

Post-operative refraction in the patients with out-of-the-bag intraocular lens implantations.

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Objective: To study the association between the estimated refraction for in-the-bag intraocular lens (IOL) implants and the post-operative refraction in the patients with out-of-the-bag implants.

Methods: This retrospective study examined medical records of all patients who had undergone complicated cataract surgery with out-of-the-bag IOL implants in Thammasat university hospital from January 1st 2013 to December 31st 2015. We recorded sex, age, diagnosis, type of cataract surgery, type of IOL, implantation position, estimated post-operative refraction for in-the-bag implants and actual post-operative refraction at the 1st and 3rd months. The estimated and the post-operative refraction association was evaluated by linear regression analysis.

Result: We identified 51 patients (51 eyes) who underwent complicated cataract surgery with out-of-the-bag IOL implants; 27 in-the-sulcus implants and 24 sclera-fixed implants. For the in-the-sulcus group, the estimated pre-operative refraction was -0.89 to +0.86 D (mean=+0.08, SD \pm 0.43) and the actual post-operative refractions at the 1st and 3rd months were -3.00 to +1.50 D (mean= -0.51, SD \pm 0.99) and -3.25 to +0.50 D (mean= -0.54, SD \pm 0.95), respectively. The pre- and 3 months post-operative refractions were significantly ($p=0.0391$) correlated. For the sclera-fixed group, the estimated pre-operative refraction was -0.34 to +1.22 D (mean=+0.33, SD \pm 0.37) and the actual post-operative refraction 1st and 3rd months were -4.00 to +1.00 D (mean= -0.99, SD \pm 1.31) and -2.75 to +0.75 D (mean= -0.83, SD \pm 1.06), respectively but there was no significant pre- and post-operative correlation.

Conclusion: Out-of-the-bag IOL implants are associated with postoperative myopic shifts, -0.54D in in-the-sulcus group and -0.83 D in scleral-fixed group. Base on our derived linear regression equation, the IOL power selection for in-the-sulcus implants should be +0.77 to achieve the post-op emmetropia.

Keyword: Post-operative refraction, Out-of-the-bag intraocular lens implant, In-the-sulcus implant, Sclera-fixed implant

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Introduction

Cataracts are common in the developing world and an increasing cause of blindness.^{1, 2} Up to 19 million cataract removal surgeries are performed each year around the world and the WHO projects this figure will rise to 32 million by 2020.³

During cataract surgery, the lens is removed from the capsular bag and replaced with a new intraocular lens (IOL). The desired result is a great improvement of the affected individual's sight and the majority of cataract surgeries are generally successful in achieving post-operative emmetropia. Pre-operatively, all patients need to be evaluated and ocular parameters; such as keratometry and axial length; measured to determine the proper IOL power necessary for the in-the-bag implantation.

Unfortunately, a small portion of patients may encounter operative difficulties e.g. the IOL could not be implanted into the capsular bags due to posterior capsular tear,⁴ lens dislocation, and zonule lysis.⁵ In order to overcome these complications, surgeons often choose to implant the intraocular lens outside of the capsular bags via sulcus or sclera-fixated implantation but these surgeons still need to be refer to the IOL power calculation as if for an in-the-bag implantation.⁶ By reducing the IOL power, surgeons may estimate the post-operative refraction they hope to achieve. However, this method rarely results in post-operative emmetropia. Therefore, this paper aims to increase the chance of post-operative emmetropia for out-of-the-bag implantation by constructing a new

equation for finding a more accurate value of estimated refraction value.

Materials and Methods

This was a retrospective review of the medical charts of patients who had undergone the out-of-the-bag cataract surgery from January 1st, 2013 to December 31st, 2015 at Thammasat University Hospital, Thailand.

The Inclusion criteria were:

1. The patients who have undergone cataract surgery with out-of-the-bag IOL implantation using an IOL power calculation based on the in-the-bag implantation
2. The patients were seen after the 1st and 3rd months post-operatively
3. The absence of concomitant eye pathology that could interfere the patient's refraction (e.g. corneal scar, pterygium with corneal invasion, severe ocular surface diseases.)

Sample size calculation and data analysis

In this study, Stata 12.1 was used to calculate the sample size. To obtain a statistically significant outcome between estimated and post-operative refraction for 2 implant techniques, 2 sample groups are required: 21 patients for the in-the-sulcus group, and 31 patients for the sclera-fixed group. With these sample sizes, it would be possible to achieve 2-sided test of 95% confidence interval with the p-value less than 0.05.

We collected data using a standard case record form: sex, age, diagnosis, type of cataract surgery, type of IOL, implantation position, estimated

post-operative refraction for in-the-bag implants and actual post-operative refraction at 1st and 3rd months. Pre-operatively, all patients were evaluated the ocular parameters; such as keratometry by the ZEISS VISUREF 100 Auto Refractor/Keratometer, Germany and axial length by the Tomey AL-100 Biometer, Germany and then these parameters were used to calculate the IOL power by the SRK/T formula. Post-operatively, the estimated refraction data corresponding to the implanted IOL power were recorded. The actual refraction data at 1st and 3rd month were determined by the ZEISS VISUREF 100 Auto Refractor/Keratometer, Germany and were expressed in spherical equivalents. The association between estimated refraction and the post-operative refraction at 1st and 3rd months was evaluated by linear regression analysis via Stata 14. The regression equations at 3rd months from each group were calculated and used to predict the proper IOL power for aiming emmetropia in both techniques.

Results

We retrieved notes from 27 patients who made up the in-the-sulcus implantation group. Their mean age was 72.5 years, 14 were males and 14 underwent operations in their left eyes. Twenty three eyes underwent phacoemulsification (PE) and the intra-operative complications were posterior capsular rupture with vitreous loss in 14

eyes, posterior capsular rupture without vitreous loss in 2 eyes, partial zonule lysis in 1 eye and nucleus drop in 6 eyes. Four eyes underwent extracapsular cataract extraction (ECCE) and the intra-operative complications were posterior capsular rupture with vitreous loss in all. The measured pre-operative refraction values (Table1) range from +0.86 to - 0.89 for a mean, (standard deviation [SD]) of +0.08 (0.43). The post-operative refraction values at the first month were +1.50 to - 3.00 (mean, SD= -0.51, 0.99), and the 3rd month were + 0.5 to - 3.25 (mean, SD= - 0.54, 0.95).

There were 24 patients in the sclera-fixated group, but 7 of them were excluded, as they did not have the IOL power calculations from in-the-bag implantations. Of the remaining 17 patients, 11 were males and 9 had surgery on their right eye (Table 1). One eye underwent extracapsular cataract extraction (ECCE) and the intra-operative complication was posterior capsular rupture with vitreous loss. Ten eyes underwent intracapsular cataract extraction (ICCE) and the intra-operative complications were posterior capsular rupture with vitreous loss in all. Six eyes underwent pars plana lensectomy (PPL). Their estimated refraction values ranged from + 1.22 to - 0.34 (mean, SD= +0.33, 0.37). The post-operative refraction values for the 1st month ranged from + 1.00 to - 4.00 (mean, SD= -0.99, 1.31), and for the 3rd month were + 0.75 to - 2.75 (mean, SD= -0.83, 1.06).

	In-the-sulcus group N=27	Scleral-fixated group N=17
Age (years) Mean (SD)	72.52 (8.73)	59.18 (14.54)
Sex, N (%) Male female	14 (51.85%) 13 (48.15%)	11 (64.71%) 6 (35.29%)
Laterality, N (%) Right Left	14 (51.85%) 13 (48.15%)	9 (52.94%) 8 (47.06%)
Estimated refraction (D) Range Mean (SD)	+0.86 to -0.89 0.08 (0.43)	+1.22 to -0.34 0.33 (0.37)
Post-op refraction 1 month (D) Range Mean (SD)	+1.50 to -3.00 -0.51 (0.99)	+1.00 to -4.00 -0.99 (1.31)
Post-op refraction 3 months (D) Range Mean (SD)	+0.5 to -3.25 -0.54, 0.95	+0.75 to -2.75 -0.83 (1.06)

Table 1: demographic data and estimated pre- and postoperative refraction values.

The distribution from the bar graph (figure 2A), it has shown the data distribution of these two groups; for in-the-sulcus group, estimated refraction was between -1.00 to +1.00, and for sclera-fixated group the estimated refraction was more positive value than in the sulcus group

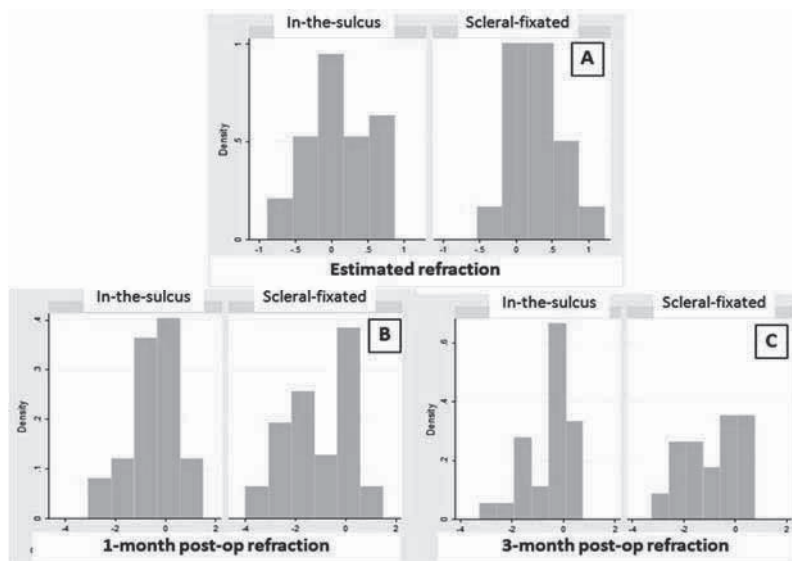


Figure 2: Histograms showing the distributions of the preoperative and postoperative distributions (A) of the refraction values at one month (B) and three months (C).

By the 3rd month, 16 of 27 patients (59.3%) in the sulcus group achieved emmetropia (>-0.50 to $\leq +0.50$ D), however, the 9 of 27 (33.3%) patients had myopic shifts. By contrast, post-operative myopic shift tended to be greater in the sclera-fixated group (10 of 17 patients (58.8%)). (Figure 2 C)

For the in-the-sulcus group (Figure 3), there was not a significant correlation between the pre- and post-operative refraction at 1st month ($p=0.1527$) but there was a significant correlation at 3 months ($p=0.0391$) as well as between the month 1 and 3. ($p=0.0001$)

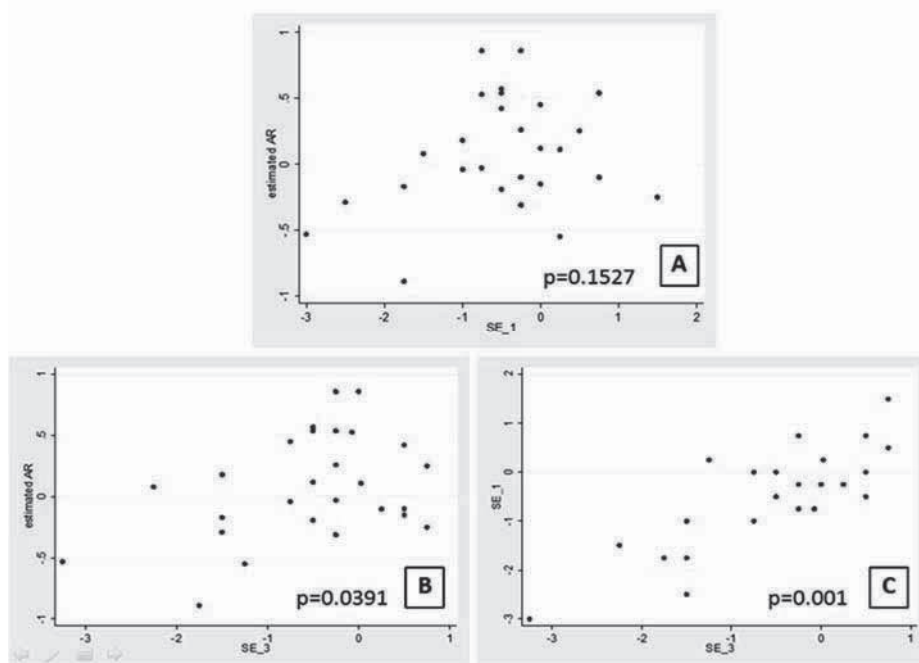


Figure 3: Scatter plots of the pre- and post-operative refraction values for the in-the-sulcus group at one month (A) and three months (B). Figure C is between months one and three.

The regression equation for the in-the-sulcus groups is “ $SE_3 = 0.88 * \text{estimate AR} - 0.61$ ”, where SE3 is the 3rd month postoperative refraction, and estimated AR means the preoperative refraction values. When emmetropia which is $SE_3 = \text{zero}$, the estimated AR is 0.69. (Figure 4)

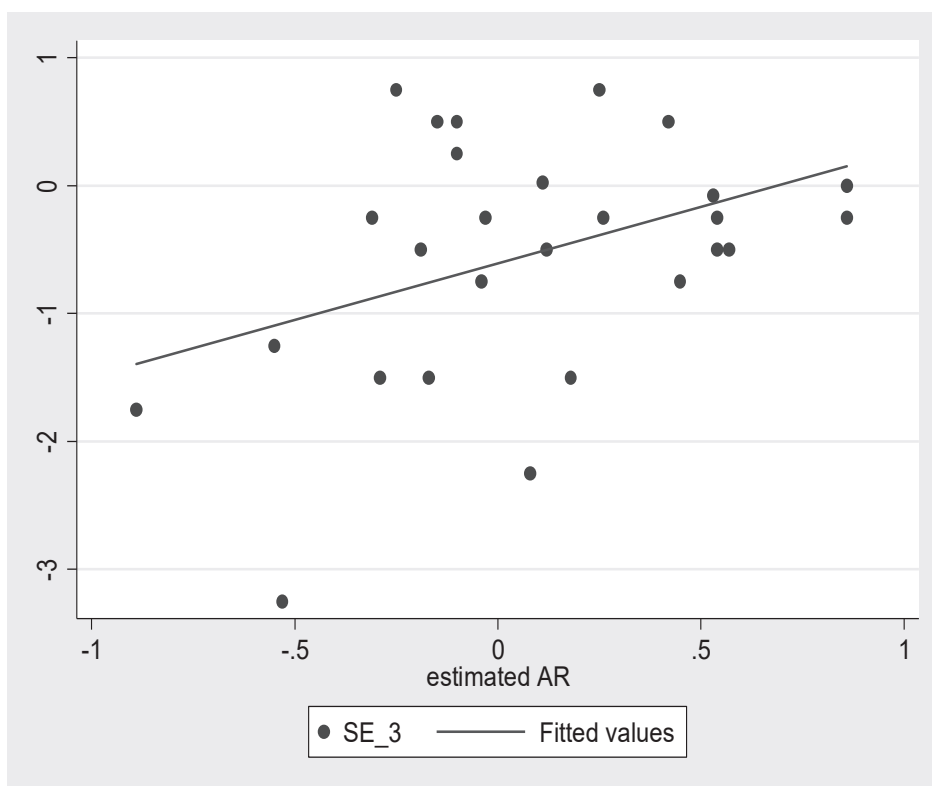


Figure 4: The linear regression line of the pre- and post-operative refraction values for the in-the-sulcus group.

For the sclera-fixated group (Figure 5), there were no statistically significant association between the estimated refraction and the 1st or 3rd month post-operative refraction values ($p=0.5051$, 0.7502 , respectively). But there was between the two postoperative refraction values ($p=0.0001$).

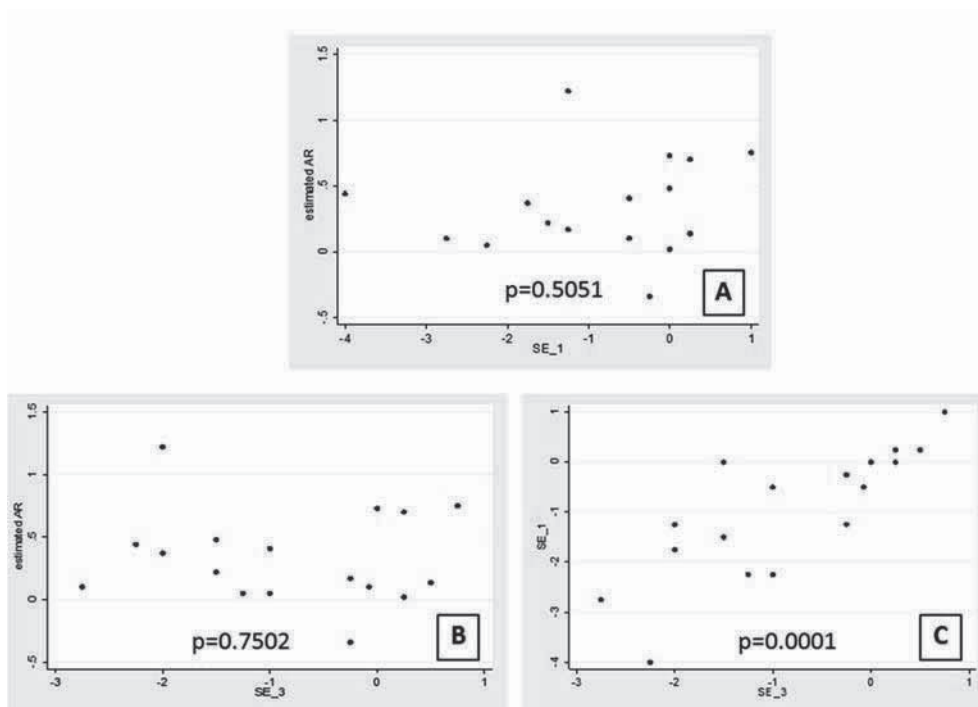


Figure 5: Scatter plots of the pre- and post-operative refraction values in the sclera fixation group at one month (A) and three months (B). Figure C is between months one and three.

Discussion

Our retrospective study has demonstrated that patients who underwent IOL implantation using either the in-the-sulcus or sclera-fixated technique experienced a myopic shift in refraction three months post implantation.

These are the two most common techniques for IOL implantation and choosing which technique to perform depends on the stability of the residual capsular bag, in-the-sulcus technique for stable anterior capsular ring or sclera-fixated technique for inadequate lens capsule. In these operations, the exact IOL power that results in emmetropia was unknown. Most surgeons prefer to estimate the approximate value by

reducing the power for achieving the postoperative emmetropia.

In our study, the myopic shift at three months was -0.54 and -0.83 diopter (D) for in-the-sulcus and sclera-fixated group, respectively, which were similar to other studies⁷⁻¹⁰ that have reported approximately -1.00 D myopic shift after out-of the-bag IOL implants. The mean refraction for in-the-sulcus group was less than the previous studies, this may due to a shorter follow up period and there may be a more myopic shift in the long term. Therefore, for sulcus-fixated IOL implants, these authors recommended reducing the power by about 1.00 to 1.50 D less than in-the-bag implant.⁸⁻⁹

However, in our study, we found a significant association between the pre- and 3 month post-operative refraction for in-the-sulcus group ($p=0.0391$), expressed by the linear equation, $SE3 = (0.88 * \text{estimate AR}) - 0.61$. To achieve emmetropia, SE3 should equal to zero, resulting in an AR of 0.69. We suggest increasing this by the mean of estimated refraction of 0.08 D, giving a final estimated refraction value of +0.77 D.

In the sclera-fixated group, the mean post-operative myopic shifts were ~ -1.00 and -0.83 D at one and three months, respectively, which were similar to results from Mimura et al¹⁰. They also reported the long term post-operative refraction. They found that the immediate post-operative refraction was -0.95 D, -1.16 D after two years, and -1.37 D after 12 years. In our study, we found no statistically significant association between pre-and post-operative refraction values at both time points and cannot calculate the regression equation to predict the proper power. These may have resulted from e.g. heterogeneity of the surgical techniques and imprecise location of the IOL. However, for sclera-fixated IOLs, Han et al. advise a reduction of IOL power of 1.00 D.¹¹

The limitations of this study include its small sample size and retrospective design, different sclera-fixated techniques performed by the surgeons, and imprecise location of IOL. A prospectively designed study following standard operative techniques would provide better quality data.

Conclusion

Post IOL, the in-the-sulcus group and scleral-fixated group experienced postoperative myopic shifts: -0.54 D and -0.83 D, respectively. The pre- and post-operative refractions were positively related in the in-the-sulcus group and the regression equation suggested that the IOL power for such implants should be $+0.77$ to achieve the post-operative emmetropia.

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