

## Considerations in the management of single-piece intraocular lenses outside the capsular bag

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### Abstract

**AIM:** To investigate the outcomes of off label single-piece acrylic intraocular lenses (SPA-IOL) ciliary sulcus placement compared to three-piece IOL (3P-IOL).

**METHODS:** The charts of eight consecutive eyes of patients who received sulcus-placed SPA-IOLs between 2006 and 2009 were reviewed. None of the patients underwent IOL exchange. Charts of six age-matched patients who received sulcus placed 3P-IOLs were reviewed as a control group.

**RESULTS:** Mean follow up was 16 mo for SPA-IOL and 23 mo for 3P-IOL. Five of 8 patients in the SPA-IOL group required chronic use of IOP lowering medications at final follow up. Of these, one patient needed glaucoma implant surgery for uncontrolled IOP. One patient in the 3P-IOL group used chronic aqueous suppression pre- and postoperatively. Four of eight eyes with SPA-IOL were treated with chronic topical steroids and or non-steroidal anti-inflammatory drugs for cystoid macu-

la edema, chronic uveitis, pigment dispersion syndrome or a combination of the above, compared to none in the control group. Mean best-corrected visual acuity was 20/35 in the SPA-IOL group and 20/47 in the 3P-IOL group.

**CONCLUSION:** Sulcus placed SPA-IOLs are associated with increased ocular morbidity. In select cases good visual acuity may be achieved. Due to postoperative rotation of sulcus placed toric SPA-IOLs stable astigmatism correction cannot be achieved. Alternative intraocular lenses should be considered when in-the-bag placement of SPA-IOL is not possible.

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**Key words:** Cataract surgery; Sulcus intraocular lens implant; Single piece intraocular lenses; Three piece intraocular lenses; Posterior capsule tear; Cataract surgery complication; Pigment dispersion; Cystoid macula edema; Posterior capsule tear; Anterior vitrectomy

**Core tip:** Single-piece acrylic intraocular lenses implants are FDA approved for placement into the capsular bag. Their off label placement into the ciliary sulcus is not recommended by the manufacturer and has been the subject of controversy in ophthalmology. This retrospective case series is unique in that patients were followed for 16 mo (range 1.2-37 mo) without intervention and visual outcomes and comorbidities were evaluated and compared with eyes receiving standard of care sulcus placed three-piece intraocular lenses implants.

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**Table 1 Patient demographics**

	Case (n)	Age at surgery	Operative eye	IOL implanted	Pre-op glaucoma diagnosis
SPA-IOL group	1	80	OD	SN60WF	No
	2	85	OD	SN60WF	No
	3	87	OS	SN60T5	No
	4	76	OD	SN60WF	No
	5	71	OS	SN60WF	No
	6	79	OS	SN60T5	No
	7	87	OD	SN60WF	Suspect
	8	76	OD	SN60WF	No
Three-piece IOL group	9	86	OD	MA60AC	Suspect
	10	74	OD	MA60AC	No
	11	88	OD	MA60AC	No
	12	86	OS	MA60AC	No
	13	76	OS	MA60AC	No
	14	87	OS	MA60AC	Yes

SPA-IOL: Single-piece acrylic intraocular lenses.

## INTRODUCTION

With the advent of small incision cataract surgery, and the development of premium intraocular lenses foldable single-piece acrylic (SPA) intraocular lenses (IOLs) have gained in popularity. For example, over 50 million AcrySof® (Alcon, Ft. Worth, Texas) IOLs have been implanted world-wide<sup>[1]</sup>. The SPA-IOL has been modified to allow for concomitant astigmatism (toric IOL) and presbyopia correction (multifocal IOL) at the time of cataract surgery. The SPA-IOL design assures excellent apposition with the posterior capsule allowing stability within the capsular bag. When placed in the bag the SPA-IOL allowed for more posterior position relative to the iris than a 3P-IOL<sup>[2]</sup>. Excellent biocompatibility and design reduce the incidence of posterior capsule opacification (PCO)<sup>[3,4]</sup>. Due to zero angulation of the haptic-optic junction it is not recommended to place SPA-IOLs into the ciliary sulcus<sup>[5]</sup>.

Chang *et al*<sup>[6]</sup> reported a series of 30 patients in a referral setting with complications related to sulcus placed SPA-IOLs. The authors strongly suggest IOL exchange as primary treatment and review alternative IOL choices for primary cataract surgeons. Conversely, Taskapili *et al*<sup>[7]</sup> reports on 89 eyes with sulcus placed SPA-IOL compared with 72 eyes with sulcus placed PMMA IOL and suggesting equal, low rates of complications, glaucoma 19% *vs* 16%, CME 8% *vs* 17%, anterior uveitis 6% *vs* 7%, IOL decentration 4% in both. Endophthalmitis was observed in the control group only (2 of 72 eyes). Other known complications associated with sulcus placed SPA-IOL include pigment dispersion syndrome, iris chafing, uveitis-glaucoma-hyphema syndrome and vitreous hemorrhage<sup>[8-12]</sup>. Uy *et al*<sup>[13]</sup> noted 35% incidence of pigment dispersion and secondary glaucoma in 15% of 20 patients with sulcus placed SPA-IOL.

The cases presented here are unique because they constitute a consecutive case series of eyes with posterior capsular tear, anterior vitrectomy, and off-label placed SPA-IOLs compared with three-piece IOLs in the ciliary

sulcus at a single hospital. Within this institution, one surgeon routinely placed SPA-IOLs in the ciliary sulcus if there was capsular support, and other surgeons did not. Given the controversy, we aimed to review cases of sulcus placed SPA-IOLs to determine visual outcomes and complications. No cases were referred from outside centers, and all operative and perioperative data was well documented in the electronic medical record.

## MATERIALS AND METHODS

This is a retrospective chart review of fourteen consecutive patients who underwent cataract surgery complicated by posterior capsule tear and sulcus placed IOL at one medical center. The study was approved by the institutional human subjects review board. Eight eyes with sulcus placed SPA-IOLs and six eyes with three-piece (3P) acrylic IOLs were included. One patient was lost to follow up after one month. All patients were male, mean age was 80 years (range 71-87 years) at the time of surgery. Demographic characteristics of the two groups were similar and are summarized in Table 1. During phacoemulsification a posterior capsule tear with vitreous prolapse was encountered. Anterior vitrectomy was performed and the IOL was placed into the ciliary sulcus. None of the eyes had retained lens material at the end of the procedure. Six of the SPA-IOLs were monofocal Acrysof® SN60WF implants, two implants were toric SPA-IOLs. No IOL was suture fixated to the iris or the sclera.

## RESULTS

Clinical data on all patients in the two IOL groups are summarized in Table 2. Mean pre-operative spherical equivalent was similar in the SPA-IOL and 3P-IOL groups (+0.47 and +0.32 respectively). Persistent iritis, pigment dispersion and CME were documented in several patients with SPA-IOL, while only one patient with a 3P-IOL had documented CME after surgery. No patient with 3P-IOL had pigment dispersion or prolonged iritis defined as anterior chamber cellular reaction present more than one month after surgery. It is also noteworthy that in the SPA-IOL group, elevated intraocular pressure above 21 mmHg was recorded in 63% of cases. This was treated with intraocular pressure lowering medications beyond postoperative week one. One of the eyes had aqueous drainage implant surgery. The patients were continued on glaucoma medications six month or more after surgery. In contrast, only patient in the three-piece IOL group required intraocular pressure lowering medication after post operative week one, this patient had pre-existing glaucoma. Best corrected visual acuity (BCVA) was 20/30 or better in 4/8 patients in the SPA-IOL group and in 3/7 patients in the 3P-IOL group at post-op month one. In the 3P-IOL group poor vision at month one was attributable to suture-induced astigmatism and resolved after suture removal. Four of eight patients with SPA-IOL and four of six with 3P-IOL achieved a BCVA of 20/30 or better at the time of last follow up.

Table 2 Pre- and postoperative best corrected visual acuity

	Case	Pre-op BCVA	Pre-op refraction	POM1 refraction	POM1 BCVA	Most recent BCVA	Re-operation	CME	PDS	Post-op Glc meds	Glc meds last F/U	Months of F/U
SPA-IOL	1	20/50	+1.25 + 1.25X012	-4.50 + 4.75X001 <sup>1</sup>	20/40	20/20	Wound leak	No	No	Yes	No	37
	2	20/60	-3.25 + 3.50X180	-2.75 + 2.25X003	20/50	20/50	Bgi	Yes	No	Yes	No	32
	3	20/100	+0.50 + 0.50X180	-3.75 + 3.00X138	20/20	20/40	No	No	Yes	No	No	7
	4	20/60	-0.75 + 1.00X163	-1.50 + 1.75X005 <sup>1</sup>	20/25	20/25	No	No	No	No	No	15
	5	20/70	+3.25 + 1.00X105	+2.00 + 0.75X105 <sup>1</sup>	20/60	20/50	No	Yes	Yes	No	No	19
	6	20/40	+0.50 + 2.25X178	-3.75 + 3.75X025 <sup>1</sup>	20/40	20/40	No	Yes	Yes	Yes	Yes	15
	7	20/60	-3.25 sph	-2.75 + 2.00X015	20/25	20/25	No	No	No	Yes	Yes	1.5
	8	20/40	+0.75 sph	-0.50 + 1.00X125	20/30	20/30	No	No	No	Yes	Yes	1.2
Three-piece IOL	9	20/60	-5.75 + 2.00X177	-2.00 + 1.75X175	20/30	20/30	No	Yes	No	No	No	31
	10	20/80	-2.50 + 0.50X155	Unable <sup>1</sup>	20/400	20/60	No	No	No	No	No	38
	11	20/60	+3	-1.75 + 1.75X004 <sup>1</sup>	20/25	20/25	No	No	No	No	No	2
	12	20/70	+2.00 + 1.25X162	Unable <sup>1</sup>	CF	CF <sup>2</sup>	No	No	No	No	No	25
	13	20/50	-2.00 + 2.25X005	-2.50 + 1.00X006 <sup>1</sup>	20/60	20/25	No	No	No	No	No	2
	14	20/100	-2.75 + 1.50X165	Unable <sup>1</sup>	CF	CF <sup>3</sup>	No	No	No	Yes	Yes	24

<sup>1</sup>Patients 10, 12, and 14 were not able to achieve a refraction at the post-operative month 1 visit. In all cases, this was attributed to sutures present at the clear corneal incisions; <sup>2</sup>Patient 12 achieved a visual acuity of 20/40 at post operative month 7 (-2.50 + 3.75X168) and later lost vision (Count Fingers) attributed to wet age related macular degeneration; <sup>3</sup>Patient 14 achieved a visual acuity of 20/50 at post operative month 2 (-2.75 + 3.00X165) and later lost vision (Count Fingers) due to advanced glaucoma. PDS: Pigment dispersion syndrome; SPA-IOL: Single-piece acrylic intraocular lenses.

Two patients in the 3P-IOL group had documented comorbidities preoperatively and therefore reduced visual prognosis. One eye was diagnosed with age related macula degeneration (ARMD) and one eye with advanced glaucoma. Loss of follow up after two month or less occurred in two individuals (25%) with SPA-IOL (one patient deceased, one for unknown reason) compared to three patients (43%) in the 3P-IOL group (for unknown reasons). All patients lost to follow up had best corrected visual acuities of 20/30 or better at their last exam.

## DISCUSSION

The question of whether SPA-IOLs should be placed in the ciliary sulcus is not decisively answered in the peer reviewed literature. Many previous reports have been case reports<sup>[7,8,12-17]</sup>, or are comprised of patients referred to tertiary care centers for management of complications<sup>[6,11,18-20]</sup>. This case series shows that good corrected visual acuity can be achieved with sulcus placed IOLs of either SPA or three-piece type, however, visual recovery was prolonged in several cases using both types of IOL. Secondary intervention was needed in 20% of cases (two of eight eyes) after SPA-IOL. Importantly, this case series is not based on referral to a tertiary care center for complications associated with the procedure and may therefore represent an unbiased look at a controversial issue.

We believe that SPA-IOL rotation, even months after implantation, did occur in some patients and resulted in unstable manifest refraction in at least one patient who had received an AcrySof<sup>®</sup> toric SN60T5 lens (Alcon, Ft. Worth, Tx). The AcrySof<sup>®</sup> SPA-IOL has a diameter of 13 mm from end to end and is thus shorter than the ciliary sulcus diameter of most eyes. There is no accurate way to estimate the ciliary sulcus diameter by external measurements. In addition, the horizontal sulcus diameter is typically shorter than the vertical diameter<sup>[21]</sup>. Therefore,

an initially well centered SPA-IOL in the sulcus may later decenter following rotation into a wider sulcus meridian, unless reverse optic capture can be achieved<sup>[22]</sup>. SPA-IOL decentration after initial correct placement is particularly undesirable in patients with high visual expectations after premium (toric or multifocal) IOL implantation. Given the possibility of rotation after sulcus implantation of toric SPA IOL, it appears preferable to instead implant an alternate three-piece lens combined with other methods of astigmatism correction such as limbal relaxing incisions. Suture fixation of SPA IOL has been reported to result in stable lens position in the literature but was not attempted our cases.

Placement of any posterior chamber IOL in the ciliary sulcus carries increased risk for complications such as pigment dispersion due to IOL proximity to the iris<sup>[23]</sup>. A three-piece posterior chamber IOL with posterior angulation of the haptics will move the optic away from the posterior pigment epithelium of the iris. Additionally, a three-piece IOL with a relatively thin optic edge and small, round haptics will reduce potential problems related to iris chafing when placed in the sulcus. The full picture of uveitis-glaucoma-hyphema syndrome was not observed in our case series, though pigment dispersion and iris transillumination defects were noted in three of eight patients with SPA-IOLs and in none of the eyes with 3P-IOLs. Perhaps more importantly, chronic secondary glaucoma developed in several patients with SPA-IOL, although it is unclear whether this was a direct result of pigment dispersion alone. None of the patients in this series underwent IOL exchange as of their most recent follow-up. It should be noted that this study includes a relatively small number of patients and is retrospective in nature. As such, it may lack sufficient power to definitively demonstrate differences between the two IOLs implanted in the ciliary sulcus.

A recent report on complications after SPA-IOL im-

plantation into the sulcus<sup>[6]</sup> and the corresponding editorial<sup>[24]</sup> provide a comprehensive review and discussion of associated risks, complications, and management of complications. Surgical alternatives for SPA-IOL placement in the sulcus are detailed and discussed in that publication. Technological advancement in cataract surgery has raised today's patients' and surgeons' expectations for an elegant, fast surgery followed by a smooth postoperative course and rapid visual recovery. While posterior capsular rupture inherently leads to a more complex surgery, our results suggest that a three-piece IOL in the sulcus is preferred over an SPA-IOL in such situations. New developments in IOL design may allow reliable use of SPA-IOL in the sulcus<sup>[25]</sup>.

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## COMMENTS

### Background

Single-piece acrylic intraocular lenses (SPA-IOL) implants are FDA approved for in the bag placement. There is controversy about the SPA-IOL placement in the ciliary sulcus when in the bag placement is not feasible. Surgeons at tertiary centers advocate categorical IOL exchange to achieve stable IOL position and eliminate IOL induced complications such as iris chaffing, uveitis-glaucomahyphema syndrome, fluctuating visual acuity, glaucoma and others.

### Research frontiers

The clinical course after sulcus placed SPA-IOL is not known. The experience with sulcus placed SPA-IOL at tertiary care centers is hampered by selection bias due to referral of more complicated cases. This retrospective case series offers an unbiased evaluation of sulcus placed SPA-IOLs compared to the alternative three-piece IOL (3P-IOL) placement.

### Innovations and breakthroughs

With the introduction of small incision phacoemulsification and premium IOLs not necessitating wound enlargement for IOL inserting, the temptation exists to use a SPA-IOL in the sulcus. This off label use does not achieve as stable a placement as when positioned in the capsular bag. Postoperative prevalence of cystoid macula edema, pigment dispersion, and need for glaucoma medications is increased after sulcus placed SPA-IOL compared to 3PA-IOL. IOL exchange can be deferred on a case by case basis.

### Applications

This retrospective study illustrates the sequelae of SPA-IOL placement in the sulcus and clinical results in eyes where IOL exchange was not pursued.

### Terminology

The terminology used here should be familiar to any eye care specialist.

### Peer review

This paper is interesting and can be accepted.

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