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Efficacy comparison between rigid and foldable anterior iris-fixated phakic intraocular lens implantation for treating high myopia in Asian eyes

Nia Milastuti, Indra Tri Mahayana, Suhardjo, Agus Supartoto

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Department of Ophthalmology, Faculty of Medicine, Public Health and Nursing-Dr.Sardjito General Hospital, Yogyakarta 55162, Indonesia

Correspondence to: Indra Tri Mahayana. Department of Ophthalmology, Faculty of Medicine, Public Health and Nursing - Dr. Sardjito General Hospital, Yogyakarta 55162, Indonesia. tri.mahayana@gmail.com

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硬性和可折叠前虹膜固定人工晶状体植入治疗亚洲眼高度近视的疗效比较

Nia Milastuti, Indra Tri Mahayana, Suhardjo, Agus Supartoto
作者单位:(55162)印度尼西亚日惹,Dr.Sardjito 综合医院眼科
通讯作者:Indra Tri Mahayana.tri.mahayana@gmail.com

摘要

目的:比较 Artisan 和 Artiflex 有晶状体眼人工晶状体(PIOL)矫正亚洲人群高度近视的屈光度和安全性。

方法:历史队列研究。回顾 2016/2020 在印度尼西亚日惹市 Yap 眼科医院接受 PIOL 植入术的 81 例高度近视眼。根据植入 PIOL 分为 Artisan 组 43 眼,Artiflex 组 38 眼。分别记录术前及术后 1d、1、3mo 的视力、角膜生物显微镜参数和眼压,包括术前前房深度。

结果:Artisan 和 Artiflex 组的平均随访时间分别为 9.64±6.93mo和 8.96±4.28mo(P=0.736)。Artisan 组的疗效指数为 1.03±0.47,Artiflex 组为 1.02±0.17(P=0.119);安全性指数分别为1.10±0.45 和 1.05±0.21(P<0.001)。Artisan 组的平均等效球镜度(SE)为-0.64±0.996D,Artiflex 组为-0.22±0.58D(P=0.076)。两组术后内皮细胞密度(ECD)较术前均显著下降(P<0.05),累积 ECD 缺失率为 7.44%和 5.79%(P=0.418)。

结论:Artisan 和 Artiflex 矫正亚洲人高度近视的屈光效果相当。与 Artiflex 相比,Artisan 的安全指数略高,而两组的疗效指数和累积 ECD 缺失率相似。

关键词:有晶状体眼人工晶状体;前虹膜固定;Artisan;Artiflex;内皮细胞密度;高度近视

Abstract

• AIM: To compare refractive and safety outcome of Artisan and Artiflex phakic intraocular lens (PIOL) for the correction of high myopia in Asian population.

• METHODS: Historical cohort study. A total of 81 high myopic eyes that underwent PIOL implantation from 2016 to 2020 at Yap Eye Hospital in Yogyakarta, Indonesia were reviewed. The patients were divided into two groups based on PIOL implanted, with 43 eyes using Artisan PIOL in Artisan group and 38 eyes using Artiflex PIOL in Artiflex group. Visual acuity, corneal biomicroscopy parameters, and intraocular pressure (IOP) were respectively recorded prior to the implantation and at 1d, 1 and 3mo after surgery. In addition, anterior chamber depth was documented before PIOL implantation.

• RESULTS: Mean follow-up period were 9.64±6.93mo and 8.96±4.28mo in Artisan an Artiflex group, respectively (P=0.736). The efficacy index was 1.03±0.47 in Artisan group, and 1.02±0.17 in the Artiflex group (P=0.119).The safety index was 1.10±0.45 and 1.05±0.21 in Artisan and Artiflex group, respectively (P<0.001). The mean spherical equivalent (SE) in Artisan group was -0.64±0.996D, and it was -0.22±0.58D in Artiflex group (P=0.076). In both groups, there was a significant loss of endothelial cell density (ECD) postoperatively compare to baseline (P<0.05), and the cumulative ECD loss was 7.44% and 5.79% in the Artisan and Artiflex groups, respectively (P=0.418).

• CONCLUSION: Artisan and Artiflex are comparable in terms of refractive outcome to correct high myopia in Asian eyes. Artisan had a slightly better safety index compare to Artiflex. However, the efficacy index and cumulative ECD loss was similar in both the Artisan and Artiflex groups.

• KEYWORDS: phakic intraocular lens; anterior iris-fixated; Artisan lens; Artiflex lens; endothelial cells density; high myopia

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INTRODUCTION

Currently corneal excimer laser procedures, such as: photorefractive keratectomy (PRK), laser subepithelial keratomileusis (LASEK) and laser *in situ* keratomileusis (LASIK), are considered as treatment of choice of myopia. However, they have limitation in minimum threshold of corneal thickness for deep ablation which lenticular refractive procedure might overcome this issue[1-2].

Phakic intraocular lens (PIOL) implantation, refractive lens exchange (RLE), and cataract extraction with intraocular lens (IOL) implantation are several types of lenticular refractive procedures. PIOL implantation provides an advantage for the younger patients where this technique enables accommodation to be preserved. Some studies also indicated that PIOL implantation is safer than excimer laser surgery to correct moderate to high myopia[3]. Most early designs of PIOL have been abandoned due to the high complication rates related to endothelial cell loss, iridocyclitis, hyphema, cataract, and glaucoma. Currently, there are 3 types of PIOLs according to the fixation area: anterior chamber angle-fixated, anterior chamber iris-fixated, and posterior chamber[2,4].

Artisan (Opthec, Groningen, Netherlands) is an iris claw-fixated PIOL with a rigid convex-concave polymethyl methacrylate (PMMA) material with an optic of 6mm, implanted through a 5.0-6.0mm incision and Artiflex (Opthec, Groningen, Netherlands), with a flexible 6.0mm poly-silicone optic and iris claw-fixated PMMA haptics, implanted through a 3.2mm incision even without sutures[5]. However, both Artisan and Artiflex were reported to be safe and effective for the correction of high myopia[5-9]. Both of them have the same location of fixation in the anterior iris, but they have different materials. However, all of those studies were done in Caucasian eyes with less pigmented iris. On the contrary, more stromal melanocytes in the iris tissue made a higher incident of pigment dispersion during surgery in Asian eyes. Another characteristic of Asian eyes is that the anterior chamber is described to be markedly shallower compared to Caucasian eyes[10]. Those characteristics may cause PIOL implantation in Asian eyes more challenging for some reasons, such as more contact between PIOL and corneal endothelial layer leading to progressive loss of corneal endothelial cells density (ECD) and also increase of IOP due to pupillary block or pigment dispersion[11]. We aimed to compare Artisan and Artiflex in terms of refractive and safety outcomes, especially corneal ECD changes, in Asian patients.

SUBJECTS/MATERIALS AND METHODS

Ethical Approval The study and data collection were approved by Institutional Review Board Faculty of Medicine Public Health and Nursing, Universitas Gadjah Mada, Yogyakarta, Indonesia (No. KE/FK/1112/EC/2019). This study was in adherence to the tenets of the Declaration of Helsinki.

Study Design and Subject Population We performed historical cohort study to high myopic patients who had undergone PIOL implantation from 2016 to 2020 at Yap Eye Hospital in Yogyakarta, Indonesia. The patients were divided into two groups based on PIOL implanted: Artisan and Artiflex. All patients underwent comprehensive ophthalmic examination including uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), intraocular pressure (IOP), anterior chamber depth (ACD), indirect funduscopy, kinetic perimetry, and slit lamp were performed prior to surgery. Endothelial parameters were obtained from microscopy of central corneal position using Specular Microscope SP-2000P (Topcon, Tokyo, Japan), the obtained parameters were ECD in cells/mm2, cell variations (CV in percentage), and hexagonality (Hex).

The inclusion criteria were as follows: patient with 18 years of age or more at the time of surgery, has myopia -6 D or more, ACD 3.20 mm or more measured from the epithelium, and ECD > 2000cell/mm^2. Exclusion criteria were as follows: surgical time more than 1h, PIOL enclavation more than six times during the surgery, patient with IOP more than 21 mmHg preoperative, and duration of follow-up less than 3mo.

Phakic intraocular lens designs Artisan model 206 was used in this study because it has wider range availability of PIOL power from -3.0D up to -23.5D with 0.5 increment. Artiflex lens power was only available from -2.0D to -14.5D with 0.5 increments. The lens optic diameter of Artisan was 5.0 mm while Artiflex lens optic was 6.0 mm. Both of PIOLs have similar total length of 8.5 mm[12]. The PIOL power was calculated by manufacture software according to Van der Heijd formula. The IOL power was chosen for emmetropia with slight residual myopia as the second option.

Surgical Procedure All procedures were performed by single surgeon (AS) at the Yap Eye Hospital, Yogyakarta, Indonesia. Surgery was performed under general anesthesia. Operating site was prepared by cleaning the eye and surroundings using povidone-iodine (Betadine®), draping the eyelid and lashes, and inserting the speculum. The main corneal incision was made superiorly and 2 paracenteses were made at 10 and 2 o'clock. Differences between the Artisan and Artiflex surgical procedures included main incision size (6 mm Artisan; 2.75 mm Artiflex), special forceps was used to insert the Artiflex (Figure 1B), wound closure with a single 10-0 nylon suture after Artisan implantation and with corneal hydration after Artiflex implantation. Injection of cohesive viscoelastic material (Healon GV®) through the paracentesis site was needed during inserting and fixation the PIOL to maintain the ACD and to protect the corneal endothelium. The enclavation technique and post operative medication were similar between two groups.

Statistical Analysis The primary outcome measures were the efficacy index and safety index. The efficacy index was defined as the ratio of postoperative UCVA/preoperative BCVA, while the safety index was defined as postoperative BCVA/preoperative BCVA. Both efficacy and safety index reflect the refractive profile of the PIOL. The secondary refractive outcome measures were the changes in UCVA, BCVA,

spherical equivalent (SE), and cylinder.

The safety profile of the PIOL was indicated by the cumulative ECD change in the end of each patient's last visits and also the change of IOP in each visit. Other corneal endothelial parameters were also analyzed between both groups, including CV and Hex. Correlation of ECD changes with ACD, duration of surgery, and age were also considered as additional outcomes measured. Change in IOP and the presence of any complication were also recorded during follow up period to reflect safety profile of PIOLs.

Statistical analysis was performed using SPSS for Mac (version 21.0, IBM, Chicago, IL, USA) and the associated graphics were generated with Microsoft Excel 2011 (Microsoft Corporation, Seattle, WA, USA). To compare parameters between two groups, we used Chi-square for categorical data, and independent t-test or Mann Whitney for numerical data. Postoperative changes within group were analyzed using paired t-test or Wilcoxon signed-rank test. Differences were considered statistically significant when $P<0.05$. Univariate linear regression was used to analyze the correlation between ECD changes and ACD.

RESULTS

A total of 81 eyes including 43 eyes in the Artisan group and 38 eyes in the Artiflex group were analyzed. Mean age was 24.14±6.83 years and 23.63±6.39 years in Artisan and Artiflex group, respectively (range 18-49). There were no statistically significant differences in terms of age and follow-up duration between both groups (Table 1).

Visual Acuity and Spherical Equivalent Mean preoperative UCVA was 1.72±0.25 and 1.61±0.20LogMAR in Artisan and Artiflex group, respectively ($P<0.05$). Mean UCVA was significantly different between both groups in the baseline, and 1d, 1mo and last follow-up-month (Figure 1). Mean preoperative BCVA was significantly different between both groups with 0.40±0.22 in Artisan-treated eyes and 0.19±0.27 in Artiflex-treated eyes ($P<0.001$). Mean postoperative BCVA also showed significant differences with 0.19±0.25 and 0.04±0.11 in Artisan and Artiflex group, respectively ($P=0.007$; Table 2).

Efficacy index showed no significant differences with 1.03±0.47 in Artisan group and 1.02±0.17 in Artiflex group ($P=0.119$). However, safety index was significantly higher in Artisan (1.10±0.45) compared to Artiflex (1.05±0.21; $P<0.001$). Table 2 also showed significant cylinder power changes in each group postoperatively.

The baseline SE value was −19.76±2.68D in Artisan group and −12.32±2.89D in Artiflex group ($P=0.000$). Although the preoperative SE was statistically significant different between groups, it showed no significant difference postoperatively ($P=0.076$). The mean postoperative SE in Artisan group was −0.64±0.996D (71% eyes were within ±1D of target refraction), and −0.22±0.58D in Artiflex group (83% eyes were within ±1D of target refraction; Figure 3). The accuracy of SE to intended target is described in Figure 4. More than half of the samples in Artiflex group (58%) were in −0.25D to +0.25D SE postoperatively, while postoperative SE in Artisan group was more diverse with majority in +0.26D to +0.75D (31.58%).

Table 1 Baseline preoperative characteristics $\bar{x}\pm s$

Parameters	Artisan group	Artiflex group	P value
Age (years)	24.14±6.83	23.63±6.39	0.736
SE (D)	−19.76±2.68	−12.32±2.89	<0.001[a]
ACD (mm)	3.59±0.23	3.52±0.29	0.355
Surgical time (minutes)	21.46±9.47	20.53±8.50	0.550
Enclavation (time)	3.25±1.29	2.92±1.21	0.338
Follow-up(month)	9.64±6.93	8.96±4.28	0.734

SD: Standard deviation; SE: Spherical equivalent; ACD: Anterior chamber depth; [a]statistically significant different ($P<0.05$).

Corneal Endothelial Cells Parameters Figure 5 shows the corneal ECD changes over the study follow-up. ECD was similar between both groups preoperatively and postoperatively in every visit. There was a significant loss of ECD in the first month and in the last month of follow-up visit in each PIOL groups compared to baseline (Table 3). The mean cumulative ECD losses in the Artisan and Artiflex groups were 7.43% and 5.79%, respectively ($P=0.418$). Annual ECD loss for Artisan was 9.47% and for Artiflex was 12.68% ($P=0.750$). The cell variations and hexagonality did not show significant changes in every follow-up visit in both PIOL groups. The measurements of CV and Hex were also found to be similar between Artisan and Artiflex.

A negative correlation was found between ACD and endothelial cell loss, although it was not statistically significant ($r=0.144$; $P=0.288$). Same findings were also demonstrated in the correlation between duration of surgery and patient's age with ECD loss, with $r=0.026$ ($P=0.865$) and $r=0.132$ ($P=0.325$), respectively.

Complications A significant increase in IOP occurred on the first day postoperatively (D1) in both PIOL groups (Artisan $P=0.008$; Artiflex $P=0.000$) with no significant difference between both group ($P=0.874$). Mean IOP at 1mo postoperative visit was decreased although not significantly different compared to D1 IOP (Artisan $P=0.306$; Artiflex $P=0.50$). The mean IOP in the two groups fell again at the last-month postoperative visit (Table 4).

Glare complaints were found in 26% of patients in the Artisan group and 16% in the Artiflex group ($P=0.528$). A decrease in pupillary response was not found in the Artisan group, but was found in 1 patient (2.6%) in the Artiflex group ($P=0.284$). These results are not statistically significant different. A decrease in pupillary response occurred in patients with PIOL Artiflex, who had 5 times PIOL enclavation during surgery.

DISCUSSION

The present study included 81 eyes with high myopia treated with PIOL Artisan and Artiflex. All the implantation was performed by single surgeon who may increase the internal validity of this study. We found the refractive (UCVA, BCVA, SE, efficacy index, and safety index) and safety (as resemble

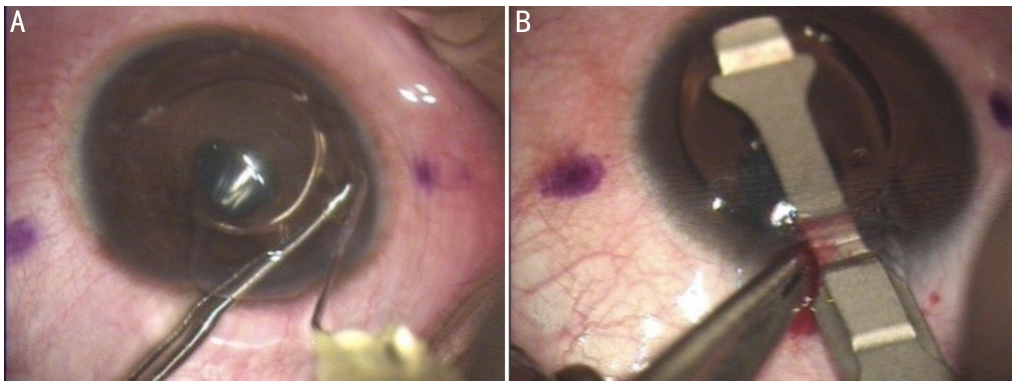


Figure 1 A: Enclavation process of Artisan phakic intraocular lens using special forceps; B: Insertion of phakic intraocular lens Artiflex using special inserter.

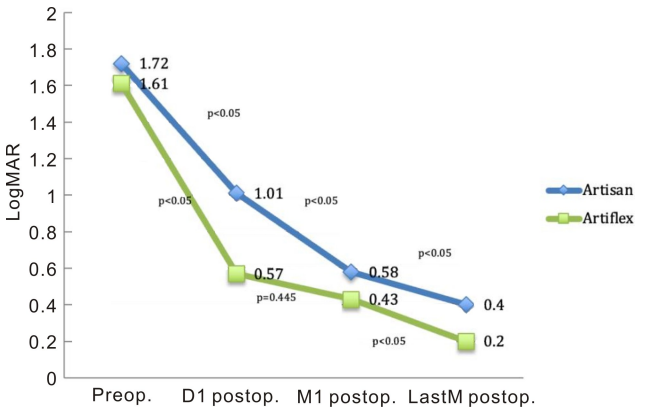


Figure 2 Mean uncorrected visual acuity changes in both groups. Preop: Preoperative baseline; D1: 1d; M1: 1mo; LastM: Last month of postoperative follow-up.

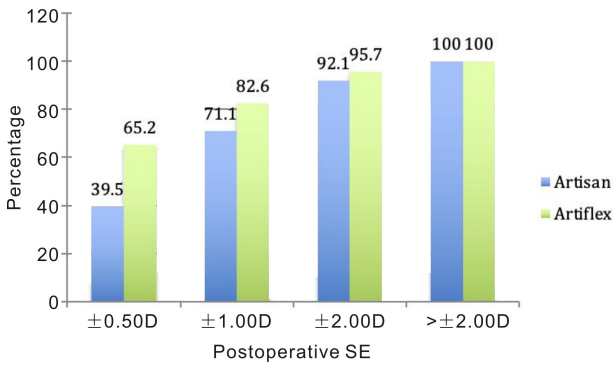
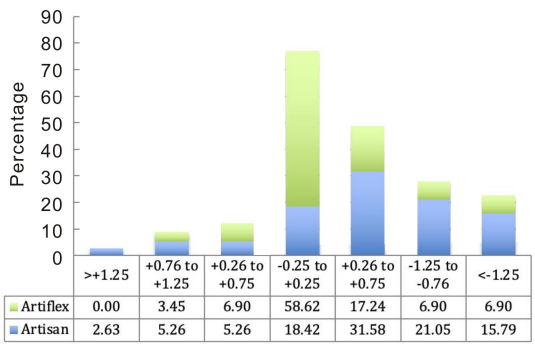


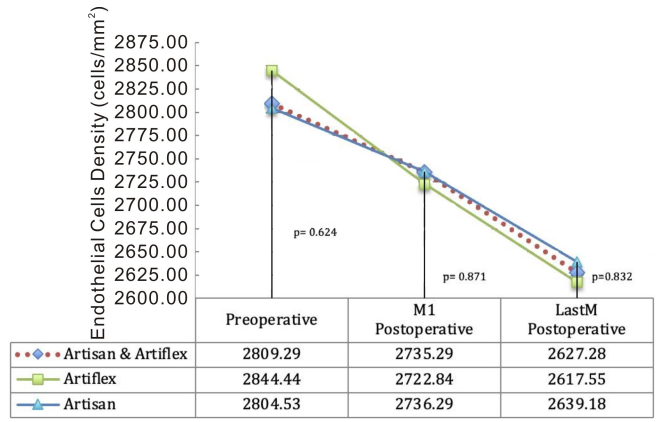
Figure 3 Cumulative percentage of postoperative spherical equivalent in Artisan and Artiflex groups.



	>+1.25	+0.76 to +1.25	+0.26 to +0.75	-0.25 to +0.25	+0.26 to +0.75	-1.25 to -0.76	<-1.25
Artiflex	0.00	3.45	6.90	58.62	17.24	6.90	6.90
Artisan	2.63	5.26	5.26	18.42	31.58	21.05	15.79

Figure 4 Accuracy of spherical equivalent to intended target (in Diopter).

by endothelial cell density and IOP) profiles are comparable between PIOL Artisan and Artiflex.



	Preoperative	M1 Postoperative	LastM Postoperative
Artisan & Artiflex	2809.29	2735.29	2627.28
Artiflex	2844.44	2722.84	2617.55
Artisan	2804.53	2736.29	2639.18

Figure 5 Comparison of endothelial cells density changes between Artisan and Artiflex group. (M1: month 1, LastM: last postoperative follow up).

Table 2 Visual and refractive status in Artisan and Artiflex groups $\bar{x}\pm s$

Parameters	Artisan Group	Artiflex Group	*P* value
Efficacy index	1.03±0.47	1.02±0.17	0.119
Safety index	1.10±0.45	1.05±0.21	<0.001[a]
BCVA (LogMAR)			
Preoperative	0.40±0.22	0.19±0.27	<0.001[a]
Postoperative	0.19±0.25	0.04±0.11	0.007[a]
Changes	0.24±0.15	0.08±0.27	<0.001[a]
SE (D)			
Preoperative	−19.76±2.68	−12.32±2.89	<0.001[a]
Postoperative	−0.64±0.996	−0.22±0.58	0.076
Changes	−19.28±2.46	−11.56±3.17	<0.001[a]
Cylinder (D)			
Preoperative	−3.05±1.33	−1.72±1.22	<0.001[a]
Postoperative	−1.15±1.04	−0.51±0.70	0.01[a]
Changes	−2.03±1.33	−1.07±1.23	0.003[a]

SD: Standard deviation; BCVA: Best corrected visual acuity; SE: Spherical equivalent; D: Diopter, [a]statistically significant different (P<0.05).

In terms of UCVA, both PIOL groups had significant increases in mean final UCVA. Artiflex group had significant improvement since the day-1 postoperatively. The same thing was expressed by Coullet *et al*[6], that UCVA in the Artiflex

Table 3 Corneal parameters changes in Artisan and Artiflex group $\bar{x}\pm s$

Corneal Parameters	Artisan Group	Artiflex Group	*P* value
ECD (cells/mm^2)			
Preoperative	2804.5±312.8 (ref)	2844.4±308.4 (ref)	0.624
M1 postoperative	2736.3±320.1 (0,011[a])	2722.8±299.7 (0,012[a])	0.871
LastM postoperative	2639.2±413.5 (0,027[a])	2617.6±326.3 (0,002[a])	0.832
Cumulative ECD loss (%)			
M1 postoperative	−8.10±25.67	−3.88±6.95	0.756
LastM postoperative	−7.44±12.03	−5.79±8.01	0.418
ECD changes/year (%)	−9.47±16.80	−12.68±17.49	0.750
CV (%)			
Preoperative	33.57±7.68 (ref)	31.19±4.27 (ref)	0.401
M1 postoperative	34.14±7.56 (0.619)	32.87±5.28 (0.144)	1
LastM postoperative	33.44±6.07 (0.755)	34.13±4.74 (0.715)	0.521
Hex (%)			
Preoperative	57.96±11.083 (ref)	59.42±86.540 (ref)	0.598
M1 postoperative	54.50±8.435 (0.162)	56.33±8.836 (0.069)	0.427
LastM postoperative	59.41±35.309 (0.904)	54.38±12.374 (0.535)	0.494

ECD: Endothelial cell density; CV: Cell variation; Hex: Cell hexagonality; M1: first month follow-up visit; LastM: Last month of follow-up visit; ref: Reference value, [a]statistically significant different ($P<0.05$).

Table 4 Comparison of pre- and postoperative intraocular pressure changes between Artisan and Artiflex group (mmHg, $\bar{x}\pm s$)

IOP	Artisan Group	Artiflex Group	*P* value
Preoperative	16.84±3.71 (ref)	15.45±2.71 (ref)	0.061
D1 postoperative	27.22±17.23 (0.008[a])	25.23±15.20 (0.000[a])	0.874
M1 postoperative	21.00±4.65 (0.306)	19.23±5.43 (0.50)	0.038[a]
LastM postoperative	17.36±5.00 (0.001[a])	17.47±6.03 (0.169[a])	0.786

IOP: Intraocular pressure; SD: Standard deviation; D1: day 1 follow-up examination; M1: first month follow-up visit; LastM: Last postoperative follow up; ref: Reference value, [a]statistically significant different ($P<0.05$).

group was significantly better than Artisan in the first 3 months postoperatively. This suggests that the Artiflex group experienced better visual recovery since the early postoperative period. Compared with other lens, such as Visian ICL V4c, Artiflex shows comparable visual recovery in term of contrast sensitivity outcomes with no vision threatening complications[7].

We observed comparable good efficacy index in both groups. This finding was correlated with previous short-term study from Karimian *et al*[8], that showed efficacy index to be 1.09 and 1.19 for Artisan and Artiflex, respectively ($P>0.05$). There was a wide range from 0.43 to 1.03 of PIOL efficacy index in middle- and long-term period[13-14]. However, none of the studies performed in Asian eyes.

Our study found a significant difference between PIOL Artisan and Artiflex in term of safety index. Artisan had better safety index with 1.10, while Artiflex had 1.05 ($P<0.05$). The higher improvement in Artisan postoperative BCVA was probably the reason of the higher safety index, despite of the residual refractive error. Improvement in BCVA, after PIOL implantation has been reported in previous studies. The neutralization of minification effect of the concave spectacle lenses in high myopic subjects was probably the reason of the BCVA improvement[8,15]. Even if significant improvement in visual and refractive results could be achieved in early postoperative period, significant myopization might occur overtime in high-myopic patients as a result of axial elongation. This condition may cause decrease in UCVA and BCVA at a later time[16].

Although preoperative SE was significantly higher in PIOL Artisan group ($P<0.05$), there was no significant difference in residual postoperative SE in the last examination visit. Postoperative SE in the short term reflects the accuracy of Van der Heijde's formula in determining the power of the PIOL implanted as well as the changes caused by surgical procedure. Our study found a higher proportion of postoperative SE percentage within ±1D in Artiflex group compare to Artisan. Coullet *et al*[6] suggested a hypothesis that this outcome might cause by a better accuracy of the lens power calculation by the manufacturer for Artiflex than to Artisan.

One of the major concern after PIOL implantation is the decrease in the corneal endothelial cells count. The prediction of annual ECD loss was slightly high in Artiflex group (−12.68±17.49) compare to Artisan group (−9.47±16.80), although it was not statistically significant. Artiflex was made of silicone that is expected to cause more anterior chamber inflammation leading to more ECD loss overtime, compare to

Artisan which made of PMMA[17]. Regardless of the type of PIOLs, there was a significant decrease in the ECD at each follow-up time, both in the Artisan and Artiflex group. Previous short-term study also stated that there was no difference in the decrease of ECD at the end of the study (mean follow-up duration 30±11 months). The percentage of postoperative endothelial decline was 10%±9% and 9%±6% in the Artisan and Artiflex groups, respectively[7]. Another study conducted on Asian eyes showed different results, namely that there was no decrease at anytime of examination up to 2 years postoperatively, but researchers only observed one type of PIOL (Artisan) and with a smaller sample size compare to other studies[18]. Early ECD loss in period up to 3 years postoperatively was considered as intraoperative trauma[19-20]. Long-term endothelial tolerance to PIOL in Caucasian population was good based on a study from Chebli *et al*[20] which develop a model to predict post-implantation endothelial cell survival. However, phakic IOLs might associated with long term (>6 years) possible postoperative vision-threatening complications such as corneal decompensation and rhegmatogenous retinal detachment[21].

Our study also found that PIOL implantation was not associated with endothelial cell pleomorphism or polymegathism because cell hexagonality was not affected and cell variations were still under 60%. The stability of the percentage of hexagonality and variation of endothelial cells indicated that the implanted PIOL did not exert continued stress on the corneal endothelium[21-22].

The risk factor that has been known to be associated with a decrease in ECD is shallow ACD that narrows the distance between the endothelium and central and peripheral edge of PIOLs[11,22]. Our study analysed the relationship between decreased ECDs and the ACD. We found a weak and insignificant relationship ($r=0.144$, $P=0.288$). This finding was supported by some studies[11,14,23]. These conflicting results between studies may be caused by different duration of follow-up period. Saxena *et al* found a significant correlation between ECD loss with shallow ACD only after 3 years of follow-up. These results indicate that other factors may contribute to ECD loss. Inflammation caused by surgery and PIOL biomaterials may damage the endothelium[24-25]. This study also looked at other factors, including duration of surgery and patient's age that may be associated with ECD loss. However, we did not find a strong and significant relationship between the percentage of ECD loss with the duration of surgery and the age of patient. Previous studies also did not find any significant correlation between ECD loss and other basic factors such as gender, age, degree of myopia, and keratometry[11,14].

This study observed temporary changes in IOP postoperatively. There is a risk of secondary glaucoma due to pigment dispersion or pupillary blocked in early postoperative time[13]. All patients in this study underwent peripheral iridectomy to prevent pupillary block, so that the follow-up did not find glaucoma complication due to papillary block. The increase of IOP on the first day is most likely due to residual ophthalmic viscosurgical devices (OVD). Previous reports also found the increase of IOP on the first day after PIOL implantation, ranged 1.5%-15%. The incidence was more often caused by the use of high-viscosity OVDs such as sodium hyaluronate than OVD types of hydroxyl propyl methylcellulose (HPMC)[26-27]. IOP elevation is uncommon in the long term. Transient increase in IOP is most often caused by the use of corticosteroids in the early postoperative period and generally resolved without causing complications[13,28,26].

This current study did not find any significant complication leading to PIOL exchange or explantation. The majority of PIOL explantation was due to cataract formation and severe ECD loss. However, the incidence of PIOL explantation was notably low in 2% after a mean time of 7.5 year[29].Subjective phenomena such as glare or halo were often bothersome and could be related to poor PIOL centration, wide scotopic pupil diameter, or improper iridectomy. Surgical procedure of PIOL implantation needs surgeon's skill and practice. We found no significant difference in percentage of glare/halo between two PIOLs with single operator. The reports of these optical phenomena were varied between studies with a range of 0%-22%. However, glare/halo seem to decrease overtime and rarely need secondary intervention[13,20]. In terms of pupillary condition, we evaluated one subject with decrease pupillary response due to strenuous Artiflex enclavation. Difficulty in PIOL enclavation can lead to iris atrophy and PIOL decentration[30].

In conclusion, it was found that Artisan had a slightly better safety index compared to Artiflex. However, the efficacy index and cumulative ECD loss was similar in both the Artisan and Artiflex groups. Both PIOL are comparable in terms of refractive outcome to correct high myopia in Asian eyes. Considering complications, no obvious superiority was noted among these PIOLs. We believe that this study is the first unsponsored, comparative study of outcomes and complications of PIOLs in Asian population. Prospective studies with larger patient groups and longer follow-up periods are needed to support these findings.

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