

Sulcus add-on intraocular lenses

Background and *in vitro* analyses

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Incorrect intraocular lens (IOL) power remains one of the most important causes of IOL explantation, according to the tenth annual survey of members of the ASCRS/ESCRS evaluating the complications of foldable IOLs requiring explantation or secondary intervention.¹ Surgical means that have been used to deal with post-cataract surgery ametropia errors, besides IOL explantation/exchange, include implantation of a supplementary IOL (piggyback), and corneal refractive procedures.

When implantation of a piggyback pseudophakic IOL is the chosen method to deal with this problem, surgeons must be aware of the possibility of interlenticular opacification (ILO).^{2,3} This is the opacification of the opposing surfaces of piggyback IOLs, which led to the explantation of pairs of lenses analysed in our laboratory. All cases analysed so far involved pairs of piggyback hydrophobic acrylic IOLs implanted in the bag, via a relatively small capsulorhexis.² Therefore, one of the surgical methods for the prevention of this complication is the

implantation of the first IOL inside of the bag, and the supplementary IOL in the sulcus, so that the equatorial region of the capsular bag with residual lens epithelial cells remains sequestered.³

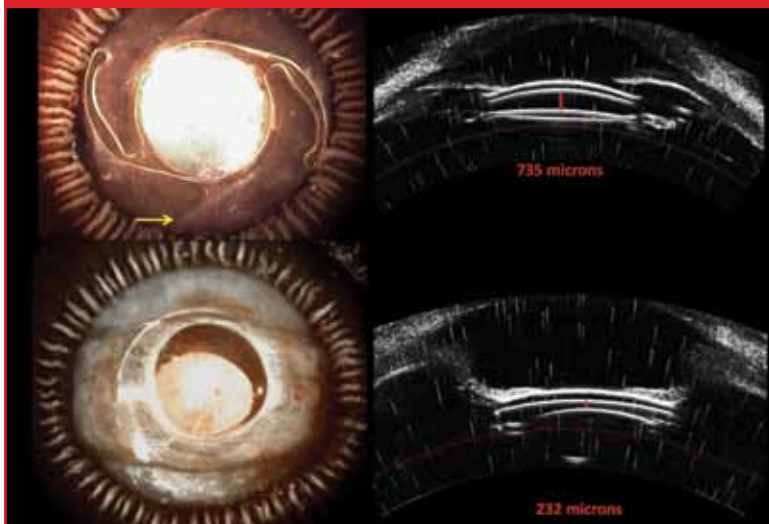
However, not all IOLs are appropriated for sulcus implantation in this configuration. IOLs with relatively thick and square edges are associated with increased interaction with the posterior surface of the iris, therefore, carrying a higher risk of pigmentary dispersion.⁴ Also, single-piece IOLs with square and thick optic and haptic edges (e.g., single-piece AcrySof) are not appropriate for sulcus implantation, and indeed this is not recommended by the manufacturer.⁵

Piggyback implantation

An IOL for piggyback implantation in the sulcus should ideally be manufactured from a soft, biocompatible material, with a relatively large optic and overall diameters, as well as round and smooth optic and haptic edges. Also, the design configuration should provide appropriate clearance with uveal tissues and the in-the-bag IOL. In collaboration with Dr Nick Mamalis, and research fellows, we have recently had the opportunity to evaluate such an IOL in our laboratory, at the John A. Moran Eye Center.⁶

The Sulcoflex is a hydrophilic acrylic IOL that was designed by Prof. Michael Amon (Vienna, Austria) specifically for piggyback implantation.⁷ The design platform, which exhibits the above-mentioned characteristics for a sulcus-fixed piggyback IOL is currently manufactured by Rayner (UK) in 3 models: aspheric, multifocal, and toric. In our study, we obtained

Figure 1: Gross photographs from the posterior or Miyake-Apple view (left) and corresponding ultrasound scans (right) of 2 pseudophakic eyes experimentally implanted with the Sulcoflex. The top eye had a single-piece AcrySof lens in the bag, and practically no Soemmering's ring formation (therefore the loops of the Sulcoflex can be visualized; arrows). The distance between the optics was 735 microns. The bottom eye had a plate silicone lens in the bag, and significant Soemmering's ring formation. The distance between the optics was 232 microns.



In short...

According to a recent survey of members of the ASCRS/ESCRS incorrect IOL power is one of the most important causes of IOL explantation. To surgically overcome this problem, clinicians can implant a secondary IOL (piggyback), however, this can lead to interlenticular opacification (ILO). Dr Werner has examined the Sulcoflex hydrophilic acrylic IOL on cadaver eyes to assess the fitting, centration, tilt, haptic position and clearance with the primary IOL in eyes with different overall sizes, Soemmering's ring formation and in-the-bag IOLs. The Sulcoflex lens was found to be an attractive option as a supplementary IOL.

pseudophakic human cadaver eyes from the Lions Eye Institute for Transplant & Research (Tampa, Florida, USA), as well as the San Diego Eye Bank (California, USA), which had been implanted with different IOLs in the bag. Our objective was to assess the Sulcoflex fitting, centration, tilt, haptic position and clearance with the primary IOL in eyes with different overall sizes, Soemmering's ring formation and in-the-bag IOLs.⁶

Method

Sixteen pseudophakic human cadaver eyes were obtained within 72 hours of enucleation. Each eye was measured grossly then imaged with a very-high frequency ultrasound system (Artemis, Ultralink) to assess the overall position of the primary IOL and the sulcus diameter. The eyes were then injected with the Sulcoflex lens through a clear corneal incision, and the lenses were fixated in the sulcus. The ophthalmic viscosurgical device was removed by aspiration, and the incision was sutured to prevent the presence of any air bubble inside of the eye.

After fixation in formalin, the eyes were re-evaluated with the same very-high frequency ultrasound for assessment of IOL fixation, fitting, centration, tilt, haptic position, and clearance with the primary IOL and intraocular structures. Further analyses of the position of the Sulcoflex haptics in the sulcus were performed from the posterior or Miyake-Apple view, as well as from anterior and oblique views.

Results and discussion

All primary IOLs were located within the capsular bag. Challenges in the performance of cadaver eye studies may include significant zonular insufficiency and/or cloudy corneas, which did not allow appropriate Sulcoflex injection and evaluation in 5 eyes. For the other 11 eyes, different foldable IOLs were represented (5 single-piece hydrophobic acrylic lenses, 3 three-piece hydrophobic acrylic lenses, and 3 plate silicone

lenses), as well as different degrees of Soemmering's ring formation (from grade 0 in 4 quadrants, to grade 4 in 4 quadrants).

Gross mean axial length of the eyes included in the study was 25.13 ± 0.9 mm; mean ultrasound measurement of the ciliary sulcus diameter was 11.06 ± 0.45 mm. The Sulcoflex could be injected and positioned within the ciliary sulcus, exhibiting overall appropriate centration and no or minimum tilt in all eyes. Clearance between both lenses ranged from 232 to 779 microns (517.4 ± 159.9), depending on the thickness of the primary IOL and the degree of Soemmering's ring formation (Figure 1). Assessment of the sulcus-fixated haptics revealed no disturbances to the ciliary processes.

In this ongoing study using pseudophakic cadaver eyes of different sizes, implanted with different in-the-bag IOLs, and with different amounts of Soemmering's ring formation, the Sulcoflex lens demonstrated appropriate fixation within the ciliary sulcus, appropriate centration, minimal or no tilt, and appropriate clearance with the primary IOL. The thin, undulating haptics of the lens minimize the interaction with the ciliary processes. We cannot comment on the clearance between the Sulcoflex and the posterior surface of the iris, as iris collapse is usually observed postmortem. A preliminary study in 12 eyes of 10 patients confirmed clearance between the Sulcoflex and the iris by ultrasound examination.⁷

The overall configuration of the optic (anterior convex; posterior concave) minimize the possibility of contact with the in-the-bag IOL, decreasing the likelihood of induced refractive error and optic aberrations. Besides secondary piggyback implantation to correct postoperative ametropia, or to provide multifocality in an eye previously implanted with a monofocal IOL, primary implantation of the Sulcoflex can also be performed (e.g., to deal with refractive changes

of paediatric eyes, among other indications). The surgical trauma associated with Sulcoflex implantation is significantly less in comparison to explantation/exchange of an in-the-bag IOL, especially after a long-term postoperative period. Therefore, we believe the concept of the Sulcoflex lens as a supplementary IOL is very attractive and certainly deserves further investigation.

References

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