Single-Piece Foldable Intraocular Lenses versus Three-Piece Intraocular Lenses in the Sulcus following Posterior Capsular Rupture

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Abstract

Purpose

Successful intraocular lens (IOL) placement in cataract surgery is synonymous with the IOL being placed in the capsular bag. When the bag is violated, the ciliary sulcus becomes an option to be able to place an intraocular lens in a near in-the-bag position. Studies report that single-piece foldable acrylic (SPA) IOLs are a poor choice for the sulcus. This study aimed to compare the visual outcomes and complications between sulcus placement of single-piece intraocular lenses and three-piece intraocular lenses.

Methods:

The medical records of patients were retrospectively reviewed in a single center.

Results:

A total of 245 patients were included in the study with mean age of 61 with male predominance. Majority of sulcus implantation occurred during phacoemulsification (87%). Around 82% (n=202) were implanted with SPA IOLs and 18% (n=43) were three-piece IOLs. Best corrected distance visual acuity (BCDVA) was 20/20 after 6 months for both groups. Comparison between two groups showed no superiority with each other. Complications notable were elevated IOP, corneal edema, loss of IOL centration and pigment dispersion. Results showed more proportions of complications with SPA IOLs than three-piece IOL. Smaller optic diameter and overall length predispose to increase in decentrations.

Conclusions:

We found no significant difference between the visual outcomes of three-piece IOLs with SPA IOLs. Complications were found to be more significant in SPA IOLs. Knowledge on the outcomes and complications of SPA IOLs would help ophthalmologists in their decision making and help set realistic expectations for both doctors and patients.

Introduction

Successful intraocular lens (IOL) placement in cataract surgery is synonymous with the IOL being placed in the capsular bag. Ideally, the IOL is placed safely inside the lens capsule after removal of the nucleus in lens extraction surgery, well-centered to the pupillary axis, and the IOL-capsular complex is adequately supported by lens zonules.[1,2] This “in-the-bag” placement of an IOL approximates an optimal surgical and refractive outcome. However, complications are unavoidable and may arise in a routine lens extraction surgery.[3] The capsular bag when violated, can be compromised. There are situations that when the posterior capsular bag becomes violated i.e., posterior capsular rent, the ciliary sulcus, where the zonules insert, is still intact and may be a safe option to place an intraocular lens. The ciliary sulcus becomes an option since sulcus placement is almost synonymous to in-the-bag placement because of the near proximity of the sulcus with the bag.[1,2]

The recommended intraocular lens placed in the sulcus is the three-piece intraocular lens because of its versatility, and its large optic diameter and long haptics are crucial to keep the IOL in the sulcus. Various haptic designs are being compared in terms of position stability of IOLs.[1,2,4] In contrast to single-piece IOLs, these have soft and broader haptics which are made of the same material as the optic, usually hydrophobic or hydrophilic acrylic, whereas three-piece IOLs have rigid haptics which are made of poly methyl methacrylate (PMMA). Numerous studies[1-6] contradict the use of single-piece IOLs in the sulcus. Because of the broader haptics, it causes chaffing of the posterior iris and eventually causes a pigment dispersion syndrome. Pigment dispersion syndrome clinically becomes a dilemma when the pigments block the trabecular meshwork causing glaucoma. The soft and relatively smaller optic diameter of a single-piece IOL make it also incompatible for a sulcus placement. If the capsulorrhexis is larger than the optic diameter, a single-piece IOL is prone to decentration, subluxation or dislocation.

Since placement of a single-piece IOL in the sulcus is not a common practice worldwide, only a few studies are available discussing the outcomes and complications associated with it. Review of local studies has not been conclusive about the visual outcomes and complications of sulcus placement of single-piece intraocular lenses. Due to the small number of studies reporting the outcomes, this study will be conducting a local study on the outcomes of sulcus placement of single-piece IOLs.

Objectives

This study determined and compared the visual outcomes and complications associated with sulcus placement of single-piece intraocular lenses in a tertiary hospital in the Philippines. Specifically, this study aimed to identify patients who underwent sulcus placement of both single-piece and three-piece intraocular lenses (as the standard IOL of choice for sulcus placement). We identified the material, whether acrylic or polymethacrylate material, and foldable or rigid. We also described demographics of patients based on age, gender, laterality, and type of lens extraction performed (i.e., phacoemulsification, extracapsular cataract extraction), with or without anterior vitrectomy done. We determined the IOL characteristics such as average length of the IOL, average optic diameter and average central thickness. We identified the postoperative complications (i.e., increased intraocular pressure (IOP) with or without the need for glaucoma co-management, dropped intraocular lens, corneal edema, corneal decompensation, intraocular lens decentration, retinal detachment, pigment dispersion and others), and associated the presence of the preoperative risk factors to the presence of postoperative complications.

Methods

This study was a retrospective, comparative chart review study employing retrieval of 345 medical charts of patients who underwent sulcus placement of intraocular lenses (both single-piece and three-piece) from January 1, 2016 to December 31, 2019. Our study was approved by a local Institutional Ethics Review Board prior to the conduct of the study.

All patients who underwent intraocular lens implantation in the sulcus, either of same sitting (primary) or staged procedure (secondary) were included. Excluded were patients with preexisting retinal pathology, glaucoma, corneal pathology and optic nerve pathology, pediatric patients, less than 2 months of follow up, and incomplete medical records.

Primary outcomes were best corrected visual acuity at day 1, 1st month, 3rd month and 6th month postoperatively, and the complications.

Clinicodemographic profile of the subjects of the study and characteristics of the intraocular lens implanted to the subjects were described. Continuous numerical variables were summarized as mean and standard deviation, if the data was normally distributed as assessed by Shapiro-Wilk test of normality, and, median and interquartile range (IQR) if otherwise. Discrete numerical variables were summarized as median and IQR. Categorical variables were summarized as count and proportion. Prevalence of preoperative risk-factors predisposing to difficult routine lens extraction, and intra-operative risk-factors affecting visual outcomes, as well as cumulative incidence of the different postoperative complications were presented as percentage. Comparison of the cumulative incidence of the different postoperative complications were assessed by chi-square test or Fisher exact test of homogeneity, as appropriate. The association between the presence of preoperative risk factors and occurrence of postoperative complications was assessed by chi-square test of association. Comparison of the IOL characteristics between those with versus without different postoperative complications were assessed by Mann-Whitney U test. Assumptions of both repeated-measures ANOVA and Friedman test were not met by the dataset, hence comparison of the BCVA between single-piece and three-piece IOL across different time-points was done graphically using box plots.

Results

Data were collected from a total of 245 patients which satisfied criteria for sulcus implanted intraocular lens. For the patient characteristics (see Table 1), results showed a mean age of 61 years old with more males than females. Follow up period was 6 ± 2.42 months. For the surgical characteristics, majority of the sulcus implantation occurred during phacoemulsification primarily on the same sitting setup. Anterior vitrectomy was done in 97% of the total eyes and posterior vitrectomy was done in 21% of total eyes. 97% eyes had vitreous loss. There were 20% of which had dropped nuclear fragments.

For the IOL characteristics (see Table 1), majority of the sulcus implanted IOLs were single-piece; majority of which were foldable and 10% were rigid polymethymethacrylate intraocular lenses. Intraocular lens dimensions, namely the central thickness or the optic thickness, optic diameter and overall length, the single-piece IOLs were found to be relatively thicker in the central portion of the optic as compared with three-piece IOLs. Generally, single-piece IOLs were smaller as compared to three-piece IOLs.

In Figure 1, breaking down where the different IOLs were implanted, sulcus single-piece acrylic IOLs predominates during phacoemulsification. Single-piece rigid PMMA IOLs were implanted more in

ECCEs. Majority of the etiologies of the complicated surgeries were brought about by dense cataracts, followed by myopia and small pupil (see Table 2).

Best corrected distance visual acuity (BCDVA) was represented in the graph as logarithm of the minimal angle of resolution or logMAR units. Generally, the preoperative BCVA was 0.75 logMAR units or 20/100 or worse. Postoperatively, there was an improving trend of visual outcomes for both three-piece and single-piece acrylic IOLs as time passed (see Figure 2). Table 3 shows comparison between the preoperative and postoperative BCVA. There was a significant difference across all points (P = 0.04). However, comparing the outcomes of a single-piece vs three-piece IOL per period in time, single-piece and three-piece IOLs demonstrate no superiority over the other.

Correlation between the general presence of preoperative risk factors to the presence of complications showed no sufficient evidence to conclude that the presence of preoperative risk factors was associated with occurrence of postoperative complications (see Table 4).

Moving to the complications, there were more complications in single-piece acrylic IOL group (65%) versus three-piece IOL group (40%). The following complications were elevated intraocular pressure that may or may not progress to glaucoma, corneal edema, loss of centration, pigment dispersion and retinal detachments.

Although anterior chamber inflammation is expected after a surgery, we identified the presence of inflammation postoperative and which of these inflammations were only transient (occurring less than 2 weeks), or persistent (more than 2 weeks). Majority of the inflammation developing postoperatively were noted to be transient at around 92% in both groups. Around 5-7% or 16 eyes had persistent inflammation. From these 16 eyes, 13 eyes from single-piece and three-piece groups resolved after 4 weeks of topical steroids managed by the surgeon however, 3 eyes from single-piece group warranted uveitis specialist co-management. The cumulative incidences of postoperative inflammation between single-piece and three-piece IOLs showed no sufficient evidence to conclude that there is a significant difference (see Table 5).

For the elevated intraocular pressures, we noted more elevated intraocular pressure in three-piece IOLs as compared to single-piece. Of these 56 eyes which had elevated IOP, 19 eyes spontaneously resolved without treatment, and a total of 41 eyes in both groups were managed with topical medications. Twenty-eight eyes were from single-piece group; 8 eyes from three-piece group. Most common medications given to address the elevated IOP were timolol (63%), acetazolamide (21%) and brimonidine (19%). Approximately half (n=20) of the eyes were controlled with only 1 topical medication, 12 eyes required 2 medications, 2 eyes required 3 medications, and 1 eye for 4 medications. Mean IOP elevations of 23 mmHg and 21 mmHg for single-piece and three-piece, respectively. Twelve (12) eyes warranted a glaucoma specialist co-management. Ten (10) from them were from the single-piece group, 2 eyes from the three-piece group. Three (3) eyes progressed to glaucoma and all of these were from the single-piece group. Of these 3 glaucomas identified, two were open angle glaucomas, and one was a secondary angle closure glaucoma. One eye from these required trabeculectomy. Elevated IOP had a mean 30 days of duration. We categorized an elevated IOP into the following: early or defined as onset of elevated IOP

within 2 weeks, late – onset is beyond 2 weeks; transient or within 4 weeks regardless of management, or chronic or more than 4 weeks. We have found that there was a significantly higher proportion of early onset increase in IOP in single-piece group than in three-piece group, and that there was higher incidence of late onset increase in IOP in three-piece group than in single-piece group (p-value = 0.02). With regards to chronicity, there were more chronically increased IOP in three-piece group than in single-piece group, but this was not significant. Among those eyes needing glaucoma co-management, we have found that the IOLs implanted have a significantly lower median optic diameter than those without need for glaucoma co-management. Central thickness and overall diameters were found to not correlate with need for glaucoma co-management.

A total of 89 eyes had corneal edema postoperatively. Fifty (57) from which were observed, and no medications were given. Thirty-two (32) eyes received sodium chloride and no patients were deteriorated to corneal decompensation. Most corneal edemas occurred transiently, operationally defined as within 2 weeks, with spontaneous resolution, mostly not needing sodium chloride treatment. Around 45% of patients from single-piece foldable group extended to persistent corneal edema, or more than 2 weeks of edema, because of either a peripheral DM detachment, or scarring progression. Some of these patients with persistent corneal edema were only focal not affecting the visual axis. There was no sufficient evidence to conclude that there is a significant difference in the cumulative incidence of postoperative corneal edema between single-piece and three-piece IOL.

There were more losses of intraocular lens centration with single-piece acrylic IOLs than three-piece IOLs. For loss of IOL centrations, we operationally classified loss of centration as decentration, subluxation and dislocation. IOL decentration is loss of centration where IOL is retained in the ciliary sulcus, but the geometric center is not in the visual axis. Subluxation is partial displacement out of the ciliary sulcus (i.e., haptic may be incarcerated in anterior chamber or iris), but is confined within the anterior segment (i.e., anterior chamber, incarcerated in the iris). Dislocation is complete displacement out of the ciliary sulcus (i.e., entire IOL in the anterior chamber, IOL dropped in the posterior segment)[8,9,10]. Majority of loss of IOL centration occurred in eyes implanted with single-piece acrylic IOLs. Two eyes had decentrations, 4 subluxations and 9 dislocations all of which dropped into the retina. There were 2 decentrations and 1 subluxation in three-piece group. 8.42% developed loss of IOL centration in a shorter onset of time of 7 days in single-piece group. Despite the high number of decentrations in the single-piece group, there was no sufficient evidence to conclude that this was significant. Those with loss of centration have significantly lower median overall and optic diameters than those without loss of centration (see Table 6).

A total of 15 patients had pigment dispersion: 13 from single-piece group and 2 from three-piece group. No patients were diagnosed with pigment dispersion glaucoma. Three (3) eyes noted with retinal detachment at a mean onset of 5 days in single-piece IOL group. All eyes with retinal detachment were predisposed to IOL explant prior to the retinal detachment.

Discussion

Current literature showed that despite increasing reports of postoperative complications associated with sulcus implantation, the visual outcomes remain excellent for those stable single-piece in the sulcus. Taskapili et al[9] in 2005 supported implantation of a single-piece acrylic IOL in the sulcus because it maintains the advantages of a small incision surgery with good postoperative visual results with final BCVA of 20/40 or better in majority of the cases. A retrospective, noncomparative case series review of 20 eyes by Uy, et. al in 2005[11] in the Philippines showed a good visual outcome for majority of patients (20/40 or better in all eyes). In a study by Mohebbi et al[2] in 2017 and Renieri et al[7] in 2012, results of sulcus placement of single-piece intraocular lenses showed a visual acuity of better than or equal to 20/40 after surgery in majority of the patients. Generally, implantation of an intraocular lens in the sulcus is relatively safe and provides good visual and refractive outcomes since sulcus placement of an IOL is almost synonymous to placing an IOL in the bag because of the near proximity of the sulcus with the bag[2,4,6].

Several studies[1,2,4,6,10] have reported that single-piece acrylic (SPA) intraocular lenses are not designed for sulcus placement, and there is growing evidence of chronic complications related to their use in the ciliary sulcus. Many of these eyes ultimately require surgical intervention, including lens exchange, pars plana vitrectomy and trabeculectomy for IOL-induced glaucomas. In one study, postoperative complications were corneal edema, descemet folds, intraocular pressure elevations, and severe anterior segment inflammation[2]. No significant IOL decentration was reported. In the study of Renieri et al in 2012, complications were foveopathy, iris transillumination defects, iris chafing, pigmented keratic precipitates, clinical IOL tilt, IOL decentration and endothelial pigment dusting. Additionally, this study performed ultrasound biomicroscopy (UBM) in these eyes were they significantly found IOL tilt in 4 eyes.

The currently recommended[4,6] intraocular lenses to be placed in the sulcus are the three-piece intraocular lens or a single-piece PMMA rigid intraocular lens. This is precisely because three-piece IOLs and single-piece PMMA rigid IOLs are designed to be more stable in sulcus because of their large optic diameters and long haptics which are crucial to maintain stability in the sulcus. Many studies theorized that because of the square-edged optic design, thick haptics, and unpolished side walls, these cause friction at the edges of the lens. The thicker optic of single-piece IOLs predisposes more to a pupillary block mechanism hence an angle closure glaucoma could happen. At the same time, the adherent surface of the acrylic IOL and the bulkier single-piece haptics promote iris chafing, increasing the risk for pigment dispersion syndrome, uveitis-glaucoma-hyphema (UGH) syndrome, iridocyclitis, and increased IOP. This could also be the reason why there were more persistent uveitis or inflammation in single-piece IOLs than three-piece IOLs. Most of the studies[4,6] have identified more than 30% of pigment dispersion among their patients, as opposed to our study which only caught 6% of pigment dispersion, and the reason behind may be secondary to underdiagnosis or underreporting of the surgeons regarding pigment dispersion.

Studies show that there is a range of loss of centration from none to as high as 70%. A UBM-based study in living eyes has identified that sulcus-to-sulcus approximately measures 12.5mm[12]. The overall diameter of these lenses, while ideal for capsular fixation, is undersized for the ciliary sulcus. Even when

optic capture is possible, these lenses are not well suited for sulcus fixation. They have minimal to no posterior angulation[2,4,6] and the optic may be more likely to prolapse anteriorly, increasing the risk for dislocation. In our study, we were able to prove that there is higher likelihood of decentration for smaller overall and optic diameters.

Conclusion

In a cohort of 245 patients, we found no significant differences between the visual outcomes of three-piece IOLs with SPA IOLs. Complications were found to be more significant in SPA IOLs. Knowledge on the outcomes and complications of SPA IOLs would help ophthalmologists in their decision making and help set realistic expectations for both doctors and patients.

Declarations

FUNDING

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AUTHOR CONTRIBUTION

Torrefranca – drafted and conducted the study; Drafted and finalized the final manuscript

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Tables

Table 1

Clinicodemographic profile and characteristics of the IOL implanted in the subjects of the study.

Demographics	N / Median	% / IQR
Age group		
19 – 40	11	4.49%
41 – 60	89	36.33%
> 60	145	59.18%
Sex		
Male	133	54.29%
Female	112	45.71%
Laterality		
Left	126	51.43%
Right	119	48.57%
Lens extraction procedure		
Phacoemulsification	214	87.35%
Extracapsular cataract extraction	18	7.35%
Secondary IOL	13	5.31%
Anterior vitrectomy performed	238	97.14%
Posterior vitrectomy performed	52	21.22%
IOL implantation timing		
Primary	213	86.94%
Secondary (staged procedure)	32	13.06%

Intraocular Lens	n / Median	% / IQR
Three-piece	43	17.55%
Single-piece	202	43%
Foldable	182	89.66%
Rigid	20	90.10%
Material		
Acrylic	181	90.05%
Polymethacrylate	20	9.95%
Undisclosed	1	0.41%
Central thickness	0.45	0.07
Optic diameter	6	0
Overall diameter	12.5	0.5

Table 2

Prevalence of preoperative risk-factors predisposing to difficult routine lens extraction, and intra-operative risk-factors affecting visual outcomes.

Risk factors	N	%
Preoperative		
Small pupil	4	1.63%
Dense cataract	38	15.51%
Low extracapsular cataract	2	0.82%
Phacodonesis	1	0.41%
Myopia	5	2.04%
Trauma	2	0.82%
Polar	4	1.63%
Intraoperative		
Posterior capsular rent	239	97.55%
Dropped nuclear fragments	49	20.00%
Iridodialysis/ iris defect	6	2.45%

Table 3

Comparison of LogMAR between single-piece and three-piece IOL across different time points.

Visual Outcomes	**Log MAR**, *median (IQR)*				
	Preoperative	*Postoperative day 1*	*Postoperative month 1*	*Postoperative month 3*	*Postoperative month 6*
Single-piece	0.6989 (1.1645)	0.544 (0.824)	0.176 (0.457)	0.0969 (0.301)	0.0969 (0.301)
Three-piece	0.62145 (0.16505)	0.544 (0.8239)	0.301 (0.4471)	0.0969 (0.301)	0 (0.176)

Table 4

Association between presence preoperative risk factors and occurrence of postoperative complications.

Preoperative risk factors	**Postoperative complication**				**p-value**
	With		Without		
	n	*%*	*N*	*%*	
With	39	72.22%	15	27.78%	0.350
Without	125	65.45%	66	34.55%	

Table 5

Comparison of the cumulative incidence of postoperative complications between single-piece and three-piece IOL.

Postoperative complications	Overall	Single-piece		Three-piece		p-value
	n (%) / Median (IQR)	*n / Median*	*% / IQR*	*n / Median*	*% / IQR*	
Inflammation						
Grade	2 (1)	2	1	2	1	0.442
Chronicity						1.000
Transient	210 (92.92%)	173	92.51%	37	94.87%	
Chronic	16 (7.08%)	14	7.49%	2	5.13%	
Increased intraocular pressure	56 (22.86%)	43	21.29%	13	30.23%	0.205
Duration, days	30 (29)	30	29	30	29	0.944
Onset						0.024
Early	47 (83.93%)	39	90.70%	8	61.54%	
Late	9 (16.07%)	4	9.30%	5	38.46%	
Chronicity						0.315
Transient	24 (42.86%)	20	46.51%	4	30.77%	
Chronic	32 (57.14%)	23	53.49%	9	69.23%	
Need for glaucoma co-management	12 (21.43%)	10	23.26%	2	15.38%	0.711
Number of glaucoma medications	1 (2)	1	2	1	2	1.000
Corneal edema	89 (36.33%)	74	36.63%	15	34.88%	0.828
Duration, days	7 (23)	7	23	7	23	0.237
Chronicity						0.199
Transient	52 (58.43%)	41	55.41%	11	73.33%	
Chronic	37 (41.57%)	33	44.59%	4	26.67%	
Intraocular lens decentration	19 (7.76%)	17	8.42%	2	4.65%	0.541
Onset, days	15 (58)	7	28	60	60	0.304
Retinal detachment	4 (1.63%)	3	1.49%	1	2.33%	0.540
Onset, days	5.5 (5.5)	5	4	12	0	0.500

Pigment dispersion	15 (6.12%)	13	6.44%	2	4.65%	1.000
Others	5 (2.04%)	3	1.49%	2	4.65%	0.212

Table 6

Comparison of IOL characteristics with presence of loss of IOL centration

	single-piece Acrylic Group		three-piece Group		
	n / Median	% / IQR	n / Median	% / IQR	p-value
Central thickness	0.43	0.02	0.45	0.07	0.1285
Optic diameter	5.90	0.25	6.00	0	0.0232
Overall length	12.5	0.25	12.75	0.5	0.0093

Figures

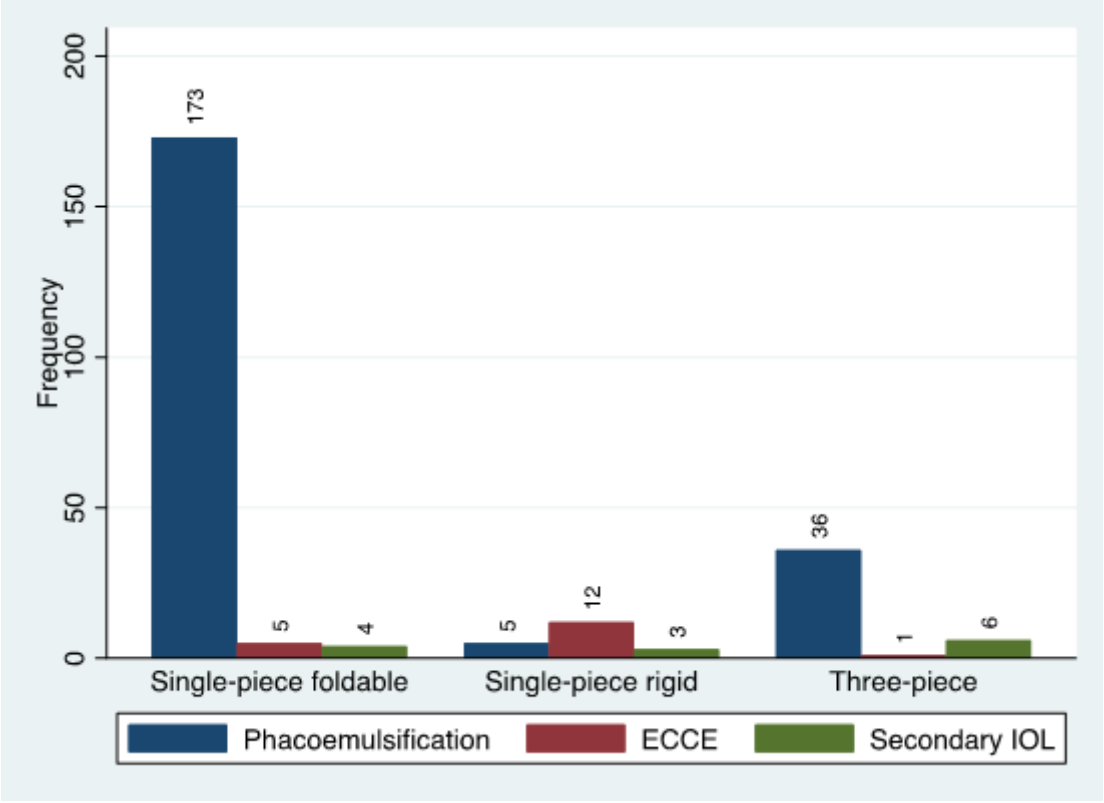

Figure 1

Type of IOL used for each procedure

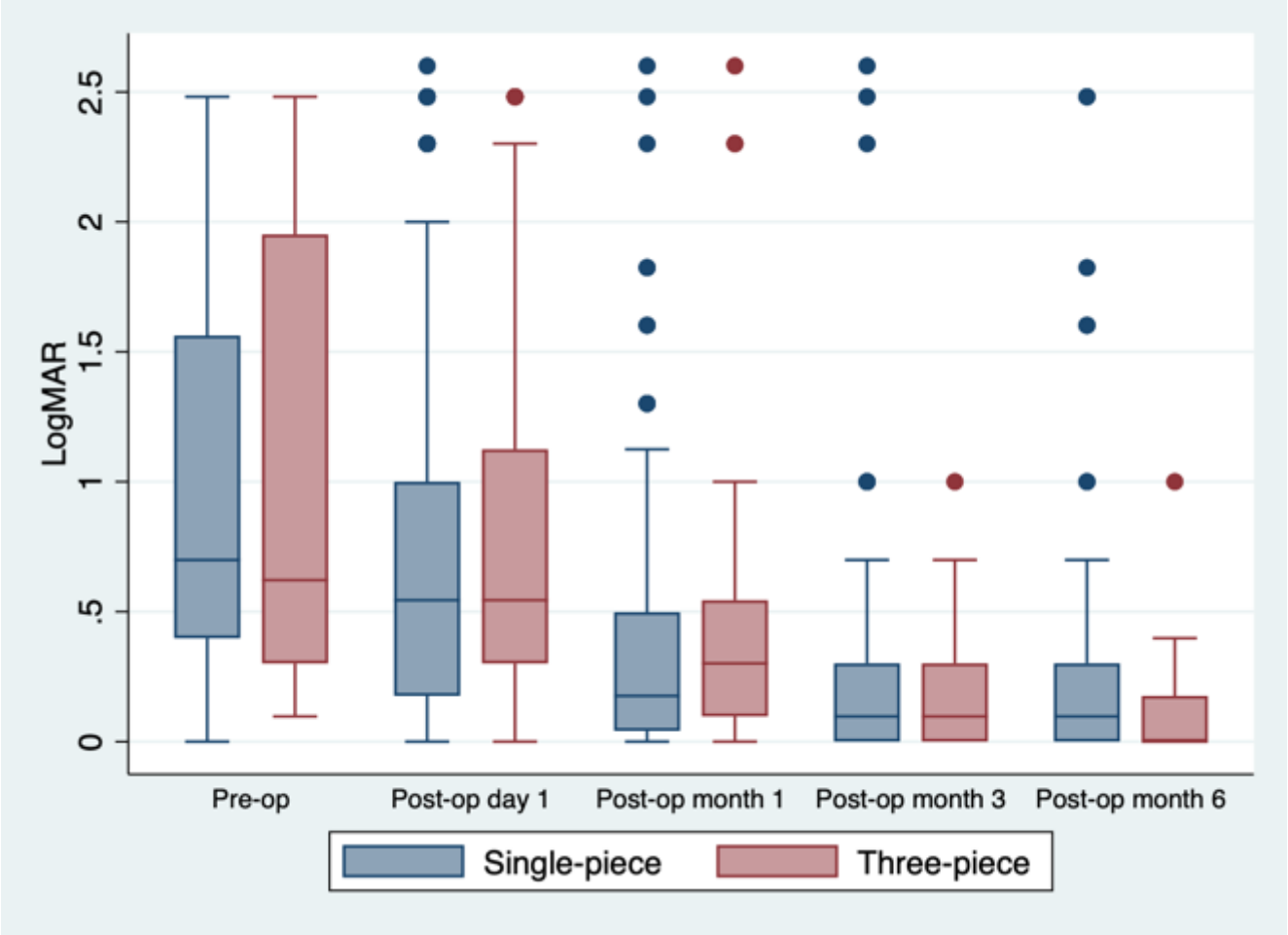

Figure 2

Comparison of LogMAR between single-piece and three-piece IOL across different time points.