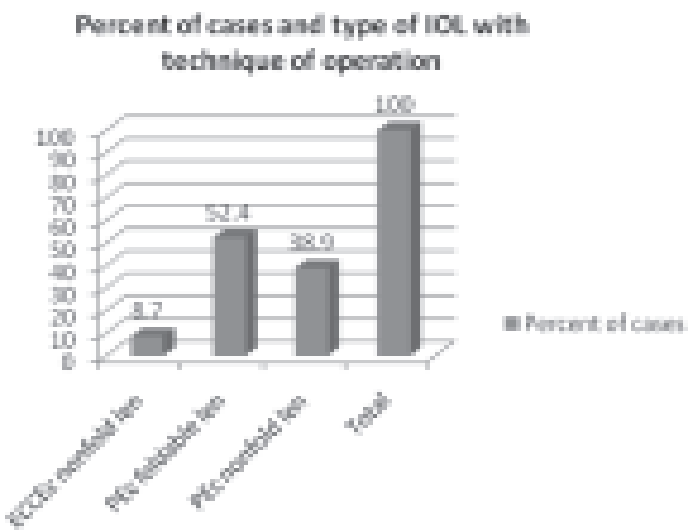

Fig. 1 Percent of cases and type of IOLs with technique of operation

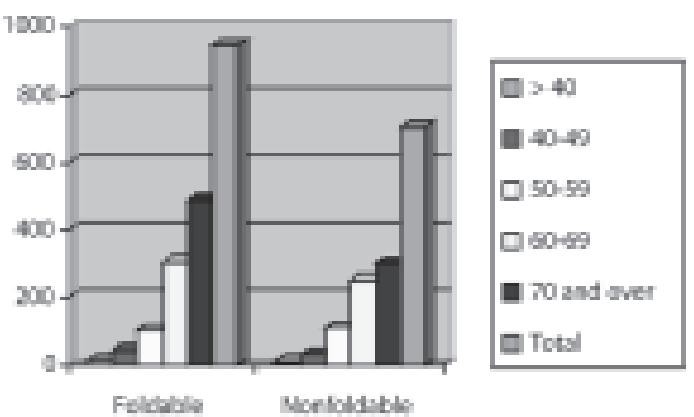

Fig. 2 Age group of PE patients with type of IOLs using

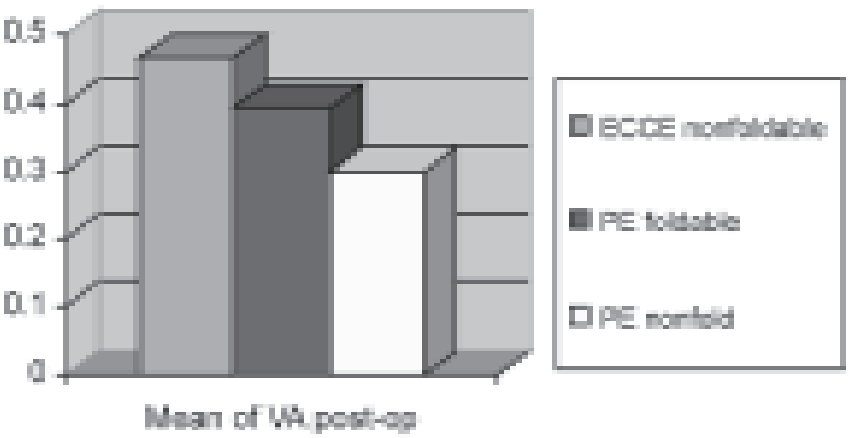

Fig. 3 Mean post-operative VA (in LogMar) of ECCE with non-foldable IOL, PE with foldable IOL, PE with non-foldable IOL (1,807 cases)

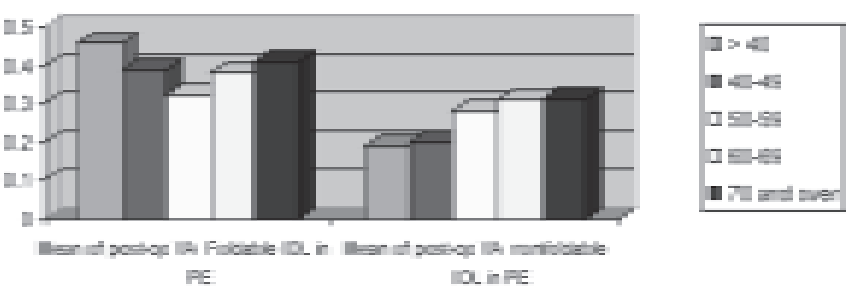

Fig. 4 Mean of post-operative VA in LogMar of cataract patients under gone PE in different age group (1,649)

Table 1. Age, sex distribution, techniques of cataract operation and IOLs used in patients from Priest, Lerdsin and Lampang Hospital

Age range (years)	Male			Female			Total	Percent
	ECCE with non-foldable IOLs	PE with foldable IOLs	PE with non-foldable IOLs	ECCE with non-foldable IOLs	PE with foldable IOLs	PE with non-foldable IOLs		
Less than 40	2	10	6	0	2	4	24	1.33
40-49	7	35	17	0	7	13	79	4.37
50-59	10	80	54	8	20	56	228	12.62
60-69	33	244	114	16	60	136	603	33.37
70 and over	58	386	112	24	102	191	873	48.31
Total	110	755	303	48	191	400	1807	100.00

Table 2. Mean VA (in LogMar unit) of ECCE with non-foldable IOL, PE with foldable IOL, PE with non-foldable IO(L (1,807 cases)

Operation and IOLs using	Mean VA	95% Confidence interval		Standard deviation	Standard error of mean	Kruskal-Wallis	
		Lower	Upper			Median VA	Interqualite range
ECCE, nonfoldable IOLs	0.4673 (VA = 20/59)	0.4219	0.5128	0.28920	0.02301	0.4200	0.3300
PE, foldable IOLs	0.3916 (VA = 20/49)	0.3739	0.4097	0.28306	0.00920	0.3000	0.3700
PE, nonfoldable IOLs	0.3000 (VA = 20/39)	0.2838	0.3101	0.21821	0.00823	0.2200	0.2400

Table 3. Tests of normality of LogMar curves in Table 2

Type of operation and IOL	Kolmogorov - Smirnov[a]			Shapiro - Wilk		
	Statistic	Df	Sig.	Statistic	Df	Sig.
E CC E c̄ nonfoldable IOL	0.223	158	.000	0.826	158	.000
PE c̄ foldable IOL	0.172	946	.000	0.803	946	.000
PE c̄ nonfoldable IOL	0.225	703	.000	0.839	703	.000

a Lilliefors Significance Correction

Table 4. Comparison means of post-operative VA (in LogMar) of ECCE with non-foldable IOL, PE with foldable IOL, PE with non-foldable IOL with Kruskal-Wallis Test

	Cataract surgery and IOL	Number	Mean Rank
LogMar	ECCE with nonfoldable IOL	158	1126.63
	PE with foldable IOL	946	957.89
	PE with nonfoldable IOL	703	781.45
	Total	1807	

Method

Retrospective study of cataract patients operated from Priest , Lerdsin and Lampang Hospital during May 2005-July 2005. Techniques of operation, type of IOLs used and post operative VA were recorded. End point of the study was 6 months post operative VA. The exclusion criteria was applied to the patients with co-morbidity as hypertension, diabetes, cardio-vascular diseases and major eye diseases of glaucoma,

Table 5. Test Statistics(a,b)

	LogMar
Chi-Square	80.395
df	2
Asymp. Sig.	.000

a Kruskal Wallis Test
b Grouping Variable: cataract studied

Table 6. Mean of post-operative VA in LogMar of cataract patients undergone PE in different age group (n = 1,649)

Age range (year)	Procedure	n	Mean post-op VA	95% Confidence interval		Standard deviation	Standard error of mean
				lower	upper		
Less than 40	PE with foldable IOL	12	0.4583(VA=20/57)	0.2603	0.6564	0.31171	0.08998
	PE with non-foldable IOL	10	0.1900(VA=20/30)	0.0763	0.3037	0.15895	0.05027
40 - 49	PE with foldable IOL	42	0.3890(VA=20/50)	0.2199	0.5582	0.54281	0.08376
	PE with unfoldable IOL	30	0.1973(VA=20/31)	0.1120	0.2827	0.22855	0.04173
50 - 59	PE with foldable IOL	100	0.3199(VA=20/41)	0.2734	0.3664	0.23415	0.02341
	PE with non- foldable IOL	110	0.2803(VA=20/38)	0.2317	0.3289	0.25726	0.02453
60 - 69	PE with foldable IOL	304	0.3813(VA=20/48)	0.3531	0.4094	0.24902	0.01428
	PE with non- foldable IOL	250	0.3092(VA=20/41)	0.2810	0.3375	0.22673	0.01434
70 and over	PE with foldable IOL	488	0.4114(VA=20/52)	0.3867	0.4361	0.27772	0.01257
	PE with non-foldable IOL	303	0.3132(VA=20/41)	0.2915	0.3349	19184	0.01102

Table 7. Test of Normality distribution of LogMar post-operative VA of cataract patients after PE in different age groups

Age range (year)	IOL	n	Kolmogorov - Smirnov[a]		Shapiro - Wilk	
			statistic	significant	statistic	significant
Less than 40	Foldable	12	0.218	0.121	0.910	0.216
	Non - foldable	10	0.184	0.200*	0.884	0.145
40-49	Foldable	42	0.264	0.000	0.636	0.000
	Non - foldable	30	0.206	0.002	0.801	0.000
50-59	Foldable	100	0.215	0.000	0.842	0.000
	Non - foldable	110	0.233	0.000	0.831	0.000
60-69	Foldable	304	0.150	0.000	0.880	0.000
	Non - foldable	250	0.248	0.000	0.791	0.000
70 and over	Foldable	488	0.192	0.000	0.800	0.000
	Non - foldable	303	0.221	0.000	0.854	0.000
	Total	1,649				

*This is a lower bound of the tree significant , a Lilliefors significance correction

diabetic retinopathy, age-related macular degeneration, corneal diseases and scar including posterior capsule opacity that cause subnormal post operative VA. Cataract cases with complications during operation as rupture posterior capsule or post operative complications as IOL decentation and corneal edema were also excluded. The reasons for poor post- operative VA were recorded. Data analysis using mean, percentage, student t-test, Mann-Whitney test was done.

Results

There were 1,807 cataract patients operated from Priest , Lerdsin and Lampang Hospital. The age range was 15-95 years with mean of 67.44 years and standard deviation of ± 10.006 years. IOLs were used in three groups:

1) Extra-capsular Cataract Extraction (ECCE) with rigid non foldable IOLs 158 patients

2) Phacoemulsification (PE) with rigid non foldable IOLs 703 patients

3) PE with foldable IOLs 946 patients

The age group, sex distribution and the method used for operating cataract including type of IOLs using were shown in Table 1. To compare post-operative VA, the LogMar VA system was used. Com-

parison between non foldable and foldable IOLs were done only in 1,649 patients operated by PE. Foldable IOLs were used more than non foldable IOLs (946:703 or 1.34:1). The results showed that the mean post-operative VA with non foldable IOL were better than foldable IOL with normality of LogMar curve (Table 2, 3, 4, 5). These were correlated with mean post-operative VA in every age group(Table 6).The test for normality of the curve of LogMar post-operative VA was done and showed that only the post operative VA in LogMar of age group less than 40 years old had normal curve (Table 7,8) which meant that post operative VA (in LogMar) can be compared with t-test (Table 9) which proved to be statistical significant different and the group with non-foldable lens had better post operative VA at p- value less than 0.05. In other age

Table 8. Compare mean of post-operative VA in LogMar of patients operated by PE with foldable and nonfoldable in age group less than 40 with t – test.

	PE with IOL	n	Mean	Std. Deviation	Std. Error Mean
LogMar	age <40 PE c foldable len	12	.4583(VA=20/57)	.31171	.08998
	age <40 PE c nonfoldable len	10	.1900(VA=20/30)	.15895	.05027

Table 9. Test for equality of mean

		Levene's Test for Equality of Variances		t-test for equality of means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
LogMar	Equal variances assumed	3.578	.073	2.462	20	.023	.2683	.10900	.04096	.49571
	Equal variances not assumed			2.603	16.922	.019	.2683	.10307	.05080	.48587

Table 10. Compare post-op VA in LogMar in each age group between patients operated by PE with foldable IOL and non foldable IOL using non parametric test, 2 independent Mann-Whitney

Age range (years)	IOL	Mean rank	Sum of ranks	Mann-Whitney	Wilcoxen	Z	Asymp Sig (2 tailed)
40 – 49	Foldable	39.93	1678.00	485.000	950.000	-1.697	0.090
	Non foldable	31.67	950.00				
50 – 59	Foldable	111.97	11197.50	4852.500	10957.500	-1.510	0.131
	Non foldable	99.61	10957.50				
60 - 69	Foldable	299.74	91120.50	31239.500	62614.500	-3.683	0.000
	Non foldable	250.46	62614.50				
70 and over	Foldable	426.37	208066.50	59113.500	105169.50	-4.827	0.000
	Non foldable	347.09	105268.50				

groups the LogMar VA post operation showed abnormal curves, so Mann Whitney test was used in every age group (Table 10). The results showed that the 40-49 years old and 50-59 years old group had better VA of non-foldable but no statistically significant difference. In contrast to the 60-69 years old and 70 years old or older age groups showed different post operative VA between non-foldable and foldable IOL and that the non-foldable was better with statistically significant p-value of less than 0.05. Overall speaking, the group using non-foldable IOL had better post operative VA than foldable IOL with statistically significant differences in the group of age range less than 40 and the group of age range over 59. One cause of poor post operative VA was suspected from astigmatism .

Discussion

Because the study was retrospective, the pre-operative astigmatism was not recorded. According to the PE surgeons, the most common and easiest PE incision is clear corneal incision in temporal part, 2.7-4.0 mm wide. A grooved or biplanar incision is theoretically more watertight, which some surgeons believe is more likely to affect astigmatisms. The deeper the vertical groove, the more likely it is to flatten the cornea in the meridian[9]. Ozkurt *et al*[10] stated that the surgically induced astigmatism was lower in the temporal incision group than in the nasal incision group so they preferred superotemporal incision. Most of the phaco-surgeons in Thailand prefer clear corneal temporal incision. Using non-foldable IOL, an incision has to enlarge to 5-5.5 mm and one or more stitches had to apply to close the wound. Using foldable IOL, the original incision size is wide enough to put the foldable IOL and the surgeon preferred not to put the suture to close the temporal incision. From post operative refraction record revealed that the reasons for the poor post operative VA (less than 20/20) in this study was mostly from astigmatism and followed by mild myopic setting. The temporal wound closure was expected to cause less post-surgically astigmatism and created better post operative VA and another reason explaining post-surgically astigmatism was rotation after implantation of IOLs which were common in 3 pieces IOLs but unusual for the intact posterior capsule[11].

In the aging group, the astigmatic pattern is with the rule with the steep meridian in 90°; if they were operated at temporal part with wound closure by suture, the astigmatism will be less. So using non foldable IOLs with wound suture offer better VA. In the middle age group (40-49,50-59 years old) their astigmatism were less so to operate at temporal part without suture cause some astigmatism (more flat in 180°). If the stitch was applied, it caused less flattening so post operative VA of foldable and non-foldable IOL were not different.

However, using foldable IOL is more convenience and favorable for phaco-surgeons due to their take less surgical time. Although this study showed better post operative VA in some age groups using non- foldable IOLs, to stitch was time consuming and more resource-intensive (injectable replaced topical anesthesia and suture costs), so it was non-preferable by some phaco-surgeon. Posterior capsular opacity (PCO) was another cause of decrease post operative VA. By comparing among different type of foldable IOL, PCO was higher in an IOL type of incomplete sharp edge at the optic-haptic junctions which representing a step for cell growth[12]. Foldable IOLs are known to reduce PCO by preventing migration of lens epithelial cells with its square edge design and its property of tackiness[12]. Studies have reported a mean adhesiveness to posterior capsule more than three times higher for certain acrylic foldable IOLs than polymethyl methacrylate IOLs. However PCO which more than 2^{+} were in the exclusion criteria, but mild PCO could cause decrease post operative VA. In this study, no specific type of IOLs was asked in the questionnaire except foldable or non foldable. At this time in Thailand, new types of aspheric, accommodative or photochromic foldable IOL[13] are starting, each IOL implantation lead to equivalent VA but different color perception and contrast sensitivity. Regular foldable IOLs have both monofocal and multifocal type. There was a study[14] showed that monofocal IOL implantation suffer from significant higher order spherical aberrations, responsible by the optical design and the dioptric power of the IOL.

Multifocal IOLs are preferred by some ophthalmologists, which caused less price of monocular foldable IOL. One point that PE surgeon should keep in mind is that post operative endoph-thalmitis[15,16] is an emerging problem all over and one risk factor is sutureless surgery[17]. Using non foldable IOL and put suture will cost less expense and decrease risk of endophthalmitis at the same time. If the ophthalmologists accept that foldable IOL provides the good visual outcomes but will only be accessible to our countries if their cost would decrease.

For further study to compare the post operative VA of using foldable and non-foldable IOL, the pre-operative astigmatism and the specific type or

brand of IOLs should be recorded. Cataract incision with astigmatic correction should be done with the record of type of wound closing will be made possible to evaluate clearly the effect of foldable and non-foldable IOLs.

Conclusion

Post operative VA of cataract patients was better than pre-operation VA and the result persisted for every age group. With phacoemulsification (PE) techniques, non-foldable IOLs offered better post operative VA than foldable IOLs in every age group except in age group of less than 40 and age group over 59 that showed statistically significant differences.

Recommendation to health administrators and policy makers

IOL is the most commonly used organ substitute in the world. It improves quality of life of the aging population, making for independent and productive living. To make the IOLs'price lower is a mandate for health administrators and policy makers.

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ระดับสายตาของผู้ป่วยหลังผ่าตัดต้อกระจกที่ใส่เลนส์ (แก้วตา)เทียม ชนิดพับและไม่พับ

ศุภลักษณ์ รายวา, สมชาย สมัยพร เสริมพงษ์ ศิริกุล, วัฒนีย์ เย็นจิตร, ฉวีวรรณ เย็นจิตร, มงคล ทะปัญญา

ภูมิหลัง *: ตามมาตรฐานและแนวทางการดูแลรักษาของกระทรวงสาธารณสุข และราชวิทยาลัยจักษุแพทย์แห่งประเทศไทยกำหนดว่า ผู้ป่วยหลังผ่าตัดต้อกระจกทุกคนต้องใส่เลนส์(แก้วตา)เทียมทดแทน เพื่อที่จะมองเห็นได้ดี เลนส์เทียมที่จำหน่ายในประเทศไทยมีหลายชนิด และมีราคาแตกต่างกันมาก จึงมีปัญหาสงสัยว่าเลนส์เทียมที่ชนิดต่างกัน และราคาต่างกันจะทำให้การมองเห็นของผู้ป่วยหลังผ่าตัดต้อกระจกแตกต่างกันหรือไม่*

วัตถุประสงค์ *: คณะทำงานส่งเสริมสุขภาพตาของกระทรวงสาธารณสุขและสำนักพัฒนานโยบายสุขภาพระหว่างประเทศ จึงทำการศึกษาเปรียบเทียบการมองเห็นของผู้ป่วยที่ใส่เลนส์เทียมแบบพับและไม่พับโดยวิธีการผ่าตัดสลายต้อกระจกด้วยการใช้คลื่นเสียงความถี่สูง*

วัสดุและวิธีการ *: ศึกษาย้อนหลังในผู้ป่วยที่ได้รับการสลายต้อกระจกจำนวน 1,649 รายจากโรงพยาบาลสงฆ์ เลิดสิน และลำปาง ดูประวัติวิธีผ่าตัดและเลนส์(แก้วตา)เทียมที่ใช้ ดูระดับสายตาหลังผ่าตัดที่ระยะ 6 เดือน ผู้ป่วยที่มีปัญหาโรคของกระจกตา โรคของจอประสาทตาและน้ำวุ้น รวมทั้งมีภาวะแทรกซ้อนขณะผ่าตัด และหลังผ่าตัด จะถูกตัดออกจากการศึกษา*

ผลการดำเนินการ *: พบว่าการใส่เลนส์เทียมชนิดไม่พับ จะมองเห็นดี (VA=20/39) กว่าใส่เลนส์พับ(VA=20/49) ในทุกกลุ่มอายุ ในกลุ่มผู้ป่วยอายุน้อยกว่า 40 ปี และกลุ่มอายุมากกว่า 59 ปี จะแตกต่างอย่างมีนัยสำคัญทางสถิติที่ p-value น้อยกว่า 0.05 ส่วนกลุ่มอายุ 40-59 ปี การใช้เลนส์ใส่เลนส์ไม่พับจะมองเห็นดีกว่าใส่เลนส์พับเช่นกัน แต่ไม่มีความแตกต่างกันอย่างนัยสำคัญทางสถิติที่ p-value น้อยกว่า 0.05 สาเหตุอาจเกิดจากการมีสายตาเอียง เนื่องจากเมื่อผ่าตัดแบบใส่เลนส์พับ จักษุแพทย์มักไม่นิยมเย็บแผลผ่าตัดที่กระจกตา*

สรุป *: เนื่องจากเป็นการศึกษาแบบมองย้อนไปด้านหลัง จึงไม่ได้วัดความเอียงของสายตาก่อนผ่าตัดในผู้ป่วยทุกคน จึงไม่สามารถสรุปได้ว่าสายตาเอียงหลังผ่าตัดมีมาตั้งแต่ก่อนผ่าตัดหรือเกี่ยวข้องกับรูปแบบการผ่าตัดและชนิดของเลนส์เทียมที่ใช้ได้ชัดเจน และเนื่องจากเลนส์เทียมชนิดพับแม้จากการศึกษาจะมองเห็นไม่ดีเท่าเลนส์เทียมชนิดไม่พับ แต่เป็นที่นิยมของจักษุแพทย์ ผู้บริหารจึงสมควรทำให้มีเลนส์เทียมชนิดนี้มีราคาลดลง เพื่อจะได้ใช้แพร่หลายและสามารถประเมินผลได้ชัดเจนมากขึ้น*