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Pathological assessment of complications with asymmetric or sulcus fixation of square-edged hydrophobic acrylic intraocular lenses

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Abstract

Objective—One-piece hydrophobic acrylic intraocular lenses (IOLs) are not indicated for sulcus fixation because of complications, such as uveitis-glaucoma-hyphema syndrome. Similar complications may also be observed with 3-piece lenses having a square optic edge on the anterior surface. The objective of this study was to provide pathological evidence of complications related to out-of-the-bag fixation of 1-piece or 3-piece hydrophobic acrylic IOLs with anterior and posterior square optic edges.

Design—Comparative case series with pathology.

Participants—559 pseudophakic cadaver eyes obtained from eye banks within the United States, implanted with different IOLs.

Methods—Anterior segment scanning of whole eyes with a high-frequency ultrasound system, or with a high-resolution anterior segment magnetic resonance imaging, followed by gross examination. Selected eyes were processed for complete histopathological analysis; some of them were explanted before histopathology to allow for direct light microscopic evaluation of the lenses.

Main Outcome Measures—Findings from imaging, gross, and histopathological evaluation that could be related to out-of-the-bag fixation of the lenses.

Results—256 eyes were implanted with hydrophobic acrylic IOLs with anterior and posterior square optic edges; 18 of them exhibiting asymmetric or sulcus IOL fixation (six 1-piece, and twelve 3-piece IOLs) underwent complete histopathological evaluation and were compared to the contralateral eyes with symmetric in-the-bag IOL implantation. Pathological findings were composed of IOL decentration and tilt, pigmentary dispersion within the anterior segment and on

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the IOL surface, iris transillumination defects, iris changes including vacuolization/disruption/loss of the pigmented layer, iris thinning, and iris atrophy, as well as synechiae and loop erosion in the case of 3-piece lenses. Findings were more significant in comparison with the control contralateral eyes, and were particularly evident in relation to the sulcus-fixated haptic in the case of 1-piece lenses. The majority of the eyes with 3-piece lenses showed signs of complicated surgery.

Conclusions—This study provides pathological correlation of complications that were clinically reported in the peer-reviewed literature in relation to sulcus fixation of one-piece hydrophobic acrylic IOLs. The eyes with 3-piece lenses generally exhibited evidences of complicated surgery; therefore all pathological findings in those cases may not be strictly attributed to the out-of-the-bag fixation.

Introduction

Several studies have described the advantages of implantation of posterior chamber intraocular lenses (IOLs) in the capsular bag, in comparison to sulcus fixation. Symmetric in-the-bag IOL fixation, with a complete coverage of the optic periphery by the capsulorhexis edge helps preventing interaction with the posterior iris surface. Posterior iris chafing by the loop or the optic portion of sulcus-fixated IOLs may cause a spectrum of disorders that include iris transillumination defects, pigment dispersion with or without elevation of intraocular pressure (IOP), intermittent microhyphemas, and the uveitis-glaucoma-hyphema (UGH) syndrome.¹⁻⁶ Since the introduction of one-piece hydrophobic acrylic lenses in the market, there have been several reports on complications related to the presence of their relatively thick and bulky haptics in the sulcus, whether this fixation site was inadvertent or elective after complicated cataract surgery.⁷⁻¹⁴ Similar complications have also been reported with 3-piece hydrophobic acrylic lenses with a square edge on the anterior optic surface, in a piggyback configuration or standard sulcus placement.¹⁵⁻²⁰ It is usually recommended to implant an IOL having a smooth anterior optic surface with rounded edges in cases of sulcus fixation to minimize the possibility of iris chafing, should any posterior iris contact occur.⁸

The above-mentioned reports were generally based on clinical series with or without analyses of explanted IOLs. The objective of this study was to provide, for the first time, complete pathological assessment of human donor eyes with asymmetric or sulcus fixation of square-edged hydrophobic acrylic IOLs.

Materials and Methods

This study was performed in cooperation with the San Diego Eye Bank and other eye banks nationwide; therefore, only Food and Drug Administration (FDA) approved IOLs were included. The employees of the participating eye banks were instructed to attempt to obtain the date of the implantation, generally done through interaction with the donor family. Upon enucleation, the eye banks were instructed to place the whole globes in 10% neutral buffered formalin in order to prevent significant distortion of their geometry due to postmortem changes.

Once available in our laboratory, the whole eyes underwent anterior segment scanning with a high-frequency ultrasound system with digital enhancement (Artemis, Ultralink LLC, St. Petersburg, FL). The system uses a broad-band 50 MHz transducer (bandwidth 10 to 60 MHz), which sweeps in a reverse arc high-precision mechanism to acquire B-scans. Each scan sweep takes 0.5 seconds and is designed to follow the contours of the cornea, iris and ciliary body structures. This ultrasound provided imaging of the entire anterior segment of the eye via a noncontact, immersion technique.^{21,22} Pseudophakic donor eyes were also obtained from MRI Research, Inc. Upon enucleation, the whole eyes underwent high-

resolution anterior-segment magnetic resonance imaging (MRI) using a clinical magnetic resonance imager (1.5 Tesla, General Electric, Waukesha, WI), a purpose-designed eye-imaging magnetic resonance receiver coil (MRI Research, Inc.), and a standard spin-echo radiofrequency pulse sequence (T1-weighted, single echo, multi-slice).^{23,24} The eyes were then fixated in formalin, and forwarded to the Moran Eye Center. Information such as the position of the implant in relation to intraocular structures, tilt, and decentration was obtained from ultrasound and MRI evaluation before any disruption was caused by sectioning.

The eyes were then bisected coronally just anterior to the equator. Gross examination of the anterior segment was done from the posterior aspect (Miyake-Apple view) to assess IOL fixation (e.g., bag-bag, bag-sulcus, sulcus-sulcus). Eyes containing 1-piece or 3-piece hydrophobic acrylic IOLs with a square edge on the anterior and posterior optic surfaces, without symmetric in-the-bag fixation were selected for further analyses. Whenever the contralateral eye of the same donor was pseudophakic, with symmetric in-the-bag IOL fixation, these eyes were used as controls. IOL tilt was qualitatively scored by ultrasound or MRI evaluation as none, mild, moderate and severe, according to the angle formed by the plane of the IOL optic in relation to the plane of the ciliary sulcus. IOL centration was also qualitatively scored by ultrasound or MRI, and gross evaluations, in relation to the ciliary sulcus in each eye. Other aspects analyzed under gross examination were the presence of posterior capsular rupture, as well as pigmentary dispersion and iris transillumination defects (which were qualitatively scored from none to severe).

Two selected study eyes containing a 1-piece and a 3-piece hydrophobic acrylic IOL were explanted before histopathological processing. The lenses were carefully removed through a pre-existent posterior capsular opening, and directly analyzed under light microscopy for signs of pigmentary dispersion. After gross examination and scoring, anterior and posterior segments of each study and control eye were processed for complete histopathological evaluation. Following dehydration and embedding in paraffin, the eyes were sectioned and stained with hematoxylin and eosin (H&E) and Masson's trichrome stains. Multiple 3 micron-thick sections of each eye were then examined under a light microscope (Olympus, Optical Co. Ltd., Japan) for signs of chronic inflammation, pigmentary dispersion, glaucoma, and cystoid macular edema. Photomicrographs were taken for documentation.

Results

559 pseudophakic cadaver eyes coming directly from eye banks nationwide to our laboratory were examined. 217 of these eyes were found to be implanted with hydrophobic acrylic (AcrySof; Alcon Laboratories) lenses, which have square edges on the anterior and posterior optic surfaces. Of the 217 eyes, 14 of them were found to have asymmetric or sulcus fixation, with at least one of the haptics outside the bag (3 eyes with 1-piece, and 11 eyes with 3-piece lenses). 102 cadaver eyes were forwarded to our laboratory by MRI Research, Inc. 39 of these eyes were found to be implanted with the same type of hydrophobic acrylic lenses. Of the 39 eyes, 4 of them were found to have asymmetric or sulcus fixation, with at least one of the haptics outside the bag (3 eyes with 1-piece, and 1 eye with 3-piece lenses). Therefore, further analyses were performed on 6 eyes with 1-piece lenses, and on 12 eyes with 3-piece lenses.

Table 1 (available at <http://aaojournal.org>) shows characteristics of the 18 study eyes, including findings from ultrasound/MRI and gross examinations. Eyes number 4 and 5 were from the same donor. The mean age of the donors was 85.6 $\pm$ 5.8 years, ranging from 74 to 97 years. Information on the time from cataract surgery to death was available for 10 eyes (mean: 71.9 $\pm$ 65.8 months; range: 24 to 231 months). All eighteen study eyes had some

degree of IOL decentration in relation to the ciliary sulcus. Six eyes had mild, eight had moderate, and four had severe IOL decentration. Imaging of the anterior segment via ultrasound or MRI revealed that fourteen of the eighteen eyes were found to have IOL tilt. Four eyes had mild, six had moderate, and four had severe tilt (Figure 1).

Table 1 (available at <http://aaojournal.org>) also shows that twelve of the eighteen eyes had a posterior capsule rupture. All study eyes had some degree of pigment dispersion. Two eyes had mild, thirteen had moderate, and three had severe pigment dispersion. Transillumination defects were also seen in all eighteen eyes. Three eyes had mild, nine had moderate, and six had severe transillumination defects (Figure 2). More significant defects were especially evident in relation to the side of the IOL fixated in the sulcus (in asymmetric fixation cases), particularly in relation to the sulcus-fixated haptic in the case of 1-piece lenses (Figures 2A and 2C).

Ten of the 17 donors had a contralateral eye that was pseudophakic, with symmetric in-the-bag IOL fixation, and were therefore used as controls. Table 2 (available at <http://aaojournal.org>) shows characteristics of the 10 control eyes, which are referred to according to the number of the contralateral study eye (listed in Table 1, available at <http://aaojournal.org>). The mean age of the donors was 86.2 $\pm$ 5.6 years, ranging from 74 to 93 years. Information on the time from cataract surgery to death was available for 6 eyes (mean: 54.3 $\pm$ 33.2 months; range: 24 to 114 months). Six of the ten controls had no IOL decentration, two had mild, one had moderate, and one had severe decentration. The eyes with moderate and severe IOL decentration contained a silicone plate, and a 3-piece silicone lens with Prolene haptics (SI30, Advanced Medical Optics – AMO), respectively. This later was decentered due to asymmetric contraction of the capsular bag. IOL tilt was almost non-existent with 7 eyes having no tilt and the remaining 3 having a mild tilt. Seven of the ten control eyes had intact posterior capsules with the remaining three exhibiting a posterior capsulotomy compatible with an Nd:YAG laser procedure (including some Nd:YAG optic pits). Pigment dispersion was mild in two eyes with the other eight having no pigment dispersion. Iris transillumination defects were mild to very mild in six eyes and were generally limited to the pupil border; three eyes had no defect and one had severe defect (also around the pupil border) along with a peripheral iridectomy.

Examination of the explanted lenses from 2 study eyes under direct light microscopy showed that the explanted 1-piece lens exhibited significant pigment dispersion on its anterior surface, especially at the level of the haptics and the optic periphery. The explanted 3-piece lens also exhibited significant pigment dispersion at the optic periphery; a fragment of tissue that appeared to be consistent with iris tissue was enrolled around one of its haptics (Figure 3, available at <http://aaojournal.org>).

Light microscopic examination of multiple sections from each study eye showed pigment dispersion, ranging from mild to severe. Pigment was observed in the trabecular meshwork, peripheral cornea, and on the lens capsule. All eyes exhibited changes at the level of the iris, including vacuolization of the pigmented layer on the posterior iris surface (which is consistent with chronic irritation), mild to severe disruption/loss of the pigmented layer, iris thinning, as well as iris atrophy. Disruption/loss of the iris pigmented layer was seen at the pupil border, iris root and midperiphery, and around the area of sulcus-fixated haptics. Additional histopathological findings in some of the eyes with 3-piece lenses included peripheral anterior synechia, posterior synechia, and a haptic loop eroding through the sulcus (Figure 4, available at <http://aaojournal.org>). Eye number 12 also exhibited initial signs of optic nerve disc cupping. In cases of bag-sulcus fixation of the lens, anterior segment histopathological findings were always more significant on the side of sulcus

fixation, whereas the side with the haptic fixated in the capsular bag appeared overall unremarkable. This was particularly observed in the eyes with one-piece lenses (Figure 5).

Light microscopic examination of multiple sections from each control eye was essentially unremarkable. One eye showed minimal disruption of the pigmented layer and the remaining nine eyes had no noteworthy histopathological findings.

Discussion

One-piece and 3-piece AcrySof lenses have a square optic edge on the anterior and posterior optic surfaces. The finishing of the square edges of these lenses was modified to give the side walls an unpolished or “textured” appearance, which was found to improve postoperative glare phenomena.²⁵ This feature was extended along the length of the optic and haptics in the one-piece lenses. Because of the flexibility and thickness/bulk of its haptics, the square optic and haptic edges, and the unpolished side walls, implantation of the one-piece AcrySof lens in the sulcus is not recommended, and this design is not indicated for sulcus fixation in the Direction for Use labeling. Furthermore, the haptics of the one-piece lens are planar and therefore do not vault the optic posteriorly from the iris. The overall lens diameter is up to 13.0 mm, which is too short for many eyes; if the haptics do not fully extend because of their low compressive force, the IOL will be prone to decentration in the ciliary sulcus of larger eyes.⁸ A study from our laboratory reported on 3 one-piece lenses that were explanted because of pigmentary dispersion syndrome related to the presence of their haptics in the ciliary sulcus.⁷ Those cases revealed the presence of significant amounts of iris pigment on the anterior surface of the lens (optics and haptics). Other similar cases of pigmentary dispersion with this lens have been described in the literature, which were generally managed with explantation/exchange of the lens, or by surgical repositioning within the capsular bag.⁸⁻¹⁴

In a retrospective study, Chang et al. described the findings in 30 eyes with sulcus fixated one-piece lenses (29 of those were one-piece AcrySof; one was a Rayner 570C hydrophilic acrylic design).⁸ Posterior capsule rupture and IOL decentration were observed in approximately two thirds of the eyes. No IOL was suture fixated to the iris or sclera. At the time of initial consultation, the corrected distance visual acuity ranged from 20/20 to 20/400 and the mean IOP was 22.1 mm Hg. Approximately one third of the patients were taking at least one IOP-lowering medication. The most common complications were pigment dispersion and iris transillumination defects, followed by IOL edge symptoms and elevated IOP. Intraocular hemorrhage and cystoid macular edema were relatively infrequent. The authors hypothesized that the latter may have been underreported because of the retrospective nature of the data collection.

Our study provides pathological evidence of damage related to the presence of the haptics of one-piece AcrySof lenses in the sulcus. Two of the 6 eyes had a posterior capsular rupture (Table 1, available at <http://aaojournal.org>). In these 2 cases the one-piece lens may have been electively placed out of the bag following complicated surgery (Figure 2B), while in the other 4 cases asymmetric fixation might have been inadvertent. Assuming asymmetric IOL fixation in the absence of posterior capsule rupture followed relatively uncomplicated surgery, all pathological findings in these 4 eyes can reasonably be attributed to the presence of the haptics of the one-piece lens in the sulcus. Gross and histopathological examination confirmed more significant pigmentary dispersion and iris transillumination defects in relation to the sulcus-fixated haptic of 1-piece lenses (Figures 2A, 2C, and 5). Iris pigment present within the trabecular meshwork was a common finding in these eyes, although other clear histopathological signs of glaucoma were not found. Clinical information provided by

the eye banks does not contain details on whether or not the donors were being treated for any ocular condition.

Similar complications have also been reported with 3-piece AcrySof lenses, in a piggyback configuration or standard sulcus fixation.¹⁵⁻²⁰ In piggyback implantation, fixation of the anterior lens in the sulcus has been recommended to prevent interlenticular opacification. However, a previous publication from our laboratory described a case of pigmentary dispersion syndrome resulting from secondary piggyback implantation of a low power 3-piece hydrophobic acrylic, square-edged IOL in the ciliary sulcus (AcrySof MA60MA; +5 D).¹⁵ Chang and Lim,¹⁷ as well as Iwase and Tanaka,¹⁶ have also described cases of pigmentary dispersion syndrome with the same 3-piece hydrophobic acrylic lens implanted in a piggyback configuration.

Wintle and Austin reported a case of pigmentary dispersion syndrome one month following implantation of a three-piece hydrophobic acrylic lens (AcrySof IOL model MA60BM, 6.0 mm optic, 13.0 mm overall length) placed electively in the ciliary sulcus following a posterior capsule tear.¹⁸ In that patient, IOP control was achieved pharmacologically, with eventual discontinuation of treatment and stabilization of IOP after 6 months of therapy, though hyperpigmentation of the trabecular meshwork continued. A similar case was also described by Almond et al.¹⁹

Other studies did not show excessive interaction between these 3-piece, sulcus-fixated lenses and the posterior iris surface. Brazitikos et al. prospectively followed 28 eyes implanted with the MA60BM lens in the sulcus because of posterior capsule rupture.²⁶ The most common postoperative complications were transient corneal edema in 12 eyes and increased IOP in 11 eyes. Slight asymptomatic decentralization from the center of the pupil (1.0 to 2.0 mm) and pseudophacodonesis were observed in 5 eyes each. Friction of the IOL with the iris occurred in only 1 eye. Clinically significant cystoid macular edema occurred in 3 eyes. It has to be highlighted that the follow up in that study was of only 6 months. Mackool described no instances of persistent IOP elevation or pigmentary dispersion syndrome after implanting more than 100 AcrySof MA60 BM IOLs in the ciliary sulcus (follow up time not specified).²⁷ The author suspected that a transient pigmentary dispersion might have occurred because many of the procedures involved iris-IOL contact during insertion or iris manipulation.

In our series, 10 of the 12 eyes with 3-piece lenses had a posterior capsule rupture (Table 1, available at <http://aaojournal.org>). Therefore, it appears that the 3-piece lenses were electively placed out of the bag following complicated surgery. In these cases, the pathological findings observed could have been in a great extent related to the surgery itself. As an example, Figure 2 E shows that the iris transillumination defect is limited to approximately ½ quadrant, with a pattern that could correspond to the area of insertion of the phacoemulsification handpiece. Studies comparing this series with donor eyes implanted with other 3-piece designs in the sulcus (including lenses with smooth and round anterior edges) are necessary to confirm the amount of damage that is related to the anterior square edge. In the current study the damage was always more significant in the side of the lens fixated in the sulcus, but not as prominent as damage related to the presence of single-piece IOL haptics in the sulcus. The fact that eye number 14 contained a 3-piece multifocal lens with ciliary body/sulcus fixation is noteworthy. Presence of posterior capsule rupture in this case suggests that the lens was electively placed out of the bag. Asymmetric fixation increases the risk of decentration and tilt,^{28,29} which may affect clinical outcomes after IOL implantation. Clinical results with special lenses, such as multifocal or aspheric may be particularly influenced by these complications.^{30,31}

In summary, pathological findings of eyes with asymmetric or sulcus-fixated hydrophobic acrylic IOLs with square anterior and posterior optic edges were composed in this series of IOL decentration and tilt, pigmentary dispersion within the eye and on the IOL surface, iris transillumination defects, iris changes including vacuolization/disruption/loss of the pigmented layer, iris thinning, and iris atrophy, as well as synechiae and loop erosion in the case of 3-piece lenses. All findings were more significant in comparison with the control contralateral eyes, with IOLs symmetrically fixated in the bag. Of particular interest are the findings from 4 eyes with bag-sulcus fixated 1-piece lenses in the absence of posterior capsule rupture, suggesting inadvertent asymmetric fixation following relatively uncomplicated surgery. In these cases, the findings were probably directly related to the sulcus fixation of one of the haptics. The eyes with 3-piece lenses generally exhibited evidence of complicated surgery; therefore all pathological findings in those cases may not be strictly attributed to the out-of-the-bag fixation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1. High-frequency ultrasound scans (A and B) and magnetic resonance imaging scans (C and D) of 4 study eyes, showing various degrees of intraocular lens decentration and tilt. A through D: Eyes number 1, 17, 5, and 6, respectively.

Figure 2.

Gross photographs from the posterior view of the anterior segment (Miyake-Apple view) of study eyes implanted with 1-piece (A through C) or 3-piece (D through F) hydrophobic acrylic lenses, without symmetric in-the-bag fixation. Various degrees of intraocular lens decentration, pigment dispersion, iris transillumination defects, as well as Soemmering's ring formation within the capsular bag can be seen. A through F: Eyes number 1, 2, 5, 14, 17, and 15, respectively.

Figure 5.

Gross photograph (A) and light photomicrographs (B and C) obtained from eye number 3, implanted with a 1-piece hydrophobic acrylic lens with bag-sulcus fixation. Although the posterior capsule was intact in this eye, an anterior capsule tear appears to be present at 10 o'clock. The haptic on the left was in the sulcus, which caused disruption of the iris pigmented layer in regions close to the iris root and midperiphery (arrows). The haptic on the right was in the bag. The iris pigmented layer on this side does not exhibit any major disruption. Note the space inside the capsular bag on the right, corresponding to the intraocular lens haptic emplacement. B and C: Hematoxylin & Eosin stain; original magnification $\times 20$.