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CLINICAL STUDY

Stability and safety of MA50 intraocular lens placed in the sulcus

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Abstract

Purpose **To describe the safety and stability of sulcus placement of the MA50 intraocular lens (IOL).**

Patients and methods **Consecutive patients with MA50 IOLs placed in the sulcus at the University of Iowa Hospitals and Clinics, Iowa City, Iowa, USA, from 1997 to 2012 were identified. Inclusion criteria included patients with over 4 weeks of follow-up data. AEL was compared with incidence of IOL decentration using at two-tailed Student's *t*-test.**

Results **Fifty eyes of 49 patients meeting the inclusion criteria were identified. Four weeks post-operatively, the average best-corrected visual acuity was 20/30. IOL decentration occurred in 14% of patients; patients with decentered IOLs had a significantly longer average AEL (25.37 mm) than patients whose IOL remained centered (23.94 mm, $P = 0.017$). Other complications included uveitis-glaucoma-hyphema syndrome (12%), iritis (8%), and glaucoma (6%). There were no cases of pigment dispersion syndrome or need for lens exchange. Twelve eyes (24%) had intra-operative optic capture by the anterior capsule, none of which had post-operative decentration.**

Conclusion **The MA50 IOL is a reasonable, stable option for placement in the sulcus, with a low-risk profile; however, in eyes with longer AEL and presumably larger anterior segment, surgeons should consider placing an IOL with longer haptic distance than the MA50 to maintain centration. Optic capture of the MA50 IOL by the anterior capsule should be considered for longer eyes, as it is protective against decentration.**

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Introduction

In cataract surgery, a wide variety of pre-operative and intra-operative complications can necessitate the placement of a sulcus supported intraocular lens (IOL).[1] The choice of an appropriate IOL is integral in preventing post-surgical morbidity. Single-piece IOLs placed in the sulcus have been shown to have multiple complications,[2] including pigment dispersion syndrome,[3] pigmentary glaucoma,[4,5] and uveitis-glaucoma-hyphema (UGH) syndrome. Ideal characteristics of a sulcus-based IOL include a large optic, long thin angulated haptics, a smooth anterior optic surface, and a safe optic material. A large optic of at least 6.0 mm allows for mild decentration in the sulcus and will allow for capture with a centered anterior capsulotomy. IOLs with a large haptic loop-to-loop dimension (eg, >13.0 mm) improve lateral stability within the ciliary sulcus even in large eyes, which helps to reduce the risk of uveal irritation and hyphema. IOLs with posteriorly angulated haptics and a smooth anterior surface of the optic allow for sufficient iris clearance and minimize the risk of uveal irritation and pigment dispersion syndrome. Acrylic material is preferred, as these patients are often at higher risk for future retinal issues and silicone lenses may compromise surgical visibility in vitreoretinal surgeries if silicone oil or expansile gas is used. Finally, an ideal sulcus IOL would fold and allow for a smaller incision using an injector the surgeon is comfortable with.[1]

Options for a suitable sulcus-based lens include the Staar AQ2010V[1] and the Alcon MN60AC, MA60AC, and MA50BM, among others. For several years, we have used the Alcon MA50 IOL as our IOL for sulcus placement. Although it only has a 13.0 mm haptic length and has a square-anterior optic edge, we choose this lens due to its favorable optic size of 6.5 mm, hydrophobic acrylic and foldable material, posteriorly angulated haptics, and ease of loading in a known inserter. We hereby report our results.

Materials and methods

This is a retrospective cohort study examining cataract extraction with MA50 IOLs placed in the sulcus at University of Iowa Hospitals and Clinics from 1997 to 2012. The Institutional Review Board of the University of Iowa approved this study. Consecutive patients with MA50 IOLs placed in the sulcus at University of Iowa Hospitals and Clinics were identified based on a review of surgical records from 1997 to 2012. Inclusion criteria included patients with over 4 weeks of follow-up data. Data collection focused on age, gender, axial eye length (AEL, as measured with optical coherence or A-scan echography), pre-operative best-corrected visual acuity, reasons for IOL placement in the sulcus, intra-operative complications, post-operative best-corrected visual acuity, and complications at 4 weeks and at the last available data point.

Results

The study population characteristics of the 50 eyes of 49 patients meeting the inclusion criteria are outlined in Table 1. The most common reasons for IOL placement in the sulcus were: capsular tear during phacoemulsification, zonular problems during phacoemulsification, and aphakia (Table 2); several patients had more than one cause, that is, anterior and posterior capsular tear. The pre-operative comorbidities of the patient population included: diabetes mellitus ($n=13$), of which 7 patients had diabetic retinopathy, trauma resulting in globe laceration (6), aphakia (5), retinal detachment (5), Fuchs' dystrophy (4), other trauma (4), ocular hypertension (2), glaucoma suspect (2), anterior ischemic optic neuropathy (2), retinitis pigmentosa (2), and amaurosis fugax (2). The study included 41 primary IOL placements at the time of complicated cataract surgery, 5 secondary IOL placements and 4 IOL exchanges.

Intraoperative case data showed that only 1 case had mild marring of the IOL intraoperatively. There were 12 cases of optic capture using an intact capsulorrhexis, which may be the ideal position of an IOL in the sulcus. There were no cases of pupil capture or posterior loss of IOL intraoperatively. Immediate post-operative data showed that 4 pars plana vitrectomies were performed, 2 of which were planned and 2 of which were necessitated by retained lens material. There was one case of immediate post-operative IOL decentration, which improved by 4-week follow-up. Four-week follow-up data is shown in Table 3. Long-term follow-up data, (mean 102 weeks, median 50 weeks) is shown in Table 4. Iritis occurred in the operative eye of 4 patients (8%), one of which may be attributed to a possible acute-rejection episode of a corneal transplant. Glaucoma occurred in the operative eye in 3 patients. Two of these patients were treated with intraocular pressure lowering medications: one for normal tension glaucoma, and the other for glaucoma that subsequently developed in the patient's non-operative eye. The third patient developed proliferative diabetic retinopathy and neovascular glaucoma and needed intervention with an Ahmed seton device, which was not thought to be secondary to the IOL.

Table 2 Most common reasons for IOL placement in sulcus

Posterior capsule tear	23
Anterior capsule tear	14
Zonular integrity loss	9
Aphakia	5
IOL exchange	3
Pre-existing capsular trauma	2

Table 3 Four-week follow-up data

	Mean	*SD*
Post-operative BCVA	20/30 (logMAR 0.19)	logMAR 0.29
Improvement in BCVA	20/250 to 20/30	logMAR 1.00
Difference of spherical equivalent from target refraction	−0.51 D	0.87 D

Table 4 Comprehensive follow-up data

IOL decentration	7 (14%)
McCannel sutures	4 (8%)
Iritis	4 (8%)
Glaucoma intervention	2 (4%)[a]
	1 (2%)[b]
Ocular hypertension	1 (2%)
UGH syndrome	6 (12%)
Pigment dispersion syndrome	0
Lens exchange	0

[a] Treated with topical medications. [b] Treated with Ahmed glaucoma drainage device for neovascular glaucoma secondary to proliferative diabetic retinopathy.

Table 1 Study population characteristics

Mean age	56.7 years	Range: 4–93 years; SD: 19.9 years
Gender	30 Male	20 Female
Laterality	33 OD	17 OS
Mean best-corrected visual acuity (BCVA)	20/250 (logMAR 1.09)	Range: 20/20 to HM; SD: 1.04 logMAR)

One patient was treated for ocular hypertension. Six patients (12%) thus had findings within the spectrum attributable to IOL-induced UGH syndrome, including one patient with concurrent glaucoma and iritis. None of the optic capture patients developed glaucoma or iritis. There was no significant difference in AELs of eyes that developed iritis, glaucoma, or symptoms attributed to UGH syndrome when compared with eyes that did not experience these complications. The most common complication was IOL decentration (14%), with over half of the decentered IOLs needing subsequent McCannel suture fixation. Mean time to decentration was 7.4 weeks, with 6 of 7 cases noted to be decentered within the first month, and only one noted at 9 months post-operatively. Mean time to McCannel suture was 45 weeks. None of the eyes with McCannel suture fixation developed UGH syndrome or pigmentary dispersion (mean follow-up time of all decentered lenses 148 weeks). Of the seven cases of decentration, five were noted to have a direction of decentration; four decentered inferiorly and the other nasally. One patient in the decentration group underwent successful IOL repositioning at 2 days post-operatively, with chronic uveitis noted 11 months after the procedure.

In the group of patients with optic capture, there were no cases of decentration. The optic capture eyes were excluded from AEL risk factor analysis for decentration or UGH syndrome, as capsular capture greatly diminishes the risk of IOL movement in the sulcus. When the AELs of non-optic captured eyes were analyzed, we found that eyes that experienced IOL decentration were significantly longer compared with eyes in which the IOL remained centered ($P = 0.017$) based on a two-tailed Student's *t*-test, as shown in Table 5. The AEL of optic captured IOLs was 24.07 mm (SD: 0.80 mm), which was not significantly different than the AEL of eyes in which the IOL remained centered ($P = 0.65$). When the optic captured IOLs are included in the group of IOLs that remained centered, the correlation of increased AEL to IOL decentration increased in significance to $P = 0.009$.

Discussion

The safety of an IOL in the sulcus is determined by multiple characteristics including large optic size, haptic length, lens material, angulation of haptics, shape of optic edge, and intra-operative ease of use, such as a foldable lens which uses a standard inserter. The MA50 lens meets nearly all of these characteristics, accounting for the low incidence of iritis, glaucoma, pigment dispersion syndrome, and UGH syndrome in our series. Our study found an 8% likelihood of future pars plana vitrectomy in this set of complicated eyes and the acrylic material of the MA50 may allow visualization more readily than silicone material.[1] The attribute in which the MA50 is lacking is the loop-to-loop dimension of only 13.0 mm, leading to increased risk of lateral instability. Although the square-anterior edge of the optic has been associated with pigment dispersion syndrome in piggyback implantation of 3-piece hydrophobic acrylic IOLs in the sulcus,[3,4,6,7] our series shows that in non-piggyback situations, the MA50 in the sulcus did not result in any cases of pigment dispersion syndrome.

Table 5 Average axial eye length (excluding eyes with optic capture)

	Mean AEL	*AEL SD*
Decentered IOLs	25.37 mm	1.78 mm
Centered IOLs	23.94 mm	1.22 mm
Student's *t*-test	$P = 0.017$	

In our series, IOL decentration was the most common complication when placing the MA50 in the sulcus without optic capture, especially in long eyes (≥25.0 mm). However, optic capture by the anterior capsule is protective for IOL decentration, as shown by the lack of IOL decentration in the optic capture group. Interestingly, the AEL of optic captured IOLs was not significantly different from the centered IOLs ($P = 0.65$), but was significantly different from the decentered IOLs ($P = 0.46$), which could indicate that the AEL was the cause; however, with the optic securely captured by the anterior capsule, decentration would be mechanically unlikely.

Decentration has been found to be the most common reason for explantation of foldable posterior chamber IOLs.[8] When sulcus foldable acrylic IOLs were studied in the pediatric population, lens decentration was found to be present in ~5% of eyes.[9,10] In one study, 3 of 55 eyes had decentration, none of which needed surgery or were considered visually significant.[9] In another study, 4 of 77 eyes had decentration which required surgical repositioning or IOL exchange.[10] Decentration was seen more in eyes with a longer AEL, postulated to be secondary to the disparity in the size of the IOL and the fixation site.[9]

Alternatives for sulcus IOLs are not plentiful, but include the Staar AQ2010 V, which has a 13.5 haptic loop-to-loop dimension and rounded anterior optic edge. The AQ2010 V is silicone, however, which is not ideal in eyes which have often had vitreous loss during loss of posterior capsular support, leading to higher risk of retinal detachment and need for silicone oil later on.[2] No long-term studies of the Staar AQ2010 V have been published to date in our search. The Sulcoflex, an IOL designed for the sulcus with 6.5 mm optic, 14.0 mm length, and 10 degree posterior haptic angulation with rounded optic edges, is not available in the United States, although small European studies indicate safety and stability in the sulcus. At this time, however, the Sulcoflex

only comes in −5 D to +5 D, with its intended use being piggyback post-refractive enhancement.[11–13]

A limitation of the study is the inclusion of one patient with both eyes included, which may lead to a small correlation effect in statistical analysis. No other patients had a fellow eye which fit into the inclusion criteria of the study. Future studies comparing the MA50 with other similar three-piece posteriorly angulated IOLs would be beneficial to show whether the MA50 is superior to other sulcus IOL options. The goal of this study, however, is to show that the MA50 is a stable lens for the sulcus in most eyes with a low-risk profile. Its desirable characteristics may outweigh the shorter loop-to-loop dimension in most eyes. We recommend caution in eyes with increased AEL, due to higher risk of IOL decentration. Placing the haptic in the sulcus with the optic prolapsed posteriorly seems to be the ideal position to limit the risk of decentration, iritis, and glaucoma.

Summary

What was known before

- Placement of an intraocular lens (IOL) in the sulcus, rather than the capsular bag, is associated with an increased risk of IOL decentration, glaucoma, and iritis.

What this study adds

- The MA50 IOL is a stable lens for the sulcus in most eyes, with low risk of iritis, glaucoma, and pigment dispersion syndrome. MA50 IOL decentration is more likely in eyes with increased axial eye length (≥25.0 mm). Optic capture of the MA50 IOL by the anterior capsule is protective against decentration and the UGH syndrome.

Conflict of interest

The authors declare no conflict of interest.

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